

FEDERAL TRADE COMMISSION DECISIONS

**FINDINGS, OPINIONS, AND ORDERS
JULY 1, 2002 TO DECEMBER 31, 2002**

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VOLUME 134



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**MEMBERS OF THE FEDERAL TRADE COMMISSION
DURING THE PERIOD JULY 1, 2002 TO DECEMBER 31, 2002**

TIMOTHY J. MURIS, *Chairman*
Took oath of office June 4, 2001.

SHEILA F. ANTHONY, *Commissioner*
Took oath of office September 30, 1997.

MOZELLE W. THOMPSON, *Commissioner*
Took oath of office December 17, 1997.

ORSON SWINDLE, *Commissioner*
Took oath of office December 18, 1997.

THOMAS B. LEARY,, *Commissioner*
Took oath of office November 17, 1999.

DONALD S. CLARK, *Secretary*
Appointed August 28, 1998.

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FEDERAL TRADE COMMISSION DECISIONS
VOLUME 134

1

Complaint

IN THE MATTER OF

MED GEN, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4053; File No. 0023211
Complaint, July 12, 2002--Decision, July 12, 2002*

This consent order addresses the marketing of "Snorenz" – a dietary supplement consisting of oils and vitamins that is sprayed on the back of the throat of persons who snore – by Respondent Med Gen, Inc. and its president, Respondent Paul Kravitz. The order, among other things, requires the respondents to possess competent and reliable scientific evidence to substantiate representations that Snorenz – or any other food, drug, or dietary supplement – reduces or eliminates snoring or the sounds of snoring, or eliminates, reduces or mitigates the symptoms of sleep apnea. The order also requires the respondents – whenever they represent that certain products are effective in reducing or eliminating snoring or the sounds of snoring – to affirmatively disclose a warning statement about sleep apnea and the need for physician consultation. In addition, the order requires the respondents to possess and rely upon adequate substantiation to support any representation about the benefits, performance, efficacy, or safety of Snorenz or any other food, drug, or dietary supplement. The order also prohibits the respondents from making false claims about scientific support for any product, service, or program. In addition, the order requires the respondents – if they use any consumer endorsement or testimonial to promote a product, service or program – either to possess competent and reliable scientific evidence that the testimonial represents the typical or ordinary experience of users, or to affirmatively disclose that the testimonial is not typical. The order also requires the respondents to affirmatively disclose any material connection between themselves and any endorser of their products.

Participants

For the Commission: *Lemuel W. Dowdy, Walter Gross,
Laureen Kapin, James Reilly Dolan, Elaine D. Kolish and Randi
M. Boorstein.*

For the Respondents: *Craig B. Sherman, Sherman Law
Offices, Chartered.*

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that Med Gen, Inc., a corporation, and Paul B. Kravitz, individually and as an officer of the corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Med Gen, Inc. is a Nevada corporation with its principal office or place of business at 7284 West Palmetto Road, Suite 106, Boca Raton, Florida 33433.
2. Respondent Paul B. Kravitz is an officer of the corporate respondent. Individually or in concert with others, he formulates, directs, controls or participates in the policies, acts, or practices of the corporation, including the acts or practices alleged in this complaint. His principal office or place of business is the same as that of Med Gen, Inc.
3. Respondents have manufactured, advertised, labeled, offered for sale, sold, and distributed products to the public, including SNORenz. SNORenz is a topical spray that purports to reduce or eliminate snoring or the sounds associated with snoring by lubricating the vibrating tissues in the throat with a combination of oils, vitamins, and trace ingredients. SNORenz is a "food," and/or "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.
4. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.
5. Respondents have disseminated or have caused to be disseminated advertisements and labeling for SNORenz, including but not necessarily limited to television infomercials that were aired on various broadcast and cable channels. These advertisements contain the following statements:

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PRODUCT LABELING

A. [Outer Box] **[Exhibit A]**

[Front and sides]

FAST RELIEF
SNORenz
Easy to Use SPRAY
97% Effective in Reducing Snoring Noise*
- Natural ingredients
- Clinically tested
- No after effects
- Vitamin Enriched
- Mint Flavor

[Top and back tab]

97% Effective in Reducing Snoring Noise*

[Back]

...

*Double Blind Study – 1997

B. [Bottle Label] **[Exhibit B]**

97% EFFECTIVE IN REDUCING SNORING NOISE

SNORenz

CLINICALLY TESTED
NO AFTER - EFFECTS
NATURAL INGREDIENTS
VITAMIN ENHANCED
FRESH BREATH

Complaint

INFOMERCIAL: MED GEN, INC. VIDEOTAPE
[Exhibit C]

C. ANNOUNCER: The fact is snoring is not a joke. It's a serious problem. It interrupts your sleep, your partner's sleep, and the way you and your family feel and perform throughout the day.

ON SCREEN:
EXPENSIVE APPLIANCES!
PAINFUL PROCEDURES!
INVASIVE SURGERIES!
DON'T WORK!

ANNOUNCER: In the past, people have gone through extensive appliances, painful procedures, even invasive surgeries that just don't work. But now there's an amazing, revolutionary, breakthrough spray that's safe and easy to use and guaranteed to work the very first night. . . . Stay tuned to this incredible program and learn how you can stop snoring and finally get a restful, peaceful night's sleep.

D. PAUL KRAVITZ: Today, what we have is a product that's made through liposome technology, which is a patented process where the oil sits -- or the actual oils and the ingredients, all-natural ingredients, sit in a water molecule, an ionized water molecule.

ON SCREEN:
SNORenz
Stop Snoring NOW!
Free Bottle Offer! Call NOW!
1-800-956-7293
Safe, Simple to Use!

. . .

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PAUL KRAVITZ: So, wherever you place the solution, it sticks, and it lasts for six to eight hours.

...

PAUL KRAVITZ: And it stops you from snoring.

E. JOHN ZIGLAR: Tell us, Doctor, you have done a little bit of research into the product. You have some patients that are using it?

ON SCREEN:
Dr. Robert Currier

...

DR. BOB CURRIER: I had to find out if it works. So, I had 40 patients within my practice try the product. And we probably ran five days.

ON SCREEN:
Used by Dentists!

DR. BOB CURRIER: Anyway, just to see if it would work, we did a double-blind study, and it worked.

JOHN ZIGLAR: Really?

DR. BOB CURRIER: Highly, highly effective. And it works real well. These same people are using it to this day.

F. PAUL KRAVITZ: If you go into the drug store, you can look on the shelves and you can see little strips that go across your nose, you can see pills that you swallow, you can see solutions that you gargle with, you know. And if you go to a physician -- Doctor, you can tell us -- there's laser surgery; there is -- they can take and they cut the uvula out. It's just unbelievable to me some of the invasive tactics that have gone on to try to eliminate the problem.

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**ON SCREEN:
Non-Invasive!**

DR. BOB CURRIER: The beauty of this product, SNORenz, is that it is non-invasive, and it's easy to use.

G. FEMALE TESTIMONIAL: The other day I was introduced to a product called SNORenz. And since my husband has a problem with snoring, I wanted to try it on him, so I brought it home and he tried it. And that was the first time we had a peaceful night's sleep in a long time.

MALE TESTIMONIAL: I had considered having the laser surgery, but too many people told me that it was extremely painful and not always effective. Then I tried SNORenz, and it worked the very first night. I've used it ever since.

HUSBAND TESTIMONIAL: Before I found SNORenz, I had tried everything, tapes, tablets, nose sprays.

WIFE TESTIMONIAL: Nothing worked like SNORenz worked.

FEMALE TESTIMONIAL: SNORenz really works, and it's so easy to use, I wake up feeling refreshed.

WIFE TESTIMONIAL: Now anyone can stop snoring.

HUSBAND TESTIMONIAL: Just like I did.

FEMALE TESTIMONIAL: And me.

MALE TESTIMONIAL: And me.

ANNOUNCER: Your partners can't sleep. You're restless and tired the next day. You're cheating your family out of a restful night's sleep. The fact is, snoring can be a major problem, and people in the past have gone through

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expensive appliances, painful procedures, even invasive surgeries that cost up to \$3,600, and they still don't work.

H. FEMALE TESTIMONIAL: We've used SNORenz which is about 10 to 12 days. We have both slept very, very well. Me, because I don't hear the noise; him, because I'm not waking him up to stop the noise. What it does, it doesn't stop the snoring, it actually calms the noise so you do not hear it. It still happens, but you do not hear it happen. Consequently, when you wake up in the morning, you're a much happier couple. It really does make a difference in your life when you wake up and you have gotten a good night's sleep.

DR. JANE: Hello, my name is Dr. Jane. I just wanted to mention that SNORenz has been very effective for our patients. Again, thank you, SNORenz.

WIFE TESTIMONIAL: Thanks to a friend that introduced us to SNORenz, my sleepless nights are pretty much over. For the past year and a half –

HUSBAND TESTIMONIAL: Year and a half.

WIFE TESTIMONIAL: It's been about a year and a half. We hadn't been able to really sleep together due to the fact that my husband snored and has a snoring problem. But SNORenz has put an end to that and we've been sleeping quite well. Restful, peaceful.

I. ON SCREEN:
Dr. Alliert S. Jerome
Clinical Nutrition Specialist

ON SCREEN:
All Natural
No Chemicals
No Additives

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**No Preservatives
No Side Effects**

DR. JEROME: What I recommend to patients, family and friends is not a prescription medicine but an all-natural vitamin and oil, lipostate formula called SNORenz, that thanks to liposome technology is absorbed by the mucous membranes of the soft palate and quickly quiets the noise caused by the vibration of the uvula against the soft palate.

**ON SCREEN:
(Anatomical throat graphic/snoring photo with sound)**

MALE TESTIMONIAL: Snorenz did wonders for my snoring problem, and it helped the very first time I used it.

J. JOHN ZIGLAR: This product will solve that problem for them and they will love you for it. It absolutely works and the beauty of it is it's all-natural. . . . It will actually last that whole night for six to eight hours so that when you wake up in the morning you will wake up rested and refreshed.

INFOMERCIAL: TRU SNORENZ 1 - KT [Exhibit D]

K. KEVIN TRUDEAU: And this is a patented product. It has been clinically tested in double-blind studies –

JOHN ZIGLAR: Yes.

KEVIN TRUDEAU: Tell us about that.

JOHN ZIGLAR: What we did is we had two double-blind studies done in two separate locations. Basically, we had where the doctors did not know which was the placebo product nor did the patient know. And in each of the cases, the people that took the product that had the SNORenz product in it in 97 percent of the cases they quit snoring immediately.

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L. KEVIN TRUDEAU: If you use this product one time, for the first time in years, you will get the best night's sleep you've ever had. You'll actually go and get deep sleep for the very first time. And you'll wake up the next morning probably with more energy than you've ever imagined having. Because, folks, if you snore, I can tell you right now you are not getting deep sleep and you are not full of the energy that you can be by just getting a full night's rest. You'll also be more pleasant, you won't be as irritable, your body could even function better, your immune system and all of your systems can work better when you've had a full-night's rest.

M. KEVIN TRUDEAU: -- just make sure you spray it at the back of your throat, we'll show you exactly how to do that, and make sure 30 minutes before you use the product, don't drink or eat anything, primarily alcohol, that way it will stay on the throat, then go to sleep and guaranteed to work or your money back. Double-blind studies -- two of them -- proved -- clinical research -- that 97 percent of the times this was effective in eliminating the snoring noise all night long. It's all natural, it's patented and you can't beat the value.

N. KEVIN TRUDEAU: This is exclusive, it's a breakthrough, we're announcing it for the very first time, this is a revolutionary product that's patented, guaranteed to work, you get a three-month's supply -- this is your refill -- and this is the little squirter. You just put this by the bed stand and then all you do -- you can see how it sprays out here -- you just put three squirts in your mouth, on the back of your throat, just squirt it in right before you go to sleep, it tastes great, it's all natural, it's a patented product. In double-blind studies, clinical testing, guaranteed to work 97 percent of the time. And, you know, we have never seen it fail. And I think the reason it says 97 percent, if they put 100 percent people would think, oh, it sounds too good to be true. And it does sound too good to be true, but the double-blind

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studies, the people that use it, and you can find out for yourself –

O. KEVIN TRUDEAU: If you are a snorer or know somebody that is, it will eliminate the snoring just like that, guaranteed or your money back. It's a patented process, double-blind studies, clinical research. If it doesn't work, send it back for a full refund, no questions asked. But the statistics show, 97 percent effective in eliminating the noise of snoring the very first application. Folks, your life can be changed when you get a good night's rest.

INFOMERCIAL: VP SNORenz 2- JD [Exhibit E]**ON SCREEN: Dr. Bob Courier, Physician Surgeon**

P. DR. BOB COURIER: Another side effect, a cute story, my brother's also a snorer, I think this is just something that runs in families, as well. Anyway, he has since tried the product, as I have, and I use it, and I think it's fantastic, because it does stop the snoring. . . .

Q. JOHN ZIGLAR: Jon, what we've done is we have taken all natural oils, and we have taken and put them together in a liposome formulation, and we have taken it so that you can actually spray this product into the back of your throat, and the process is really quite simple. Have you ever seen a car go down the road that didn't have enough oil in it, and you hear the clatter and the clanking?

**ON SCREEN: John Ziglar, Master Strategies
Researcher**

JOHN ZIGLAR: Well, what happens is we took that same philosophy, that same technology, and we said, Hey, if we can oil the parts and we can take and make a topical solution that will stay in a place for an extended period of time, we can eliminate the noise of snoring. You're still going to

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have the same amount of air that's going to pass through the passage, but all we're going to do is we're going to lubricate the parts so that there is no noise associated so that you don't then wake up or wake up your neighbor.

R. DR. BOB COURIER: Well, to take this just a little bit further, a dentist has studied this and has actually sprayed this in models, and he actually used a dye at the time so he could see where it was applied. In the soft tissues, in the back of the throat, the ones that we see that flap and flutter and that need the lubrication, what -- it is applied there, but where the technology goes even further and better through this liposome technology is to apply it evenly, and the very neat thing about this is it stays. It stays there all night. That's where others have failed. And that's also where a lot of the appliances, that's where also a lot of the applications of surgeries, pills, other things that have been attempted and tried have failed. This product here stays there. It's easy application.

S. JON DENNY: If you have a snoring problem, if you have problems sleeping next to a snorer, then SNORenz may be the answer you've been waiting for. Remember, snoring is a medical condition. Studies have shown that snoring can seriously reduce your energy levels, your concentration and can seriously affect your work habits, as well, and you can be sure your snoring is seriously bothering someone other than you. SNORenz is the first all-natural spray that has been proven to give you a healthy, natural, good night's sleep. It has no side effects. It's as easy as a few sprays before bed, and it lasts all night, and if you want more information on SNORenz, if you want to stop the snoring, if it's a snorer next to you or if you be the snorer, you may want to call the 800 number on your screen.

T. JON DENNY: We have I believe a caller on the line from Arizona, and I believe it's Tina Hines (phonetic). Tina, are you on the air with us?

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...

TINA HINES: I'm listening to your show, and I have to tell you that snoring, you know, is a lot more dangerous than people think. My husband was a chronic snorer, he's a firefighter/paramedic, so I wasn't the only one affected by this. I mean, we didn't sleep together for years.

JON DENNY: Now, you've been married for how long, Tina?

TINA HINES: Sixteen years.

JON DENNY: Sixteen years, and this was a problem that occurred right from the start of your marriage?

TINA HINES: Oh, yeah.

JON DENNY: You found you were married to a snorer?

TINA HINES: Oh, absolutely, and the poor guy, it would be all night, John, turn over, turn over. It did not matter, he could be sleeping on his head, and he would still snore. Well, it got so bad that even at the fire department, he was being hassled at the fire department, because these guys sleep at different shifts, they don't all sleep at the same time, and when John was sleeping, he would be waking everybody else up, so they would be pounding on the walls and he'd come home all aggravated, he'd come home and want to sleep. They even built a partition around my husband's bunk bed to try to keep out the noise. Well, it got so bad he finally went to the doctor, and in order for the insurance company to pay for this surgery, they put him in the hospital, in the sleep center, and found out that he also had sleep apnea, which is very dangerous, because when you're snoring, you stop breathing, then you forget to sleep. So, they did the surgery, and needless to say, it lasted for a while, and then after that he started up again, and he would

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not even believe when I would tell him, John, you're snoring again. You don't want to go through surgery and find out that you're snoring again.

JON DENNY: So, this was after a surgery, he had -- the problem re-emerged.

TINA HINES: Right, they did surgery on all his sinuses, they went through his nose and removed all his polyps, thinking that was the problem. So, now he's in for the second surgery, and they decided they are going to remove part of his uvula, and the roof of his mouth, his tonsils and his adenoids, and this way it will give his tongue more room, I guess is what they said, so he wouldn't snore. Well, he went through this, and it was a horrible surgery. I really felt very, very bad for him. He was out of work for six weeks, and he had high hopes that this was going to work and our life was going to change, we could sleep in the same room together, go on vacation, the guys wouldn't be hassling him. Well, that did work for quite a while, and then it started up again, and I'll tell you what, I was even afraid to tell him, because I couldn't believe it myself. It's aggravating, it's annoying, I don't get a good night's sleep, he doesn't get a good night's sleep. I hated to say it, but I was happier when he was at the fire department because I got a good night's sleep.

...

TINA HINES: And I was aggravated. You're talking two surgeries, what's it going to take? He tried those stupid nose strip things, they didn't work. So, one day I'm sitting here watching TV and I see a commercial out here in Phoenix and a couple is talking about the same thing, and I'm thinking, Well, what have I got to lose? Well, my husband tells me I'm nuts, because if two surgeries didn't work, the spray was not going to work. I figure, Well, I'm going to try it. So, I sent for it, put it on the nightstand, the first night he

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was home, I woke him up, I said, John, spray your throat. He said, Yeah, yeah, yeah, yeah. I said, John, please, spray your throat. So, we sprayed his throat, and I'm like waiting -- I'm laying there, I'm laying there, I'm like, Oh, wow, he was sleeping, there was no noise coming out of him. And I was -- I was pretty well hooked. And he still was not a believer. He said it was just a fluke. So, it took a few times of using the SNORenz. Now, I'll tell you what, he's taken it up to the fire department. I have the wives calling from the fire department asking me the 800 number. I've given away more bottles, I can't tell you, because I belong to the SNORenz Bottle of the Month Club, and I just gave one to my daughter last week, she came over, and she was like, Mom, I'm going crazy, Kenny's snoring. I said, Here, take my last bottle, take it home.

INFOMERCIAL: VP SNORENZ 3 - KT [Exhibit F]

U. KEVIN TRUDEAU: Now . . . was this a patented process that this Korean gentleman invented?

JOHN ZIGLAR: No, it wasn't, Kevin. At the time, what he had was a combination of oils that he had in a little formula that he sprayed in the back of his throat and then Paul went to his laboratories and he developed a liposome formulation of the all-natural oils. He put some vitamins, minerals in it and put a whole lot better taste. He put a spearmint taste into the product so that it would taste good and then still solve the problem.

KEVIN TRUDEAU: So, now this is a patented formula?

JOHN ZIGLAR: Yes, it is.

KEVIN TRUDEAU: Okay. Patented process.

V. KEVIN TRUDEAU: So, this -- this -- this is an all-natural product; this is clinically tested; no after effects; natural

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ingredients; vitamin enhanced; fresh breath -- 97 percent effective. . . .

W. KEVIN TRUDEAU: Tell me how this eliminates the snoise of noring (sic). What exactly happens when I spray this in my mouth before I go to sleep?

JOHN ZIGLAR: Because of the technology -- what we have been able to do with the oils in this product, is we have been able through a liposome technology, put it so that when it lands on the back of your throat it will actually stay there. It will stay topical for up to eight hours.

X. KEVIN TRUDEAU: It's a patented product. It's not available in any stores. It's only available directly from the company. Call the number on your screen to get more information on SNORenz. It's very inexpensive, it tastes great, it's all-natural, it's clinically proven to eliminate the noise of snoring in 97 percent of the cases, and in my personal experience is virtually 100 percent.

Y. KEVIN TRUDEAU: The person who snores, Dr. Leonard, if they are snoring and it "doesn't bother them."

DR. LEONARD: Um-hmm.

KEVIN TRUDEAU: They don't get woken up. Is it, in fact, having an adverse effect on the person's sleep patterns, thus making them more potentially irritable and fatigued during the day?

DR. LEONARD: Certainly. Potential irritability and fatigue throughout the day has got to be commonplace.

KEVIN TRUDEAU: Now, why is that? I mean, if I snore and I don't wake up during the night and I don't -- I don't even know I snore --

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DR. LEONARD: Um-hmm.

KEVIN TRUDEAU: -- how is it having that effect on me?

DR. LEONARD: If you're sleeping and snoring, obviously, like you're talking about exchanging air and still breathing and your air passage is restricted, once things are restricted to a point, you automatically or for the most part most people will wake up, catch a deep breath, roll over, what-have-you. So, yeah, your sleep pattern is disturbed by that.

KEVIN TRUDEAU: So, a person may not even realize that he's constantly waking up and going back to bed during the night?

DR. LEONARD: That's right.

Z. KEVIN TRUDEAU: Folks, if you're watching right now and you are a snorer or if you know someone that is, get on the telephone and call to get SNORenz. It's a very simple, all natural product, it's just natural oils with some vitamins and minerals. You simply just spray it in your mouth three times before you go to bed. It tastes great, it's a patented product, it has been proven to be 97 percent effective in eliminating the snoise -- the noise of snoring. . . . It's all natural, it's patented, and it's not available in any store. So, pick up the phone right now for more information on SNORenz. And it's pennies, it's very cheap and it'll eliminate your snoring.

. . .

(Music playing.)

**ON SCREEN: For more information or to order
Snorenz call:**

**Tru-Vantage International, 7300 N. Lehigh Ave, Niles,
IL 60714 (847)647-0300.**

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**If snoring is accompanied by any signs of Sleep Apnea,
you should consult a physician before using any
product.**

**The preceding has been a paid commercial for
SNORENZ brought to you by Kevin Trudeau's Tru-
Vantage International, America's premier direct
response marketing company.**

INFOMERCIAL: VP SNORENZ 4 - JD [Exhibit G]

- AA. JON DENNY: If you have a snoring problem, if you have problems sleeping next to a snorer, then SNORenz may be the answer you've been waiting for. Snoring can seriously reduce your energy levels, your concentration, and can seriously affect your work habits, as well. And you can be sure your snoring is seriously bothering someone other than you. SNORenz is the first all-natural spray that has been proven to give you a healthy, natural, good night's sleep. It has no side effects, it's as easy as a few sprays before bed, and it lasts all night.
- BB. JON DENNY: And if you want more information about this revolutionary, breakthrough product which has been proven effective in 97 percent of cases to eliminate or reduce the sound of snoring, call the toll-free 800 number on your screen, get more information about SNORenz. Do it for him, do it for yourself, do it for your family. It is worth the phone call, and it is pennies per day to end the snoring problem. This is a product, as I mentioned, that has been proven effective in studies. And you actually conducted the studies out of your offices in Michigan. Tell us about how SNORenz worked.

DR. BOB CURRIER: Interestingly enough, it's not only the results of the studies we got, but the comments we received. Many people, again, they're aware of snoring, but they aren't aware of the problems that come with it. And actually it's

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like until it's resolved, the snoring itself, oh, my word, what a problem it was. And you can see the changes it's made. That was probably the most interesting part of doing that whole study –

JON DENNY: Um-hmm.

DR. BOB CURRIER: -- was the comments that we got back, the little stories that people had through the week –

JON DENNY: Yes.

DR. BOB CURRIER: -- you know, of using this product. And that was the beauty of this. I loved doing the study, it was highly effective.

INFOMERCIAL: VP SNORenz 8 JD/JPK [Exhibit H]

CC. JON DENNY: For millions of Americans, this is the most annoying and unwelcome sound in the world. That's right, more than 90 million Americans have a snoring problem, and it could cause sleeplessness, headaches and a lack of energy, and that goes for the snorer as well as the person trying to sleep next to the snorer. What can be done about it? On Vantage Point today, hear about a new discovery that could eliminate the sound of snoring.

ON SCREEN: Vantage Point with Jon Denny

DD. JON DENNY: Hi, I'm Jon Denny, and welcome to Vantage Point. We are going to talk about snoring today and we're going to do it with Paul Kravitz, who has brought to the market an exciting break-through product called SNORenz, which has been proven from snorers around the country to reduce or eliminate their snoring problem. Paul, welcome to the show.

PAUL Kravitz: Thank you, Jon.

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JON DENNY: Tell me, is this a break-through medical discovery; is this a revolutionary new direction to help people stop this snoring problem?

ON SCREEN: Paul Kravitz/SNORenz/TVI

PAUL Kravitz: Well, Jon, I don't know if you'd call it a medical breakthrough or a new discovery. To me it was a major breakthrough. In fact, it saved my marriage. I had been a heavy snorer for years and at one point in my life my -- my ribs hurt so much in the morning from my wife poking me to wake up to stop snoring, it was just a terrible thing. And over the course of many years I was thinking about surgery -- there were a lot of potential cures that I -- that I thought I would find to help the situation out. And I met somebody about six or seven years ago, a Korean gentleman who lived in Brazil, actually, and who was working with an EMT specialist who lived next door, and they came up with a -- with a product and I had met him, they were looking for somebody to invest in a company, and things just went -- went the way of the world -- and finally I asked him if I could try the product, and I did. And it worked. It was -- at the it was in its infancy, it was terrible tasting, and -- but it worked, and I used it for five days straight and I made a small investment, which became a larger investment, and even a larger investment. Until, finally, I bought the formula from the Korean and we went to work on it. It took a year and a half to develop, and, Jon, we've tested it, we've proven it, it works. And it works and it's a very simple way it does work.

EE. JON DENNY: How does SNORenz work to correct or address the problem you're talking about?

PAUL Kravitz: Well, very simply put, it oils the vibrating parts of your -- of your throat. And when you put oil on a -- on a rusty part, it silences it. And that's exactly how it does work. The secret of the product, and what we've spent

Complaint

millions of dollars to find out, is how to get it to attach itself -- the product itself -- the spray -- to stay in the back of the throat so that the noise stays -- I mean, that the noise stays away for six to eight hours.

FF. JON DENNY: Now, why is snoring a problem? On one hand we know it's a problem for the person sleeping next to us, the snorer, they're not getting enough sleep because of that sound coming right next to them, but in what other ways is snoring a real problem for both the snorer as well as the person trying to sleep next to them?

PAUL KRAVITZ: Well, from the snorer's point of view, Jon, it's a major problem. First of all, you don't know it, but if you were a snorer, you wake up maybe a thousand times a night, because the snoring does wake you up. You go right back to sleep again, and then you wake up again. Even if your wife doesn't wake you up or your girlfriend doesn't wake you up, you are really not sleeping soundly.

GG. JON DENNY: Interestingly. We have Dr. Mike Leonard on the line from Kalamazoo, Michigan. Dr. Leonard, are you with us?

DR. LEONARD: Yes, I am.

JON DENNY: Dr. Leonard, I believe, conducted some tests on the efficacy of this product out of his offices in Michigan. Dr. Leonard, let me ask a question. As a dentist, is this something that you have recommended to your patients who have sleep problems, most particularly snoring problems?

**ON SCREEN: caller: Dr. Michael Leonard/Kalamazoo,
MI/TVI**

DR. LEONARD: Yes. Initially, as a dentist, we -- in the -- historically we fabricate occlusal appliances or guards that

Complaint

go in your mouth that, oh, essentially keep your mouth open wider or really position your lower jaw forward so you can keep the airway open like you were talking about earlier and don't have those tissues vibrating and rolling around. The problem is a lot of people can't tolerate those appliances. They are large, they are cumbersome and throughout the night if you've got it in your mouth you may end up with it on your pillow in the morning because you just subconsciously take it out.

JON DENNY: These are clamps that dentists have in the past put into people's mouths to create more air space?

DR. LEONARD: Exactly. Very -- of varying different sizes and shapes, et cetera, but they're custom-made appliances and for some people that can't tolerate them, it's - - it's an expense to go through if you're not going to be able to utilize it.

So, I had -- through the grapevine -- heard about a spray to use and got the name of the company, called them up and ordered a case of SNORenz and had it sent to my office to start dispensing to patients and having them try it out and see what they thought, because, quite simply, it's easily reversible. If you are not tolerating it, if it was not working, you just stop using it. You're not really out anything. And that -- the feedback that I got was very, very positive. People were getting good results and the people that were coming in with the problems were not the snorers themselves, it was the mate -- the partner -- that was sleeping next to them that was kept up all night or irritated all night that they're having to roll their spouse over to get them to quiet down a little bit so they could get a more restful sleep.

HH. JON DENNY: Now, there have been not only clamps but also pills that have been tried and also strips across one's nose, and very expensive and painful surgeries as well.

Complaint

DR. LEONARD: That's right.

JON DENNY: So, Doctor, would you consider SNORenz to be a logical common-sense approach to a typical snoring problem?

DR. LEONARD: It's an extremely logical, common-sense, first-line approach to dealing with it. Use it and if you use it properly and if you use it consistently, I find that it works. It works for me and it works for a number of the patients that I'm having use it in the practice.

II. JON DENNY: If you want more information about SNORenz, the patented process, all-natural spray that could help reduce or eliminate the sound of snoring, if you are a snorer or you sleep next to a snorer, this may be the product for you. Money-back guarantee, it costs pennies to address this very serious problem, and hopefully you shall all get a full, restful, silent night's sleep. I'm Jon Denny on Vantage Point. I think I'm going to knock off a few sprays, because I've been told I'm a snorer. We'll see you next time on Vantage Point. Take care.

**ON SCREEN: For more information or to order
Snorenz call:**

**Tru-Vantage International
7300 N. Lehigh Ave.
Niles, IL 60714
(847)647-0300**

**If snoring is accompanied by any signs of Sleep Apnea,
you should consult a physician before using any
product.**

**The preceding has been a paid commercial program
for SNORENZ.**

Complaint

SNORenz INTERNET SITE at www.snorenz.com [Exhibit I]

JJ. SNORenz Testimonials

Dear Med Gen:

My husband had the good fortune to make his snoring cease. He had apnea and has snored heavily for years. We noticed little or no improvement in his snoring even after his operation. I ordered *SNORENZ®* from a TV advertisement. He tried it and snores lightly now -- no rattling the house and he dreams now which is an indication of REM sleep. I suppose he feels rested – and we feel rested too. After 44 years of heavy snoring, it is a real pleasure to find a product that works. An additional fortune is that it is natural.
Ahhhh....Thanks *SNORENZ®*!

Beth Anderson
Perry, Florida

PRESS RELEASES [Exhibit J]

KK. Med Gen Inc. manufactures and distributes *SNORENZ®*, an all natural throat spray that reduces or eliminates the sounds caused by snoring. Laboratory tests have proven the spray to be effective in reducing snoring noise.

6. Through the means described in Paragraph 5, respondents have represented, expressly or by implication, that:
 - A. SNORenz significantly reduces or eliminates snoring or the sound of snoring in users of the product.
 - B. A single application of SNORenz significantly reduces or eliminates snoring or the sound of snoring for six to eight hours.

Complaint

- C. SNORenz can eliminate, reduce or mitigate the symptoms of sleep apnea including daytime tiredness and frequent interruptions of deep restorative sleep.
 - D. Testimonials from consumers appearing in the advertisements for SNORenz reflect the typical or ordinary experience of members of the public who use the product.
7. Through the means described in Paragraph 5, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 6, at the time the representations were made.
8. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 6, at the time the representations were made. Among other reasons, the single study that respondents relied upon that purported to use a double blind, controlled design contained basic flaws in design (such as failure to apply an appropriate measurement to assess sound reduction, failure to include a statistical analysis of the results, insufficient duration of the testing period, and failure to develop a baseline against which any improvement could be measured). Therefore, the representation set forth in Paragraph 7 was, and is, false or misleading.
9. Through the means described in Paragraph 5, respondents have represented, expressly or by implication, that clinical research proves that SNORenz significantly reduces or eliminates snoring or the sound of snoring.
10. In truth and in fact, the respondents' clinical research does not prove that SNORenz significantly reduces or eliminates snoring or the sound of snoring. Among other things, critical components of the research were not done by an independent entity qualified to conduct studies or by Robert Currier, M.D. Rather, the respondents composed the questionnaire used in the study and compiled the results from completed questionnaires

Complaint

submitted by study participants. Therefore, the representation set forth in Paragraph 9 was, and is, false or misleading.

11. In their advertising and sale of SNORenz, respondents have represented, expressly or by implication, that the product reduces or eliminates snoring or the sound of snoring. Respondents have failed to disclose or to disclose adequately that SNORenz is not intended to treat sleep apnea for which snoring is a primary symptom, that sleep apnea is a potential life-threatening condition, and that persons who have symptoms of sleep apnea should consult a physician. These facts would be material to consumers in their purchase or use of the product. The failure to disclose adequately these facts, in light of the representation made, was, and is, a deceptive practice.

12. In their advertising and sale of SNORenz, respondents have represented, expressly or by implication, that a physician, Robert (or "Bob") Currier (or "Courier"), M.D., endorses SNORenz. Respondents have failed to disclose or failed to disclose adequately that Dr. Currier has a material connection with respondent, Med Gen, Inc., in that he is an investor in the company and may have a financial interest in promoting the sale of SNORenz. This fact would be material to consumers in their purchase decision regarding SNORenz. The failure to disclose this fact, in light of the representations made, was and is a deceptive practice.

13. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this twelfth day of July, 2002, has issued this complaint against respondents.





**97% Effective
in Reducing
Snoring Noise***

**DO NOT USE IF SAFETY SEAL IS
BROKEN OR MISSING ON BOTTLE.
KEEP OUT OF REACH OF CHILDREN.**

Supplement Facts

Serving Size 3 mL (3 sprays)

Servings Per Container 20

	Per Serving	%DV
Vitamin E	7.5 mg	25%
Vitamin C	4.5 mg	75%
Vitamin B-6	3.0 mg	150%
Olive oil	210 mg	***
Sunflower oil	90 mg	***
Peppermint oil	60 mg	***
Almond oil	37.5 mg	***
Sesame oil	30 mg	***

*** Daily Value not established

DIRECTIONS: Shake before using. Tilt head back and spray 3 to 4 times to the back of the throat and uvula. Hold towards the back of your mouth for about 15-20 seconds and then swallow. For best results, do not eat or drink 30 minutes before going to bed and after this application. You should repeat this process if liquid is ingested during the night. Snorenz™ is an all natural, safe product. Each application lasts 6 to 8 hours per night. Store in cool dry place.

This product is not intended to diagnose, treat, cure or prevent any disease.

*Double Blind Study - 1997

LABORATORY TESTED

PATENTED LIPOSOME FORMULA.
ADDITIONAL INGREDIENTS IN
GLYCERINE AND PURIFIED WATER
BASE WITH PEPPERMINT EXTRACT. NO
ARTIFICIAL FLAVORS, COLORS OR
PRESERVATIVES.

Made in USA
Mfg for: MedGen, Inc.
Deerfield Beach, FL
Patent Pending

FAST RELIEF

**SNOR D
enZ™**

**97% Effective
in Reducing
Snoring Noise***

- Natural ingredients
- Clinically tested
- No after-effects
- Vitamin Enriched
- Mint Flavor



4799
74











[1]
[2] OFFICIAL TRANSCRIPT PROCEEDING
[3]
[4] FEDERAL TRADE COMMISSION
[5]
[6] MATTER NO. 0023211
[7]
[8] TITLE MED GEN INC.
[9]
[10] DATE RECORDED: NOVEMBER 14, 1999
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[16] SNORENZ (3) VIDEOTAPE
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[1] FEDERAL TRADE COMMISSION
[2]
[3] In the Matter of:)
[4] Med Gen, Inc.,) Matter No. 0023211
[5]
[6] November 14, 1999
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[12] The following transcript was produced from a
[13] videotape provided to For The Record, Inc. on May 8,
[14] 2000.
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Page 3

[1] PROCEEDINGS
[2]
[3] ON SCREEN:
[4] The following is a paid presentation by Med Gen
[5] Solutions.
[6] ANNOUNCER: The following is a paid
[7] presentation by Med Gen Solutions.
[8] (Music playing.) (Snoring.)
[9] ANNOUNCER: Does this sound like you? Your
[10] partner can't sleep; you're restless and tired the next
[11] day; your family has had enough. Now you can eliminate
[12] the sound of snoring forever. If you have a snoring
[13] problem, the next half-hour could change your life, and
[14] just as important, the people's lives around you.
[15] The fact is snoring is not a joke. It's a
[16] serious problem. It interrupts your sleep, your
[17] partner's sleep, and the way you and your family feel and
[18] perform throughout the day.
[19] ON SCREEN:
[20] EXPENSIVE APPLIANCES!
[21] PAINFUL PROCEDURES!
[22] INVASIVE SURGERIES!
[23] DON'T WORK!
[24] ANNOUNCER: In the past, people have gone
[25] through extensive appliances, painful procedures, even

Page 4

[1] invasive surgeries that just don't work. But now there's
[2] an amazing, revolutionary, breakthrough spray that's safe
[3] and easy to use and easy to use, and guaranteed to work
[4] the very first night.

[5] Stop sleeping on the couch or in the guest
[6] room. Stop being exhausted the next day. Stop being
[7] tired in class or in that board meeting. Stop those
[8] embarrassing episodes in public. Even eliminate stale
[9] mouth, morning breath. Enjoy a more vigorous, joyous and
[10] energized day.

[11] Stay tuned to this incredible program and learn
[12] how you can stop snoring and finally get a restful,
[13] peaceful night's sleep.

[14] **ANNOUNCER:** Stay tuned. Med Gen Solutions
[15] presents Snorenz, and now here is the host of our show,
[16] John Ziglar.

ON SCREEN:

[17] MED GEN Solutions

[18] John Ziglar

[19] JOHN ZIGLAR: Hi, I'm John Ziglar with Med Gen
[20] Solutions. Today we're going to be covering a special
[21] topic, how to stop and eliminate the noise of snoring
[22] forever. We have two special guests with us this
[23] afternoon. We have Paul Kravitz, the CEO of Med Gen, and
[24] Bob Currier, a doctor from Michigan.

Page 5

[1] Paul, you're introducing this product called
[2] Snorenz to the world. Tell us how it came about.

ON SCREEN:

[3] Paul Kravitz

[4] CEO Med Gen

[5] PAUL KRAVITZ: The product itself was developed
[6] by an ENT specialist in Brazil, of all places.

[7] JOHN ZIGLAR: Yeah.

[8] PAUL KRAVITZ: And it was really in its rough
[9] stages and it was shown to me because I happened to be a
[10] snorer.

[11] JOHN ZIGLAR: Sure.

[12] PAUL KRAVITZ: And it's been really bothering
[13] me, actually bothering my wife more than it's been
[14] bothering me, for a long — for a long time now. And I
[15] tried it. I said Gee, if it works for me, what a
[16] wonderful thing this is going to be.

[17] JOHN ZIGLAR: Sure.

[18] PAUL KRAVITZ: It's going to be a blessing for
[19] my family and myself, and I did, I tried it and it
[20] worked. And every day for a week I would ask my wife,
[21] Diane, did it — did you wake up last night?

[22] JOHN ZIGLAR: Um-hmm.

[23] PAUL KRAVITZ: And she would say I slept
[24] through last night.

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[1] JOHN ZIGLAR: Wow.

[2] PAUL KRAVITZ: But, you know, on the third day

[3] I felt something else. My ribs felt better.

[4] JOHN ZIGLAR: I understand.

[5] PAUL KRAVITZ: Because when I woke her up, she
[6] would go whack to make me move over. John, it worked.
[7] It worked for me for five days in a row, and I really got
[8] interested in the product. We invested some money, we
[9] formed a company, and we took a hard road to perfect the
[10] product.

[11] JOHN ZIGLAR: Yeah.

[12] PAUL KRAVITZ: Today, what we have is a product
[13] that's made through liposome technology, which is a
[14] patented process where the oil sits — or the actual oils
[15] and the ingredients, all-natural ingredients, sit in a
[16] water molecule, an ionized water molecule.

ON SCREEN:

[17] SNORENZ

[18] Stop Snoring NOW!

[19] Free Bottle Offer! Call NOW!

[20] 1-800-956-7293

[21] Safe, Simple to Use!

[22] JOHN ZIGLAR: Wow.

[23] PAUL KRAVITZ: So, wherever you place the
[24] solution, it sticks, and it lasts for six to eight hours.

Page 7

[1] JOHN ZIGLAR: Wow.

[2] PAUL KRAVITZ: And it stops you from snoring.

[3] JOHN ZIGLAR: Tell us, Doctor, you have done a
[4] little bit of research into the product. You have some
[5] patients that are using it?

ON SCREEN:

[6] Dr. Robert Currier

[7] DR. BOB CURRIER: Well, I have plenty of
[8] patients that are using it. Interestingly enough, how I
[9] became involved through a mutual friend that knows Paul,
[10] and I became — you know, I had known Paul, too. What I
[11] did to introduce the product was not to — it was to make
[12] me a believer. Let's put it honestly.

[13] JOHN ZIGLAR: Sure.

[14] DR. BOB CURRIER: I had to find out if it
[15] works. So, I had 40 patients within my practice try the
[16] product. And we probably ran five days.

ON SCREEN:

[17] Used by Dentists!

[18] DR. BOB CURRIER: Anyway, just to see if it
[19] would work, we did a double-blind study, and it worked.

[20] JOHN ZIGLAR: Really?

[21] DR. BOB CURRIER: Highly, highly effective.

[22] And it works real well. These same people are using it
[23] to this day.

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[1] PAUL KRAVITZ: Outstanding. Well —
 [2] DR. BOB CURRIER: There's a lot of products
 [3] that claim that they stop you from snoring, John.
 [4]

ON SCREEN:

[5] Paul Kravitz

[6] CEO Med Gen

[7] JOHN ZIGLAR: I know.

[8] PAUL KRAVITZ: I mean, if you get on the
 [9] website, there's 1,285 products. It's amazing.

[10] JOHN ZIGLAR: It's unbelievable.

ON SCREEN:

[11] John Ziglar

[12] DR. BOB CURRIER: All right?

ON SCREEN:

[13] 30 Day Guarantee!

[14] PAUL KRAVITZ: If you go into the drug store,
 [15] you can look on the shelves and you can see little strips
 [16] that go across your nose, you can see pills that you
 [17] swallow, you can see solutions that you gargle with, you
 [18] know. And if you go to a physician, Doctor, you can tell
 [19] us, there's laser surgery; there is — they can take and
 [20] they cut the uvula out. It's just unbelievable to me
 [21] some of the invasive tactics that have gone on to try to
 [22] eliminate the problem.

ON SCREEN:

[25]

Page 9

[1] Non-Invasive!

[2] DR. BOB CURRIER: The beauty of this product,
 [3] Snorenz, is that it is non-invasive, and it's easy to
 [4] use.

[5] JOHN ZIGLAR: Yeah.

[6] DR. BOB CURRIER: It's — we had talked about
 [7] earlier, before the program, one of the things that we as
 [8] physicians face is compliance, the compliance issue, is
 [9] somebody going to use something. They go, they have the
 [10] surgery; they go, they have an appliance from a dentist
 [11] put in their mouth, which basically alters the structure,
 [12] the anatomical structure, to let the air pass through so
 [13] they do not snore.

ON SCREEN:

[14] Dental Appliance (with graphic)

[15] PAUL KRAVITZ: How do you sleep with an
 [16] appliance in your mouth?

[17] DR. BOB CURRIER: They don't, that's where some
 [18] of the problem comes in, because they say they do —

[19] JOHN ZIGLAR: Sure.

[20] DR. BOB CURRIER: — they'll go and be —
 [21] they'll BS the family to go and have this done. Once it
 [22] is done, they've done their duty, okay? But will they
 [23] use it? That's the problem. With this product, it goes
 [24] into the throat and it lasts.

Page 8

Page 10

[1] The interesting thing about this, the
 [2] interesting part of the technology is the way it coats,
 [3] it lubricates. Again, snoring is formed by the passage
 [4] of air past the soft tissues in the back of our throat,
 [5] the palate.

ON SCREEN: (Graphic)

[7] DR. BOB CURRIER: And what it does, I like to

[8] liken it to the whoopy cushion effect where we get air in
 [9] a, you know, a plastic or a rubber —

[10] JOHN ZIGLAR: Yeah.

[11] DR. BOB CURRIER: — and then what it does is

[12] it passes past this to create this noise. We do the same
 [13] thing with the soft tissues in our palate. This coats,
 [14] lubricates, and therefore attenuates the noise of
 [15] snoring.

[16] JOHN ZIGLAR: Outstanding. Gentlemen, we have
 [17] on the telephone with us today Dr. Leonard from
 [18] Kalamazoo, Michigan.

[19] PAUL KRAVITZ: Great.

[20] JOHN ZIGLAR: Dr. Leonard, are you there?

[21] DR. LEONARD: Yes, I am.

[22] JOHN ZIGLAR: How about telling us what you
 [23] have experienced with the product?

ON SCREEN:

[25] On The Phone

Page 11

[1] Dr. Michael Leonard, D.D.S.

[2] DR. LEONARD: Well, I guess initially looking
 [3] for something to offer patients that kind of raised the
 [4] oral appliance or some other device that they would wear
 [5] at night to help eliminate their snoring. I found out
 [6] about this particular spray and went ahead and ordered a
 [7] case of it to begin distributing to patients, dispensing
 [8] it to them and having them try it out. And, again, on
 [9] follow-up found out that they had significant, positive,
 [10] positive results.

[11] And I was talking to my wife about it at home,
 [12] and she said also bring it home, because, I, too, you
 [13] know, along with the other crew on the show today, I am a
 [14] snorer also. So, I began dispensing it to patients,
 [15] began using it myself. This has been probably 16 or 18
 [16] months ago, and every single night, I'm reminded with a
 [17] slight nudge to make sure I've used the spray.

[18] JOHN ZIGLAR: You know, when I started using
 [19] the product myself, I — when I would go to bed at night,
 [20] it was really kind of interesting because I'd roll over
 [21] in bed to give my wife a kiss, you know, and she would
 [22] always want to give me a kiss, but — and I thought what
 [23] a sweet thing, but she was checking to see if I had
 [24] sprayed that night. Okay? So she was checking to see,
 [25] you know, the impact it would have.

Page 12

[1] Dr. Leonard, question for you, you fixed an
[2] appliance for your patients and all, what is the —
[3] what's the major problem that your patients have with
[4] that particular kind of apparatus?

ON SCREEN:

[5] Dental Appliance (with graphic)

[6] DR. LEONARD: Well, it's — think of it as a
[7] big piece of plastic that fits over your upper and lower
[8] teeth and forces your lower jaw forward. It's
[9] uncomfortable, and they're fairly costly. So, if you
[10] have somebody that is fitted for one of those, they've
[11] gone through the initial expense of having it fabricated,
[12] if they can't tolerate it, they're fairly unhappy because
[13] they spent a lot of money on this piece of plastic that's
[14] going to sit in the drawer, and they still have a
[15] problem.

[16] So, my thought was let's get them started on
[17] the most cost-effective and easily reversible solution to
[18] this problem, which is the Snorenz, and again finding
[19] very, very good results, excellent results with it.

[20] JOHN ZIGLAR: Thank you, Dr. Leonard, for being
[21] with us.

[22] Gentlemen, one of the problems that he was
[23] teaching us is this compliance problem with the apparatus
[24] that the dentists all across the country are using as a

Page 13

[1] solution for the problem.

ON SCREEN:

[2] Paul Kravitz

[3] CEO Med Gen

[4] PAUL KRAVITZ: John, the only solution for the
[5] problem, when it's all said and done, really, is to
[6] somehow get a solution that lubricates the parts that
[7] move that cause the noise called snoring.

[8] ANNOUNCER: Your partners can't sleep. You're
[9] restless and tired the next day. You're cheating your
[10] family out of a restful night's sleep.

ON SCREEN:

[11] EXPENSIVE APPLIANCES!

[12] PAINFUL PROCEDURES!

[13] INVASIVE SURGERIES!

[14] DON'T WORK!

[15] ANNOUNCER: The fact is, snoring can be a major
[16] problem, and people in the past have gone through
[17] extensive appliances, painful procedures, even invasive
[18] surgeries that cost up to \$3,600, and they still don't
[19] work. But now there's an amazing new breakthrough for
[20] snoring sufferers, Snorenz.

ON SCREEN:

[21] ALL NATURAL!

[22] VITAMIN BASED!

Page 14

[1] EASY TO USE!

[2] GUARANTEED!

[3] ANNOUNCER: This revolutionary, all-natural,
[4] vitamin-based spray is easy to use and guaranteed to work
[5] the very first night.

[6] ON SCREEN: (Graphic), Med Gen Solutions

[7] ANNOUNCER: Just a few sprays to the back of
[8] the throat before you go to sleep and the sound of
[9] snoring disappears. It's just that simple. And it's
[10] guaranteed or your money back.

ON SCREEN:

[11] 30 DAY Money Back Guarantee!

[12] ANNOUNCER: No more sleeping on the couch or in
[13] the guest room. No more being exhausted the next day
[14] because of lost sleep. No more being tired in class or
[15] at that board meeting. No more embarrassing episodes in
[16] public. Snorenz is recommended by dentists.

ON SCREEN:

[17] Recommended by Dentists!

[18] Dr. Robert Currier, MED GEN Solutions

[19] ANNOUNCER: It even eliminates stale mouth,
[20] morning breath. Don't deprive yourself or your partner
[21] of a restful, peaceful night's sleep anymore. Enjoy a
[22] more vigorous, joyous and energized day. Surgical
[23] procedures can cost you \$3,600, and be dangerous.

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ON SCREEN:

SURGICAL PROCEDURES

[1] UP TO \$3,600!

[2] DANGEROUS!

DENTAL APPLIANCES

[3] COST HUNDREDS!

[4] VERY PAINFUL!

[5] TAPES, PILLS, NOSE PINCHERS

[6] DON'T WORK!

[7] ANNOUNCER: Dental appliances can cost you
[8] hundreds and be very painful. Tapes, pills, nose-
[9] pinchers just don't work. Order your Snorenz today.

ON SCREEN:

[10] CALL NOW!

[11] John Ziglar

[12] JOHN ZIGLAR: I'll tell you something, I got
[13] introduced to the product about 14 months ago, as you
[14] well know, and when I first came home, I went home and I
[15] told my wife, I said Honey, I have been introduced to a
[16] product, I'm getting involved with a company that's going
[17] to be doing some infomercials and doing some work on a
[18] product called Snorenz. And she says well, boy, you
[19] ought to bring some of it home. And I said well, really,
[20] you don't snore that bad.

[21] PAUL KRAVITZ: (Laughter).

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[1] DR. BOB CURRIER: (Laughter).
[2] JOHN ZIGLAR: (Laughter). She said it wasn't
[3] for her. And, you know, quite honestly, I've been
[4] married now for 27 years, and I didn't really realize
[5] that I snored, but I tell you what, since I have been
[6] using this product, a couple of things have occurred.
[7] Number one, my ribs have healed up —

ON SCREEN:

[8] Restful, Peaceful Sleep!

[9] PAUL KRAVITZ: (Laughter).

[10] JOHN ZIGLAR: — over the course of the last
[11] year and a half. And I can also say this, I do a good
[12] bit of traveling with my job, and because I do travel I
[13] end up in hotel rooms across the country, and I found
[14] that I don't turn over in bed as much at night, and I
[15] have had several physicians to tell me that it's because
[16] I'm getting a more peaceful, restful sleep, because I'm
[17] not waking myself up with the noise of snoring.

ON SCREEN:

[18] Dr. Robert Currier

[19] DR. BOB CURRIER: What you're doing is you're
[20] actually repositioning yourself so that anatomically we
[21] change so that our airway becomes more open. When we
[22] start to snore, it becomes an obstruction to the passage
[23] of air. And of course we need air, we need oxygen to

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[1] breathe, and any time we change positions, we're trying
[2] to reposition that. If you can also attenuate the noise,
[3] the noise that actually — actually the noise that wakes
[4] us up.

[5] JOHN ZIGLAR: Sure.

[6] DR. BOB CURRIER: It helps immensely.

[7] JOHN ZIGLAR: Ladies and gentlemen, if you're a
[8] snorer, or if you know someone who is, pick up the
[9] telephone, call the number on your screen.

ON SCREEN:

[10] 30 Day Guarantee!

[11] JOHN ZIGLAR: We have a money-back guarantee on
[12] this product. And the beauty of this product is this:
[13] it's all-natural. It's a blend of five different oils
[14] that you spray to the back of your throat.

[15] ON SCREEN: (Graphic)

[16] JOHN ZIGLAR: When you spray into the throat,
[17] the beauty of this one is it will work the very first
[18] night that you use it.

ON SCREEN:

[19] Works Very First Night!

[20] JOHN ZIGLAR: If you need a good night's sleep,
[21] Snorenze can be a solution that will help to make your
[22] night more peaceful, more restful, so that when you wake
[23] up tomorrow, you'll be able to function better.

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[1] PAUL KRAVITZ: Just tilt your head back, three
[2] sprays in the back of your throat, and guess what? It
[3] tastes great.

ON SCREEN:

[4] SNORENZE Works Because It Is Easy to Use!

[5] DR. BOB CURRIER: Well, and my patients will
[6] tell you that its efficacy or the way that it works and
[7] the effectiveness for them is its ease of use.

ON SCREEN:

[8] Tastes Great!

[9] JOHN ZIGLAR: Yes.

[10] DR. BOB CURRIER: The appliance, they put the
[11] appliance in, it's hard, it's firm and they have to sleep
[12] like this (demonstrating). Oftentimes it keeps them from
[13] sleeping because of the appliance. Okay, also with
[14] surgery, which can be effective for many people; the
[15] appliance can be effective; but do they use it? Is it
[16] something that is going to be used and is simple and is
[17] cost-effective for them? That's where you get the —

[18] PAUL KRAVITZ: John, everybody makes a joke out
[19] of snoring.

[20] JOHN ZIGLAR: Sure.

[21] DR. BOB CURRIER: Um-hmm.

[22] PAUL KRAVITZ: Snoring is no joke.

[23] JOHN ZIGLAR: You're right.

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[1] PAUL KRAVITZ: This is a product that works,
[2] for less than a dollar a day, why wouldn't your listeners
[3] buy this product?

[4] JOHN ZIGLAR: Let me go to another area here
[5] real quick, guys.

[6] PAUL KRAVITZ: Um-hmm.

ON SCREEN:

[7] John Ziglar

[8] JOHN ZIGLAR: I was in Chicago a couple of
[9] months ago, picked up a newspaper, the Chicago Sun-Times.
[10] And I was reading in there and all of a sudden the
[11] headline comes up and it says to me, Snoring Causes
[12] Students to do Work — Less — Be Less Effective in
[13] School.

ON SCREEN:

[14] Have More Energy!

[15] JOHN ZIGLAR: And, so, I read through the
[16] article, and actually what I found, guys, is that they
[17] actually did a study at a medical school over in West
[18] Germany. And in West Germany, they had 200 students that
[19] they were testing, and they had 100 students that snored
[20] and 100 that didn't snore. At the end of one year, they
[21] took all of their grades and they combined them all
[22] together and they found that the snorers actually scored
[23] 6 percent less than the non-snorers.

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Page 22

[1] **PAUL KRAVITZ:** I got a phone call the other day
[2] from a woman whose husband is a fireman.

ON SCREEN:

[4] **Graphic:** Newspaper clippings

[5] **JOHN ZIGLAR:** Yes.

ON SCREEN:

[7] Paul Kravitz

[8] CEO Med Gen

[9] **PAUL KRAVITZ:** All right? The guy sleeps every
[10] night with his buddies in the firehouse. They can't
[11] stand it. They built this huge wall to stop the noise
[12] that this — this guy must snore tremendous. Guess what,
[13] his wife tells me he had a lot of surgery, that did not
[14] stop the noise of snoring.

[15] **JOHN ZIGLAR:** Uh-huh.

[16] **PAUL KRAVITZ:** He has tried everything, I mean,
[17] everything on the market. Happened to see a commercial
[18] in Phoenix, on Channel 3, about this product.

[19] **ON SCREEN:** CALL NOW To Get Your SNOREnz

[20] **PAUL KRAVITZ:** They did a study of five days to
[21] prove that it worked or didn't work. It worked. And she
[22] called the station, tried to get our phone number, got
[23] us, used the product, called me up and said, Mr. Kravitz,
[24] I don't know how to thank you. I mean, you have really
[25] not only saved the firemen in the firehouse —

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Page 23

[1] **JOHN ZIGLAR:** Sure.

[2] **PAUL KRAVITZ:** — but you've saved my life and
[3] my husband's life. Thank you very much. Now, we have a
[4] portfolio of testimonials from people who have used this
[5] product. If it's used properly, and you don't drink
[6] something before you go to bed at night, and you don't
[7] drink liquid before you go to bed, and if you do, then
[8] you have to gargle or wash your throat. But if you use
[9] this product carefully and spray it three times before
[10] you go to bed at night, you will be like me, rested in
[11] the morning when you get up, with a sweet-smelling
[12] breath. It's just great. John, it's a great product.

[13] **FEMALE TESTIMONIAL:** The other day I was
[14] introduced to a product called Snorenz. And since my
[15] husband has a problem with snoring, I wanted to try it on
[16] him, so I brought it home and he tried it. And that was
[17] the first time we had a peaceful night's sleep in a long
[18] time.

[19] **MALE TESTIMONIAL:** I had considered having the
[20] laser surgery, but too many people told me that it was
[21] extremely painful and not always effective. Then I tried
[22] Snorenz, and it worked the very first night. I've used
[23] it ever since.

[24] **HUSBAND TESTIMONIAL:** Before I found Snorenz, I
[25] had tried everything, tapes, tablets, nose sprays.

[1] **WIFE TESTIMONIAL:** Nothing worked like Snorenz

[2] worked.

[3] **FEMALE TESTIMONIAL:** Snorenz really works, and
[4] it's so easy to use, I wake up feeling refreshed.

[5] **WIFE TESTIMONIAL:** Now anyone can stop snoring.

[6] **HUSBAND TESTIMONIAL:** Just like I did.

[7] **FEMALE TESTIMONIAL:** And me.

[8] **MALE TESTIMONIAL:** And me.

[9] **ANNOUNCER:** Your partners can't sleep. You're
[10] restless and tired the next day. You're cheating your
[11] family out of a restful night's sleep. The fact is,
[12] snoring can be a major problem, and people in the past
[13] have gone through extensive appliances, painful
[14] procedures, even invasive surgeries that cost up to
[15] \$3,600, and they still don't work.

ON SCREEN:

[17] **EXPENSIVE APPLIANCES!**

[18] **PAINFUL PROCEDURES!**

[19] **INVASIVE SURGERIES!**

[20] **DON'T WORK!**

[21] **ANNOUNCER:** But now there's an amazing new
[22] breakthrough for snoring sufferers, Snorenz.

ON SCREEN:

[24] **ALL NATURAL!**

[25] **VITAMIN BASED!**

[1] **EASY TO USE!**

[2] **GUARANTEED!**

[3] **ANNOUNCER:** This revolutionary, all-natural,
[4] vitamin-based spray is easy to use and guaranteed to work
[5] the very first night. Just a few sprays to the back of
[6] the throat before you go to sleep and the sound of
[7] snoring disappears.

[8] **ON SCREEN:** (Graphic)

[9] **ANNOUNCER:** It's just that simple. And it's
[10] guaranteed or your money back.

ON SCREEN:

[12] **30 DAY MONEY BACK GUARANTEE**

[13] **ANNOUNCER:** No more sleeping on the couch or in
[14] the guest room. No more being exhausted the next day
[15] because of lost sleep. No more being tired in class or
[16] at that board meeting. No more embarrassing episodes in
[17] public.

ON SCREEN:

[19] Recommended by Dentists!

[20] Dr. Robert Currier, MED GEN Solutions

[21] **ANNOUNCER:** Snorenz is recommended by dentists.

[22] It even eliminates stale mouth, morning breath. Don't
[23] deprive yourself or your partner of a restful, peaceful
[24] night's sleep anymore. Enjoy a more vigorous, joyous and
[25] energized day.

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[1] **ON SCREEN:**
[2] SURGICAL PROCEDURES
[3] UP TO \$3,600!
[4] DANGEROUS!
[5] **DENTAL APPLIANCES**
[6] COST HUNDREDS!
[7] VERY PAINFUL!
[8] TAPES, PILLS, NOSE PINCHERS
[9] DON'T WORK!
[10] **ANNOUNCER:** Surgical procedures can cost you
[11] \$3,600, and be dangerous. Dental appliances can cost you
[12] hundreds and be very painful. Tapes, pills, nose-
[13] pinchers just don't work. Order your Snorenz today.
[14] **JOHN ZIGLAR:** You know, I've talked to hundreds
[15] and hundreds of people, couples, most of them who call
[16] in, a lot of them is the ladies.
[17] **ON SCREEN:**
[18] CALL NOW To Get Your SNORenz
[19] **JOHN ZIGLAR:** And the wives call in because
[20] their husband snores. Now, they love their wives. It's
[21] not a matter of them not loving their wife, but it's an
[22] irritation they cannot control. And so they call in, the
[23] ladies call in, want to know what kind of help can you
[24] give me. We've got this product, they use it, it's easy
[25] because it doesn't taste bad.

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[1] **ON SCREEN:**
[2] Safe, Simple to Use!
[3] Over 1 Million Sold!
[4] **JOHN ZIGLAR:** They can use it and it's very,
[5] very simple. It's very —
[6] **ON SCREEN:**
[7] Paul Kravitz
[8] CEO Med Gen
[9] **PAUL KRAVITZ:** John, we have sold over a
[10] million bottles in less than a year, in nine months now.
[11] And we have satisfied users. You know why we have
[12] satisfied users? Because we get repeats, and it works.
[13] **JOHN ZIGLAR:** When I was up in Chicago, we
[14] introduced the product to a young couple, been married
[15] for about — been married four years. For the last two
[16] years, the lady — the wife had been waking up because
[17] the husband snored, went out, slept on the couch, okay?
[18] **PAUL KRAVITZ:** Um-hmm.
[19] **ON SCREEN:**
[20] SNORenz Works Because It is Easy to Use!
[21] **JOHN ZIGLAR:** Okay? And we've heard it many,
[22] many times, you know. And so she would go out, she would
[23] sleep on the couch. And, so, we gave the product to her
[24] and said hey, try this, see how it works for you. And,
[25] so, she took the product, she went home, she gave it to

[1] her husband, he sprayed just like he was supposed to,
[2] three nights in a row, worked perfect every single time.
[3] **DR. BOB CURRIER:** Oftentimes with snoring, it's
[4] by the recognition of others that we find out that we do
[5] or don't snore.
[6] **ON SCREEN:**
[7] Dr. Robert Currier
[8] **DR. BOB CURRIER:** And we tell others that they
[9] snore, so it's always by the recognition of others.
[10] **ON SCREEN:**
[11] Used by Dentist!
[12] **DR. BOB CURRIER:** Interestingly enough, I have
[13] an optician friend of mine who had to take his certifying
[14] exam, so he has to get a good night's sleep to take his
[15] test. He was really concerned with it because he
[16] couldn't sleep. I said, well, you know, why don't you
[17] try Snorenz. We had already had many patients that use
[18] it for multiple different reasons.
[19] He tried it; he got a good night's sleep. He
[20] finally started thinking about why, why am I not sleeping
[21] well. Because he snored, he would wake himself up. And,
[22] so, as an individual, he didn't have anyone to tell him
[23] that he did snore —
[24] **JOHN ZIGLAR:** Right.
[25] **DR. BOB CURRIER:** — but he just assumed that

[1] he would try this out and it did work for him. It was
[2] fantabulous. You know, it really worked well for him.
[3] **PAUL KRAVITZ:** Um-hmm.
[4] **DR. BOB CURRIER:** It really works.
[5] **PAUL KRAVITZ:** Like you, we get stories from
[6] all over the world.
[7] **DR. BOB CURRIER:** All over.
[8] **JOHN ZIGLAR:** Folks, what I'm going to say to
[9] you right now is this: When you go to sleep at night,
[10] what happens is all of the muscles and the tissues in
[11] your body relax.
[12] **ON SCREEN:**
[13] John Ziglar
[14] **JOHN ZIGLAR:** When they do, your tongue
[15] relaxes, the tongue actually slides back into the throat
[16] a little bit; the uvula sits down on the back of the
[17] tongue; when you breathe past it the tissues begin to
[18] dry; as they dry they get a little sticky and tacky; and
[19] then what happens is they start to clasp and clatter.
[20] **ON SCREEN:**
[21] Safe, Simple to Use!
[22] (Throat Anatomical Graphic, with snoring sound
[23] and photo).
[24] **JOHN ZIGLAR:** That's the noise that you hear
[25] from snoring. And what we're doing here is we are

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[1] providing a solution that you can spray to the back of
[2] your throat. It's all-natural and it's got no chemicals,
[3] additives or preservatives.

ON SCREEN:

- [4] All Natural
- [5] No Chemicals
- [6] No Additives
- [7] No Preservatives
- [8] No Side Effects

[9] JOHN ZIGLAR: If you spray this product to the
[10] back of your throat before you go to sleep at night, you
[11] will not snore. It's our guarantee to you.

ON SCREEN:

[12] Over 1 Million Sold!

[13] JOHN ZIGLAR: Pick up the telephone; give us a
[14] call; and we'll be able to solve that problem for you
[15] right now.

[16] Paul, you have got a whole lot of stories,
[17] people who have bought product from you. I understand
[18] you just took a trip up to Chicago and there was a
[19] gentleman on the airplane that was snoring. Tell us what
[20] happened.

[21] PAUL KRAVITZ: It was kind of funny, John.

[22] JOHN ZIGLAR: Yeah.

[23] PAUL KRAVITZ: I mean, this guy just fell

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[1] asleep and he's snoring. And he's sitting right next to
[2] me. Obviously, I carry my bottle of Snorenz with me no
[3] matter where I go.

[4] JOHN ZIGLAR: Sure.

[5] PAUL KRAVITZ: And I said gee, let's see if it
[6] works. So, I wake him a little bit, I shake him and he
[7] startles, you know, and he says so, what do I do, what do
[8] I do. I said, sir, you are really snoring, you are
[9] bothering everybody around you.

[10] JOHN ZIGLAR: Right.

[11] PAUL KRAVITZ: Would you just try spraying this
[12] in your mouth? And he looked at it and it said Snorenz.
[13] I said yes, it's a product we manufacture, try it. He
[14] did, conked right back to sleep again, silence in the
[15] plane.

[16] JOHN ZIGLAR: I talk to people also that are
[17] ladies that snore. And it's not just a man thing.

ON SCREEN:

[18] 60 % of Snorers are Men

[19] 40 % are Women

[20] JOHN ZIGLAR: Actually, what we have found is
[21] about 60 percent of the snorers in our country are men,
[22] but the other 40 percent are women. So, ladies, this is
[23] not purely gender-specific.

[24] PAUL KRAVITZ: I'll go one better than that.

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[1] JOHN ZIGLAR: Yeah.

[2] PAUL KRAVITZ: A friend calls me up, he says

[3] Paul, I use the snoring product every day, but my dog is
[4] snoring right next to me.

[5] JOHN ZIGLAR: (Laughter).

[6] PAUL KRAVITZ: I go whish, whish, whish

[7] (spraying). And he says and the dog just went like that,
[8] went back to sleep, no snoring from the dog either.

[9] **FEMALE TESTIMONIAL:** We've used Snorenz for

[10] just about 10 to 12 days. We have both slept very, very

[11] well. Me, because I don't hear the noise; him, because

[12] I'm not waking him up to stop the noise. What it does,

[13] it doesn't stop the snoring, it actually calms the noise

[14] so you do not hear it. It still happens, but you do not

[15] hear it happening. Consequently, when you wake up in the
[16] morning, you're a much happier couple. It really does
[17] make a difference in your life when you wake up and you
[18] have gotten a good night's sleep.

[19] **DR. JANE:** Hello, my name is Dr. Jane. I just

[20] wanted to mention that Snorenz has been very effective
[21] for our patients. Again, thank you, Snorenz.

[22] **WIFE TESTIMONIAL:** Thanks to a friend that

[23] introduced us to Snorenz, my sleepless nights are pretty
[24] much over. For the past year and a half —

[25] **HUSBAND TESTIMONIAL:** Year and a half.

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[1] **WIFE TESTIMONIAL:** It's been about a year and a
[2] half. We hadn't been able to really sleep together due
[3] to the fact that my husband snored and has a snoring
[4] problem. But Snorenz has put an end to that and we've
[5] been sleeping quite well. Restful, peaceful.

[6] **HUSBAND TESTIMONIAL:** Every night —

[7] (inaudible) — go to bed anymore.

[8] **LADY:** Yep.

[9] **MAN:** Wake up in bed, instead of the couch.

[10] **FEMALE TESTIMONIAL:** And he gets an opportunity
[11] to really get a good, decent, deep sleep, which is really
[12] important. We feel extremely refreshed in the morning.
[13] So, we're really thankful for that, it's a great, great
[14] product. It's really changed our lives.

[15] **ANNOUNCER:** Your partners can't sleep. You're
[16] restless and tired the next day. You're cheating your
[17] family out of a restful night's sleep.

ON SCREEN:

[18] **EXPENSIVE APPLIANCES!**

[19] **PAINFUL PROCEDURES!**

[20] **INVASIVE SURGERIES!**

[21] **DON'T WORK!**

[22] **ANNOUNCER:** The fact is, snoring can be a major
[23] problem, and people in the past have gone through
[24] extensive appliances, painful procedures, even invasive

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[1] surgeries that cost up to \$3,600, and they still don't
[2] work. But now there's an amazing new breakthrough for
[3] snoring sufferers, Snorenz.

[4] **ON SCREEN:**

[5] ALL NATURAL!

[6] VITAMIN BASED!

[7] EASY TO USE!

[8] GUARANTEED!

[9] **ANNOUNCER:** This revolutionary, all-natural,
[10] vitamin-based spray is easy to use and guaranteed to work
[11] the very first night.

[12] **ON SCREEN:**

[13] (Graphic), Med Gen Solutions

[14] **ANNOUNCER:** Just a few sprays to the back of
[15] the throat before you go to sleep and the sound of
[16] snoring disappears. It's just that simple. And it's
[17] guaranteed or your money back.

[18] **ON SCREEN:**

[19] 30 DAY MONEY BACK GUARANTEE!

[20] **ANNOUNCER:** No more sleeping on the couch or in
[21] the guest room. No more being exhausted the next day
[22] because of lost sleep. No more being tired in class or
[23] at that board meeting. No more embarrassing episodes in
[24] public.

[25] **ON SCREEN:**

Page 33

[1] Recommended by Dentists!

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[3] **ANNOUNCER:** Snorenz is recommended by dentists.

[4] It even eliminates stale mouth, morning breath. Don't
[5] deprive yourself or your partner of a restful, peaceful
[6] night's sleep anymore. Enjoy a more vigorous, joyous and
[7] energized day.

[8] **ON SCREEN:**

[9] **SURGICAL PROCEDURES**

[10] UP TO \$3,600!

[11] DANGEROUS!

[12] **DENTAL APPLIANCES**

[13] COST HUNDREDS!

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[18] \$3,600, and be dangerous. Dental appliances can cost you
[19] hundreds and be very painful. Tapes, pills, nose-
[20] pinchers just don't work. Order your Snorenz today.

[21] **ON SCREEN:**

[22] Dr. Alliert S. Jerome

[23] Clinical Nutrition Specialist

[24]

[25] **ON SCREEN:**

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[1] All Natural

[2] No Chemicals

[3] No Additives

[4] No Preservatives

[5] No Side Effects

[6] DR. JEROME: What I recommend to patients,

[7] family and friends is not a prescription medicine but an
[8] all-natural vitamin and oil, lipostate formula called
[9] Snorenz, that thanks to liposome technology is absorbed
[10] by the mucous membranes of the soft palate and quickly
[11] quiets the noise caused by the vibration of the uvula
[12] against the soft palate.

[13] **ON SCREEN:**

[14] (Anatomical throat graphic/snoring photo with
[15] sound)

[16] **MALE TESTIMONIAL:** Snorenz did wonders for my
[17] snoring problem, and it helped the very first time I used
[18] it.

[19] **MALE TESTIMONIAL:** Now I wake up without that
[20] dry, sticky feeling in my mouth, and no more morning
[21] breath.

[22] **JOHN ZIGLAR:** That's incredible. Paul, doesn't
[23] it make you feel good all over?

[24] **PAUL KRAVITZ:** Oh, it really does.

[25] **JOHN ZIGLAR:** To know the impact that you've

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[1] had on all these people's lives.

[2] **PAUL KRAVITZ:** John, I had a singer call me up.

[3] She said Mr. Kravitz, I have used your product for the
[4] last year. I said really?

[5] **ON SCREEN:**

[6] Paul Kravitz

[7] CEO Med Gen

[8] **JOHN ZIGLAR:** Yeah.

[9] **PAUL KRAVITZ:** I said does this famous snorer
[10] really sing? And she said no, she said I use the product
[11] because my throat gets very dry.

[12] **ON SCREEN:**

[13] Works Very First Night!

[14] **JOHN ZIGLAR:** Yeah.

[15] **PAUL KRAVITZ:** And after the first performance,
[16] I spray Snorenz in my throat and it feels great and it
[17] tastes great and it lasts for a long time. And I just
[18] carry the bottle with me every place I go.

[19] **DR. BOB CURRIER:** Well, there's a doctor that
[20] does ear, nose and throat work, and he's actually done
[21] throat surgery.

[22] **ON SCREEN:**

[23] Dr. Robert Currier

[24] **DR. BOB CURRIER:** And often this is very

[25] invasive surgery for cancer or a stripping of a vocal

Page 36

[1] cord, well, anything where they come in — what happens
[2] is the tissues become very irritated.

ON SCREEN:

[4] Non-invasive!

[5] **DR. BOB CURRIER:** With the coating, soothing
[6] properties of this product, what it does when it's
[7] sprayed, and I'm sure this happens with a singer, as
[8] well, it gives the coating that is needed for the passage
[9] of air so it does not become raw. Or it helps to keep it
[10] moist.

ON SCREEN:

[11] CALL NOW To Order Your SNOREnz

[13] PAUL KRAVITZ: Soothes it.

[14] **DR. BOB CURRIER:** It soothes it immensely. And
[15] that's a feeling that someone gets when they use it other
[16] than for snoring. And that's the reason why.

[17] **PAUL KRAVITZ:** You know, it's difficult to talk
[18] about a product, it really is, when you're not using it.
[19] So, I implore every one of the people that are listening
[20] in today to this show, to try this product one time.
[21] They try it once, they're going to be our customers
[22] forever, John.

ON SCREEN:

[24] John Ziglar

[25] JOHN ZIGLAR: Ladies and gentlemen, if you have

Page 36

[1] this product. It's really a wonderful feeling to know
[2] that we've been able to literally help millions of people
[3] at this point to get a good, peaceful, restful night's
[4] sleep 365 days a year.

ON SCREEN:

[6] FREE Bottle Offer! Call Now!

[7] **ANNOUNCER:** Your partner can't sleep. You're
[8] restless and tired the next day. You're cheating your
[9] family out of a restful night's sleep. The fact is,
[10] snoring can be a major problem, and people in the past
[11] have gone through extensive appliances, painful
[12] procedures, even invasive surgeries that cost up to
[13] \$3,600, and they still don't work.

ON SCREEN:

[15] EXPENSIVE APPLIANCES!

[16] PAINFUL PROCEDURES!

[17] INVASIVE SURGERIES!

[18] DON'T WORK!

[19] **ANNOUNCER:** But now there's an amazing new
[20] breakthrough for snoring sufferers, Snorenz.

ON SCREEN:

[22] FREE Bottle Offer! Call NOW!

[23] 1-800-956-7293

[24] ANNOUNCER: This revolutionary, all-natural,

[25] vitamin-based spray is easy to use and guaranteed to work

Page 37

[1] a snoring problem or you know someone who does, do
[2] yourself and them a favor. Get on the telephone, give us
[3] a call.

ON SCREEN:

[5] All Natural

[6] No Chemicals

[7] No Additives

[8] No Preservatives

[9] No Side Effects

[10] JOHN ZIGLAR: This product will solve that
[11] problem for them and they will love you for it. It
[12] absolutely works and the beauty of it is it's all-
[13] natural. There's no chemicals, no preservatives, no side
[14] effects, so that you can freely use this product every
[15] single day.

[16] And when you do use the product, you can know
[17] and you can be assured that when you use this product it
[18] will work that very night. It's not something that you
[19] have to use and have to have a residual effect. It will
[20] actually last that whole night for six to eight hours so
[21] that when you wake up in the morning you will wake up
[22] rested and refreshed.

ON SCREEN:

[24] CALL NOW To Get Your SNOREnz

[25] JOHN ZIGLAR: Paul, thank you for introducing

Page 37

[1] this product. It's really a wonderful feeling to know
[2] that we've been able to literally help millions of people
[3] at this point to get a good, peaceful, restful night's
[4] sleep 365 days a year.

ON SCREEN:

[6] FREE Bottle Offer! Call Now!

[7] **ANNOUNCER:** Your partner can't sleep. You're

[8] restless and tired the next day. You're cheating your

[9] family out of a restful night's sleep. The fact is,

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[11] have gone through extensive appliances, painful

[12] procedures, even invasive surgeries that cost up to

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[23] 1-800-956-7293

[24] ANNOUNCER: This revolutionary, all-natural,

[25] vitamin-based spray is easy to use and guaranteed to work

Page 37

Page 39

[1] the very first night. Just a few sprays to the back of
[2] the throat before you go to sleep and the sound of
[3] snoring disappears.

ON SCREEN:

[5] (Graphic)

[6] Free Bottle Offer! Call NOW!

[7] 1-800-956-7293

[8] **ANNOUNCER:** It's just that simple. And it's

[9] guaranteed or your money back. No more sleeping on the

[10] couch or in the guest room. No more being exhausted the

[11] next day because of lost sleep. No more being tired in

[12] class or at that board meeting. No more embarrassing

[13] episodes in public.

ON SCREEN:

[15] Recommended by Dentists!

[16] Dr. Robert Currier, MED GEN Solutions

[17] **ANNOUNCER:** Snorenz is recommended by dentists.

[18] It even eliminates stale mouth-morning breath.

ON SCREEN:

[20] Free Bottle Offer! Call NOW!

[21] 1-800-956-7293

[22] **ANNOUNCER:** Don't deprive yourself or your

[23] partner of a restful, peaceful night's sleep anymore.

[24] Enjoy a more vigorous, joyous and energized day.

ON SCREEN:

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- [1] EXPENSIVE APPLIANCES!
- [2] PAINFUL PROCEDURES!
- [3] INVASIVE SURGERIES!
- [4] DON'T WORK!
- [5] **ANNOUNCER:** Surgical procedures can cost you
- [6] \$3,600, and be dangerous. Dental appliances can cost you
- [7] hundreds and be very painful. Tapes, pills, nose-
- [8] pinchers just don't work. Order your Snorenz today.

ON SCREEN:

- [10] CALL NOW!
- [11] **RECORDED MESSAGE:** The preceding was a paid presentation by Med Gen Solutions.
- [12] **ON SCREEN:**
- [14] The preceding was a paid presentation by Med Gen Solutions.
- [15] (End of videotape.)

[17]
[18]
[19]
[20]
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[22]
[23]
[24]
[25]

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CERTIFICATION OF TYPIST

- [1]
- [2]
- [3] **MATTER NUMBER:** 0023211
- [4] **CASE TITLE:** MED GEN INC.
- [5] **TAPING DATE:** NOVEMBER 14, 1999
- [6] **TRANSCRIPTION DATE:** MAY 13, 2000
- [7]
- [8] I HEREBY CERTIFY that the transcript contained
- [9] herein is a full and accurate transcript of the tapes
- [10] transcribed by me on the above cause before the FEDERAL
- [11] TRADE COMMISSION to the best of my knowledge and belief.

[12]
[13] **DATED:** MAY 15, 2000

[14]
[15]

SARA J. VANCE

CERTIFICATION OF PROOFREADER

- [16]
- [17]
- [18] I HEREBY CERTIFY that I proofread the transcript for
- [19] accuracy in spelling, hyphenation, punctuation and
- [20] format.

[21]
[22]
[23]
[24]

ELIZABETH M. FARRELL

Lawyer's Notes

[1]
[2] OFFICIAL TRANSCRIPT PROCEEDING
[3]
[4] FEDERAL TRADE COMMISSION
[5]
[6] MATTER NO. 0023211
[7]
[8] TITLE MED GEN INC.
[9]
[10] DATE RECORDED: OCTOBER 13, 1999
[11] TRANSCRIBED: MAY 12, 2000
[12]
[13] PAGES 1 THROUGH 34
[14]
[15]
[16] TRU SNORENZ 1 - KT \$49.95 TRS1 - HARD
[17] VIDEOTAPE
[18]
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[25]

[1] FEDERAL TRADE COMMISSION
[2]
[3] In the Matter of:)
[4] Med Gen, Inc.,) Matter No. 0023211
[5]
[6] October 13, 1999
[7]
[8]
[9]
[10]
[11]
[12] The following transcript was produced from a
[13] videotape provided to For The Record, Inc. on May 8,
[14] 2000.
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[1] FEDERAL TRADE COMMISSION
[2] INDEX
[3]
[4] VIDEOTAPE PRESENTATION: PAGE:
[5] TRU SNORENZ 1 - KT \$49.95 TRS1 - HARD 3
[6]
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Page 1

[1] PROCEEDINGS
[2]
[3] ON SCREEN:
[4] Client: Trudeau Marketing/TVI
[5] Project: VP SNORENZ 1
[6] Price Point: \$49.95
[7] Edit Date: 9/29/98
[8] Editor: SR
[9] Audio: Mixed
[10] Notes: 800-385-6663
[11] The following is a paid commercial for SNORENZ
[12] brought to you by Kevin Trudeau's Tru-Vantage
[13] International, America's premier direct response
[14] marketing company.
[15] TRU-VISION
[16] UNIDENTIFIED MALE: The following is a paid
[17] commercial brought to you by Kevin Trudeau's Tru-Vantage
[18] International.
[19] (Music playing.)
[20] ON SCREEN:
[21] John Ziglar Kevin Trudeau
[22] KEVIN TRUEAU: Hi, I'm Kevin Trudeau, you're
[23] watching Tru-Vision. If you're a snorer or know someone
[24] that is, stay with us for this half-hour. I have my good
[25] friend, John Ziglar, with me. We're going to be talking

October 13, 1999

Matter Number 0023211

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[1] about a — almost a medical breakthrough. It's not quite
[2] a medical breakthrough, but it's certainly a
[3] revolutionary breakthrough —
[4] JOHN ZIGLAR: Yes, it is.
[5] KEVIN TRUDEAU: — for getting rid of the noise
[6] of snoring. And if you are a snorer or you know somebody
[7] that is a snorer, we have a product being introduced on
[8] Tru-Vision for the very first time. It's called Snorenz.
[9] It's an all-natural product that you simply just spray
[10] into your mouth and it gets rid of the noise of snoring
[11] in 97 percent of the cases.

[12] John, tell us a little bit about the problems
[13] people have with snoring, what people have tried in the
[14] past and why this works.

[15] JOHN ZIGLAR: Kevin, I was introduced to the
[16] product a couple of months ago by a friend named Paul
[17] Kravitz down in Florida.

[18] KEVIN TRUDEAU: Um-hmm.

[19] JOHN ZIGLAR: And he was a snorer and he had a
[20] Korean man that came into his office one day and
[21] introduced him to this product. It was a similar
[22] product, it wasn't this one exactly.

[23] And Paul was a snorer and, so, he took the
[24] product home, he used it, he quit snoring immediately.

[25] KEVIN TRUDEAU: Hmmm.

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[1] JOHN ZIGLAR: The problem was it didn't taste
[2] very good, so Paul took it to his own laboratories, put
[3] spearmint flavor into the product so that it didn't have
[4] a bad after-taste, came up with this product, Snorenz,
[5] with a lysosome, patented product — process — and it's
[6] been phenomenal

[7] KEVIN TRUDEAU: Now, this is a patented, all-
[8] natural product and, basically, what's in it is just
[9] natural oils, correct?

[10] JOHN ZIGLAR: That's correct.

[11] KEVIN TRUDEAU: And this is a patented product.

[12] It has been clinically tested in double-blind studies —

[13] JOHN ZIGLAR: Yes.

[14] KEVIN TRUDEAU: Tell us about that.

[15] JOHN ZIGLAR: What we did is we had two double-
[16] blind studies done in two separate locations. Basically,
[17] we had where the doctors did not know which was the
[18] placebo product or did the patient know. And in each of
[19] the cases, the people that took the product that had the
[20] Snorenz product in it in 97 percent of the cases they
[21] quit snoring immediately.

[22] KEVIN TRUDEAU: Now, let's talk about how this
[23] actually works. And by the way, if you're watching right
[24] now, and you would like to get Snorenz — it's not
[25] available in any stores, it's made available right now

[1] exclusively through Tru-Vision, you can buy it at an
[2] incredible price, look on your screen.

[3] ON SCREEN: Limited Time Only!

[4] Exciting New Product

[5] SNORENZ

[6] End Your Snoring Problem, Now!

[7] All-Natural

[8] 3 Month's Supply!

[9] Compare \$99.95

[10] Now Only

[11] \$49.99 +S&H

[12] Results

[13] Guaranteed or

[14] Your Money Back!

[15] 1-800-385-6663

[16] This is a three-month's supply of Snorenz.

[17] It's all natural, it's patented, it's available

[18] exclusively through Tru-Vision. You can call right now.

[19] This is a limited-time offer. This is a three-month's

[20] supply and the suggested retail price for a three-month's

[21] supply is \$99 — that's the suggested retail price.

[22] That's only \$33 per month.

[23] But you can buy it right now, \$49.95 — just

[24] \$49.95, plus shipping and handling, gets you a three-

[25] month's supply. That's about \$15 a month, a little bit

Page 8

[1] happening in the mouth to get rid of the snoring, just
[2] like that, instantly?

[3] JOHN ZIGLAR: What happens, when you go to
[4] sleep, Kevin, is all of your muscles and your tissues
[5] begin to relax. The same thing occurs inside of your
[6] throat. And, so, what happens is the — the hole, the
[7] air passageway, inside your throat will actually become
[8] smaller. And as it becomes smaller than the air that
[9] passes through passes through faster because it's going
[10] through a smaller hole.

[11] And when it does, it rubs against — it causes
[12] the uvula and the soft tissues inside your throat to
[13] flutter. And what they do is they hit against each
[14] other, they begin to stick and that is the noise that we
[15] call snoring.

[16] What this product does is lubricates the parts.

[17] KEVIN TRUDEAU: Un-huh.

[18] JOHN ZIGLAR: And what the patented process
[19] does is we have found a way to keep this product inside
[20] your throat for eight hours, and that's why you don't
[21] have the noise of snoring.

[22] KEVIN TRUDEAU: So, you just spray it in your
[23] mouth, just like that, it tastes great. I mean —

[24] JOHN ZIGLAR: Yeah.

[25] KEVIN TRUDEAU: — it really tastes incredible.

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[1] I was concerned about it was going to give me a crummy
[2] feeling or anything, but it just tastes wonderful. It
[3] smells great, and you just go to sleep and it basically
[4] eliminates that noise.

[5] JOHN ZIGLAR: That's exactly right. That was
[6] my biggest concern too. I thought, you know, if it
[7] doesn't taste good, people won't take it on a consistent
[8] basis.

[9] KEVIN TRUDEAU: Right.

[10] JOHN ZIGLAR: This one is easy.

[11] KEVIN TRUDEAU: Now, what other techniques or
[12] methods or drugs is available out there right now for
[13] somebody who's watching that's a snorer?

[14] JOHN ZIGLAR: You've seen a lot of different
[15] things that people have introduced as snoring fixes.
[16] You've seen the little strips that go across the bridge
[17] of your nose.

[18] In the dental industry what you have is you
[19] have a mechanical piece that goes inside your mouth and
[20] it will actually pull your jaw forward and it's very
[21] uncomfortable and they have a very hard time getting
[22] people to wear it because it's hard to sleep with this in
[23] your mouth.

[24] KEVIN TRUDEAU: Right.

[25] JOHN ZIGLAR: There have been pills that people

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[1] have suggested will help you to stop snoring. At this
[2] point in time, there has not been anything that has
[3] lasted long-term.

[4] They even have surgical procedures where a
[5] surgeon will come in and they will take the uvula, which
[6] is the little hangy-down part of your throat, they'll
[7] take that, Kevin, and they will surgically remove all or
[8] part of that, and then the back part of your tongue and
[9] parts of your throat.

[10] It's a very painful process; it's expensive and
[11] the recovery time is about six months.

[12] KEVIN TRUDEAU: Folks, if you're watching right
[13] now, get on the telephone, this is a three-month's
[14] supply, unconditionally guaranteed, you will know whether
[15] it works the very first night you use it, and if it
[16] doesn't work for you, send it back for a full refund, no
[17] questions asked.

[18] This is a revolutionary — it should be called
[19] a medical breakthrough — what can you call it?

[20] JOHN ZIGLAR: I call it miracle in a bottle.

[21] I'll just tell you.

[22] (Laughter.)

[23] KEVIN TRUDEAU: And if you're a snorer, you
[24] know how powerful this can be. Now, we're going to talk
[25] about some of the health benefits of getting a full-

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[1] night's sleep in a just a moment.

[2] But get on the telephone right now. This is a
[3] limited-time offer. This is normally going to sell —
[4] manufacturer's suggested retail price — \$99 for a three-
[5] month's supply. That's \$33 a month. But if you call
[6] right now, get on the telephone, call right now, while
[7] the supply lasts, this is the only place you can buy this
[8] product today, on sale, a three-month's supply, \$49.95.
[9] That's an incredible value — this is a limited-time
[10] offer — it is an all-natural product, it's patented,
[11] it's guaranteed to work or your money back,
[12] unconditionally guarantee.

[13] There's been a double-blind study, clinical
[14] testing, 97+ percent effective, will guarantee to wipe
[15] out all the noise of snoring, all night long, just three
[16] squirts, this is really — as John said — a miracle in a
[17] bottle.

[18] I want to go to the phone lines. We have Tina
[19] from Phoenix on the line. Tina, are you there?

[20] TINA: I'm here.

[21] KEVIN TRUDEAU: How you doing?

[22] TINA: I have a little cold, so bear with me.

[23] KEVIN TRUDEAU: Oh, that's fine. That's fine.

[24] Now, tell us about your experience with your husband's
[25] snoring, what — what you've done — and how this product

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[1] has worked.

[2] TINA: Well, everything you've spoken about,
 [3] actually, my husband's had done. He's had two surgeries,
 [4] he's a fire fighter/paramedic, so I'm not the only one
 [5] who was affected by his snoring.

[6] I mean, we do not sleep in the same room —
 [7] well, we do not, thank God, because of Snorenz, but at
 [8] the station where he works the guys even built a
 [9] partition around his bunk bed because they couldn't stand
 [10] the snoring any longer.

[11] He went in for one surgery, they removed all
 [12] the polyps in his nose, they thought it was his sinuses

[13]

[14] KEVIN TRUDEAU: Un-huh.

[15] TINA: — that didn't work. Then, they put him
 [16] in the Sleep Center for sleep apnea, then they okayed —
 [17] because you have to get an okay because it's a very
 [18] expensive operation, as — you know — you said, they
 [19] removed part of his uvula, part of the roof of his mouth
 [20] — his tonsils, his adenoids — and this poor man, this
 [21] was a very, very, very painful operation.

[22] And it did work for a while. We were thinking,
 [23] thank, God, we can go on vacation, we can sleep in the
 [24] same room together, and then the one night when he
 [25] started snoring again, I woke him up, he thought I was

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Page 15

[1] nuts, he was telling me there is no way, he's had two
 [2] surgeries, that it's in my imagination, he's just
 [3] breathing hard.

[4] Well, that wasn't the case. So, back to the
 [5] couch again and arguing about the snoring and I saw a
 [6] commercial out here in Phoenix on my news station and
 [7] this couple was talking about this Snorenz. So, I
 [8] figured what have I got to lose?

[9] I called up and I ordered it. And my husband
 [10] thinks, okay, you're a real nut. If two surgeries didn't
 [11] work, some spray stuff is not going to work.

[12] Well, I've got to tell you, it's now been — it
 [13] has to be at least six months that we're using this
 [14] product. I belong to the Snorenz Bottle of the Month
 [15] Club, my husband brought it up to the station because
 [16] there was fire fighter up there that was driving him
 [17] crazy now snoring —

[18] KEVIN TRUDEAU: (Laughter.)

[19] TINA: — wives are calling me for the number.

[20] My daughter was here last Sunday and she says why didn't
 [21] I tell her about this product. So, I gave her my last
 [22] bottle, so I have to go call another order in, because I
 [23] will not be without it. I keep it on my nightstand and
 [24] I'm telling you, my husband, the minute he starts
 [25] snoring, he turns around, sprays his throat, and it

[1] stops.

[2] KEVIN TRUDEAU: Now, when you said — when they
 [3] start snoring — when your husband starts, you have to
 [4] spray his throat. Is that because he forgot to spray
 [5] before he went to sleep?

[6] TINA: He doesn't — he doesn't even think
 [7] about it. He'll wake up maybe — it doesn't happen even
 [8] all the time. If he had a hard night, if he was working
 [9] all night on a shift or whatever, and I start hearing
 [10] that it's coming on — I'm a light sleeper — I just say,
 [11] John, he turns over, reaches for the bottle, sprays his
 [12] throat, and that's it.

[13] KEVIN TRUDEAU: And it's — and for the whole
 [14] night —

[15] TINA: The whole night.

[16] KEVIN TRUDEAU: — there's no more sound?

[17] TINA: That's it. We're good to go.

[18] KEVIN TRUDEAU: That's —

[19] TINA: It's amazing, it really is. And to

[20] think he went through all of these surgeries and what he
 [21] — I'll tell you, he was out of work for at least, I
 [22] would say six weeks with this. He was black and blue, he
 [23] couldn't eat, he had food coming out of his nose when
 [24] he'd try to eat —

[25] KEVIN TRUDEAU: Hmmm.

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[1] TINA: So, everybody's happy.
 [2] KEVIN TRUDEAU: That's terrific. Tina, thanks
 [3] very much for calling. I hope you get better with that
 [4] cold.
 [5] TINA: Thank you.
 [6] KEVIN TRUDEAU: All right, have a great day.
 [7] TINA: Okay. Bye-bye.
 [8] KEVIN TRUDEAU: Now, John, we hear stories like
 [9] that all the time —
 [10] JOHN ZIGLAR: I know.
 [11] KEVIN TRUDEAU: — about this product. Really,
 [12] I wish we could call it a medical breakthrough. I mean,
 [13] it's really a revolutionary breakthrough, certainly for
 [14] snorers, a miracle in a bottle.
 [15] Well, let's talk about what really is the
 [16] problem with not only the snorer but the person that
 [17] they're snoring, you know, with.
 [18] Why is it bad for a person to snore? What's
 [19] the problem with snoring? I mean, if I snore and don't
 [20] know I snore —
 [21] JOHN ZIGLAR: Right.
 [22] KEVIN TRUDEAU: — why would I want to get
 [23] this?
 [24] JOHN ZIGLAR: Right.
 [25] KEVIN TRUDEAU: Hey, I'm not affecting

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[1] everybody. Nobody's complaining —
 [2] JOHN ZIGLAR: Exactly.
 [3] KEVIN TRUDEAU: — what's the problem?
 [4] JOHN ZIGLAR: Kevin, when I was introduced to
 [5] the product, and I started using the product myself in my
 [6] own home, I didn't realize I was a snorer. Now, I'm been
 [7] married for 25 years and Linda had never really
 [8] complained.
 [9] But when I told her that we had this new
 [10] product, she suggested that I bring it home. And I
 [11] obviously suggested that I didn't think she snored that
 [12] bad.
 [13] KEVIN TRUDEAU: (Laughter.)
 [14] JOHN ZIGLAR: She told me it wasn't — it
 [15] wasn't her that had the problem.
 [16] KEVIN TRUDEAU: (Laughter.)
 [17] JOHN ZIGLAR: So — but here's the point: The
 [18] point is when you do snore what happens to you is you
 [19] wake yourself up multiple times in a nighttime. And, so,
 [20] what I did is I found myself waking up 10, 15, 20 times a
 [21] night and turning over. And what I did is I never got
 [22] deep sleep.
 [23] KEVIN TRUDEAU: Hmm.
 [24] JOHN ZIGLAR: I got a letter from a lady a
 [25] couple of weeks ago and she had said that for the first

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[1] time in his life she is now beginning to remember dreams.
 [2] KEVIN TRUDEAU: Hmm.
 [3] JOHN ZIGLAR: She got to deep sleep, where she
 [4] was able now to recognize dreams patterns that she had
 [5] had. And she wasn't getting that before when she was in
 [6] the bed with a husband that snored.
 [7] KEVIN TRUDEAU: If you're watching right now,
 [8] we are offering a three-month's supply of Snorenz — this
 [9] is the refill bottle, this is the pump spray — you just
 [10] spray three squirts in your mouth before you go to sleep,
 [11] guaranteed to instantly stop the snoring noise all night
 [12] long.
 [13] And what John's saying is, if you are a snorer
 [14] and maybe you think, oh, it doesn't affect me, it doesn't
 [15] wake me up, it doesn't affect my partner. It is.
 [16] JOHN ZIGLAR: Yeah.
 [17] KEVIN TRUDEAU: If you use this product one
 [18] time, for the first time in years, you will get the best
 [19] night's sleep you've ever had. You'll actually go and
 [20] get deep sleep for the very first time. And you'll wake
 [21] up the next morning probably with more energy than you've
 [22] ever imagined having. Because, folks, if you snore, I
 [23] can tell you right now you are not getting deep sleep and
 [24] you are not full of the energy of that you can be by just
 [25] getting a full night's rest.

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[1] You'll also be more pleasant, you won't be as
 [2] irritable, your body could even function better, your
 [3] immune system and all of your systems can work better
 [4] when you've had a full-night's rest.
 [5] Get on the phone right now. This normally
 [6] sells — manufacturer's suggested retail price for a
 [7] three-month's supply is \$99 — that's only \$33 a month —
 [8] this is a patented process, it's exclusive, you cannot
 [9] buy this in any stores, but for a first time, as our
 [10] introductory special on Tru-Vision, you can get this
 [11] product, while the supplies last, just \$49.95.
 [12] Call the number on your screen for Snorenz,
 [13] unconditionally guaranteed.
 [14] Now, let's talk about — in addition to the
 [15] sleep patterns — how about kids or younger people that
 [16] may actually snore and does it affect their school work
 [17] or job performance.
 [18] JOHN ZIGLAR: There's actually a study, Kevin,
 [19] that's been done over in West Germany with medical
 [20] students. And what they did is they divided the class
 [21] into snorers and nonsnorers. And what they did is they
 [22] took and they did a profile on these students and they
 [23] measured their performance over the entire process of
 [24] their medical career —
 [25] KEVIN TRUDEAU: Um-hmm.

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[1] JOHN ZIGLAR: — and they found that snorers
 [2] actually tested six percent lower than the nonsnorers
 [3] did.
 [4] KEVIN TRUDEAU: Hmmmm.
 [5] JOHN ZIGLAR: And in our own office, we have
 [6] people who have children who snore. I know myself with
 [7] four children that when they don't get enough sleep, then
 [8] the next day their performance is hampered. They simply
 [9] are not as pleasant —
 [10] KEVIN TRUDEAU: Um-hmm.
 [11] JOHN ZIGLAR: — with themselves, with each
 [12] other, with the work that they do — whatever it is.
 [13] Sleep deprivation is a big problem in our
 [14] country.
 [15] KEVIN TRUDEAU: Now, of all the medical
 [16] discoveries out there, there's nothing that we know of
 [17] right now that gets rid of snoring. I mean, you've got
 [18] surgery, there's no drugs, there's these little things
 [19] you put on your nose — they don't work. There's —
 [20] there's really not a lot of things out there. A person
 [21] doesn't have a lot of choices or options —
 [22] JOHN ZIGLAR: No, they don't.
 [23] KEVIN TRUDEAU: — it's just basically roll
 [24] over, turn around — you're basically stuck with the
 [25] problem.

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[1] KEVIN TRUDEAU: Um-hmm.
 [2] JOHN ZIGLAR: — or else it will not work.
 [3] KEVIN TRUDEAU: Right.
 [4] JOHN ZIGLAR: Next thing is, we — you cannot
 [5] — you've got to have a clean palate. In other words,
 [6] what I'm saying, before you go to bed, drink a glass of
 [7] water or else don't drink anything or eat anything at
 [8] least 30 minutes before you go to bed.
 [9] And particularly alcohol. If you drink any
 [10] alcohol, then what it will do is it will naturally cut
 [11] the oils in the product, it'll flow down your throat and
 [12] it simply will not be there. So, it cannot work.
 [13] KEVIN TRUDEAU: So, that's really the only
 [14] thing —
 [15] JOHN ZIGLAR: That's the only thing.
 [16] KEVIN TRUDEAU: — just make sure you spray it
 [17] at the back of your throat, we'll show you exactly how to
 [18] do that, and make sure 30 minutes before you use the
 [19] product, don't drink or eat anything, primarily alcohol,
 [20] that way it will stay on the throat, then go to sleep and
 [21] guaranteed to work or your money back; double-blind
 [22] studies — two of them proved, clinical research, that 97
 [23] percent of the times this was effective in eliminating
 [24] the snoring noise all night long. It's all natural, it's
 [25] patented, and you can't beat the value.

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[1] JOHN ZIGLAR: Or go to the next room.
 [2] KEVIN TRUDEAU: Or go to the next room.
 [3] JOHN ZIGLAR: Yeah.
 [4] KEVIN TRUDEAU: This product, folks, guaranteed
 [5] — get on the telephone right now — guaranteed —
 [6] JOHN ZIGLAR: Um-hmm.
 [7] KEVIN TRUDEAU: — the first time you open this
 [8] bottle, you open up your mouth, go to sleep — three
 [9] squirts — and it tastes good.
 [10] JOHN ZIGLAR: I know it does.
 [11] KEVIN TRUDEAU: I mean, it tastes good. It's
 [12] got that smermint — spearmint — taste, tastes great —
 [13] all night long, no snoring.
 [14] Now, let's talk about why it wouldn't work.
 [15] JOHN ZIGLAR: Yes.
 [16] KEVIN TRUDEAU: Because there are a couple
 [17] situations where you just need to know about this.
 [18] There's just kind of — kind of a couple directions to
 [19] make sure that you — that it does work for you.
 [20] JOHN ZIGLAR: Absolutely. What you have is —
 [21] you have to use the product correctly, okay? We had a
 [22] dentist that did a research project for us to find out
 [23] exactly where this product lands when you squirt it in
 [24] your throat. You've got to get it on the back of your
 [25] throat —

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[1] You can't beat this value, folks. If this
 [2] thing works, and it does, guaranteed, how much would you
 [3] pay? As a matter of fact, you don't even know how much
 [4] it's worth, because you haven't gotten a good night's
 [5] rest in years. You have no idea of how much energy you
 [6] can have the next day when you get a good night's rest.
 [7] We're going to go to the phone lines again. I
 [8] believe we have Kevin and Cindy from Sandwich, Illinois,
 [9] on the phone.
 [10] Kevin and Cindy, are you there?
 [11] CINDY: Yes, we are.
 [12] KEVIN: Yeah.
 [13] KEVIN TRUDEAU: How you doing?
 [14] CINDY: Good.
 [15] KEVIN: Terrific, how about yourself?
 [16] KEVIN TRUDEAU: I'm well. It's a little rainy
 [17] out here today, but okay. Wish I was on the golf course.
 [18] KEVIN: I heard that.
 [19] CINDY: (Laughter.)
 [20] KEVIN TRUDEAU: So, tell me about your
 [21] experience. I sent you a bottle of this stuff and tell
 [22] me what happened.
 [23] KEVIN: Well, actually, first of all, I was
 [24] king of skeptical about it. I'm like, yeah, what — I
 [25] didn't know who sent it at first —

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[1] KEVIN TRUDEAU: (Laughter.)
[2] KEVIN: And I thought, yeah, what am I going to
[3] do with this? I thought it was a joke. But then Cindy
[4] kind of conned me into trying it, and I tried it and it's
[5] really weird because we've only been married like three
[6] years, and so we — some say you're still in the
[7] honeymoon stage, but I used to wake up in bed by myself
[8] because I didn't realize that I was snoring so bad my
[9] wife would get up and go sleep on the couch.

[10] KEVIN TRUDEAU: Wow.

[11] KEVIN: I couldn't understand why. But I
[12] started taking it and I started waking up with my wife
[13] every morning and things have been a whole lot better
[14] since.

[15] CINDY: His snoring was so bad that he would be
[16] in the room and I would be in the living room and the
[17] door would be closed and I still could hear him.

[18] KEVIN TRUDEAU: Now, Cindy, you knew that his
[19] snoring was bad and, obviously, it affected your sleep so
[20] you had to leave the room, correct?

[21] CINDY: Oh, it was awful, yes.

[22] KEVIN TRUDEAU: Kevin, did you — you never
[23] realized how bad your snoring was, right?

[24] KEVIN: I didn't realize I snored that bad,
[25] other than in the mornings I waked up — woke up and, you

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[1] know, had that nasty taste in my mouth and just couldn't
[2] get enough water down — like dry mouth almost every
[3] morning.

[4] KEVIN TRUDEAU: Right.

[5] KEVIN: That's the only way I knew, you know, I
[6] wasn't breathing well.

[7] KEVIN TRUDEAU: Have you noticed when you —
[8] because this product really tastes good —

[9] KEVIN: Right.

[10] KEVIN TRUDEAU: Now, I just tried it for the
[11] first time today, so I know how good it tastes. Have you
[12] noticed any difference in that dry mouth or that morning
[13] breath in the mornings since you've been using the
[14] product or when you use it?

[15] KEVIN: Oh, absolutely. I mean, it's — it's
[16] night and day difference. I wake up in the morning, I
[17] don't have that taste, I don't need to get a drink first
[18] thing in the morning. Plus, I honestly, myself, feel
[19] that I'm getting a better night's sleep, absolutely. I
[20] mean, wake up in the morning with more energy and ready
[21] to face the day instead of dragging my butt out of bed
[22] and whining and pissing and moaning about going to work.

[23] KEVIN TRUDEAU: Yeah. Does — does it — so
[24] you feel that a good night's rest is maybe even affecting
[25] your personality or pleasantness?

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[1] KEVIN: Absolutely, I feel.

[2] CINDY: Yes, he's much better.

[3] (Laughter.)

[4] KEVIN TRUDEAU: Well, wait a minute. Wait a
[5] minute, Cindy. If you're getting a good night's rest
[6] now, too —

[7] CINDY: Oh, exactly.

[8] KEVIN TRUDEAU: — it's probably affecting your
[9] — your maybe personality or happiness level or emotional
[10] level also, right?

[11] CINDY: Exactly. Yeah, because, I mean, I
[12] would never get a good night's sleep because I kept
[13] thinking, oh, he'll stop, I'll turn him over this way or
[14] I'll turn him over the other way, and it — it doesn't
[15] work.

[16] KEVIN: Hey, another added benefit is I'm
[17] getting a lot less bruises in my sleep.

[18] (Laughter.)

[19] KEVIN TRUDEAU: Hey, would you recommend this
[20] — and, obviously, you've seen the results — and would
[21] you recommend this to other people that snore, do you
[22] think they can get the same benefits?

[23] KEVIN: Absolutely.

[24] CINDY: Highly recommend it.

[25] KEVIN TRUDEAU: It's easy to use, right, Kevin?

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[1] KEVIN: Oh, it's simple. I mean, at first I —
[2] you know — I was real apprehensive. I thought it was
[3] going to taste nasty, like you said earlier. I mean, the
[4] taste is just — it's very pleasant. I thought it was
[5] going to be like a medicine. I'm almost ready to pinch
[6] my nose, but the taste is like, Wow!

[7] But it's simple. You just need a couple of
[8] squirts in your mouth and you're done.

[9] KEVIN TRUDEAU: That's great. And did it seem
[10] to work all night long?

[11] KEVIN: Yeah, absolutely, for me. I mean, I —
[12] I don't know, I didn't realize I was waking up, but it's
[13] very evident with my wife.

[14] KEVIN TRUDEAU: Right. Well, that's great.

[15] Well, listen, thanks very much for calling in. I
[16] appreciate it.

[17] CINDY: Okay.

[18] KEVIN TRUDEAU: You guys have a great day.

[19] KEVIN: You, too, take care.

[20] CINDY: Thank you.

[21] KEVIN TRUDEAU: Bye-bye.

[22] CINDY: Bye.

[23] KEVIN TRUDEAU: You know, it's funny, because
[24] he said he's — oh, I feel better, I'm not, you know,
[25] pissing —

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[1] JOHN ZIGLAR: Yes.

[2] KEVIN TRUDEAU: — and moaning when I wake up.
 [3] And so forth and so on. And this is interesting because
 [4] people who snore really don't realize that they are
 [5] waking up throughout the night. I mean, every little
 [6] while they're waking up and then going back to sleep; and
 [7] then waking up and then going back to sleep; waking up —
 [8] and they don't realize that that's never allowing them to
 [9] get into that deep sleep.

[10] JOHN ZIGLAR: That's right.

[11] KEVIN TRUDEAU: But when they wake up they
 [12] don't realize that they haven't gotten a good night's
 [13] rest.

[14] JOHN ZIGLAR: Right. I didn't personally
 [15] realize it until I came up to the apartment in Chicago
 [16] and I was sleeping in the bed by myself and I realized
 [17] that I was not having to make the bed up all the time
 [18] where I had pulled the covers out of the foot of the bed
 [19] because I didn't turn over so many times —

[20] KEVIN TRUDEAU: Oh, that's interesting.

[21] JOHN ZIGLAR: — as a result of using the
 [22] Snorenz. It's the only single other difference.

[23] KEVIN TRUDEAU: Folks, if you're watching right
 [24] now. Get on the phone and get Snorenz. This is
 [25] exclusive, it's a breakthrough, we're announcing it for

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[1] the very first time, this is a revolutionary product
 [2] that's patented, guaranteed to work, you get a three-
 [3] month's supply — this is your refill — and this is the
 [4] little squirter. You just put this by the bed stand and
 [5] then all you do — you can see how it sprays out here —
 [6] you just put three squirts in your mouth, on the back of
 [7] your throat, just squirt it in right before you go to
 [8] sleep, it tastes great, it's all natural, it's a patented
 [9] product. In double-blind studies, clinical testing,
 [10] guaranteed to work 97 percent of the time.

[11] And, you know, we have never seen it fail. And
 [12] I think the reason it says 97 percent, if they put 100
 [13] percent people would think, oh, it sounds too good to be
 [14] true.

[15] And it does sound too good to be true, but the
 [16] double-blind studies, the people that use it, and you can
 [17] find out for yourself —

[18] JOHN ZIGLAR: Yes.

[19] KEVIN TRUDEAU: — it's guaranteed to work or
 [20] your money back. You'll know the very first time you try
 [21] it.

[22] It normally sells for the three-month's supply,
 [23] \$99. You can buy it here today on Tru-Vision — look at
 [24] the price on your screen — just \$49.95. That's less
 [25] than \$15 a month for a great night's sleep. That's \$.50

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[1] a day for a restful, peaceful, wonderful sleep. You're
 [2] not going to wake up your partner.
 [3] If you are a snorer or you know somebody that
 [4] is a snorer, get on the phone right now. This will be
 [5] the best gift you could ever give yourself or you could
 [6] ever give anyone else.

[7] They will get a good night's sleep, and I'll
 [8] tell you something, when — and you found this out —
 [9] JOHN ZIGLAR: Yeah.

[10] KEVIN TRUDEAU: — when people are getting a
 [11] good night's sleep for the very first time, they wake up
 [12] — and from people who order this — they don't realize
 [13] for maybe five, 10, 20, 30 years, they haven't gotten a
 [14] good night's rest.

[15] JOHN ZIGLAR: Right.

[16] KEVIN TRUDEAU: And I can guarantee you
 [17] something. When a person gets a good night's rest and
 [18] wakes up the next morning, they're going to have —
 [19] probably have more energy than they've had in years.
 [20] They're going to feel better about themselves, they're
 [21] going to have a better relationship with their spouse and
 [22] family and friends —

[23] JOHN ZIGLAR: Exactly.

[24] KEVIN TRUDEAU: — they're going to do better
 [25] on the job, better in school, they're going to

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[1] potentially think clearer, they're going to be less
 [2] irritable, they're going to be happier.

[3] You know, we hear all these people are
 [4] depressed today —

[5] JOHN ZIGLAR: I know.

[6] KEVIN TRUDEAU: — taking Prozac and everything
 [7] else, and a lot of it may have to do with just getting a
 [8] good night's rest.

[9] JOHN ZIGLAR: Sleep is a — sleep deprivation
 [10] is huge. It's a huge, huge problem.

[11] KEVIN TRUDEAU: You know, when a person gets a
 [12] good night's rest — you mentioned this too —

[13] JOHN ZIGLAR: Um-hmm.

[14] KEVIN TRUDEAU: — people can actually start
 [15] dreaming better —

[16] JOHN ZIGLAR: Yes.

[17] KEVIN TRUDEAU: — thinking clearer. And,
 [18] again, that relationship with your spouse can get much,
 [19] much better.

[20] It's a big problem, folks, snoring. If you
 [21] know a snorer, if you are one, get on the phone right now
 [22] and get Snorenz. This is a limited-time offer, this is
 [23] the first time we've made it available on Tru-Vision. We
 [24] don't know how long this will be made available at this
 [25] price, it is a limited inventory. We're not sure how

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[1] long we'll be making it available at this price.
[2] You get a three-month's supply, it's all
[3] natural, it's easy to use. If you are a snorer or know
[4] somebody that is, it will eliminate the snoring just like
[5] that, guaranteed or your money back. It's a patented
[6] process, double-blind studies, clinical research. If it
[7] doesn't work, send it back for a full refund, no
[8] questions asked.
[9] But the statistics show, 97 percent effective
[10] in eliminating the noise of snoring the very first
[11] application. Folks, your life can be changed when you
[12] get a good night's rest.
[13] Get on the telephone right now and get Snorenz.
[14] This is Kevin Trudeau with John Ziglar. You're
[15] watching Tru-Vision. It's a limited supply, one-time
[16] only price, get on the phone and get a good night's rest
[17] for the first time in years.
[18] Kevin Trudeau, Tru-Vision, with John Ziglar.
[19] John, thanks very much for being here.
[20] JOHN ZIGLAR: Thank you, Kevin.
[21] KEVIN TRUDEAU: We'll see you next time —
[22] order now.
[23] JOHN ZIGLAR: Bye-bye.
[24] (Music playing.)
[25] ON SCREEN: The preceding has been a paid

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CERTIFICATION OF TYPIST

[1]
[2]
[3] MATTER NUMBER: 0023211
[4] CASE TITLE: MED GEN INC.
[5] TAPING DATE: OCTOBER 13, 1999
[6] TRANSCRIPTION DATE: MAY 12, 2000
[7]
[8] I HEREBY CERTIFY that the transcript contained
[9] herein is a full and accurate transcript of the tapes
[10] transcribed by me on the above cause before the FEDERAL
[11] TRADE COMMISSION to the best of my knowledge and belief.

[12]
[13] DATED: MAY 12, 2000

[14]
[15]
[16]
DIANE QUADE

[17] CERTIFICATION OF PROOFREADER

[18]
[19] I HEREBY CERTIFY that I proofread the transcript for
[20] accuracy in spelling, hyphenation, punctuation and
[21] format.

[22]
[23]
[24]
[25] ELIZABETH M. FARRELL

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[1] commercial for SNORENZ brought to you by Kevin Trudeau's
[2] Tru-Vantage International, America's premier direct
[3] response marketing company.
[4] (End of video.)

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Lawyer's Notes

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[1] FEDERAL TRADE COMMISSION
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[3] In the Matter of:)
[4] Med Gen, Inc.)Matter No. 0023211
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[6]
[7] October 13, 1999
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[13] The following transcript was produced from a
[14] live tape provided to For The Record, Inc. On May 8,
[15] 2000.
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Page 4

[1] Point.
[2] ON SCREEN: Vantage Point with Kevin Trudeau
[3] Jon Denny
[4] JON DENNY: I'm Jon Denny, and this is a
[5] special edition of Vantage Point. We're going to talk
[6] about snoring today, and if you're a snorer or just
[7] happen to sleep next to one, then you know snoring is
[8] no laughing matter. Snoring can and does seriously
[9] diminish the quality of your sleep, your life and it
[10] could drive two people apart, meaning the snorer and
[11] the person next to the snorer.
[12] My guests today are Dr. Bob Courier, physician,
[13] surgeon and associate clinical professor at Michigan
[14] State University, and John Ziglar, who represents a
[15] company that manufactures a product called Snorenz,
[16] which is designed to end your snoring problem.
[17] Gentlemen, thank you for joining me.
[18] Guys, got to ask you this first question,
[19] because for some people it's a light matter, and for
[20] others it seriously impacts their life, certainly
[21] impacts their sleep. What causes snoring? What is the
[22] reason behind that all-too-familiar rumbling sound that
[23] keeps half of America, it seems, up every night?
[24] ON SCREEN: DR. BOB COURIER, Physician Surgeon
[25] DR. BOB COURIER: Well, what snoring really is,

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[1] Jon, is simply a relaxation of the tissues in the back
[2] of your throat. It's when we fall asleep, much of our
[3] muscles in our body as well as our throat relax.
[4] That's the time we sleep. We're supposed to get our
[5] rest.

[6] What happens with that, though, unfortunately
[7] is as the tissues relax, they occlude or actually
[8] narrow, and they cause a funnel effect for the air as
[9] it goes through, flapping the tissue. This is in the
[10] back of the throat, hence creating the noise. It's
[11] very positional, it's very — also very dependent on
[12] habits that we have, such as smoking, our dietary
[13] habits, and then also it affects really how much we
[14] sleep and how much rest we actually get throughout a
[15] night.

[16] **JON DENNY:** Now, you were both snorers
[17] presumably.

[18] **DR. BOB COURIER:** Absolutely.

[19] **JOHN ZIGLAR:** Sure.

[20] **JON DENNY:** Tell me, how did you get involved
[21] in Snorenz? How did this all come about?

[22] **JOHN ZIGLAR:** This all came about, Jon, I met a
[23] friend down in Fort Lauderdale, Florida named Paul
[24] Cravitz. Paul Cravitz was in the banking industry, and
[25] he had a Korean man that came into his office with a

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[1] product in a little bottle and it didn't have any
[2] labels on it or anything, but he says, This will make
[3] you quit snoring. And Paul looked at it, and he put it
[4] over on the side of his desk and didn't think too much
[5] about it, but he did make the mistake of telling his
[6] wife that somebody had come in with this product, and
[7] she asked him would he go ahead and bring it home and
[8] try it.

[9] **ON SCREEN:** John Ziglar, Master Strategies
[10] Researcher

[11] **JOHN ZIGLAR:** The bottom line is, he did use
[12] the product, it did make him quit snoring, but it
[13] tasted terrible, and so Paul says, Whoa, you know, what
[14] a price to pay. So, he took that product, he developed
[15] it, he took it to the laboratories, and they did some
[16] liposome technology with the product, and they put a
[17] flavor to the product to make it so that it tasted
[18] good, and we now call the product Snorenz, and it's
[19] just phenomenal.

[20] **JON DENNY:** And in your first exposure to it,
[21] you were a rumbler. We heard Harley Davidson sounds
[22] coming from you at night is the word on the street.
[23] Tell me your first experience with the product.

[24] **JOHN ZIGLAR:** My first experience really, when
[25] I — I had been married for 25 years, my wife, Linda, I

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[1] came home after talking with Paul, and I told my wife
[2] about this new product that we were looking at, and she
[3] said — and she says, Well, when are you going to bring
[4] it home? And I said, Well, honey, I said really, you
[5] know, you don't snore that bad. And she said it really
[6] wasn't for her. And up until that point, I really
[7] didn't realize that I snored.

[8] **JON DENNY:** Um-hum.

[9] **JOHN ZIGLAR:** But I did turn over in the bed an
[10] awful lot at night, and I knew that, and so I used the
[11] product, and John, what I found is for me personally, I
[12] quit turning over so many times at night, and I began
[13] to get a more peaceful, restful sleep. So, that's what
[14] personally happened in my life.

[15] **JON DENNY:** Well, that raises an interesting
[16] point, because for some people snoring — in a litany
[17] of problems that we face on an everyday basis, snoring
[18] is not at the top of the list. But in fact, if you
[19] speak to people who sleep next to a snorer, as well as
[20] the snorer themselves, there are some real health
[21] issues, there are some real serious concerns that a
[22] snorer has or should have. How does and why does a
[23] snorer — why should a snorer worry about this? Why is
[24] it a problem?

[25] **DR. BOB COURIER:** Well, it is a problem, but

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[1] the real problem is an awareness. A lot of people
[2] aren't aware, as you were, that you didn't snore. You
[3] don't snore. It's — and people don't want to offend
[4] someone else that they may sleep with or someone in
[5] their family by telling them they snore, and they have
[6] put up with it for years.

[7] The problem with that is all the things that go
[8] with it, even on a personal level. Me personally, I
[9] snore and have snored, and I've used the product, as
[10] well, and it's worked great for me. Why do I know
[11] this? Because of my energy level, I feel better, I get
[12] better sleep. The problems that happen, I think people
[13] go to sleep, they assume they're automatically going to
[14] wake up rested. They don't. And then they wake up
[15] with a headache, less energy, they hurt, they're sore,
[16] they're irritable.

[17] The health problems are really insidious. We
[18] can go into hypertension, problems with your heart,
[19] your cardiovascular system that can go into this, but
[20] let's not even go that deep. Let's just talk about the
[21] things that happen to us on an everyday basis, the
[22] energy level that we have. We're not rested. That's
[23] the problem.

[24] **JON DENNY:** So, you're saying snorers get less
[25] rest — get a less restful sleep?

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[1] DR. BOB COURIER: Absolutely, they do not
[2] sleep.
[3] JOHN ZIGLAR: See, what happened to me — what
[4] was going on in my night is I would literally turn over
[5] 20 or 30 times a night, and the reason I would is
[6] because I would go to sleep, my tissues would relax, I
[7] would snore — I would literally wake myself up, and
[8] then I would turn over, and I would turn — I didn't
[9] wake up and get up out of the bed to turn over.
[10] I would just wake up and turn over, and what
[11] that does is it keeps me, John, from getting the deep,
[12] restful sleep.
[13] We get letters, we've got a letter from a lady
[14] out in Phoenix, also, who told us that for the first
[15] time in her life she started taking this product, and
[16] she can remember her dreams. Well, you see, dreaming
[17] is an important thing, and we all dream if we get
[18] peaceful, restful sleep.
[19] JON DENNY: But isn't — isn't dreaming or the
[20] dream state indicative of a deep, restful, REM sleep I
[21] think they call it?
[22] JOHN ZIGLAR: Yes, it is.
[23] JON DENNY: So, if you're a snorer, you won't
[24] dream as much, meaning you're not getting as deep a
[25] sleep. Is that the point?

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[1] DR. BOB COURIER: That is correct. You almost,
[2] because of the snoring, and sometimes we're not aware
[3] of it, we keep waking ourselves up. We snore, then we
[4] wake up, then we try to reposition ourselves. We're
[5] just not comfortable. We can't get our air, we can't
[6] get the oxygen we need, hence the headache, the
[7] irritability when we wake up. We're not rested, that's
[8] the problem.
[9] ON SCREEN: Dr. Bob Courier, Physician Surgeon
[10] DR. BOB COURIER: Another side effect, a cute
[11] story, my brother's also a snorer, I think this is just
[12] something that runs in families, as well. Anyway, he
[13] has since tried the product, as I have, and I use it,
[14] and I think it's fantastic, because it does stop the
[15] snoring. My brother has also — he doesn't have the
[16] aches and pains he used to wake up with.
[17] You were also talking about the tossing and
[18] turning. We're also forgetting his wife used to jab
[19] him in the middle of the night. So, he does not wake
[20] up bruised. So, this also helps, a little sidelight
[21] there.
[22] JON DENNY: How does Snorenz work? Is there
[23] have been other products available over the course of
[24] the last, you know, 10 to 20 years that have been in
[25] pill form, surgeries, people have gone through painful,

[1] expensive surgeries. In fact, we're going to — I
[2] think we're going to talk to a caller later who has a
[3] story to share with us about this product and the
[4] journey she went through with her husband to
[5] essentially reduce this problem or eliminate this
[6] problem. How does this product work?
[7] JOHN ZIGLAR: John, what we've done is we have
[8] taken all natural oils, and we have taken and put them
[9] together in a liposome formulation, and we have taken
[10] it so that you can actually spray this product into the
[11] back of your throat, and the process is really quite
[12] simple. Have you ever seen a car go down the road that
[13] didn't have enough oil in it, and you hear the clatter
[14] and the clanking?
[15] ON SCREEN: John Ziglar, Master Strategies
[16] Researcher
[17] JOHN ZIGLAR: Well, what happens is we took
[18] that same philosophy, that same technology, and we
[19] said, Hey, if we can oil the parts and we can take and
[20] make a topical solution that will stay in a place for
[21] an extended period of time, we can eliminate the noise
[22] of snoring. You're still going to have the same amount
[23] of air that's going to pass through the passage, but
[24] all we're going to do is we're going to lubricate the
[25] parts so that there is no noise associated so that you

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[1] don't then wake up or wake up your neighbor.
[2] JON DENNY: So, it's essentially lubricating
[3] what part of the throat and which part of the throat is
[4] causing that sound?
[5] DR. BOB COURIER: Well, to take this just a
[6] little bit further, a dentist has studied this and has
[7] actually sprayed this in models, and he actually used a
[8] dye at the time so he could see where it was applied.
[9] In the soft tissues, in the back of the throat, the
[10] ones that we see that flap and flutter and that need
[11] the lubrication, what — it is applied there, but where
[12] the technology goes even further and better through
[13] this liposome technology is to apply it evenly, and the
[14] very neat thing about this is it stays. It stays there
[15] all night. That's where others have failed. And
[16] that's also where a lot of the appliances, that's where
[17] also a lot of the applications of surgeries, pills,
[18] other things that have been attempted and tried have
[19] failed. This product here stays there. It's easy
[20] application.
[21] As a physician, one of the problems that I have
[22] with patients is compliance, trying to get them to use
[23] and continually use something. If we're going to get
[24] restful sleep, we need it on an every-night basis.
[25] This is accrued, we have a clock and a bank and it's

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[1] for sleeping purposes.
 [2] So, this isn't something just one night good
 [3] sleep will help. This is something that's accrued over
 [4] time. When you get good sleep, that helps a lot. We
 [5] need compliance. With the ease of application, what he
 [6] is talking about, where the effectiveness of it staying
 [7] there, it's a winner, and that's how it works.

[8] **JON DENNY:** So, it's basically, correct me if
 [9] I'm wrong, it's two or three sprays in the back of your
 [10] mouth. I have a friend who underwent a session with a
 [11] dentist who fitted him with a clamp of some sort, which
 [12] pushed his jaw out and tried to create more breathing
 [13] space essentially, and that lasted for about three or
 [14] four months. This works, and it stays working for
 [15] people?

[16] **DR. BOB COURIER:** Yes, and what you're trying
 [17] to do with the appliance is just simply trying to open
 [18] up the airway more so you don't get the fluttering of
 [19] the tissues, and that's what we do when we snore. When
 [20] we snore, we essentially wake ourselves up in a snore
 [21] and then reposition ourselves, trying to, again, open
 [22] up our airway to get more air so we get more oxygen.

[23] What happens with this product, this
 [24] lubricates, stays there, again through the technology,
 [25] and then you don't have the snore; hence, you don't

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[1] wake up; hence, you get a more restful sleep.
 [2] **JOHN ZIGLAR:** And the problem, John, with the
 [3] appliance is it's very uncomfortable, and there have
 [4] been a lot of people — and dentists will tell you that
 [5] they have got patients who have paid for the procedure,
 [6] paid to get the appliance, could not sleep with it
 [7] hooked up, and so it did not work for them, because
 [8] they were so uncomfortable.

[9] **JON DENNY:** Right.
 [10] **JOHN ZIGLAR:** Okay? So, when I saw this first
 [11] — this product the first time, I looked at this thing
 [12] and I thought, Oh, my goodness, you know, I'm going to
 [13] spray oil in the back of my throat, I'm thinking WD-40
 [14] or something like that and an oil slick, and I'm going,
 [15] Oh, but it's the consistency of water, and the nice
 [16] thing about it is that it doesn't — there's no feeling
 [17] associated with the spray in the back of your throat.
 [18] All you get is a nice, clean, peppermint taste, which

[19] made it wonderful, so compliance — people will do it.
 [20] **JON DENNY:** Well, the after taste —
 [21] **JOHN ZIGLAR:** Yes.
 [22] **JON DENNY:** — in the morning when you wake up
 [23] is much better.
 [24] **JOHN ZIGLAR:** Exactly.
 [25] **JON DENNY:** You don't feel like you have an oil

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[1] sludge at all. It's a minty taste.
 [2] **ON SCREEN:** 800-392-4006
 [3] **MR. DENNY:** If you have a snoring problem, if
 [4] you have problems sleeping next to a snorer, then
 [5] Snorenz may be the answer you've been waiting for.
 [6] Remember, snoring is a medical condition. Studies have
 [7] shown that snoring can seriously reduce your energy
 [8] levels, your concentration and can seriously affect
 [9] your work habits, as well, and you can be sure your
 [10] snoring is seriously bothering someone other than you.
 [11] Snorenz is the first all-natural spray that has
 [12] been proven to give you a healthy, natural, good
 [13] night's sleep. It has no side effects. It's as easy
 [14] as a few sprays before bed, and it lasts all night, and
 [15] if you want more information on Snorenz, if you want to
 [16] stop the snoring, if it's a snorer next to you or if
 [17] you be the snorer, you may want to call the 800 number
 [18] on your screen.

[19] We have I believe a caller on the line from
 [20] Arizona, and I believe it's Tina Hines (phonetic).

[21] Tina, are you on the air with us?

[22] **TINA HINES:** I'm here.

[23] **JON DENNY:** Great. How are you feeling today?

[24] **TINA HINES:** I've got a sore throat, but other
 [25] than that, good. I'm listening to your show, and I

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[1] have to tell you that snoring, you know, is a lot more
 [2] dangerous than people think. My husband was a chronic
 [3] snorer, he's a firefighter/paramedic, so I wasn't the
 [4] only one affected by this. I mean, we didn't sleep
 [5] together for years.

[6] **JON DENNY:** Now, you've been married for how
 [7] long, Tina?

[8] **TINA HINES:** Sixteen years.

[9] **JON DENNY:** Sixteen years, and this was a
 [10] problem that occurred right from the start of your
 [11] marriage?

[12] **TINA HINES:** Oh, yeah.

[13] **JON DENNY:** You found you were married to a
 [14] snorer?

[15] **TINA HINES:** Oh, absolutely, and the poor guy,
 [16] it would be all night, John, turn over, turn over. It
 [17] did not matter, he could be sleeping on his head, and
 [18] he would still snore.

[19] Well, it got so bad that even at the fire
 [20] department, he was being hassled at the fire
 [21] department, because these guys sleep at different
 [22] shifts, they don't all sleep at the same time, and when
 [23] John was sleeping, he would be waking everybody else
 [24] up, so they would be pounding on the walls and he'd
 [25] come home all aggravated, he'd come home and want to

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[1] sleep.

[2] They even built a partition around my husband's
[3] bunk bed to try to keep out the noise. Well, it got so
[4] bad he finally went to the doctor, and in order for the
[5] insurance company to pay for this surgery, they put him
[6] in the hospital, in the sleep center, and found out
[7] that he also had sleep apnea, which is very dangerous,
[8] because when you're snoring, you stop breathing, then
[9] you forget to sleep.

[10] So, they did the surgery, and needless to say,
[11] it lasted for a while, and then after that he started
[12] up again, and he would not even believe when I would
[13] tell him, John, you're snoring again. You don't want
[14] to go through surgery and find out that you're snoring
[15] again.

[16] **JON DENNY:** So, this was after a surgery, he
[17] had — the problem re-emerged.

[18] **TINA HINES:** Right, they did surgery on all his
[19] sinuses, they went through his nose and removed all his
[20] polyps, thinking that was the problem. So, now he's in
[21] for the second surgery, and they decided they are going
[22] to remove part of his uvula, and the roof of his mouth,
[23] his tonsils and his adenoids, and this way it will give
[24] his tongue more room, I guess is what they said, so he
[25] wouldn't snore.

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[1] Well, he went through this, and it was a
[2] horrible surgery. I really felt very, very bad for
[3] him. He was out of work for six weeks, and he had high
[4] hopes that this was going to work and our life was
[5] going to change, we could sleep in the same room
[6] together, go on vacation, the guys wouldn't be hassling
[7] him.

[8] Well, that did work for quite a while, and then
[9] it started up again, and I'll tell you what, I was even
[10] afraid to tell him, because I couldn't believe it
[11] myself. It's aggravating, it's annoying, I don't get a
[12] good night's sleep, he doesn't get a good night's
[13] sleep. I hated to say it, but I was happier when he
[14] was at the fire department because I got a good night's
[15] sleep.

[16] **JON DENNY:** Tina, I want to interrupt you for a
[17] second, because this is a — you know, a real relatable
[18] story to some. Perhaps not all have gone through
[19] surgeries and so forth, but for the millions of people
[20] who sleep next to a snorer, their lives are affected,
[21] as well. How did you find your life or your sleep
[22] quality affected by sleeping next to a snorer?

[23] **TINA HINES:** Well, I didn't, I chased him out.
[24] Actually, I had insomnia and I don't get a good — I
[25] mean, I could hear the dog turn over. So, he would

[1] have to go out in the other room, but I could still
[2] hear him through the vents, but I'd get up in the
[3] morning, and I would be a grouch at work, because I was
[4] — I was tired.

[5] **JON DENNY:** Yes.

[6] **TINA HINES:** And I was aggravated. You're
[7] talking two surgeries, what's it going to take? He
[8] tried those stupid nose strip things, they didn't work.
[9] So, one day I'm sitting here watching TV and I
[10] see a commercial out here in Phoenix and a couple is
[11] talking about the same thing, and I'm thinking, Well,
[12] what have I got to lose?

[13] Well, my husband tells me I'm nuts, because if
[14] two surgeries didn't work, the spray was not going to
[15] work. I figure, Well, I'm going to try it. So, I sent
[16] for it, put it on the nightstand, the first night he
[17] was home, I woke him up, I said, John, spray your
[18] throat. He said, Yeah, yeah, yeah, yeah. I said,
[19] John, please, spray your throat. So, we sprayed his
[20] throat, and I'm like waiting — I'm laying there, I'm
[21] laying there, I'm like, Oh, wow, he was sleeping, there
[22] was no noise coming out of him. And I was — I was
[23] pretty well hooked. And he still was not a believer.
[24] He said it was just a fluke. So, it took a few times
[25] of using the Snorenz.

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[1] Now, I'll tell you what, he's taken it up to
[2] the fire department. I have the wives calling from the
[3] fire department asking me the 800 number. I've given
[4] away more bottles, I can't tell you, because I belong
[5] to the Snorenz Bottle of the Month Club, and I just
[6] gave one to my daughter last week, she came over, and
[7] she was like, Mom, I'm going crazy, Kenny's snoring. I
[8] said, Here, take my last bottle, take it home.

[9] **JON DENNY:** And how long now has your family or
[10] your husband in particular been using Snorenz?

[11] **TINA HINES:** Oh, for — oh, months.

[12] **JON DENNY:** For months.

[13] **TINA HINES:** Months, absolutely.

[14] **JON DENNY:** And it works for him pretty much
[15] every night.

[16] **TINA HINES:** Well, he takes it in his little
[17] duffle bag when he goes to the fire department, because
[18] being a medic, also, he might be called to another
[19] station, he doesn't want to go to another station with,
[20] you know, guys he doesn't know and start snoring. So,
[21] he carries it in his little bag, and everyplace he
[22] goes, the Snorenz goes with him.

[23] **JON DENNY:** Right. Well, Tina, thank you for
[24] calling from Arizona.

[25] **TINA HINES:** Hey, thanks for the Snorenz, I'll

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[1] tell you.

[2] JON DENNY: Well, we appreciate you calling and
[3] continue to get a full silent night's sleep.

[4] TINA HINES: Absolutely.

[5] JON DENNY: Okay, Tina, thank you.

[6] TINA HINES: Thank you.

[7] JON DENNY: Bob, tell us about some of your
[8] patients who have been turned on to Snorenz.

[9] DR. BOB COURIER: Well, I'll give you a good
[10] example. I have Mike. Now, we always think of a
[11] snorer as someone that's older, okay, that's a little
[12] bit more passed middle age, always a male, and it's
[13] always grandpa, the chainsaw, somebody like that.
[14] Interestingly enough, I had a 25-year-old patient of
[15] mine named Mike who is an optician. Now, Mike was
[16] trying to qualify, okay, for the certifying exam to
[17] become a certified optician. He was losing energy.

[18] He just couldn't — he couldn't understand it.

[19] He couldn't understand why he didn't have the get-up
[20] and go to do his job, plus go home to study. He's
[21] single. He lives by himself.

[22] So, he's wondering why. I said, Well, you
[23] know, maybe you're not sleeping well. And he said,
[24] Well, you know, I just can't sleep. So, what happens
[25] to him is I give him some Snorenz. I said, Well just

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[1] try this, it's just an outside shot, I said you have
[2] got to try this, let me know how it works.

[3] He comes back, now, I don't see him in a week
[4] or two on another appointment basis, he comes back, and
[5] my word, he just — he's just aglow. He passed the
[6] certifying exam, he feels like he is more awake, more
[7] energetic, he feels like he can do anything, he can
[8] conquer the world. He's 25 years old.

[9] What has happened is he relayed this story:

[10] What happened to him is he would fall asleep, he
[11] couldn't get to sleep at night, okay, so he'd sit up
[12] and watch late night TV and he becomes an insomniac.

[13] What he would do is fall asleep, but he would
[14] awake with a snore. This way, with using Snorenz, he
[15] could get his clock back in order, he could go to
[16] sleep, and he could go to sleep snoring free, wake up
[17] refreshed in the morning. He figured it all out real
[18] simply, and it took us years to figure all this out,
[19] and he did it in a very short time.

[20] Now, he doesn't have a bed partner, and so what
[21] happens is he did this for himself, for his own energy
[22] level, and so, you know, it has worked successfully for
[23] him. It isn't always a bedmate telling someone that
[24] they have it. He did it for himself.

[25] JON DENNY: You think of snorers as older

[1] people, your grandfather, your father. I remember
[2] growing up my father — listening to my father across
[3] the hallway snoring, it sounded like the start of the
[4] Indianapolis 500 every night. But, in fact, younger
[5] people snore, too, do they not? In fact, there's a
[6] study out about students who were snorers who were
[7] proven to have lower test scores. Tell me about that.

[8] JOHN ZIGLAR: I was reading the newspaper here
[9] in Chicago one day and the Sun Times has an article,
[10] and the top of the article says, "Test scores affected
[11] by snoring." So, I'm looking at it, I'm thinking, Wow,
[12] you know, there's actually been a study done, and what
[13] had happened is a research program was done over in
[14] West Germany with medical students, and what they did
[15] is they tracked an entire medical school class from the
[16] day they started until the day they finished, and they
[17] put them in two categories.

[18] One category was the snorers and over here was
[19] the category of the nonsnorers, and after everything
[20] was said and done, are from start to finish, the
[21] nonsnorers scored six percent higher on their test than
[22] the snorers did, all other things being equal.

[23] JON DENNY: And you just happened to run across
[24] this. So, it's now becoming an awareness. People are
[25] becoming aware now, and it's — see, it's all too

[1] obvious now when you read something like this why that
[2] would happen, because we're all aware, and my patients
[3] are aware of this.

[4] Interestingly enough, I store this on the —
[5] well, on shelves and such in the office. When we do
[6] our inventory at the end of the day, I find that some
[7] has been taken. I don't want to say stolen, because
[8] these are my patients, and we have created a
[9] relationship, but actually, it's missing.

[10] ON SCREEN: This is a paid commercial for
[11] Snorenz

[12] DR. BOB COURIER: So, what happens is it just
[13] plain gets taken. People want this. People are now
[14] aware, and I think this is what's happening here, and
[15] we know why people don't score well. They don't sleep
[16] well. They snore.

[17] ON SCREEN: 800-392-4006

[18] JON DENNY: Ninety million Americans snore.
[19] That doesn't include the countless millions who sleep
[20] next to a snorer, and if you want more information
[21] about this revolutionary, breakthrough product, which
[22] has been proven effective in 97 percent of cases to
[23] eliminate or reduce the sound of snoring, call the
[24] toll-free 800 number on your screen, get more
[25] information about Snorenz, do it for him, do it for

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[1] yourself, do it for your family. It is worth the phone
[2] call, and it is pennies per day to end the snoring
[3] problem forever.

[4] This is a product, as I mentioned, that has
[5] been proven effective in double-blind studies, and you
[6] actually conducted the studies out of your auspices in
[7] Michigan. Tell us about a double-blind study, what it
[8] is and how Snorenz worked.

[9] **DR. BOB COURIER:** Really, just to define what a
[10] double-blind study is in general is nobody knows what
[11] product anybody is getting. The doctor isn't aware of
[12] it, okay, and nor are the patients. For example, we're
[13] giving a block or a bunch of bottles, for example, in
[14] this case, Snorenz, and we are to distribute this out
[15] to our patients in a test pattern, they are going to
[16] use it for a week, but I am blind to the fact of what
[17] product am I giving them, the placebo or dummy product
[18] versus the actual product itself. I'm not aware, so I
[19] cannot influence the study results.

[20] I accumulate the study results, I gather the
[21] patients and have them get compliant with it for use
[22] over a week's time, but I don't — I can't affect it.
[23] The patients can't affect it. So, I am blind to it,
[24] and so are the patients.

[25] Interestingly enough, it's not only the results

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[1] of the studies we got but the comments we received.
[2] Many people, again, they're aware of snoring, but they
[3] aren't aware of the problems that come with it, and
[4] actually it's like — until it's resolved, the snoring
[5] itself, oh, my word, what a problem it was, and you can
[6] see the changes it's made. That was probably the most
[7] interesting part of doing that whole study, was the
[8] comments that we got back, the little stories that
[9] people have through the week, you know, of using this
[10] product, and that was the beauty of this.

[11] I loved doing this study. It was highly
[12] effective.

[13] **JON DENNY:** And John, this is an all-natural
[14] product?

[15] **JOHN ZIGLAR:** It's all-natural oils, and we
[16] also have some vitamins that we have also put into the
[17] product.

[18] **JON DENNY:** Tell us about snorer's breath. I'm
[19] going to test this here. I hope I don't get it in my
[20] eye. It would eliminate my — some problem in my eye,
[21] perhaps, but I — it's minty, actually it tastes a lot
[22] like mouthwash, I mean, it's — in a good way. Three
[23] sprays of this before bed, and how long will this last,
[24] through the night?

[25] **JOHN ZIGLAR:** It will last through the night.

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[1] It will last from six to eight hours.

[2] **JON DENNY:** And in what cases doesn't this
[3] work?

[4] **JOHN ZIGLAR:** You know, when I first got this
[5] product, we did test — and I have given it to
[6] everybody that I know that snores so that I could find
[7] out, you know, because I always wanted to know exactly
[8] how did it work on everybody else. So, we had one
[9] friend we gave it to, and quite honestly, they had been
[10] married for three years, they're already sleeping in
[11] different bedrooms because he snores so loudly, and he
[12] would go to bed — they would go to bed together, wake
[13] up in different rooms.

[14] And so Kevin was taking the product, and the
[15] first night it worked perfectly, the second night it
[16] worked perfectly, third night it worked perfectly,
[17] fourth night, didn't work, fifth night, didn't work.
[18] He called me up and he says, Look, you know, it works
[19] temporarily, but after that, it doesn't — it doesn't
[20] work. And I said, Wait a minute, you know, there's got
[21] to be a reason. There's something wrong here, the only
[22] guy it doesn't work on in the world.

[23] And he says, Well — so, I started to ask him
[24] some questions, and here's the point. What I found out
[25] was the night that it did not work, he had a beer just

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[1] before he went to bed, and what we had here was a
[2] situation where the alcohol in the beer literally cut
[3] through the oils in our product, and it went down his
[4] throat, so it was not there. Since it was not there,
[5] it could not work, and it proved that he still was a
[6] snorer, he just needed the product to stay where it was
[7] so that he would live without the noise.

[8] **JON DENNY:** So, you suggested that he sort of
[9] cut down his drinking right before going to bed.

[10] **JOHN ZIGLAR:** Exactly, don't eat or drink
[11] anything 30 minutes before you go to bed, or if you do,
[12] then take a couple of swallows of water just to clear
[13] your pallet so that your throat is clean so that when
[14] you put the product in on the back of your tongue, then
[15] it will stay there.

[16] **JON DENNY:** Right. Your wives are happy,
[17] gentlemen, that you —

[18] **DR. BOB COURIER:** Happier, happier.

[19] **JON DENNY:** We won't get into that, but they're
[20] happy that your snoring problems have been reduced or
[21] eliminated.

[22] **DR. BOB COURIER:** Yes, very much so.

[23] **JOHN ZIGLAR:** And now, you know, I roll over
[24] and Linda gives me a kiss before we go to bed, and I
[25] think that's just real sweet. She's checking to see if

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[1] I've taken the Snorenz, okay?
[2] **JON DENNY:** If you want more information about
[3] this revolutionary, all-natural, vitamin-based spray,
[4] no pills, no surgery, no clamps, no strips across your
[5] nose, Snorenz will end your snoring problem and do it
[6] naturally. It is pennies in comparison to the value
[7] and the almost priceless value of a full, restful,
[8] silent night's sleep for all, and that goes for the
[9] snorer as well as the person sleeping next to the
[10] snorer railroad.

[11] For more information, call the 800 number on
[12] the screen.

[13] Dr. Bob Courier, thank you for joining us on
[14] Vantage Point.

[15] **DR. BOB COURIER:** Thank you for having me.

[16] **JON DENNY:** And, John Ziglar, thank you.

[17] **JOHN ZIGLAR:** Enjoyed it.

[18] **JON DENNY:** I may knock off a few sprays
[19] tonight and try to get my snoring down. This is Jon
[20] Denny saying good-bye from Vantage Point, and we will
[21] see you next time.

[22] **ON SCREEN:** For more information on Snorenz

[23] call: 800-392-4006

[24] Tru-Vantage International

[25] 7300 Lehigh Ave.

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[1] Niles, IL 60714
[2] (847)647-0300
[3] **ON SCREEN:** The preceding has been a paid
[4] commercial for SNORENZ brought to you by Kevin
[5] Trudeau's Tru-Vantage International, America's premier
[6] direct response marketing company.
[7] (The videotape was concluded.)

[8]

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Page 31

C E R T I F I C A T I O N O F T R A N S C R I B E R

[1]
[2]
[3] DOCKET/FILE NUMBER: 0023211
[4] CASE TITLE: MED GEN, INC.
[5] RECORDING DATE: OCTOBER 13, 1999
[6] TRANSCRIPTION DATE: MAY 15, 2000
[7] I HEREBY CERTIFY that the transcript contained
[8] herein is a full and accurate transcript of the
[9] videotapes transcribed by me on the above cause before
[10] the FEDERAL TRADE COMMISSION to the best of my
[11] knowledge and belief.

[12]

[13]

[14]

[15]

[16]

[17]

DATED:

SUSANNE Q. TATE

C E R T I F I C A T I O N O F P R O O F R E A D E R

[18]
[19]
[20] I HEREBY CERTIFY that I proofread the
[21] transcript for accuracy in spelling, hyphenation,
[22] punctuation and format.

[23]

[24]

DIANE QUADE

[1]
[2] OFFICIAL TRANSCRIPT PROCEEDING
[3]
[4] FEDERAL TRADE COMMISSION
[5]
[6] MATTER NO. 0023211
[7]
[8] TITLE MED GEN INC.
[9]
[10] DATE RECORDED: OCTOBER 13, 1999
[11] TRANSCRIBED: MAY 8, 2000
[12]
[13] PAGES 1 THROUGH 34
[14]
[15]
[16] VP SNORENZ 3 - KT W/DISCLAIMERS SNR3 SOFT
VIDEOTAPE
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[1] FEDERAL TRADE COMMISSION
[2]
[3] In the Matter of:)
[4] Med Gen, Inc.,) Matter No. 0023211
[5]
[6] October 13, 1999
[7]
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[11]
[12] The following transcript was produced from a
[13] videotape provided to For The Record, Inc. on May 8,
[14] 2000.
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Page 1
[1] FEDERAL TRADE COMMISSION
[2] INDEX
[3]
[4] VIDEOTAPE PRESENTATION: PAGE:
[5] VP SNORENZ 3 - KT W/DISCLAIMERS SNR3 SOFT 3
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Page 3
[1] PROCEEDINGS
[2]
[3] ON SCREEN:
[4] Client: Trudeau Marketing/TVI
[5] Project: VP SNORENZ 3
[6] Price Point: Soft Offer
[7] Edit Date: 11/13/98
[8] Editor: WPS
[9] Audio: Mixed
[10] Notes: Generic - Keys, No Phone
[11] The following is a paid commercial for SNORENZ
[12] brought to you by Kevin Trudeau's Tru-Vantage
[13] International, America's premier direct response
[14] marketing company.
[15] Lower test scores linked to snoring
[16] There's More to Snoring Than Meets the Ears
[17] Can you win the snore war?
[18] Something to lose sleep over
[19] MALE ANNOUNCER: The following is a paid
[20] commercial brought to you by Kevin Trudeau's Tru Vantage
[21] International.
[22] (Music playing.)
[23] KEVIN TRUDEAU: For years over 150 million
[24] people have suffered from the effects of snoring. It can
[25] cause headaches, sleeplessness, irritability, poor job

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[1] performance, a lack of energy and even big relationship
[2] problems. Well, what can be done about it? Until now,
[3] nothing.

[4] On Vantage Point today, hear about a new
[5] breakthrough discovery that could possibly eliminate the
[6] sound of snoring.

[7] VANTAGE POINT with Kevin Trudeau

[8] KEVIN TRUDEAU: I am Kevin Trudeau, you're
[9] watching Vantage Point, and joining me is John Ziglar.

[10] John, how are you doing? Good to have you here.

[11] JOHN ZIGLAR: Magnificent. Good to be here,

[12] Kevin.

[13] KEVIN TRUDEAU: You have discovered a product,
[14] a new patented — I don't know if this is a medical
[15] discovery — that can solve the effects or the sound of
[16] snoring. Tell me about this product and what it does.

[17] JOHN ZIGLAR: Kevin, a friend of mine
[18] introduced me to the product from down in Ft. Lauderdale,
[19] Florida. The guy's name is Paul Cravatz. And Paul was
[20] an investment banker and a Korean man came into his
[21] office one day and had a product called Snorenz that he
[22] wanted to have Paul look at to see if he could help him
[23] to market it.

[24] Well, Paul put it over to the side of his desk,
[25] didn't think too much about it because he never really

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[1] formula?

[2] JOHN ZIGLAR: Yes, it is.

[3] KEVIN TRUDEAU: Okay. Patented process. Now,

[4] explain to me why somebody snores.

[5] JOHN ZIGLAR: The reason people snore, Kevin,
[6] when somebody lays down at night and they go to sleep,
[7] what happens is your muscles on your skeletal structure
[8] begin to relax, and the muscles and the tissues inside of
[9] your throat also relax at the same time.

[10] KEVIN TRUDEAU: Um-hmm.

[11] JOHN ZIGLAR: And when that occurs, what

[12] happens is the air passageway inside of your throat
[13] actually diminishes in size. When that happens, then
[14] you've got the same amount of air flow and so the
[15] velocity is greater and it causes the air to run across
[16] your uvula and the soft tissue from the back of your
[17] throat and your tongue and they hit against each other
[18] and that clatter is the noise that we call snoring.

[19] KEVIN TRUDEAU: Now, up until this point, John,
[20] what has been done to solve the problem? Are there any
[21] drugs, any surgery, any other herbal or natural
[22] supplements that people have tried?

[23] JOHN ZIGLAR: There've been — people have been
[24] trying to solve the problem for years. In the dental
[25] profession, they have a mechanical device that you put

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[1] thought about snoring too much.

[2] KEVIN TRUDEAU: Um-hmm.

[3] JOHN ZIGLAR: But he made the mistake of saying
[4] something about it to his wife when he went home. Paul's
[5] been married for 37 years and his wife suggested that he
[6] might bring that product home. (Laughter.)

[7] KEVIN TRUDEAU: (Laughter.)

[8] JOHN ZIGLAR: And, so, when he brought the
[9] product home, then, he tasted the product; the product
[10] tasted terrible; but he quit snoring.

[11] So, he found a product that actually worked and
[12] helped him to eliminate the noise of snoring.

[13] KEVIN TRUDEAU: Now, when he found that
[14] product, was this a patented process that this Korean
[15] gentleman invented?

[16] JOHN ZIGLAR: No, it wasn't, Kevin. At the
[17] time, what he had was a combination of oils that he had
[18] in a little formula that he sprayed in the back of his
[19] throat and then Paul went to his laboratories and he
[20] developed a lysosome formulation of the all-natural oils.
[21] He put some vitamins, minerals in it and put a whole lot
[22] better taste. He put a spearmint taste into the product
[23] so that it would taste good and then still solve the
[24] problem.

[25] KEVIN TRUDEAU: So, now this is a patented

[1] inside of your mouth that will actually bring your jaw
[2] forward to make the air passageway larger.

[3] KEVIN TRUDEAU: Um-hmm.

[4] JOHN ZIGLAR: It's very uncomfortable; very few
[5] people are able to live with that on a consistent basis.
[6] There have been — there's surgery that people have gone
[7] through where they go in and they actually take part of
[8] the uvula — the little hangy-down part in your throat —

[9] KEVIN TRUDEAU: Un-huh.

[10] JOHN ZIGLAR: — where they take and they cut
[11] that out. They take some of the soft tissues off of the
[12] back of the throat and it's an expensive surgery, it's
[13] very painful and the results up to date have been that a
[14] year, two years, down the road you've got wives poking
[15] their husbands in the chin — in their ribs again because
[16] they've begun to snore again.

[17] KEVIN TRUDEAU: Any drugs available?

[18] JOHN ZIGLAR: I'm not aware of any drugs that
[19] have been used. I know from time to time you see a thing
[20] where there have been pills that people can take to try
[21] to eliminate snoring, but I do not know exactly what the
[22] technology has been.

[23] KEVIN TRUDEAU: So, this — this — this is an
[24] all-natural product; this is clinically tested; no after
[25] effects; natural ingredients; vitamin enhanced; fresh

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[1] breath — 97 percent effective — now, let's explain
[2] exactly — all that's in here are natural oils and it
[3] just says the natural oils and is a taste like a
[4] peppermint — type of wintergreen taste. And all you do
[5] — I just want to show people what it looks like.
[6] This is the spray and you just spray this in
[7] your mouth three times before you go to sleep.
[8] JOHN ZIGLAR: Right.
[9] KEVIN TRUDEAU: I just want to spray it now.
[10] I'll just spray it once. Now, the first thing is before
[11] I did this I assume — you mentioned it tasted terrible
[12]
[13] JOHN ZIGLAR: Yes.
[14] KEVIN TRUDEAU: — but, until Paul Cravatz fixed
[15] the taste.
[16] JOHN ZIGLAR: Correct.
[17] KEVIN TRUDEAU: It tastes either like either a
[18] chewing gum or a — a mint.
[19] JOHN ZIGLAR: It tastes like spearmint gum.
[20] KEVIN TRUDEAU: Okay, it tastes just like
[21] spearmint gum.
[22] JOHN ZIGLAR: Yes, it does.
[23] KEVIN TRUDEAU: It's actually a very refreshing
[24] taste.
[25] JOHN ZIGLAR: Yes.

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[1] KEVIN TRUDEAU: Tell me how this eliminates the
[2] noise of snoring (sic)? What exactly happens when I
[3] spray this in my mouth before I go to sleep?
[4] JOHN ZIGLAR: Because of the technology — what
[5] we have been able to do with the oils in this product, is
[6] we have been able through a lysosome technology, put it
[7] so that when it lands on the back of your throat it will
[8] actually stay there. It will stay topical for up to
[9] eight hours.
[10] And, so, it's just like — Kevin, have you ever
[11] seen a car going down the road that didn't have enough
[12] oil in it and you could hear the pinging and the knocking
[13] of the engine?
[14] KEVIN TRUDEAU: Right.
[15] JOHN ZIGLAR: What we're doing right here is
[16] we're going to oil the parts inside your throat so that
[17] we eliminate the clatter and that's all this product will
[18] do.
[19] KEVIN TRUDEAU: So, you just spray this on your
[20] throat and it just basically lubricates, if you will, the
[21] inside of your throat.
[22] JOHN ZIGLAR: Exactly.
[23] KEVIN TRUDEAU: And it's designed, because of
[24] the proprietary formula, where it lasts all night long.
[25] JOHN ZIGLAR: That's right.

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[1] KEVIN TRUDEAU: And there's nothing else — you
[2] can't buy this at a store or something — they can only
[3] get it directly from the company.
[4] JOHN ZIGLAR: That's correct.
[5] KEVIN TRUDEAU: And then all night long the
[6] person sleeps without any noise?
[7] JOHN ZIGLAR: That's right.
[8] KEVIN TRUDEAU: We have on the phone, Dr.
[9] Michael Leonard. Dr. Michael Leonard is a doctor I
[10] believe in Detroit —
[11] JOHN ZIGLAR: Um-hmm.
[12] DR. LEONARD: Kalamazoo.
[13] KEVIN TRUDEAU: Kalamazoo. How you doing, Dr.
[14] Leonard?
[15] DR. LEONARD: Good, how are you.
[16] KEVIN TRUDEAU: I'm doing great. Explain to me
[17] what type of reaction or results or experience you've had
[18] with this product?
[19] ON SCREEN: Called from Kalamazoo, MI — DR.
[20] MICHAEL LEONARD — TVI.
[21] DR. LEONARD: Uh — originally I was introduced
[22] to it by a friend of mine. Again, I'm a dentist, and
[23] dealing with patients that have problems with snoring and
[24] making appliances, et cetera, that are difficult for
[25] people to comply with. We can look for, you know, making

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[1] these appliances, advancing the jaw and getting the
[2] tissues up off the — (inaudible) — aspect of the mouth,
[3] but a lot of those people won't wear the appliance but
[4] for many a couple of nights because they are fairly
[5] uncomfortable.
[6] I was told about this product and went ahead
[7] and ordered a case hoping to start dispensing to a few
[8] patients and let them try it out and see if it worked,
[9] and got positive feedback from these people.
[10] So, I was telling my wife about it and she
[11] said, Yeah, before you give all that stuff away you
[12] better bring some home for yourself, because you also
[13] have a problem with snoring. And to tell you the truth
[14] I'm using it for a year and it doesn't bother me that I
[15] snore but certainly my wife, who gets my attention at
[16] night as I'm falling asleep and, you know, she knows I
[17] haven't sprayed down just yet, she'll give me a little
[18] nudge and say, you know, be sure and use that before you
[19] go to bed, because it does eliminate to a point where
[20] she's quite comfortable also.
[21] KEVIN TRUDEAU: Now, in your profession, you
[22] said you've used other things to help patients of yours
[23] with the snoring problem, like appliances?
[24] DR. LEONARD: Correct.
[25] KEVIN TRUDEAU: And what — what's the success

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[1] rate of one of those appliances? I know they're very
 [2] uncomfortable —
 [3] ON SCREEN: Called from Kalamazoo, MI — DR.
 [4] MICHAEL LEONARD — TVI.
 [5] DR. LEONARD: Yeah, it really — it really is
 [6] dictated on patient compliance, and when things are
 [7] uncomfortable, the compliance drops to very, very low
 [8] numbers.

[9] KEVIN TRUDEAU: Un-huh.

[10] DR. LEONARD: And I don't have a percentage of
 [11] number of people that are — 100 percent comply with it
 [12] and, on the other hand, with something like this that you
 [13] can keep with you, throw it in your dog kit, have one at
 [14] home — it's there, it's available and it's easy to use
 [15] and it works.

[16] KEVIN TRUDEAU: Yeah, I mean, it tastes really
 [17] good. So, I mean, obviously, right before you go to
 [18] sleep to have this by your nightstand to just spray a
 [19] couple of squirts, it shouldn't be a problem.

[20] As a matter of fact, John was telling me that
 [21] if somebody forgets to spray it in your mouth, it's not a
 [22] problem at all because your wife will remind you about an
 [23] hour and a half after you've gone to sleep —

[24] DR. LEONARD: That's right.

[25] KEVIN TRUDEAU: — with a little nudge —

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Page 15

[1] DR. LEONARD: Yeah.
 [2] KEVIN TRUDEAU: — and you just spray it there
 [3] and then sleep the whole night.
 [4] DR. LEONARD: Yeah. Well, just like Pablo's
 [5] dog, eventually you remember to do it before you go to
 [6] sleep.

[7] (All laughing.)

[8] KEVIN TRUDEAU: Now, you've given this to many
 [9] of your patients?

[10] DR. LEONARD: Correct.

[11] KEVIN TRUDEAU: And do you find it working for
 [12] everyone? It says 97 percent effective, so there's some
 [13] people, allegedly, that it does not work for. What's
 [14] your personal experience?

[15] DR. LEONARD: My experience has been people
 [16] that use it and use it properly — and by properly, I'll
 [17] get to that in just a second — people that are using it
 [18] on a regular basis, they are getting relief.

[19] And, again, when you talk to somebody who comes
 [20] into the office and says, I'm having — my wife tells me
 [21] or my husband tells me — I've having difficulty with
 [22] snoring and it's bothering her, the next time they come
 [23] in and you don't get that complaint or the wife comes in
 [24] shortly thereafter and is not complaining at that point,
 [25] it works well.

[1] KEVIN TRUDEAU: Say —

[2] DR. LEONARD: The — the trick with using it
 [3] properly is just getting it to these tissues in the back
 [4] of your mouth. Now, if you open your mouth wide and
 [5] spray the surface of your tongue only, it's not going to
 [6] be effective.

[7] So, I ended up doing a study here in the office
 [8] and taking some photographs of distribution of the
 [9] product, staining it and spraying it in people's mouths
 [10] with different head positions so we're assured that it
 [11] gets to where it needs to go.

[12] KEVIN TRUDEAU: Um-hmm.

[13] DR. LEONARD: With the proper positioning of
 [14] the head and spraying it to the back of your throat,
 [15] letting it sit there for maybe five seconds before you
 [16] swallow, I think the effectiveness is tremendously
 [17] increased.

[18] KEVIN TRUDEAU: Hold with us just for a few
 [19] moments, but I do want people to know right now if you're
 [20] watching and you do want information on Snorenz, if you
 [21] are a snorer or if you know someone that is, this really
 [22] could be a Godsend. It's a patented product, it's not
 [23] available in any stores, it's only available directly
 [24] from the company. Call the number on your screen to get
 [25] more information on Snorenz. It's very inexpensive, it

[1] tastes great, it's all-natural, it's clinically proven to
 [2] eliminate the noise of snoring in 97 percent of the
 [3] cases, and in my personal experience is virtually 100
 [4] percent.

[5] Call right now, it's unconditionally
 [6] guaranteed. The very first time you use it, it will
 [7] eliminate your snoring.

[8] Michael, just stay with us for just a moment.
 [9] John, I want to go back to the people that it's
 [10] worked for and those it hasn't worked for.
 [11] I have a friend of mine that I sent this to
 [12] when you first came to me and said, I got this product,
 [13] it gets rid of snoring. I said, well —

[14] JOHN ZIGLAR: Right.

[15] KEVIN TRUDEAU: — you know, I know snoring can
 [16] be an issue because I've known people that snore like
 [17] freight trains.

[18] JOHN ZIGLAR: Right.

[19] KEVIN TRUDEAU: I was fishing with a fellow who
 [20] was in a log cabin, we were up north — as a matter of
 [21] fact, you were with us last year —

[22] JOHN ZIGLAR: Right.

[23] KEVIN TRUDEAU: — but this was like the year
 [24] before — and there were nine guys in this cabin. They
 [25] threw this fellow out. Now, we're there for a week, they

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[1] threw — this poor guy had to sleep in the shower cabin
[2] — the shower stall because he was so loud and still —
[3] you could still hear him in the cabin across camp.

[4] JOHN ZIGLAR: I know.

[5] KEVIN TRUDEAU: This guy was — crazy. But I
[6] had sent this to a friend of mine who snored so bad his
[7] wife was not sleeping in the bedroom anymore. They —
[8] they'd go to sleep together and then an hour later she
[9] would leave and go and sleep on the couch because she
[10] just could not get a good night's rest.

[11] JOHN ZIGLAR: That's common.

[12] KEVIN TRUDEAU: Now, he used this and the first
[13] night he called me up and said, Gosh, darn it, I sprayed
[14] this — I woke up, my wife was lying next to me for the
[15] first time in like three years. This actually worked. I
[16] mean, it knocked out my snoring. He says and better than
[17] that, Kevin, I had the best night's sleep I ever had.

[18] Now, we'll talk about what happens when you
[19] keep waking up in the middle of the night.

[20] JOHN ZIGLAR: Right.

[21] KEVIN TRUDEAU: But here's the thing: three
[22] days he called me and he said, It doesn't work any more.

[23] JOHN ZIGLAR: No.

[24] KEVIN TRUDEAU: And I said, What do you mean?

[25] So, I got back to you and let's talk about why it

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[1] wouldn't work in a particular case. We had a situation
[2] last night with Doug McCleary and with this fellow.

[3] Explain some of the reasons why it wouldn't work.

[4] JOHN ZIGLAR: Okay. Here's — there's a couple
[5] of things. What happened in this particular guy's case
[6] is before he went to bed, he had a beer.

[7] KEVIN TRUDEAU: Um-hmm.

[8] JOHN ZIGLAR: And when he had the beer, he
[9] didn't clean his palate off. In other words, there was
[10] still alcohol. Well, alcohol is an agent that will cut
[11] through oils. And, so, since this is an oil-based, a
[12] natural oil-based product, when he had the alcohol still
[13] on his palate and he sprayed it, it cut through and the
[14] Snorenze actually went right straight down his throat, was
[15] not on the tissues where it would create the lubrication.

[16] KEVIN TRUDEAU: So, you can't eat or drink for
[17] a half an hour before you use the product?

[18] JOHN ZIGLAR: Exactly.

[19] KEVIN TRUDEAU: Which is a good healthy
[20] practice anyway. You shouldn't be drinking or eating
[21] right before you go to sleep.

[22] JOHN ZIGLAR: Of course. Or you could even
[23] brush your teeth before you go to bed. It would be a
[24] good practice.

[25] KEVIN TRUDEAU: You know, a fellow last night

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[1] said it worked up until he went to bed at 11:00 at night,

[2] 10:00 at night —

[3] JOHN ZIGLAR: Yes.

[4] KEVIN TRUDEAU: — and at 5:30 in the morning
[5] got woken up because of the snoring.

[6] JOHN ZIGLAR: Exactly.

[7] KEVIN TRUDEAU: So, it worked up until 5:30
[8] a.m. What happened there?

[9] ON SCREEN: JOHN ZIGLAR, Master Strategies
[10] Researcher, TVI.

[11] JOHN ZIGLAR: What happened is when he sprayed
[12] the product in his mouth, he did it correctly, but he
[13] only put one spray.

[14] KEVIN TRUDEAU: Um-hmm.

[15] JOHN ZIGLAR: He only did one pump. And what
[16] we recommend is three. All right? So, if you do three,
[17] it will last the full eight hours.

[18] KEVIN TRUDEAU: Dr. Leonard — let's go back to
[19] you. I have a question about — you're a dentist —

[20] DR. LEONARD: Yes.

[21] KEVIN TRUDEAU: — obviously. Bad breath —

[22] DR. LEONARD: Yes.

[23] KEVIN TRUDEAU: Do you — have you found that
[24] people who snore have a worse bad breath problem when
[25] they wake up as opposed to nonsnorers?

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[1] DR. LEONARD: I don't know of a direct
[2] correlation with that —

[3] KEVIN TRUDEAU: Does this —

[4] ON SCREEN: Caller from Kalamazoo, MI — DR.

[5] MICHAEL LEONARD — TVI.

[6] DR. LEONARD: — certainly having your mouth
[7] open and all the tissues drying out and — you could see
[8] where — and it depends on the diet, also — but it's
[9] interesting. I don't know that offhand. It has to be
[10] something to look into a bit.

[11] KEVIN TRUDEAU: Does this product help with
[12] breath in the morning? I mean, a lot of us have morning
[13] breath.

[14] DR. LEONARD: Oh, yes. Just by nature of the
[15] way it tastes. You know, you're going to bed with
[16] something that tastes and has a pleasant smell to it to
[17] begin with —

[18] KEVIN TRUDEAU: Um-hmm.

[19] DR. LEONARD: — as opposed to like the guy who
[20] went to bed slugging down a beer.

[21] KEVIN TRUDEAU: Right, right.

[22] DR. LEONARD: I don't know about you, but I'd
[23] rather have somebody have a mint candy before they went
[24] to bed and slept for eight hours instead of a Miller Lite
[25] or whatever.

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VIDEO

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[1] KEVIN TRUDEAU: Right.
 [2] DR. LEONARD: So, in that case, yeah, I think
 [3] it could be — could be said that that would certainly
 [4] help out a bit with morning breath.
 [5] KEVIN TRUDEAU: Yeah, because that's one of the
 [6] things that I'm finding from people that I have actually
 [7] given this to in my testing —
 [8] DR. LEONARD: Um-hmm.
 [9] KEVIN TRUDEAU: — and I say, you know, what's
 [10] your reaction? And primarily from the wives, they say,
 [11] Wow, I can give him a kiss in the morning and it's not
 [12] that yucky morning breath.
 [13] DR. LEONARD: They're not blown away, huh?
 [14] KEVIN TRUDEAU: Yeah, which is kind of
 [15] interesting. And then, of course, the fellows are saying
 [16] the same thing. I wake up and I feel more refreshed
 [17] because my mouth is clean and it has this great taste to
 [18] it.
 [19] So, in addition to having a soundful sleep
 [20] without any snoring whatsoever, but they wake up — they
 [21] have this clean feeling in their mouth. You know, with
 [22] addition to the extra energy they'll get —
 [23] DR. LEONARD: Sure.
 [24] KEVIN TRUDEAU: — and —
 [25] DR. LEONARD: Plus they've had a good night's

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[1] KEVIN TRUDEAU: So, a person may not even
 [2] realize that he's constantly waking up and going back to
 [3] bed during the night?
 [4] DR. LEONARD: That's right.
 [5] KEVIN TRUDEAU: And, therefore, their sleep
 [6] pattern's getting —
 [7] Dr. Leonard, I know you have to get back to
 [8] your practice, thanks very much for calling in.
 [9] DR. LEONARD: Thank you.
 [10] KEVIN TRUDEAU: Have a great day.
 [11] DR. LEONARD: Thanks.
 [12] KEVIN TRUDEAU: Let's talk about that, John,
 [13] because —
 [14] JOHN ZIGLAR: Yeah, Kevin, because that's what
 [15] my experience has been.
 [16] KEVIN TRUDEAU: Okay.
 [17] JOHN ZIGLAR: When I started to take the
 [18] product myself —
 [19] KEVIN TRUDEAU: Um-hmm.
 [20] JOHN ZIGLAR: — I noticed — first of all,
 [21] that I don't turn over in my sleep as many times. And,
 [22] so, I noticed it because I don't pull the covers out of
 [23] the bottom of the bed every night.
 [24] KEVIN TRUDEAU: Right.
 [25] JOHN ZIGLAR: And, you see, it's not a

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[1] sleep.
 [2] KEVIN TRUDEAU: Correct. But, let's talk about
 [3] that. The person who snores, Dr. Leonard, if they are
 [4] snoring and it "doesn't bother them."
 [5] DR. LEONARD: Um-hmm.
 [6] KEVIN TRUDEAU: They don't get woken up. Is
 [7] it, in fact, having an adverse effect on the person's
 [8] sleep patterns, thus making them more potentially
 [9] irritable and fatigued during the day?
 [10] DR. LEONARD: Certainly. Potential
 [11] irritability and fatigue throughout the day has got to be
 [12] commonplace.
 [13] KEVIN TRUDEAU: Now, why use that? I mean, if
 [14] I snore and I don't wake up during the night and I don't
 [15] — I don't even know I snore —
 [16] DR. LEONARD: Um-hmm.
 [17] KEVIN TRUDEAU: — how is it having that effect
 [18] on me?
 [19] DR. LEONARD: If you're sleeping and snoring,
 [20] obviously, like you're talking about exchanging air and
 [21] still breathing and your air passage is restricted, once
 [22] things are restricted to a point, you automatically or
 [23] for the most part most people will wake up, catch a deep
 [24] breath, roll over, what-have-you. So, yeah, your sleep
 [25] pattern is disturbed by that.

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[1] conscious thing when you wake yourself up snoring and
 [2] then you immediately go back to sleep. We've got
 [3] testimonial letters from all over the country.
 [4] One of the ladies said that for the first time
 [5] in her life she can remember dreams.
 [6] KEVIN TRUDEAU: Hmmm.
 [7] JOHN ZIGLAR: And what that means is that she,
 [8] for the first time in a long time, has gotten some deep
 [9] sleep where she now has recollection of dreams. We all
 [10] dream —
 [11] KEVIN TRUDEAU: Um-hmm.
 [12] JOHN ZIGLAR: — if we get deep sleep.
 [13] KEVIN TRUDEAU: Now, 90 million people snore —
 [14] JOHN ZIGLAR: Yeah.
 [15] KEVIN TRUDEAU: — that means about 150 million
 [16] people are affected because of the sleeping partners.
 [17] JOHN ZIGLAR: Correct.
 [18] KEVIN TRUDEAU: How young does somebody snore,
 [19] they start snoring? I mean, can they start as child?
 [20] JOHN ZIGLAR: They can absolutely. We've got
 [21] someone in our office who has a child who started snoring
 [22] and the child is eight years old.
 [23] KEVIN TRUDEAU: I want to talk about that,
 [24] about how snoring can affect even grades in school,
 [25] because there was an article I know in the Chicago

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[1] Tribune about that.
[2] JOHN ZIGLAR: Yes.
[3] KEVIN TRUDEAU: But if you're watching right
[4] now and you do want more information on Snorenz, it's an
[5] all-natural product, it's not available at any stores,
[6] call the number on your screen. If you are a snorer or
[7] know someone that is, call that number and get this very
[8] inexpensive, it's all natural, tastes great, it's
[9] guaranteed to work the very first time you try it. You
[10] just put three squirts in your mouth before you go to
[11] sleep, no snoring all night long.
[12] If you're not thrilled, send it back for a
[13] refund. Clinically proven in studies to eliminate the
[14] sound of snoring in 97 percent of the cases. And in my
[15] personal experience, virtually everybody that we've given
[16] it to. It's all natural and it can work for you.
[17] Call the number on your screen for Snorenz if
[18] you are a snorer or know anyone that is, they need this
[19] product for their own health and the people around them.
[20] Let's talk about the kids. As young as eight
[21] years old —
[22] JOHN ZIGLAR: Yeah.
[23] KEVIN TRUDEAU: — that can start snoring. And
[24] how does that adversely affect their grade performance in
[25] school?

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[1] JOHN ZIGLAR: Kevin, as you know, I have four
[2] children myself —
[3] KEVIN TRUDEAU: Um-hmm.
[4] JOHN ZIGLAR: — and I know that with my own
[5] children if I let them stay up too late at night or they
[6] do not get enough sleep, I notice the next day whether or
[7] not they're as pleasant to their brothers and sisters. I
[8] notice, for instance, if they go for a period of time
[9] where they don't get good sleep, that it does impact
[10] their grades, their performance on the athletic field or
[11] wherever they are, and, quite honestly, it's no different
[12] for them than it is for us. Sleep deprivation affects us
[13] all.

[14] KEVIN TRUDEAU: So, it can affect us in our job
[15] performance?
[16] JOHN ZIGLAR: Certainly.
[17] KEVIN TRUDEAU: Irritability during the day?
[18] JOHN ZIGLAR: Yes.
[19] KEVIN TRUDEAU: Relationship with your spouse?
[20] JOHN ZIGLAR: Of course.
[21] KEVIN TRUDEAU: And not just because you're not
[22] maybe sleeping in the same room or same bed, but the next
[23] day because you're tired, because your sleep pattern has
[24] been interrupted all night long, that you're just
[25] probably not as pleasant and you can be a little snippy

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[1] and snappy and that's going to have an adverse affect on
[2] the relationship.
[3] JOHN ZIGLAR: Exactly.
[4] KEVIN TRUDEAU: Now, let's talk about this —
[5] there was this article we were talking about right before
[6] the start of the show —
[7] JOHN ZIGLAR: Yeah.
[8] KEVIN TRUDEAU: — in the Chicago Tribune, I
[9] think it was.
[10] JOHN ZIGLAR: Right.
[11] KEVIN TRUDEAU: What was that about?
[12] JOHN ZIGLAR: There was a study that was done
[13] with medical students over in West Germany.
[14] KEVIN TRUDEAU: Um-hmm.
[15] JOHN ZIGLAR: And what they did is they found
[16] — they did a test and they found which of the students
[17] snored and which of the students did not snore, and then
[18] what they did is they just simply took and put them in
[19] two distinct categories and then they took and they took
[20] the average of the grades of the snorers and the
[21] nonsnorers, and in this particular case, the snorers
[22] ended up with six points less than the nonsnorers did.
[23] KEVIN TRUDEAU: That seems like a major
[24] difference in grades.
[25] JOHN ZIGLAR: I would have to think so,

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[1] especially where the amount of sleep that a med student
[2] would have an opportunity to get.
[3] KEVIN TRUDEAU: Right.
[4] JOHN ZIGLAR: You — another — let me just
[5] share a story with you. This — we talked with a lady
[6] who — whose husband was a fireman —
[7] KEVIN TRUDEAU: Um-hmm.
[8] JOHN ZIGLAR: — and he was out in Phoenix, and
[9] he snored so loud and since he was a fireman he was
[10] required to sleep at the fire station —
[11] KEVIN TRUDEAU: Um-hmm.
[12] JOHN ZIGLAR: — with the other guys who were
[13] on duty at the same time. Well, they only have a certain
[14] amount of hours that they can sleep and, so, they would
[15] all rush — when it got time to go to bed — they would
[16] all rush to get to bed before John got up there because
[17] when he got to sleep — if you weren't to sleep before he
[18] got to sleep, his snoring was so loud that you couldn't
[19] get to sleep.
[20] KEVIN TRUDEAU: Um-hmm.
[21] JOHN ZIGLAR: And it was such a problem for him
[22] that he went to the expense of having the surgery and
[23] everybody in the fire station was thrilled to death that
[24] he had done that. It was an expensive process and the
[25] healing process from the surgery is six months —

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[1] KEVIN TRUDEAU: Hmm...
 [2] JOHN ZIGLAR: — so, it affected diet, it
 [3] affect a lot of different things in his life, but he
 [4] wasn't snoring.
 [5] A year after the surgery, he gets the old elbow
 [6] in the ribs from his wife and she says, Roll over, John,
 [7] you've started to snore.
 [8] And, so, even with the surgery —
 [9] KEVIN TRUDEAU: Hmm...
 [10] JOHN ZIGLAR: — he had started to snore again.
 [11] And when he started back up —
 [12] KEVIN TRUDEAU: Is that normal — is that
 [13] common, by the way? I mean, you had this expensive
 [14] surgery, you go through six months of healing, all this
 [15] pain, it eliminates the snoring for a year and then it
 [16] picks up. Is that — is that common?
 [17] JOHN ZIGLAR: I have heard lots of cases where
 [18] that has occurred.
 [19] KEVIN TRUDEAU: It's amazing.
 [20] JOHN ZIGLAR: Yes, it is. So, all of a sudden
 [21] appears at the fire station, now, the guys in his
 [22] dormitory where he sleeps, had taken and gotten some
 [23] sheet rock —
 [24] KEVIN TRUDEAU: Um-hmm.
 [25] JOHN ZIGLAR: — and built a cage around John's

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[1] bed because he had started to snore again.
 [2] KEVIN TRUDEAU: Hmm...
 [3] JOHN ZIGLAR: And we had put a small ad on a
 [4] radio station out there, his wife had heard about
 [5] Snorenz, she said, My goodness, we've got nothing to
 [6] lose. She bought the product, she squirted it in his
 [7] mouth before he went to bed that night, and from that day
 [8] to this John does not snore.
 [9] KEVIN TRUDEAU: That's incredible. I mean, it
 [10] seems incredible — you could call this a medical
 [11] breakthrough, but it's not a medical device and it's not
 [12] a drug.
 [13] JOHN ZIGLAR: No, no.
 [14] KEVIN TRUDEAU: What do you call it?
 [15] JOHN ZIGLAR: I don't know — you call it a
 [16] miracle.
 [17] KEVIN TRUDEAU: (Laughter.)
 [18] JOHN ZIGLAR: I don't know what you call it.
 [19] Let me tell you, when I — when I first got the product
 [20] myself, I, you know, I told Linda, my wife, about the
 [21] product and she says, Well, you know, you need to bring
 [22] some home. And I told her, Well, Honey, I said, you
 [23] really don't snore that bad. (Laughter.)
 [24] She suggested it wasn't for her.
 [25] KEVIN TRUDEAU: (Laughter.)

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[1] JOHN ZIGLAR: And in my own relationship I can
 [2] tell you for a fact I am getting better sleep.
 [3] KEVIN TRUDEAU: So, you're having more energy
 [4] during the day?
 [5] JOHN ZIGLAR: I am.
 [6] KEVIN TRUDEAU: Thinking clearer?
 [7] JOHN ZIGLAR: Uh — I don't know — I don't
 [8] think I was thinking unclear.
 [9] (Laughter.)
 [10] KEVIN TRUDEAU: But you definitely — well, let
 [11] me ask you this: You definitely feel better during the
 [12] day?
 [13] JOHN ZIGLAR: Yes, I do. I do not get tired.
 [14] KEVIN TRUDEAU: Because now you are actually
 [15] really getting a full night's sleep.
 [16] JOHN ZIGLAR: Exactly.
 [17] KEVIN TRUDEAU: As — and you didn't notice —
 [18] you, like most snorers —
 [19] JOHN ZIGLAR: Right.
 [20] KEVIN TRUDEAU: — did not notice that you were
 [21] actually waking up all night?
 [22] JOHN ZIGLAR: No.
 [23] KEVIN TRUDEAU: So, your rapid eye movements,
 [24] your dreams, all those things are being adversely
 [25] affected by this interruption of the breathing pattern

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[1] waking you up and then going back to sleep; and waking
 [2] you up and going back to sleep?
 [3] JOHN ZIGLAR: Exactly. I really didn't notice
 [4] that much, Kevin, except for when I'm up here in Chicago
 [5] in my apartment by myself.
 [6] KEVIN TRUDEAU: Um-hmm.
 [7] JOHN ZIGLAR: Where I have to make the bed
 [8] myself.
 [9] KEVIN TRUDEAU: (Laughter.)
 [10] JOHN ZIGLAR: And I noticed that I don't turn
 [11] over and get the sheets out of the foot of the bed.
 [12] That's when I really noticed it.
 [13] KEVIN TRUDEAU: Folks, if you're watching right
 [14] now and you are a snorer or if you know someone that is,
 [15] get on the telephone and call to get Snorenz. It's a
 [16] very simple, all natural product, it's just natural oils
 [17] with some vitamins and minerals. You simply just spray
 [18] it in your mouth three times before you go to bed.
 [19] It tastes great, it's a patented product, it
 [20] has been proven to be 97 percent effective in eliminating
 [21] the snooze — the noise of snoring. You'll wake up with
 [22] a great, fresh, clean mouth.
 [23] You'll have more energy during the day, you'll
 [24] have less irritability, you'll be more pleasant, kids get
 [25] better grades in school, as evidenced by the study in the

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[1] Chicago Tribune, you'll think clearer, potentially,
[2] throughout the day, perhaps better job performance,
[3] definitely a better relationship with your spouse or
[4] significant other. So, call the number right now for
[5] Snorenz.

[6] The reason I have John here is we tested it
[7] with the people that I know in my life and it works
[8] beyond a shadow of a doubt.

[9] It's all natural, it's patented, and it's not
[10] available in any store. So, pick up the phone right now
[11] for more information on Snorenz. And it's pennies, it's
[12] very cheap and it'll eliminate your snoring.

[13] This is Kevin Trudeau with my guest John
[14] Ziglar. We've been talking about snoring and you've been
[15] watching Vantage Point. We'll see you next time. Bye-
[16] bye.

[17] (Music playing.)

[18] ON SCREEN: For more information or to order

[19] Snorenz call:

[20] If snoring is accompanied by any signs of Sleep
[21] Apnea, you should consult a physician before using any
[22] product.

[23] Tru-Vantage International, 7300 N. Lehigh Ave,
[24] Niles, IL 60714 (847)647-0300.

[25] The preceding has been a paid commercial for

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[1] SNORENZ brought to you by Kevin Trudeau's Tru-Vantage
[2] International, America's premier direct response
[3] marketing company.

[4] (End of videotape.)

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CERTIFICATION OF TYPIST

[1]
[2]
[3] MATTER NUMBER: 0023211
[4] CASE TITLE: MED GEN INC.
[5] TAPING DATE: OCTOBER 13, 1999
[6] TRANSCRIPTION DATE: MAY 9, 2000
[7]
[8] I HEREBY CERTIFY that the transcript contained
[9] herein is a full and accurate transcript of the tapes
[10] transcribed by me on the above cause before the FEDERAL
[11] TRADE COMMISSION to the best of my knowledge and belief.
[12]
[13] DATED: MAY 9, 2000
[14]
[15]
[16]
[17]
[18]
[19]

DIANE QUADE

CERTIFICATION OF PROOFREADER

[20] I HEREBY CERTIFY that I proofread the transcript for
[21] accuracy in spelling, hyphenation, punctuation and
[22] format.
[23]
[24]
[25]

ELIZABETH M. FARRELL

Lawyer's Notes

[1]
[2] OFFICIAL TRANSCRIPT PROCEEDING
[3]
[4] FEDERAL TRADE COMMISSION
[5]
[6] MATTER NO. 0023211
[7]
[8] TITLE MED GEN INC.
[9]
[10] DATE RECORDED: OCTOBER 13, 1999
[11] TRANSCRIBED: MAY 10, 2000
[12]
[13] PAGES 1 THROUGH 35
[14]
[15]
[16] VP SNORENZE 4 - JD W/ DISCLAIMER SNR4
[17] VIDEOTAPE
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[1] FEDERAL TRADE COMMISSION
[2]
[3] In the Matter of:)
[4] Med Gen, Inc.,) Matter No. 0023211
[5]
[6] October 13, 1999
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[12] The following transcript was produced from a
[13] videotape provided to For The Record, Inc. on May 8,
[14] 2000.
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Page 3
[1] PROCEEDINGS
[2]
[3] ON SCREEN:
[4] Tru-Vantage & Mercury Media
[5] Present
[6] VP SNORENZ 4
[7] JD WITH DISCLAIMERS // SNR4
[8] 28:30 MINUTES
[9] 1-800-835-8941
[10] TUESDAY, NOVEMBER 17, 1998
[11] NCMG MASTER #293 Randy Pfeiffer
[12] CUSTOMIZATION BY NORTH COUNTRY MEDIA GROUP
[13] www.ncmg.com
[14]
[15] ON SCREEN:
[16] The following is a paid commercial for SNORENZ
[17] brought to you by Kevin Trudeau's Tru-Vantage
[18] International, America's premier direct response
[19] marketing company.
[20]
[21] ANNOUNCER: The following is a paid commercial
[22] brought to you by Kevin Trudeau's Tru Vantage
[23] International.
[24] (Music playing.)
[25] UNIDENTIFIED MALE: For millions of Americans,

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[1] this is the most annoying and unwelcome sound in the
[2] world.

[3] **ON SCREEN:** News clippings.

[4] **ANNOUNCER:** That's right, more than 90 million
[5] Americans have a snoring problem and it can cause
[6] sleeplessness, headaches and a lack of energy, and that
[7] goes for the snorer, as well as the person trying to
[8] sleep next to the snorer.

[9] What can be done about it? On Vantage Point
[10] today, hear about a new discovery that could eliminate
[11] the sound of snoring.

[12] **ON SCREEN:** VANTAGE POINT with Kevin Trudeau.

[13] **ON SCREEN:** John Denny.

[14] **JOHN DENNY:** Hi, I'm John Denny, and this is a
[15] special edition of Vantage Point. We're going to talk
[16] about snoring today, and if you're a snorer, or just
[17] happen to sleep next to one, then you know snoring is no
[18] laughing matter. Snoring can and does seriously diminish
[19] the quality of your sleep, your life, and it could drive
[20] two people apart, meaning the snorer and the person next
[21] to the snorer.

[22] My guests today are Dr. Bob Currier, physician,
[23] surgeon and associate clinical professor at Michigan
[24] State University, and John Ziglar, who represents a
[25] company that manufactures a product called Snorenz, which

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[1] is designed to end your snoring problem.

[2] Gentlemen, thank you for joining me. Guys, got
[3] to ask you this first question, because for some people
[4] it's a light matter and for others it seriously impacts
[5] their life, certainly impacts their sleep. What causes
[6] snoring? What is the reason behind that all too familiar
[7] rumbling sound that keeps half of America, it seems, up
[8] every night?

[9] **ON SCREEN:** Dr. Bob Currier, Physician/Surgeon.

[10] **DR. BOB CURRIER:** Well, what snoring really is,
[11] John, is just simply a relaxation of the tissues in the
[12] back of your throat. It's when we fall asleep, much of
[13] our muscles in our body, as well as our throat relax.
[14] That's the time we sleep. We're supposed to get our
[15] rest.

[16] **JOHN DENNY:** Um-hmm.

[17] **DR. BOB CURRIER:** What happens with that,
[18] though, unfortunately, is as the tissues relax, they
[19] occlude or actually narrow, and they cause a funnel
[20] effect for the air as it goes through, flapping the
[21] tissue.

[22] **JOHN DENNY:** Um-hmm.

[23] **DR. BOB CURRIER:** This is in the back of the
[24] throat, hence creating the noise. It's very positional.
[25] It's very — also very dependant on habits that we have,

[1] such as smoking or dietary habits. And then also it
[2] affects really how much we sleep and how much rest we
[3] actually get throughout a night.

[4] **JOHN DENNY:** Now, you were both snorers,
[5] presumably?

[6] **DR. BOB CURRIER:** Um-hmm.

[7] **JOHN ZIGLAR:** Sure.

[8] **DR. BOB CURRIER:** Absolutely.

[9] **JOHN DENNY:** Tell me, how did you get involved
[10] in Snorenz? How did this all come about?

[11] **ON SCREEN:** John Ziglar, SNORENZ.

[12] **JOHN ZIGLAR:** This all came about, John, I met
[13] a friend down in Fort Lauderdale, Florida, named Paul
[14] Kravitz.

[15] **JOHN DENNY:** Um-hmm.

[16] **JOHN ZIGLAR:** Paul Kravitz was in the banking
[17] industry. And he had a Korean man that came into his
[18] office with a product. He had a little bottle of it, it
[19] didn't have any labels on it or anything, but he says
[20] this will make you quit snoring. And Paul looked at it
[21] and he put it over on the side of his desk, he didn't
[22] think too much about it. But he did make the mistake of
[23] telling his wife that somebody had come in with this
[24] product. And she asked him would he go ahead and bring
[25] it home and try it. Bottom line is he did use the

[1] product, it did make him quit snoring, but it tasted
[2] terrible.

[3] And, so, Paul says Whoa, you know, what a price
[4] to pay, so he took that product, he developed it, he took
[5] it to the laboratories and they did some liposome
[6] technology with the product and they put a flavor to the
[7] product to make it so that it tasted good and we now call
[8] the product Snorenz, and it's just phenomenal.

[9] **JOHN DENNY:** And in your first exposure to it -

[10] **JOHN ZIGLAR:** Correct.

[11] **JOHN DENNY:** — you were a rumbler. You — we
[12] heard Harley-Davidson sounds coming from you at night —

[13] **JOHN ZIGLAR:** (Laughter).

[14] **JOHN DENNY:** — is the word on the street.

[15] **JOHN ZIGLAR:** (Laughter).

[16] **JOHN DENNY:** Tell me your first experience with
[17] the product.

[18] **JOHN ZIGLAR:** My first experience really, when
[19] I — I had been married for 25 years, my wife, Linda. I
[20] came home after talking with Paul and I told my wife
[21] about this new product that we were looking at. And she
[22] said — and she says well, when are you going to bring it
[23] home. And I said Well, honey, I said, really, you know,
[24] you don't snore that bad. And she said it really wasn't

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[1] for her.
[2] JOHN DENNY: (Laughter).
[3] DR. BOB CURRIER: (Laughter).
[4] JOHN ZIGLAR: And up until that point I really
[5] didn't realize that I snored.
[6] JOHN DENNY: Um-hmm.
[7] JOHN ZIGLAR: But I did turn over in the bed an
[8] awful lot at night, and I knew that. And, so, I used the
[9] product and, John, what I found is for me personally, I
[10] quit turning over so many times at night. And I began to
[11] get a more peaceful, restful sleep.
[12] JOHN DENNY: Um-hmm.
[13] JOHN ZIGLAR: So, that's what personally
[14] happened in my life.
[15] JOHN DENNY: Well, that raises an interesting
[16] point, because for some people snoring in a litany of
[17] problems, you know, that we face on an everyday basis,
[18] snoring is not at the top of the list. But, in fact, if
[19] you speak to people who sleep next to a snorer, as well
[20] as the snorer themselves, there are some real health
[21] issues, there are some real serious concerns that a
[22] snorer has, or should have. How does, and why does, a
[23] snorer — why should a snorer worry about this? Why is
[24] it a problem?
[25] DR. BOB CURRIER: Well, it is a problem, but

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[1] the real problem is an awareness. A lot of people aren't
[2] aware, as you were, that you didn't snore, you don't
[3] snore. It's — and people don't want to offend someone
[4] else that they may sleep with or someone in their family
[5] by telling them they snore.
[6] JOHN DENNY: Um-hmm.
[7] DR. BOB CURRIER: And they've put up with it
[8] for years.
[9] JOHN DENNY: Um-hmm.
[10] DR. BOB CURRIER: The problem with that is all
[11] the things that go with it, even on a personal level. Me
[12] personally, I snore and have snored, and I've used the
[13] product, as well, and it's worked great for me.
[14] ON SCREEN: These statements have not been
[15] evaluated by the Food and Drug Administration. This
[16] product is not intended to diagnose, treat, cure or
[17] prevent any disease.

[18] DR. BOB CURRIER: Why do I know this? Because
[19] of my energy level, I feel better, I get better sleep.
[20] The problems that happen, I think people go to
[21] sleep, they assume they're automatically going to wake up
[22] rested. They don't. And then they wake up with a
[23] headache, less energy, they hurt, they're sore, they're
[24] irritable. The health problems are really insidious.
[25] But let's not even go that deep. Let's just talk about

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[1] the things that happen to us on an everyday basis: the
[2] energy level that we have. We're not rested.
[3] JOHN DENNY: So, you're saying snorers —
[4] DR. BOB CURRIER: That's the battle.
[5] JOHN DENNY: — snorers get less rest, get a
[6] less restful —
[7] DR. BOB CURRIER: Absolutely. They do not
[8] sleep.
[9] JOHN ZIGLAR: See, what happened to me, what
[10] was going on in my night, is I would literally turn over
[11] 20 or 30 times a night. And the reason I would is
[12] because I would go to sleep, my tissues would relax, I
[13] would snore — I would literally wake myself up, and then
[14] I would turn over. And I would turn. Well, now, I
[15] didn't wake up and get up out of the bed to turn over.
[16] JOHN DENNY: Um-hmm.
[17] JOHN ZIGLAR: I would just wake up and turn
[18] over. And what that does is it keeps me, John, from
[19] getting the deep, restful sleep.
[20] JOHN DENNY: Hmm.
[21] JOHN ZIGLAR: We get letters. We got a letter
[22] from a lady out in Phoenix also who told us that for the
[23] first time in her life she started taking this product
[24] and she can remember her dreams. Well, you see, dreaming
[25] is an important thing, and we all dream, if we get

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[1] peaceful, restful sleep.
[2] JOHN DENNY: But isn't dreaming or the dream
[3] state indicative of a deep, restful, REM sleep, I think
[4] they call it?
[5] DR. BOB CURRIER: Yes. Yes, it is.
[6] JOHN DENNY: So if you're a snorer, you won't
[7] dream as much, meaning you're not getting as deep a
[8] sleep. Is that what —
[9] DR. BOB CURRIER: That is correct. You almost,
[10] because of the snoring, and sometimes we're not aware of
[11] it, keep waking ourselves up. We snore, and we huh
[12] (indicating), and then we wake up, then we try to
[13] reposition ourselves. We're just not comfortable. We
[14] can't get our air; we can't get the oxygen we need, hence
[15] the headache, the irritability when we wake up. We're
[16] not rested. That's the problem.
[17] ON SCREEN:
[18] Dr. Bob Currier
[19] Physician/Surgeon.
[20] DR. BOB CURRIER: Another side effect, a cute
[21] story, my brother is also a snorer. I think this is just
[22] something that runs in families, as well. Anyway, he has
[23] since tried the product, as I have, and I use it and I
[24] think it's fantastic because it does stop the snoring.
[25] My brother has also — he doesn't have the aches and

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[1] pains he used to wake up with.

[2] You were also talking about the tossing and
 [3] turning, we're also forgetting his wife used to jab him
 [4] in the middle of the night, so he does not wake up
 [5] bruised, so this also helps, a little sidelight there.

[6] DR. BOB CURRIER: Yes.

[7] JOHN DENNY: How does Snorenz work? There have
 [8] been other products available, over the course of the
 [9] last, you know, 10 and 20 years that are — have been in
 [10] pill form, surgeries. People have gone through painful,
 [11] expensive surgeries.

[12] In fact, we're going to — I think we're going
 [13] to talk to a caller later who has a story to share with
 [14] us about this product and the journey she went through
 [15] with her husband to essentially reduce this problem or
 [16] eliminate this problem. How does this product work?

[17] JOHN ZIGLAR: John, what we've done is we have
 [18] taken all-natural oils, and we have taken and put them
 [19] together in a liposome formulation. And we have taken it
 [20] and so that you can actually spray this product into the
 [21] back of your throat. And the process is really quite
 [22] simple. Have you ever seen a car go down the road that
 [23] didn't have enough oil in it?

[24] JOHN DENNY: Um-hmm.

[25] JOHN ZIGLAR: And you hear the clatter and the

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[1] that we say that flap and flutter and then need the

[2] lubrication —

[3] JOHN DENNY: Yeah.

[4] DR. BOB CURRIER: — when it is applied there,
 [5] but when the technology goes even further and better
 [6] through this liposome technology, is to apply it evenly.
 [7] And the very neat thing about this is it stays. It stays
 [8] there all night.

[9] JOHN DENNY: Hmm.

[10] DR. BOB CURRIER: That's where others have
 [11] failed, and that's also where a lot of the appliances,
 [12] that's where also a lot of the applications of surgeries,
 [13] pills, other things that have been attempted and tried
 [14] have failed.

[15] JOHN DENNY: Um-hmm.

[16] DR. BOB CURRIER: This product here stays
 [17] there. It's easy application. As a physician, one of
 [18] the problems that I have with patients is compliance,
 [19] trying to get them to use and continually use something.

[20] JOHN DENNY: Um-hmm.

[21] DR. BOB CURRIER: If we're going to get a
 [22] restful sleep, we need it on an every-night basis. This
 [23] is accrued, we have a clock and we have a bank and it's
 [24] for sleeping purposes. So, it isn't something that just
 [25] one night good sleep will help. This is something that's

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[1] clanking.

ON SCREEN:
JOHN ZIGLAR
SNORENZ

[5] JOHN DENNY: Yes.

[6] JOHN ZIGLAR: Well, what happens is we took
 [7] that same philosophy, that same technology, and we said
 [8] hey, if we can oil the parts and we can take and make a
 [9] topical solution that will stay in a place for an
 [10] extended period of time, we can eliminate the noise —

[11] JOHN DENNY: Um-hmm.

[12] JOHN ZIGLAR: — of snoring. You're still
 [13] going to have the same amount of air that's going to pass
 [14] through the passage, but all we're going to do is we're
 [15] going to lubricate the parts so that there is no noise
 [16] associated so that you don't then wake up or wake up your
 [17] neighbor.

[18] JOHN DENNY: So, it's essentially lubricating
 [19] what part of the throat, and which part of the throat is
 [20] causing that sound?

[21] DR. BOB CURRIER: Well, to take this just a
 [22] little bit further, a dentist has studied this and has
 [23] actually sprayed this in models, and he actually used a
 [24] dye at the time so he could see where it was applied. In
 [25] the soft tissues, in the back of the throat, the ones

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[1] accrued over time. When you get good sleep, that helps a
 [2] lot. We need compliance. With the ease of application,
 [3] as what he is talking about, okay?

[4] JOHN DENNY: Um-hmm.

[5] DR. BOB CURRIER: With the effectiveness of its
 [6] staying there, it's a winner. And that's how it works.

[7] JOHN DENNY: So, it's basically — correct me
 [8] if I'm wrong — it's two or three sprays in the back of
 [9] your mouth. I have a friend who underwent a session with
 [10] a dentist who fitted him with a clamp of some sort, which
 [11] pushed his jaw out and tried to create more breathing
 [12] space essentially, and that lasted for about three to
 [13] four months. This works, and it stays working for
 [14] people?

[15] DR. BOB CURRIER: Yes, what you're trying to do
 [16] with the appliance is just simply try to open up the
 [17] airway more so you don't get the fluttering of the
 [18] tissues.

[19] JOHN DENNY: Um-hmm.

[20] DR. BOB CURRIER: What — and that's what we do
 [21] when we snore. When we snore, we essentially wake
 [22] ourselves up in a snore, and then reposition ourselves,
 [23] trying to again open up our airway to get more air so we
 [24] get more oxygen. What happens with this product, this
 [25] lubricates, stays there, again through the technology,

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[1] and then you don't have the snore; hence, you don't wake [2] up; hence, you get a more restful sleep.

[3] JOHN ZIGLAR: And the problem, John, with the [4] appliance is it's very uncomfortable.

[5] JOHN DENNY: Um-hmm.

[6] JOHN ZIGLAR: And there have been a lot of [7] people, and dentists will tell you that they have got [8] patients who have paid for the procedure, paid to get the [9] appliance, could not sleep with it hooked up.

[10] JOHN DENNY: Um-hmm.

[11] JOHN ZIGLAR: And, so, it did not work for them [12] because they were so uncomfortable.

[13] JOHN DENNY: Um-hmm.

[14] JOHN ZIGLAR: Okay? And, so, when I saw this [15] first — this product the first time, I looked at this [16] thing and I thought oh, my goodness, you know, I'm going [17] to spray oil in the back of my throat. I'm thinking WD- [18] 40 or something like that, you know —

[19] JOHN DENNY: Right.

[20] JOHN ZIGLAR: — and an oil slick, and I'm [21] going oh, but it's the consistency of water. And the [22] nice thing about it is is that it does — there's no [23] feeling associated with the spray in the back of your [24] throat. All you get is a nice, clean, peppermint taste -

[25]

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[1] JOHN DENNY: Hmm.

[2] JOHN ZIGLAR: — which made it wonderful, so [3] compliant, people will do it.

[4] ON SCREEN: This is a paid commercial for [5] Snorenz.

[6] DR. BOB CURRIER: Well, the aftertaste.

[7] JOHN ZIGLAR: Yes.

[8] DR. BOB CURRIER: In the morning, when you wake [9] up, it's better.

[10] JOHN ZIGLAR: Exactly.

[11] DR. BOB CURRIER: You don't feel like you have [12] an oil sludge at all. It's a minty taste.

[13] ON SCREEN: 1-800-835-8941

[14] JOHN DENNY: If you have a snoring problem, if [15] you have problems sleeping next to a snorer, then Snorenz [16] may be the answer you've been waiting for. Snoring can [17] seriously reduce your energy levels, your concentration, [18] and can seriously affect your work habits, as well. And [19] you can be sure your snoring is seriously bothering [20] someone other than you.

[21] Snorenz is the first all-natural spray that has [22] been proven to give you a healthy, natural, good night's [23] sleep. It has no side effects, it's as easy as a few [24] sprays before bed, and it lasts all night. If you want [25] more information on Snorenz, if you want to stop the

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[1] snoring, if it's a snorer next to you or if you be the [2] snorer, you may want to call the 800 number on your [3] screen.

[4] We have, I believe, a caller on the line from [5] Arizona, and I believe it's Tina Heinz. Tina, are you on [6] the air with us?

[7] TINA HEINZ: I'm here.

[8] JOHN DENNY: Great. How you feeling today?

[9] TINA HEINZ: Good. I'm listening to your show, [10] and I have to tell you that snoring, you know, is a lot [11] more dangerous than people think.

[12] JOHN DENNY: Hmm.

[13] TINA HEINZ: My husband was a chronic snorer.

[14] He's a firefighter/paramedic, so I wasn't the only one [15] affected by this.

[16] JOHN DENNY: Hmm. Um-hmm.

[17] TINA HEINZ: I mean, we didn't sleep together [18] for years.

[19] JOHN DENNY: Now, you've been married for how [20] long, Tina?

[21] TINA HEINZ: Sixteen years.

[22] JOHN DENNY: Sixteen years. And this was a [23] problem that occurred right from the start of your [24] marriage?

[25] TINA HEINZ: Oh, yeah.

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[1] JOHN DENNY: I mean, you found you were married [2] to a snorer?

[3] TINA HEINZ: Oh, absolutely. And the poor guy, [4] it would be all night, John, turn over, turn over. It [5] did not matter, he could be sleeping on his head and he [6] would still snore. Well, it got so bad that even at the [7] fire department he was being, you know, hassled at the [8] fire department because these guys sleep at different [9] shifts, they don't all sleep at the same time.

[10] JOHN DENNY: Um-hmm.

[11] TINA HEINZ: And when John was sleeping, he [12] would be waking everybody else up, and they'd be pounding [13] on the walls, and he'd come home all aggravated, he'd [14] come home and want to sleep. They built a partition [15] around my husband's bunk bed to try to keep out the [16] noise.

[17] (Laughter).

[18] TINA HEINZ: Well, it got so bad he finally [19] went to the doctor and, in order for the insurance [20] company to pay for this surgery, they put him in the [21] hospital in the sleep center and found out that he also [22] had sleep apnea, which is very dangerous because when [23] you're snoring you stop breathing and you forget to [24] sleep.

[25] JOHN ZIGLAR: Um-hmm.

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[1] TINA HEINZ: So, they did this surgery, and
[2] needless to say, it lasted for a while and after that he
[3] started up again, and he would not even believe when I
[4] would tell him John, you're snoring again.

[5] JOHN DENNY: Hmm.

[6] TINA HEINZ: You don't want to go through
[7] surgery and find out that you're snoring again.

[8] JOHN DENNY: So, this was after a surgery, he
[9] had — the problem re-emerged?

[10] TINA HEINZ: Right, they did surgery on all his
[11] sinuses. They went through his nose, and they removed
[12] all his polyps, thinking that was the problem. So, now,
[13] he's in for a second surgery, and they decided that
[14] they're going to remove part of his uvula and the roof of
[15] his mouth, his tonsils and his adenoids.

[16] JOHN DENNY: Hmm.

[17] TINA HEINZ: And this will give his tongue more
[18] room, I guess is what they said, so he wouldn't snore.

[19] DR. BOB CURIER: Um-hmm.

[20] TINA HEINZ: Well, he went through this and it
[21] was a horrible surgery. I really felt very, very bad for
[22] him. He was out of work for six weeks, and he had high
[23] hopes that this was going to work and our life was going
[24] to change, we could sleep in the same room together, go
[25] on vacation, the guys wouldn't be hassling him. Well,

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[1] that did work for quite a while and then it started up
[2] again.

ON SCREEN:

[4] Caller from Phoenix, AZ

[5] Tina Heinz

[6] TINA HEINZ: And I tell you, I was even afraid
[7] to tell him, because I couldn't believe it myself. It's
[8] aggravating; it's annoying. I don't get a good night's
[9] sleep; he doesn't get a good night's sleep. I hated to
[10] say, but I was happy when he was at the fire department
[11] because I got a good night's sleep.

[12] (Laughter).

[13] JOHN DENNY: Tina, I want to interrupt you for
[14] a second, because this is, you know, a real relatable
[15] story to some, perhaps not all have gone through
[16] surgeries and so forth, but for the millions of people
[17] who sleep next to a snorer, their lives are affected as
[18] well. How did you find your life or your sleep quality
[19] affected by sleeping next to a snorer?

[20] TINA HEINZ: Well, I didn't, I chased him out.

[21] JOHN DENNY: Right.

[22] TINA HEINZ: Actually, I have insomnia, and I
[23] don't get — I mean, I could hear the dog turn over, so
[24] he'd have to go into the other room, and I would still
[25] hear him through the vents, but I would get up in the

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[1] morning and I would be a grouch at work because I was —
[2] I was tired.

[3] JOHN DENNY: Yes.

[4] JOHN ZIGLAR: Um-hmm.

[5] TINA HEINZ: And I was aggravated. You're
[6] talking two surgeries, what is it going to take? He
[7] tried those stupid nose-strip things, they didn't work.

[8] JOHN DENNY: Hmm.

[9] TINA HEINZ: So, one day I'm sitting here

[10] watching TV and I see a commercial out here in Phoenix,
[11] and a couple's talking about the same things. And I'm
[12] thinking, well, what have I got to lose. My husband
[13] tells me I'm nuts because his two surgeries didn't work,
[14] a spray was not going to work.

[15] I figure well, I'm going to try it. So, I sent
[16] for it; put it on the nightstand. First night he was
[17] home, I woke him up, I said John, spray your throat; he's
[18] like yeah, yeah, yeah, yeah. I said John, please, spray
[19] your throat. So, we sprayed his throat, and I'm like
[20] wait, I'm laying there, I'm laying there, I'm like oh,
[21] wow, he was sleeping, there was no noise coming out of
[22] him.

[23] And I was — I was pretty well hooked. And he
[24] still was not a believer; he said it was just a fluke.
[25] So, it took a few times of using the Snorenz. Now, I

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[1] tell you what, he's taking it up to the fire department.

[2] I had the wives calling up from the fire department

[3] asking me the 800 number. I've given away more bottles,

[4] I can't tell you —

[5] JOHN DENNY: (Laughter).

[6] TINA HEINZ: — because I bought the Snorenz
[7] bottle-of-the month club.

[8] JOHN DENNY: Um-hmm.

[9] TINA HEINZ: And I just gave one to my daughter
[10] last week. She came over and she was like Mom, I'm going
[11] crazy, Timmy's snoring. I said here, take my last
[12] bottle, take it home.

[13] JOHN DENNY: And how long now has your family
[14] or your husband in particular been using Snorenz?

[15] TINA HEINZ: Oh, for months.

[16] JOHN DENNY: For months?

[17] TINA HEINZ: Months, absolutely.

[18] JOHN DENNY: And it works for him pretty much
[19] every night?

[20] TINA HEINZ: Well, he takes it in his little
[21] duffle bag when he goes to the fire department, because
[22] being a medic also he might be called to another station.
[23] He doesn't want to go to another station with, you know,
[24] guys he doesn't know and start snoring.

[25] JOHN DENNY: Hmm.

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[1] TINA HEINZ: So, he carries it in his little
[2] bag and every place he goes the Snorenz goes with him.
[3] JOHN DENNY: Right. Well, Tina, thank you for
[4] calling from Arizona.
[5] TINA HEINZ: Hey, thanks for the Snorenz, I'll
[6] tell you.
[7] JOHN DENNY: Well, we appreciate your calling
[8] and continue to get a full, silent night's sleep.
[9] TINA HEINZ: Absolutely.
[10] JOHN DENNY: Okay, Tina, thank you.
[11] TINA HEINZ: Thank you.
[12] JOHN DENNY: Bob, tell us about some of your
[13] patients who have been turned on to Snorenz.
[14] DR. BOB CURRIER: Well, I'll give you a good
[15] example. I have Mike. Now, we always think of a snorer
[16] as someone that's older, okay, and that's a little bit
[17] more past middle age, always a male, and it's always
[18] Grandpa, the chain saw —
[19] JOHN DENNY: Um-hmm.
[20] DR. BOB CURRIER: — somebody like that.
[21] Interestingly enough, I had a 25-year-old patient of mine
[22] named Mike who is an optician. Now, Mike was trying to
[23] qualify, okay, for the certifying exam to become a
[24] certified optician. He was losing energy. He just
[25] couldn't — he couldn't understand it, he couldn't

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[1] understand why he didn't have the get-up-and-go to do his
[2] job plus go home to study.
[3] He's single. He lives by himself. So, he's
[4] wondering why. I said, well, you know, maybe you're not
[5] sleeping well. And he said well, you know, I just — I
[6] just can't sleep. And so what happens to him is I give
[7] him some Snorenz. I said well, just try this, it's just
[8] an outside shot, and I said you've got to try this, let
[9] me know how it works.
[10] He comes back, now I don't see him in a week or
[11] two, on another appointment basis. He comes back and my
[12] word, he says — he's just aglow. He passed the
[13] certifying exam; he feels like he is more awake, more
[14] energetic. He feels like he can do anything. He can
[15] conquer the world, he's 25 years old.
[16] ON SCREEN: These statements have not been
[17] evaluated by the Food and Drug Administration. This
[18] product is not intended to diagnose, treat, cure or
[19] prevent any disease.
[20] DR. BOB CURRIER: And what has happened is he
[21] relayed the story. What happened to him is he would fall
[22] asleep; he couldn't get to sleep at night, okay, so he'd
[23] sit up and watch late-night TV, he becomes an insomniac.
[24] What he would do is fall asleep, but he'd wake with a
[25] snore.

[1] This way, with using Snorenz, he could get his
[2] clock back in order, he could go to sleep, and he could
[3] go to sleep snoring free, wake up refreshed in the
[4] morning. He figured it all out real simple, and it took
[5] us years to figure all this out and he did it in a very
[6] short time.
[7] JOHN DENNY: Um-hmm.
[8] DR. BOB CURRIER: Now, he doesn't have a bed
[9] partner, and so what happens is he did this for himself,
[10] for his own energy level.
[11] JOHN DENNY: Um-hmm.
[12] DR. BOB CURRIER: And, so, you know, there it
[13] has worked successfully for him. It isn't always a bed
[14] mate telling someone that they have it.
[15] JOHN DENNY: Um-hmm.
[16] JOHN ZIGLAR: That's right.
[17] DR. BOB CURRIER: He did it for himself.
[18] JOHN ZIGLAR: Right.
[19] JOHN DENNY: You think of snorers as older
[20] people, your grandfather, your father. I remember
[21] growing up, my father — listening to my father across
[22] the hallway snoring. It sounded like the start of the
[23] Indianapolis 500 every night. But, in fact, younger
[24] people snore, too, do they not? In fact, there's a study
[25] out about students who were snorers who were proven to

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[1] have lower test scores. Tell me about that.
[2] JOHN ZIGLAR: I was reading the newspaper here
[3] in Chicago one day, and the Sun-Times has an article and
[4] the top of the article says Test Scores Affected by
[5] Snoring. And, so, I'm looking at it and I'm thinking
[6] wow, you know, there's actually been a study done. And
[7] what had happened is a research program was done over in
[8] West Germany with medical students.
[9] JOHN DENNY: Um-hmm.
[10] JOHN ZIGLAR: And what they did is they tracked
[11] an entire medical school class from the day they started
[12] to the day they finished, and they put them in two
[13] categories. One category was the snorers, and over here
[14] was the category of the non-snorers. And after
[15] everything was said and done from start to finished, the
[16] non-snorers scored 6 percent higher on their tests —
[17] JOHN DENNY: Hmm.
[18] JOHN ZIGLAR: — than the snorers did, all
[19] other things being equal.
[20] DR. BOB CURRIER: Hmm. And you just happened
[21] to run across this, so it's now becoming an awareness.
[22] JOHN ZIGLAR: Exactly.
[23] DR. BOB CURRIER: Right. People are becoming
[24] aware now. And it's — see, it's all too obvious now
[25] when you read something like this why that would happen,

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[1] because we're all aware, and my patients are aware.
[2] Interestingly enough, I store this on — well on shelves
[3] and such in the office. When we do our inventory at the
[4] end of the day, I find that some has been taken. I don't
[5] want to say stolen, because these are my patients and
[6] we've created a relationship, but actually it's missing.

[7] JOHN DENNY: Right.

[8] DR. BOB CURRIER: So, what happens is it just
[9] plain gets taken, people want this.

[10] JOHN DENNY: Hmm.

[11] DR. BOB CURRIER: People are now aware. And I
[12] think this is what's happening here, and we know why
[13] people don't score well, they don't sleep well, they
[14] snore.

[15] ON SCREEN: This is a paid commercial for
[16] Snorenz.

[17] JOHN DENNY: Ninety million Americans snore.
[18] That doesn't include the countless millions who sleep
[19] next to a snorer.

[20] ON SCREEN: 1-800-835-8941.

[21] JOHN DENNY: And if you wanted more information
[22] about this revolutionary, breakthrough product which has
[23] been proven effective in 97 percent of cases to eliminate
[24] or reduce the sound of snoring, call the toll-free 800
[25] number on your screen, get more information about

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[1] Snorenz.
[2] Do it for him, do it for yourself, do it for
[3] your family. It is worth the phone call, and it is
[4] pennies per day to end the snoring problem. This is a
[5] product, as I mentioned, that has been proven effective
[6] in studies. And you actually conducted the studies out
[7] of your auspices in Michigan. Tell us about how Snorenz
[8] worked.

[9] DR. BOB CURRIER: Interestingly enough, it's
[10] not only the results of the studies we got, but the
[11] comments we received. Many people, again, they're aware
[12] of snoring, but they aren't aware of the problems that
[13] come with it. And actually it's like until it's
[14] resolved, the snoring itself, oh, my word, what a problem
[15] it was. And you can see the changes it's made. That was
[16] probably the most interesting part of doing that whole
[17] study —

[18] JOHN DENNY: Um-hmm.

[19] DR. BOB CURRIER: — was the comments that we
[20] got back, the little stories that people had through the
[21] week —

[22] JOHN DENNY: Yes.

[23] DR. BOB CURRIER: — you know, of using this
[24] product. And that was the beauty of this. I loved doing
[25] the study, it was highly effective.

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[1] JOHN DENNY: And, John, this is an all-natural
[2] product?

[3] JOHN ZIGLAR: It's all-natural oils. And we
[4] also have some vitamins —

[5] JOHN DENNY: Um-hmm.

[6] JOHN ZIGLAR: — that we have also put into the
[7] product.

[8] JOHN DENNY: And tell us about snorer's breath.
[9] I'm going to test this here.

[10] JOHN ZIGLAR: Yes.

[11] JOHN DENNY: I hope I don't get it in my eye.
[12] (Laughter).

[13] JOHN DENNY: In my — in my — some problem in
[14] my eye perhaps, but it's minty.

[15] JOHN ZIGLAR: Yes.

[16] JOHN DENNY: Actually, it tastes a lot like
[17] mouthwash, I mean, in a good way. Three sprays of this
[18] before bed.

[19] JOHN ZIGLAR: Right.

[20] JOHN DENNY: And how long will this last,
[21] through the night?

[22] JOHN ZIGLAR: It'll last through the night.

[23] It'll last from six to eight hours.

[24] JOHN DENNY: Um-hmm. In what cases doesn't
[25] this work?

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[1] JOHN ZIGLAR: You know, when I first got this
[2] product, we did test, and I've given it to everybody that
[3] I know that snores —

[4] JOHN DENNY: Um-hmm.

[5] JOHN ZIGLAR: — so that I could find out, you
[6] know, because I always wanted to know exactly how did it
[7] work on everybody else. And, so, we had one friend we
[8] gave it to and, quite honestly, they've been married for
[9] three years, they're already sleeping in different
[10] bedrooms because he snores so loudly —

[11] JOHN DENNY: Hmm.

[12] JOHN ZIGLAR: — and he would go to bed, they
[13] would go to bed together, wake up in different rooms.

[14] And, so, Kevin was taking the product and the first night
[15] it worked perfectly; second night it worked perfectly;
[16] third night it worked perfectly; fourth night, didn't
[17] work; fifth night, didn't work.

[18] He called me up and he says look, you know, it
[19] works temporarily but after that it doesn't work. And I
[20] said wait a minute, you know, there's got to be a reason,
[21] there's something wrong here that only guy it doesn't
[22] work for all in the world. (Laughter). And he says well
[23] — and so I started to ask him some questions, and here's
[24] the point, what I found out was the night that it did not
[25] work, he had a beer just before he went to bed.

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[1] JOHN DENNY: Hmm.
[2] JOHN ZIGLAR: And what we have here was a
[3] situation where the alcohol in the beer literally cut
[4] through the oils in our product and it went down his
[5] throat, so it was not there.
[6] JOHN DENNY: Um-hmm.
[7] JOHN ZIGLAR: Since it was not there, it could
[8] not work, and it proved that he still was a snorer, he
[9] just needed the product to stay where it was —
[10] JOHN DENNY: Um-hmm.
[11] JOHN ZIGLAR: — so that he would live without
[12] the noise.
[13] JOHN DENNY: So, you suggested that he sort of
[14] cut down his drinking right before going to bed?
[15] JOHN ZIGLAR: Exactly. Don't eat or drink
[16] anything 30 minutes before you go to bed —
[17] JOHN DENNY: Um-hmm.
[18] JOHN ZIGLAR: — or if you do, then take a
[19] couple of swallows of water just to clear your palate so
[20] that your throat is clean —
[21] JOHN DENNY: Um-hmm.
[22] JOHN ZIGLAR: — so that when you put the
[23] product in, on the back of your tongue, that it'll stay
[24] there.
[25] JOHN DENNY: Your wives are happy, gentlemen,

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[1] that you are —
[2] DR. BOB CURRIER: Happier.
[3] JOHN DENNY: Happier. We won't get into that,
[4] but they're happy that your snoring problems have been
[5] reduced or eliminated?
[6] DR. BOB CURRIER: Yes, very much so.
[7] JOHN ZIGLAR: And now, you know, I roll over
[8] and Linda gives me a kiss before we go to bed, and I
[9] think that's just real sweet. She's checking to see if
[10] I've taken the Snorenz, okay?
[11] (Laughter).
[12] JOHN DENNY: If you want more information about
[13] this revolutionary, all-natural, vitamin-based spray, no
[14] pills, no surgery, no clamps, no strips across your nose,
[15] Snorenz will end your snoring problem and do it
[16] naturally. It is pennies in comparison to the value and
[17] the almost priceless value of a full, restful, silent
[18] night's sleep for all, and that goes for the snorer as
[19] well as the person sleeping next to the snorer.
[20] For more information, call the 800 number on
[21] the screen. Dr. Bob Currier, thank you for joining us on
[22] Vantage Point.
[23] DR. BOB CURRIER: Thank you for having me.
[24] JOHN DENNY: And, John Ziglar, thank you.
[25] JOHN ZIGLAR: You're welcome.

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[1] JOHN DENNY: I may knock off a few sprays
[2] tonight and try to get my snoring down. This is John
[3] Denny saying goodbye from Vantage Point, and we will see
[4] you next time.

[5] (Music playing.)

ON SCREEN:

[7] For more information or to order Snorenz call:
[8] 1-800-835-8941
[9] If snoring is accompanied by any signs of Sleep
[10] Apnea, you should consult a physician before using any
[11] product.

[12]

ON SCREEN:

[13] [14] Tru-Vantage International
[15] 7300 N. Lehigh Ave. Niles, IL 60714 (847)647-
[16] 0300
[17] ANNOUNCER: The preceding has been a paid
[18] commercial brought to you by Kevin Trudeau's Tru Vantage
[19] International.

[20]

ON SCREEN:

[21] The preceding has been a paid commercial for
[22] SNORENZ brought to you by Kevin Trudeau's Tru-Vantage
[23] International, America's premier direct response
[24] marketing company.

[25] (End of videotape.)

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CERTIFICATION OF TYPIST

[1]
[2]
[3] MATTER NUMBER: 0023211
[4] CASE TITLE: MED GEN INC.
[5] TAPING DATE: OCTOBER 13, 1999
[6] TRANSCRIPTION DATE: MAY 13, 2000
[7]
[8] I HEREBY CERTIFY that the transcript contained
[9] herein is a full and accurate transcript of the tapes
[10] transcribed by me on the above cause before the FEDERAL
[11] TRADE COMMISSION to the best of my knowledge and belief.

[12]

[13] DATED: MAY 15, 2000

[14]

[15]

SARA J. VANCE

[16]

CERTIFICATION OF PROOFREADER

[17]

[18] I HEREBY CERTIFY that I proofread the transcript for
[19] accuracy in spelling, hyphenation, punctuation and
[20] format.

[21]

[22]

[23]

[24]

[25]

ELIZABETH M. FARRELL

Lawyer's Notes

[1] FEDERAL TRADE COMMISSION
[2] INDEX
[3]
[4] VIDEOTAPE: Page
[5] VP Snorenz 8 JD/JPK
[6] (Replace SNZ6)
[7] Rollout SNZ8 Soft 3
[8]
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Page 3

[1] PROCEEDINGS
[2]
[3] **ON SCREEN:** Client: TVI
[4] Project: VP Snorenz 8 Generic
[5] Price Point: Soft Offer
[6] Edit Date: 3/29/99
[7] Editor: WPS
[8] Audio: Mixed
[9] Notes: Generic
[10] ON SCREEN: The following is a paid
[11] commercial program for SNORENZ.
[12] **MALE ANNOUNCER:** The following is a paid
[13] program.
[14] **JON DENNY:** For millions of Americans,
[15] this is the most annoying and unwelcome sound in
[16] the world. That's right, more than 90 million
[17] Americans have a snoring problem, and it could
[18] cause sleeplessness, headaches and a lack of
[19] energy, and that goes for the snorer as well as the
[20] person trying to sleep next to the snorer.
[21] What can be done about it? On Vantage
[22] Point today, hear about a new discovery that could
[23] eliminate the sound of snoring.
[24] **ON SCREEN:** Vantage Point with Jon Denny
[25] Jon Denny

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Page 4

[1] FEDERAL TRADE COMMISSION
[2]
[3]
[4] In the Matter of:)
[5]) Matter No. 0023211
[6] Med Gen, Inc.)
[7]
[8] October 13, 1999
[9]
[10]
[11]
[12] The following transcript was produced from
[13] a live tape provided to For The Record, Inc. On May
[14] 8, 2000.
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[1] **JON DENNY:** Hi, I'm Jon Denny, and welcome
[2] to Vantage Point. We are going to talk about
[3] snoring today, and we are going to do it with Paul
[4] Kravitz, who has brought to the market an exciting
[5] breakthrough product called Snorenz, which has been
[6] proven from snorers around the country to reduce or
[7] eliminate their snoring problem.
[8] Paul, welcome to the show.
[9] **PAUL KRAVITZ:** Thank you, Jon.
[10] **JON DENNY:** Tell me, is this a
[11] breakthrough medical discovery, is this a
[12] revolutionary new direction to help people stop
[13] their snoring problem?
[14] **ON SCREEN:** Paul Kravitz, Snorenz
[15]
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October 13, 1999

VIDEO

MED GEN INC.

Matter Number 0023211

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[1] PAUL KRAVITZ: Well, John, I don't know if
 [2] you would call it a medical breakthrough or a new
 [3] discovery. To me it was a major breakthrough. In
 [4] fact, it saved my marriage.

[5] I had been a heavy snorer for years, and
 [6] at one point in my life, my — my ribs hurt so much
 [7] in the morning from my wife poking me to wake up to
 [8] stop snoring, it was just a terrible thing, and
 [9] over the course of many years, I was thinking about
 [10] surgery, a lot of potential cures that I — that I
 [11] thought I would find to help the situation out, and
 [12] I met somebody about six or seven years ago, a
 [13] Korean gentleman who was — lived in Brazil,
 [14] actually, and who was working with an EMT
 [15] specialist who lived next door, and they came up
 [16] with a product, and I had met him, they were
 [17] looking for somebody to invest in the company, and
 [18] things just went — went the way of the world, and
 [19] finally, I asked him if I could try the product,
 [20] and I did, and it worked.

[21] It was — at that time it was in its
 [22] infancy, it was terrible tasting, and — but it
 [23] worked, and I used it for five days straight, and I
 [24] made a small investment, which became a larger
 [25] investment and even a larger investment, until

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[1] can stop the snoring noise.
 [2] JON DENNY: Well, how does Snorenz work?
 [3] It is a spray, an all-natural spray?
 [4] PAUL KRAVITZ: It's an all-natural spray,
 [5] yes:

[6] JON DENNY: Vitamin-based?
 [7] PAUL KRAVITZ: It's vitamin based, it's
 [8] all natural, and it's manufactured in a very
 [9] special technique called liposome.
 [10] JON DENNY: And is this a patented
 [11] process?
 [12] PAUL KRAVITZ: Yes, it is, it's patented.
 [13] JON DENNY: And how does it work exactly?
 [14] So, we have a snorer — we are going to go to some
 [15] video feeds of some couples who have experienced
 [16] what snoring has done in their lives and really
 [17] impacted their marriages. We may consider this a
 [18] laughing matter, but for many people, it isn't a
 [19] laughing matter at all.
 [20] PAUL KRAVITZ: No, it's a very serious
 [21] problem, John.
 [22] JON DENNY: How does Snorenz work to
 [23] correct or address the problem you're talking
 [24] about?
 [25] PAUL KRAVITZ: Well, very simply put, it

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[1] finally I bought the formula from the Korean, and
 [2] we went to work on it. It took a year and a half
 [3] to develop, and Jon, we've tested it, we've proven
 [4] it, it works. And it works, and it's a very simple
 [5] way it does work.

[6] JON DENNY: Now, before we get into how
 [7] Snorenz works, what is snoring? What causes that
 [8] terrible Harley Davidson rumbling sound that seems
 [9] to emanate from almost every bedroom across
 [10] America? I mean, I grew up with a father, and it
 [11] sounded like the start of the Indianapolis 500
 [12] every night, the house would literally rattle.
 [13] What is snoring?

[14] PAUL KRAVITZ: Well, snoring is caused by
 [15] a vibration of three parts of your mouth — in your
 [16] throat. It's a vibration of the back of your
 [17] tongue against the uvula, which is the small part
 [18] of the skin that hangs down from your throat, and
 [19] your soft pallet, which vibrates. Now, you can
 [20] either vibrate the two pieces together, either the
 [21] back of the tongue and the uvula, or you can
 [22] vibrate all three, and the deeper the resonance,
 [23] the more vibrations you're going to hear.

[24] Our product really addresses the
 [25] vibrations. You can't stop the vibration, but you

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[1] oils the vibrating parts of your — of your throat,
 [2] and when you put oil on a rusty part, it silences
 [3] it, and that's exactly how it does work. The
 [4] secret of the product and what we've spent millions
 [5] of dollars to find out is how to get it to attach
 [6] itself, the product itself, the spray, to staying
 [7] in the back of the throat so that the noise stays
 [8] for — I mean, the noise stays away for six to
 [9] eight hours.

[10] JON DENNY: Um-hum.
 [11] PAUL KRAVITZ: And we were able to find a
 [12] trace product that we use in all of our products
 [13] that let's it stick to the back of the throat,
 [14] thereby quieting the noise. So, in its simplest
 [15] form, what you're doing is greasing the noisy
 [16] parts.

[17] JON DENNY: Right, like someone would if a
 [18] car's axis or car parts were rumbling or rattling
 [19] together, oil would essentially grease those areas?

[20] PAUL KRAVITZ: That's it, right, that's
 [21] it.

[22] JON DENNY: Now, when I hear oil and I
 [23] hear grease, my word, not yours, I'm thinking
 [24] terrible tasting, I'm thinking that — I'm not sure
 [25] that I want to spray oil in my mouth. Tell me

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[1] about the taste of this.
[2] PAUL KRAVITZ: Well, we've added
[3] peppermint flavor to it, so — as a matter of fact,
[4] the taste is delicious. It almost tastes like
[5] bubble gum, and I used to love bubblegum as a kid,
[6] and I love it. I take it in every day — every
[7] night, I go to bed at night, I spray my throat, I
[8] wake up in the morning, my throat is fresh, I have
[9] had a good, restful night's sleep, and so has my
[10] wife, as a matter of fact. We both think this
[11] product is wonderful, and we've turned a lot of
[12] people on to this product.

[13] JON DENNY: Now, why is snoring a problem?
[14] On one hand we know it's a problem for the person
[15] sleeping next to us, the snorer, they're not
[16] getting enough sleep because of that sound coming
[17] right next to them, but in what other ways is
[18] snoring a real problem for both the snorer as well
[19] as the person trying to sleep next to them?

[20] PAUL KRAVITZ: Well, from the snorer's
[21] point of view, Jon, it's a major problem. First of
[22] all, you don't know it, but if you were a snorer,
[23] you wake up maybe a thousand times a night, because
[24] the snoring does wake you up. You go right back to
[25] sleep again, and then you wake up again. Even if

[1] your wife doesn't wake you up or your girlfriend
[2] doesn't wake you up, you are really not sleeping
[3] soundly.

[4] As a matter of fact, there was a Times
[5] article, the Los Angeles Times, if you don't mind
[6] me reading it, it says basically that the snoring
[7] decreased — as snoring decreased, you were able to
[8] function better in the daytime, and they've
[9] actually been able to prove that people function
[10] better with a better night's sleep, obviously if
[11] you don't snore, you do get a better night's sleep.

[12] As far as your wife is concerned or your
[13] girlfriend is concerned or anybody nearby you,
[14] obviously they're going to sleep better, as well.
[15] So, it's a dual effect.

[16] JON DENNY: Interestingly. We have Dr.
[17] Mike Leonard on the line from Kalamazoo, Michigan.
[18] Dr. Leonard, are you with us?

[19] DR. MIKE LEONARD: Yes, I am.

[20] ON SCREEN: Caller: Dr. Michael Leonard
[21] Kalamazoo, MI

[22] JON DENNY: Dr. Leonard, I believe
[23] conducted some tests on the efficacy of this
[24] product out of his auspices in Michigan. Dr.
[25] Leonard, let me ask you a question. As a dentist,

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[1] is this something that you have recommended to your
[2] patients who have sleep problems, most particularly
[3] snoring problems?

[4] DR. MIKE LEONARD: Yes. Initially, as a
[5] dentist, we — historically we fabricate occlusal
[6] appliances or guards that go in your mouth that,
[7] oh, essentially keep your mouth open wider or
[8] really position your lower jaw forward so you can
[9] keep the airway open like you were talking about
[10] earlier and don't have those tissues vibrating and
[11] rolling around.

[12] The problem is a lot of people can't
[13] tolerate those appliances. They are large, they
[14] are cumbersome, and throughout the night, if you've
[15] got it in your mouth, you may end up with it on
[16] your pillow in the morning, because you're just
[17] subconsciously take it out.

[18] JON DENNY: These are clamps that dentists
[19] are in the past put into people's mouth to create
[20] more airspace?

[21] DR. MIKE LEONARD: Exactly, of varying
[22] different sizes and shapes, et cetera, but they're
[23] custommade appliances, and for some people that
[24] can't tolerate them, it's an expense to go through
[25] if you're not going to be able to utilize it.

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[1] So, I had, through the grapevine, heard
[2] about a spray to use and got the name of the
[3] company, called them up and ordered a case of
[4] Snorenz and had it sent to my office to start
[5] dispensing to patients and having them try it out
[6] and see what they thought, because quite simply,
[7] it's easily reversible.

[8] If you are not tolerating it, if it was
[9] not working, you just stop using it. You're not
[10] really out anything. And that — the feedback that
[11] I got was very, very positive. People were getting
[12] good results, and the people that were coming in
[13] with the problems were not the snorers themselves;
[14] it was the mate, the partner that was sleeping next
[15] to them that was kept up all night or irritated all
[16] night that they were having to roll their spouse
[17] over to get them to quiet down a little bit so they
[18] could get a more restful sleep.

[19] JON DENNY: Now, the rumor out of Michigan
[20] was that not only did you dispense Snorenz to some
[21] of your patients, but you may have tried it or been
[22] urged to try it yourself. Tell me about your
[23] personal experience with the product.

[24] DR. MIKE LEONARD: Yes, exactly, I was at
[25] home one night talking — just talking to my wife

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VIDEO

MED GEN INC.

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[1] about the daily goings-on, et cetera, and I was
 [2] telling her I gave a patient of a sample of the
 [3] Snorenz, and it kind of caught her ear, and she
 [4] perked up a little bit and said, Well, what — tell
 [5] me about this stuff. And I told her, got a case of
 [6] it, been giving it out, and she said, Well, don't
 [7] give all of it out, she said, you better bring some
 [8] of it home yourself, because you snore like a
 [9] lumberjack, which was prior to that unbeknownst to
 [10] me, I had no idea.

[11] So, since then, I've been bringing it
 [12] home. I've got a bottle of it on my bedside table
 [13] that I use every night, and if I forget, as I'm
 [14] dozing off to sleep at night, if I forget to use
 [15] it, she will give me a little nudge at this point
 [16] and make sure that I've used my spray, and I get a
 [17] restful sleep, she gets a restful sleep, and we're
 [18] both happy.

[19] **JON DENNY:** Now, Paul, if people want more
 [20] information about Snorenz, this patented product
 [21] process that is apparently helping people get a
 [22] full, restful, silent night's sleep across the
 [23] country, where do they get more information about
 [24] it?

[25] **PAUL KRAVITZ:** Well, actually, for this

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[1] typical snoring problem?

[2] **DR. MIKE LEONARD:** It's an extremely
 [3] logical, common sense, first line approach to
 [4] dealing with it. Use it, and if you use it
 [5] properly and if you use it consistently, I find
 [6] that it works. It works for me and it works for a
 [7] number of the patients that I'm having use it in
 [8] the practice.

[9] **PAUL KRAVITZ:** I am really so excited
 [10] about listening to the successes of people that use
 [11] the product, Jon. Every time I get a letter — I
 [12] must have a stack of testimonials from different
 [13] people, some of Dr. Leonard's clients — patients,
 [14] as well, and I just — I get chilled all over,
 [15] because I think it's just so wonderful, because to
 [16] me, this was an affliction. I really think this is
 [17] a major breakthrough, and for something that is
 [18] really hurting people, not allowing them to sleep.
 [19] Direct application of this oil or solution that we
 [20] have that actually quiets the noise down, that's
 [21] what happens.

[22] **JON DENNY:** We want to talk — we have
 [23] from Chicago a couple, Ralph and Julie Dynek
 [24] (phonetic), who are being beamed in to us as we
 [25] speak. Welcome to the show, guys.

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[1] **JULIE DYNEK:** Hi.

[2] **RALPH DYNEK:** Thank you.

[3] **JON DENNY:** You experienced your own story
 [4] with both a snoring problem and success with this
 [5] product. Tell me a little bit about what happened
 [6] and why snoring was a problem in your life.

[7] **JULIE DYNEK:** Well, it — for as long as
 [8] I've known Ralph, as long as we've been married,
 [9] the snoring has been terrible, absolutely terrible.
 [10] Sometimes I'd get up, go sleep in another bedroom.
 [11] Many times I'd be like punching him, telling him
 [12] please stop snoring, you're snoring, I can't sleep.
 [13] He's like, I don't snore, I don't snore, but it's
 [14] been a real — it was a terrible, terrible problem,
 [15] and I thought of millions of things, I didn't know
 [16] what to do, because it was always waking me up,
 [17] every single night, and I was getting no — barely
 [18] any sleep.

[19] So, I thought of — I heard that you could
 [20] like sew a tennis ball in their T-shirt, and when
 [21] they roll over on their back, it's uncomfortable,
 [22] but I didn't know what to do. I just said — you
 [23] know, I'd just punch him overnight.

[24] **JON DENNY:** I would think you would want
 [25] to put the tennis ball in his mouth to stop the

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[1] show and this show only, Jon, we're giving a
 [2] special bonus offer, and if they — people call in
 [3] and they see this 800 number on the bottom of the
 [4] screen, all they have to do is call in and they can
 [5] get a special offer of Snorenz.

[6] **JON DENNY:** Great, great.

[7] **PAUL KRAVITZ:** And Dr. Leonard, you know,
 [8] what was interesting about what you said is that I
 [9] actually went to a dentist to get this appliance,
 [10] and I have a terrible problem with gagging, and the
 [11] appliance — I could not wear that appliance at
 [12] night, and I just — I must tell you something,
 [13] your wife turning you onto the product was really
 [14] tremendous. I have seen your orders come through
 [15] the office, so now I have gotten to speak to you,
 [16] Doctor.

[17] **DR. MIKE LEONARD:** Very good.

[18] **PAUL KRAVITZ:** And it's a pleasure.

[19] **JON DENNY:** Now, there have been not only
 [20] clamps but also pills that have been tried and also
 [21] strips across one's nose, very expensive and
 [22] painful surgeries, as well.

[23] **DR. MIKE LEONARD:** That's right.

[24] **JON DENNY:** So, Doctor, would you consider
 [25] Snorenz to be a logical, common sense approach to a

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[1] snoring problem. But you actually, Ralph, you
[2] didn't believe that you had a snoring problem until
[3] Julie did something. Is that correct?
[4] **RALPH DYNEK:** Yeah, that's true. She got
[5] up in the evening while we were sleeping and went
[6] and got the tape recorder, and it was — it was a
[7] widening of the eyes. It was just — I couldn't
[8] believe it. I mean, I was loud, and I felt really
[9] bad.

[10] I mean, I love Julie, and we have a very,
[11] very energetic life, and if you fall behind in your
[12] sleep, who knows how the next day is going to be,
[13] and sometimes, you know, we were running out of
[14] energy, and I know I was waking up, too, and the
[15] more information I got, we didn't know where to
[16] turn.

[17] We were concerned, she was concerned, and
[18] there was also threatening — you see ads in the
[19] paper or you hear ads on TV about people could be
[20] even having life-threatening situations. So, we
[21] wanted to address it. We were definitely
[22] concerned, and thank God we ran into this product.
[23] It's been just fabulous.

[24] **JON DENNY:** And Julie and Ralph from
[25] Chicago, how did the problem, before you addressed

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[1] it with Snorenz, how did the problem affect your
[2] relationship? I mean, was it difficult for Julie,
[3] for you to get a good night's sleep next to Ralph?

[4] **JULIE DYNEK:** Oh, it was terrible,
[5] especially when I was pregnant, I mean, you don't
[6] get very much sleep anyways, I would be — like I
[7] said, I would punch him, I would kick the bed, I
[8] would like be, "shh, shh," all night long, and
[9] nothing — it would stop for a little while, I
[10] would fall asleep, and then it would start roaring
[11] again.

[12] I can remember one time when my
[13] sister-in-law slept over, and she was actually
[14] sleeping in a spare bedroom in the basement and
[15] through the ceiling of the basement she actually
[16] thought that there was either a tornado or an
[17] earthquake or something. She came running up the
[18] stairs, and she said, What is that? What is that?
[19] I'm like, What? She's like, Oh, my God, it's
[20] Ralph's snoring. I'm like, Oh, yeah — that — I'm
[21] so used to it, you know, it's like, you know, you
[22] get used to it, but somebody new coming into the
[23] house, it was just horrible for her.

[24] **JON DENNY:** And tell me about the
[25] experience and the success that you've had with

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[1] Snorenz.
[2] **JULIE DYNEK:** Well, it's kind of a funny
[3] story. My same sister-in-law told me, I have this
[4] product that I heard about, I think you guys should
[5] try it, and so we tried it for a whole week, and
[6] that week, it didn't really even dawn on me, I said
[7] to her one day, I said, I feel like I have so much
[8] energy, and I have — I don't know what's going on,
[9] I feel so rested, and she said, Oh, hello, don't
[10] you think it's that product I gave you? Don't you
[11] think it's the Snorenz? And then it dawned on me
[12] that definitely it was. At that point I was very
[13] happy.

[14] **JON DENNY:** And, Ralph, do you find
[15] yourself, now that the product has helped cut down
[16] or eliminate your sound of snoring, do you feel
[17] more rested? Are you getting a better night's
[18] sleep?

[19] **RALPH DYNEK:** Clearly I am, and I'll tell
[20] you what, I didn't really believe it, but I was
[21] waking up, and when you — when you go back and you
[22] think about the times or actually when it happens,
[23] if I fall asleep sometimes in the afternoon, if I'm
[24] having a nap after a rough day at work, then all of
[25] a sudden I'll be woken up, you know, you can do

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[1] these short, ten-minute naps, and I can actually
[2] hear the tail end of the snore — of course, I'm
[3] not using the product at that time, and then I just
[4] turn and go, Oh, my gosh, I can't believe it. It's
[5] a little bit embarrassing. It's a lot
[6] embarrassing. So —

[7] **JON DENNY:** And it's worked throughout the
[8] night for you every night?

[9] **RALPH DYNEK:** Yeah, it's been a very solid
[10] performance out of it, and it's amazing, and you
[11] know what, the — I can't really tell, but — but
[12] Julie tells me, and then I can tell in the morning,
[13] because I can just take one look at her and know if
[14] she had a good night's rest, if she says 48th
[15] although to me nicely, because sometimes she was a
[16] little bitter at me in the morning.

[17] **JON DENNY:** Um-hum, oh, I bet. Ralph and
[18] Julie, thank you for joining us from Chicago.
[19] Continue to get a full and restful, silent night's
[20] sleep.

[21] **JULIE DYNEK:** Thank you.

[22] **ON SCREEN:** Paul Kravitz, Snorenz

[23] **PAUL KRAVITZ:** You know, Jon, they say

[24] snorers are broken into three categories, those who
[25] know they snore, those who are in denial and those

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[1] who sleep alone. I'm happy to hear that these
[2] people bought some of our product and it works.
[3] **JON DENNY:** Now, Paul, tell us how snoring
[4] can affect other aspects of people's lives. There
[5] have been — there's a study, I believe, in a
[6] Chicago newspaper about how — a study was
[7] conducted that students who snored actually were
[8] proven to get worse grades, that as the snoring
[9] decreased or was eliminated, energy levels were up,
[10] restlessness, and better grades. Have you heard
[11] that story?

[12] **PAUL KRAVITZ:** Yeah, I've heard it. I
[13] have heard so many stories, Jon, talking to
[14] doctors, and I'm not a doctor, I'm a businessman,
[15] but I'm happy to have introduced this product into
[16] the world.

[17] I have heard so many stories about
[18] students who are now getting better grades because
[19] they found a way to sleep well at night and get
[20] rest. I have heard stories of mothers — you know,
[21] actually, speaking, 60 percent — in studies that
[22] have been conducted, 60 percent of the men — of
[23] the people in the world are male are snorers and 40
[24] percent are female, which is kind of wild when you
[25] think about it, that there are more men snorers

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[1] than women, and I have no answer for that.
[2] The truth of the matter is that the
[3] stories that I have — that are bound today, and
[4] the medical profession is really getting into this
[5] big time. In fact, I read an article about a month
[6] ago in the New England Medical Journal that
[7] addressed the problem of snoring. They had tried
[8] almost everything, surgery and everything else, and
[9] here's a very simple product which costs very
[10] little money, easy to use, tastes good. As a
[11] matter of fact, it's a breath freshener.

[12] **JON DENNY:** I wanted to ask you about
[13] this. Essentially tree sprays, and I know Dr.
[14] Leonard is still on the line from Kalamazoo — and
[15] compliance, patient compliance is a very important
[16] issue, to actually do it right. So, it's actually
[17] three easy sprays of this.

[18] **PAUL KRAVITZ:** Three sprays in the back of
[19] your throat.

[20] **JON DENNY:** Right.

[21] **PAUL KRAVITZ:** And you will have a good
[22] night's sleep.

[23] **JON DENNY:** And tell me about morning
[24] breath, because snorers are notorious —

[25] **PAUL KRAVITZ:** Well, John, I haven't slept

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[1] with you lately, but morning breath is a problem.

[2] **JON DENNY:** And we are going to keep it
[3] that way.

[4] **PAUL KRAVITZ:** Right.

[5] **JON DENNY:** But tell me about morning
[6] breath.

[7] **PAUL KRAVITZ:** Morning breath is —

[8] actually, this takes away morning breath. I mean,
[9] everybody has a stale mouth when they wake up in
[10] the morning. This — this gives you a lasting,
[11] sweetness, pepperminty flavor in your mouth, and it
[12] lasts all day long almost. It never — it lingers,
[13] and it's just a wonderful product. It really takes
[14] away that stale breath — mouth feeling when you
[15] wake up in the morning.

[16] **JON DENNY:** Now, Dr. Leonard, how has it
[17] worked for you personally back in Kalamazoo?

[18] **ON SCREEN:** Caller: Dr. Michael Leonard

[19] Kalamazoo, MI

[20] **DR. MIKE LEONARD:** I guess I would have to
[21] sum it up by saying my wife every night nudges me
[22] to make sure I use it, so the snoring never
[23] bothered me to begin with, and the only one that it
[24] really noticeably bothered was her. She
[25] consistently has me use it, so it works.

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[1] **JON DENNY:** Right, and you would recommend
[2] this to other people out there who are experiencing
[3] the problems that snoring can bring?

[4] **DR. MIKE LEONARD:** Right, I do recommend
[5] it.

[6] **JON DENNY:** Dr. Leonard, thank you for
[7] joining us from Kalamazoo.

[8] **DR. MIKE LEONARD:** Thank you.

[9] **ON SCREEN:** This is a paid commercial for
[10] Snorenz

[11] **JON DENNY:** Paul, if people want more
[12] information about Snorenz, this revolutionary
[13] product that is reducing or eliminating the sound
[14] of snoring in cases all across the world, because
[15] this product now, through your company only, is
[16] being distributed throughout the world and being —
[17] is being made — a special offer is being made here
[18] through this show, it's — do they call an 800
[19] number that's on the screen now?

[20] **PAUL KRAVITZ:** There's an 800 number that
[21] should appear on the screen, and if the — if your
[22] listeners call in, they will receive a special
[23] price for this show.

[24] **JON DENNY:** Right.

[25] **PAUL KRAVITZ:** And they will enjoy the

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[1] product.
[2] JON DENNY: And you had a little story
[3] flying here, did you not?
[4] PAUL KRAVITZ: As a matter of fact, it was
[5] a great story. I brought — I was asked to bring a
[6] box of 24 of our Snorenz product to the show, and
[7] the box on the side had a label, it said, Snorenz,"
[8] and it says, "Stops snoring," and so forth, and I
[9] was putting it up on the top of the seat on the
[10] plane, and the plane was full as all planes are
[11] today, and I get it up there.

[12] And finally a gentleman — nice guy, got
[13] up, and he said, Let me fix it for you, and he put
[14] it up on the top, and that was — we take off, and
[15] about halfway into the flight here from — to
[16] Chicago from Florida, I hear this terrible noise,
[17] somebody snoring across the way from me. I mean,
[18] he had the plane in an uproar. It was the funniest
[19] thing you ever heard. I mean, the noise was just
[20] tremendous.

[21] So, the guy next to me, the passenger next
[22] to me said, Well, why don't we just open up the
[23] box, I saw what you — I said, Well, I'm the
[24] manufacturer of the product. He says, Why don't we
[25] break out a bottle and spray it in his throat.

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[1] But, you know, that's a remarkable thing. Sleeping
[2] — falling asleep on a plane, you're not only
[3] annoying other people, but you're just not getting
[4] a good restful sleep when you do that.

[5] JON DENNY: Right. We have Cindy Brown
[6] with us from a studio, and Cindy, you have a story
[7] about snoring and how it actually affected your
[8] marriage. Tell us about that.

[9] CINDY BROWN: Well, my husband, Kevin, and
[10] I have been married for four years now, and for the
[11] last two, he's been snoring really badly, and I
[12] always ended up on the couch because of him
[13] snoring.

[14] JON DENNY: You ended up on the couch?

[15] CINDY BROWN: Yes, I did.

[16] JON DENNY: Now, how did that happen? You
[17] couldn't like hit him a couple times and send him
[18] out to Siberia?

[19] CINDY BROWN: Yeah, I would try hitting
[20] and punching and rolling — trying to get him to
[21] roll over, and nothing worked. So, I just got
[22] frustrated and ended up on the couch.

[23] JON DENNY: Now, what — how did it affect
[24] you? I mean, was the snoring that loud that you
[25] really couldn't sleep at night? Were you awakened

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[1] in the middle of the night by his snoring?
[2] CINDY BROWN: It was awful, because he
[3] would always fall asleep before me, and I would
[4] always end up not being able to go to sleep, and if
[5] I did go to sleep, I would wake right back up
[6] because of his snoring, even with the door closed
[7] in the other room, I still could hear him.
[8] JON DENNY: You could hear him even with
[9] the door closed?

[10] CINDY BROWN: Yes.
[11] JON DENNY: So, your husband, Kevin, is
[12] snoring in the other room. You're out on the couch
[13] in the living room with the door closed still
[14] hearing the snoring. It's affecting your sleep,
[15] obviously.

[16] CINDY BROWN: Right.
[17] JON DENNY: How is it affecting your
[18] relationship?
[19] CINDY BROWN: Well, it wasn't so good. We
[20] were never sleeping together, and I would wake up
[21] the next day being very angry at him for him
[22] snoring. I knew it wasn't his fault, but it was —
[23] it sure seemed like it should be.
[24] JON DENNY: And how was it affecting you
[25] during the course of the day, you know, you're not

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[1] getting obviously the full restful, silent night's
[2] sleep that you probably deserve.
[3] CINDY BROWN: Right. Well, I was always
[4] tired, constant tired, never felt energetic. Then
[5] once he quit snoring, you realize how much you need
[6] sleep.

[7] JON DENNY: It's a good thing, sleep.

[8] CINDY BROWN: Oh, definitely.

[9] JON DENNY: How did you get turned on to
[10] or at least become aware of this product called
[11] Snorenz?

[12] CINDY BROWN: Well, it was given to us to
[13] try, and I thought, Yeah, right, this isn't going
[14] to work, but we tried it, and it ended up working.

[15] JON DENNY: Hmm. And did it work for you
[16] right away and did it work for you through the
[17] night?

[18] CINDY BROWN: Yeah, it did. Actually, it
[19] was funny, because the first week it worked, and
[20] then it quit working, and so then we found out that
[21] he shouldn't eat anything or drink anything about a
[22] half an hour to an hour before.

[23] JON DENNY: Hmm. And does it now work for
[24] you? Is it something that Kevin is using at your
[25] behest and insistence, probably, every night?

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[1] **CINDY BROWN:** Yes. Yes, it does. Yep, I
[2] make sure that if he doesn't take it, I'm waking
[3] him back up to make sure he takes it.
[4] **JON DENNY:** And I presume that you've
[5] moved book into the bedroom?
[6] **CINDY BROWN:** Yes, I have.
[7] **JON DENNY:** And I feel like I'm prying
[8] here.
[9] **CINDY BROWN:** No, no. I have — we're
[10] sleeping together again, and so everything is
[11] great.
[12] **JON DENNY:** That's terrific. Cindy, thank
[13] you for your story, and continue to get a full
[14] restful silent night's sleep with Snorenz.
[15] **CINDY BROWN:** Thank you.
[16] **PAUL KRAVITZ:** Isn't that a wonderful
[17] story?
[18] **JON DENNY:** Yeah, it really is.
[19] Now, tell me about how as a former snorer
[20] before you tried Snorenz, how has it improved your
[21] life and your marriage?
[22] **PAUL KRAVITZ:** Well, it really has.
[23] Obviously my — I'm bigger than my wife, so I —
[24] she left the bedroom, I didn't, but actually, my
[25] wife — my rest, my days are a lot more vigorous,

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[1] **JON DENNY:** That's great. Paul, thank you
[2] for being here.
[3] **PAUL KRAVITZ:** Thank you for having me.
[4] **JON DENNY:** If you want more information
[5] about Snorenz, the patented process, all-natural
[6] spray that could help reduce or eliminate the sound
[7] of snoring, if you are a snorer or you sleep next
[8] to a snorer, this may be the product for you.
[9] Money-back guarantee, it costs pennies to address
[10] this very serious problem, and hopefully you shall
[11] all get a full, restful, silent night's sleep.
[12] I'm Jon Denny on Vantage Point. I think
[13] I'm going to knock off a few sprays, because I've
[14] been told I'm a snorer. We'll see you next time on
[15] Vantage Point. Take care.
[16] **ON SCREEN:** For more information or to
[17] order Snorenz call: NO NUMBER
[18] Tru-Vantage International
[19] 7300 N. Lehigh Ave.
[20] Niles, IL 60714
[21] (847)647-0300
[22] If snoring is accompanied by any signs of
[23] Sleep Apnea, you should consult a physician before
[24] using any product.
[25] The preceding has been a paid commercial

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[1] my wife is very much happier, and even my daughter,
[2] who sleeps in a room four bedrooms down, doesn't
[3] hear me anymore. So, it really has improved my
[4] life.
[5] **JON DENNY:** Right. And if people want
[6] more information about Snorenz, the all-natural
[7] spray that people are using all around the country
[8] now to great effect, where do they get more
[9] information, Paul?
[10] **PAUL KRAVITZ:** Well, John, I'm delighted
[11] that we have a special offer today on your show,
[12] and if the listeners would call the 800 number on
[13] the bottom of the screen and call in their order
[14] today, they will receive a special price and a
[15] money-back guarantee if it doesn't work.
[16] **JON DENNY:** All right. So, it must be
[17] gratifying for you to get all these letters and
[18] phone calls and people who come up to you on the
[19] street telling you thank you, you not only helped
[20] them get better sleep, you have saved some
[21] marriages, I assume, in the process.
[22] **PAUL KRAVITZ:** It sounds like I have,
[23] John.
[24] **JON DENNY:** That's great.
[25] **PAUL KRAVITZ:** It truly does.

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[1] program for SNORENZ.
[2] (The videotape was concluded.)
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Page 33

C E R T I F I C A T E O F T R A N S C R I B E R

- [1]
- [2]
- [3] DOCKET/FILE NUMBER: 0023211
- [4] CASE TITLE: Med Gen, Incorporated
- [5] RECORDING DATE: October 13, 1999
- [6] TRANSCRIPTION DATE: May 15, 2000
- [7] I HEREBY CERTIFY that the transcript
- [8] contained herein is a full and accurate transcript
- [9] of the videotapes transcribed by me on the above
- [10] cause before the FEDERAL TRADE COMMISSION to the
- [11] best of my knowledge and belief.

DATED:

SUSANNE Q. TATE

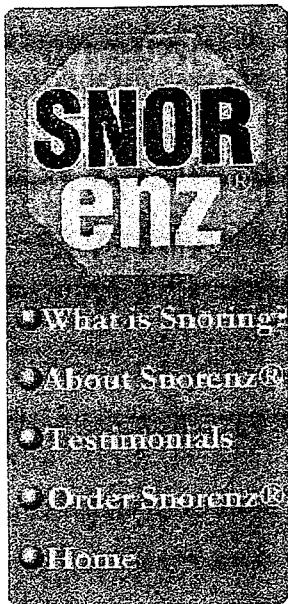
C E R T I F I C A T E O F P R O O F R E A D E R

- [12]
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- [18] I HEREBY CERTIFY that I proofread the
- [19] transcript for accuracy in spelling, hyphenation,
- [20] punctuation and format.

DIANE QUADE

Lawyer's Notes

Reduce Snoring
Noise with...



Click Here



"Before I found
SNORENZ®, I tried
everything... tapes,
tablets, nose spray."

"Nothing worked
like SNORENZ®
works."

SNORENZ® Testimonials



Dear Med Gen:

My husband has had the good fortune to make his snoring cease. He had apnea and has snored heavily for years. We noticed little or no improvement in his snoring even after the operation. I ordered SNORENZ® from a TV advertisement. He tried it and snores lightly now - no rattling the house, and he dreams now which is an indication of REM sleep. I suppose he feels rested - and we feel rested too. After 44 years of heavy snoring, it is a real pleasure to find a product that works. An additional fortune is that it is natural.
Ahhh....Thanks SNORENZ®!

Beth Anderson
Perry, Florida

Gentlemen:

I would like to inform you that I have used your SNORENZ® product and found it to be the only product I have ever tried that has had any effect on my snoring. My girlfriend particularly wants to thank you for coming up with great solutions to this problem. We look forward to enjoying many nights of good sleep thanks to SNORENZ®.

Roy Saffin
Boca Raton, Florida

Dear Sir:

Thanks for my sample of SNORENZ®. My wife has been complaining about my snoring for years and she's had me try everything under the sun. SNORENZ® is the first thing that has actually worked. When I first tried SNORENZ®, I was skeptical, but apparently it is effective because my wife says that she can finally sleep through the night. She says that my snore was equivalent to a Harley Davidson at full throttle. When I first tried SNORENZ®, she told me that the sound was reduced to the light hum of a moped and now she can't hear anything. I guess she should be writing this letter. Thanks SNORENZ®.





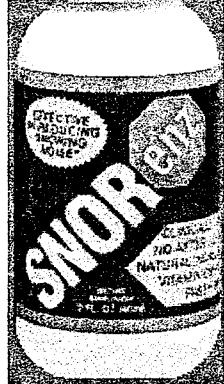
"SNORENZ® really works and it's so easy to use. I wake up feeling refreshed. And it even tastes great, so I don't wake up with morning breath."

- Greenbush, New York

"I had considered having laser surgery, but too many people told me it was extremely painful and not always effective. Then I tried SNORENZ®. It worked the very first night. I've used it ever since"

- Tampa, Florida

"Thank you for your wonderful snoring product. I have



William Kretschmar
West Palm Beach, Florida

Dear SNORENZ®:

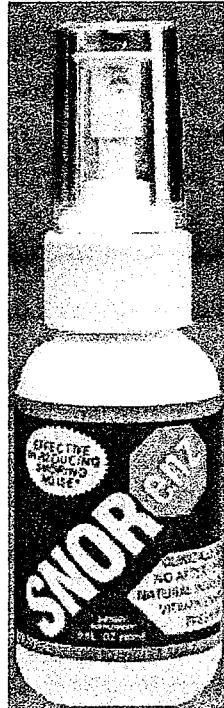
After many sleepless nights and many gimmicks we have found our snoring remedy in you. My husband Jim has snored heavily for years and surgery is just too expensive. We've tried all kinds of pills and nothing has worked until we found SNORENZ®. Now I can finally get some peace and quiet. Thanks.

Marilyn Covey
Phoenix, Arizona

Med Gen:

My girlfriend has been complaining about my snoring for years and SNORENZ® has put a silence to her whining. She is always sleeping on the couch due to my unbearable snoring and I've tried pills but they haven't worked. SNORENZ® is the best thing I've found to quiet my noise...and who would believe it's actually good for me too. Thanks again.

Jim Johnson
Phoenix, Arizona



Click Here

[What is Snoring?](#) | [About SNORENZ®](#) | [Testimonials](#)
[Order SNORENZ®](#) | [Home](#)

Top of Page



*never used anything
that worked like
this. I have even
given some to
friends who agree it
is the first time in a
long time that they
got a good night's
sleep. Thanks
again for a great
product."*

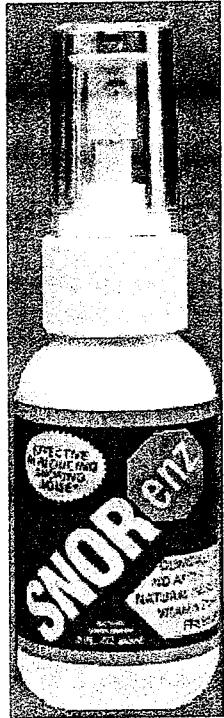
-John Touhsant

Allergy Sufferers Click
Here!

Need Pain Relief?
Click Here!

Recommend this Site to
a Friend!

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Press Releases

Med Gen Inc. Announces SNORENZ Wins ``Best New Product" Award; Presented at Superdrug Health and Beauty Awards 1999

Wednesday, September 8, 1999 11:23 AM

FORT LAUDERDALE, Fla.--(BUSINESS WIRE)--Sept. 8, 1999--Med Gen Inc. (OTC BB:MGNI) is pleased to announce that through its United Kingdom distributor, Passion For Life, SNORENZ(R) is the winner of the Superdrug 1999 Best New Product Award. Superdrug is the second-largest chain of pharmacies in the United Kingdom, with over 750 stores all across the country. After being on the shelves for only four months, sales of SNORENZ(R) in their stores are averaging (pound)10,000 per week (approx. \$16,000) at retail value. SNORENZ(R) has quickly become the number one selling anti-snoring product.

Passion For Life is moving its distribution of SNORENZ(R) into other European countries, as well. The product is now distributed in Ireland, Holland, Spain, Portugal, Belgium, Greece, Norway, Cypress and Iceland. Agreements are pending completion for distribution in Italy, France, Germany, Sweden and Eastern Europe.

Med Gen Inc. manufactures and distributes SNORENZ(R), an all natural throat spray that reduces or eliminates the sounds caused by snoring. Laboratory tests have proven the spray to be effective in reducing snoring noise. For more information, visit our web site at www.snorenz.com or e-mail us at: info@snorenz.com.

Statements herein that are not descriptions of historical facts are forward-looking and are made pursuant to the safe harbor provisions of the Private Securities Reform Act of 1995. Forward-looking statements involve known and unknown risks and uncertainties, which may cause the Company's actual results in the future periods to differ materially from forecasted results. These risks and uncertainties include, among other things, product price volatility, product demand, market competition, risk inherent in the Company's operations, and imprecision in estimating product inventories.

CONTACT: Med Gen Inc., Davie, Fla.
Glen Smith
Phone: 954-423-2525
Fax: 954-423-9612
e-mail: glen.s@snorenz.com

Quote for referenced ticker symbols: MGNI

© 1999, Business Wire

Med Gen Inc. Announces New Management Positions

Thursday, July 29, 1999 08:28 AM

FORT LAUDERDALE, Fla.--(BUSINESS WIRE)--July 29, 1999--Med Gen Inc. (OTC BB:MGNI) has appointed three employees to new management positions.

At the Annual Board Meeting on June 23, 1999, the following management changes were officially adopted. Craig Schreiber, the Company's Controller, has been promoted to the position of Chief Financial Officer. "We were fortunate to bring Craig in from another public company last August. His expertise in accounting, cost containment and day to day operations has been instrumental in



President.

Nancy Wolfe, formally Executive Assistant to the CEO, has been promoted to Director of Account Services. "Nancy not only has excellent organizational skills, but is a real 'people person' and communicates well with our distributors as well as our retail clients," said Paul B. Kravitz, Chairman and Chief Executive Officer. Mrs. Wolfe is also responsible for inventory control, scheduling product manufacturing and shipments, and serves as Assistant Operations Manager.

Glen E. Smith, Jr., Vice President of Investor Relations, has been filling in as Interim Corporate Secretary since January of this year, and now officially assumes that position. "Glen comes to us with over 17 years of experience in the investment arena, and also has a background in marketing, finance, taxes and investment banking. His familiarity with securities markets, regulations and SEC compliance, along with excellent communication skills, make him a natural for these positions," said Mr. Kravitz.

At the Annual Shareholder's Meeting on June 23, 1999, Chairman & CEO Paul B. Kravitz and President & COO Paul S. Mitchell, were unanimously re-elected to their respective positions. Shareholders also ratified the appointment of Richard Harris & Associates, Certified Public Accountants, as independent auditors for the Company. An increase in the number of authorized shares of Common Stock, \$.001 par value, from five million to twenty million shares was also unanimously approved.

"These modest changes will help propel Med Gen to the next level," said President Paul Mitchell. "We anticipate the introduction of several new products in the near future, and are considering a couple of very synergistic acquisitions. Sales of our lead product SNORENZ(R) will give us the revenue and earnings base needed for substantial and dramatic future growth."

Med Gen manufactures and distributes SNORENZ(R), an all natural throat spray that is laboratory tested and proven to reduce or eliminates the sounds caused by snoring. For more information, visit our web site at www.snorenz.com or e-mail us at: info@snorenz.com.

Statements herein that are not descriptions of historical facts are forward-looking and are made pursuant to the safe harbor provisions of the Private Securities Reform Act of 1995. Forward-looking statements involve known and unknown risks and uncertainties, which may cause the Company's actual results in the future periods to differ materially from forecasted results. These risks and uncertainties include, among other things, product price volatility, product demand, market competition, risk inherent in the Company's operations, and imprecision in estimating product inventories.

CONTACT: Med Gen Inc., Fort Lauderdale
Glen Smith, 954/423-2525
Fax: 954/423-9612
e-mail: glen.s@snorenz.com

Quote for referenced ticker symbols: MGNI

© 1999, Business Wire



Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act;
and

The respondents, their attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to section 2.34 of its Rules, and having determined to modify the Decision and Order in certain respects, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following Order:

Decision and Order

1.a Respondent Med Gen, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its office and principal place of business at 7284 West Palmetto Road, Suite 106, Boca Raton, Florida 33433.

1.b Respondent Paul B. Kravitz is an officer of said corporation. He formulates and controls the policies, acts and practices of said corporation, and his principal office and place of business is located at the above stated address.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

2. "Clearly and prominently" shall mean as follows:

A. In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet and online services), the disclosure shall be presented simultaneously in both the audio and video portions of the advertisement. Provided, however, that in any advertisement presented solely through video or audio means, the disclosure may be made through the same means in which the ad is presented. The audio

Decision and Order

disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The video disclosure shall be of a size and shade, and shall appear on the screen for a duration sufficient for an ordinary consumer to read and comprehend it. In addition to the foregoing, in interactive media, the disclosure shall also be unavoidable and shall be presented prior to the consumer incurring any financial obligation.

- B. In a print advertisement, promotional material, or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears. In multipage documents, the disclosure shall appear on the cover or first page.
- C. On a product label, the disclosure shall be in a type size and location on the principal display panel sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.

The disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or on any label.

- 3. Unless otherwise specified, "respondents" shall mean Med Gen, Inc. and its successors and assigns and its officers; Paul B. Kravitz, individually and as an officer of the corporation; and each of the above's agents, representatives, and employees.
- 4. "Drug" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.

Decision and Order

5. "Food" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.

6. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of SNORenz or any other food, drug, or dietary supplement, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication that:

- A. Such product reduces or eliminates snoring or the sound of snoring in users of the product;
- B. A single application of such product reduces or eliminates snoring or the sound of snoring for any specified period of time; or
- C. Such product can eliminate, reduce or mitigate the symptoms of sleep apnea including daytime tiredness and frequent interruptions of deep restorative sleep

unless at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product

Decision and Order

that has not been shown by competent and reliable scientific evidence to be effective in the treatment of sleep apnea, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that the product is effective in reducing or eliminating snoring or the sounds of snoring, unless they disclose, clearly and prominently, and in close proximity to the representation, that such product is not intended to treat sleep apnea, that the symptoms of sleep apnea include loud snoring, frequent episodes of totally obstructed breathing during sleep, and excessive daytime sleepiness, that sleep apnea is a potentially life-threatening condition, and that persons who have symptoms of sleep apnea should consult their physician or a specialist in sleep medicine. Provided, however, that for any television commercial or other video advertisement fifteen (15) minutes in length or longer or intended to fill a broadcasting or cablecasting time slot fifteen (15) minutes in length or longer, the disclosure shall be made within the first thirty (30) seconds of the advertisement and immediately before each presentation of ordering instructions for the product. Provided further, that, for the purposes of this provision, the presentation of a telephone number, e-mail address, or mailing address for listeners to contact for further information or to place an order for the product shall be deemed a presentation of ordering instructions so as to require the announcement of the disclosure provided herein.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of SNORenz or any other product, service, or program in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the benefits, performance, efficacy, or safety of any such product, service, or program, unless, at the time the representation is made, respondents possess and rely upon competent and reliable evidence, which, when appropriate, must

Decision and Order

be competent and reliable scientific evidence, that substantiates the representation.

IV.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, service, or program in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

V.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, service, or program in or affecting commerce, shall not represent, in any manner, expressly or by implication, that the experience represented by any user testimonial or endorsement of the product, service, or program represents the typical or ordinary experience of members of the public who use the product, service or program unless:

- A. At the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation; or
- B. Respondents disclose, clearly and prominently, and in close proximity to the endorsement or testimonial, either:
 1. what the generally expected results would be for users of the product, or

Decision and Order

2. the limited applicability of the endorser's experience to what consumers may generally expect to achieve, that is, that consumers should not expect to experience similar results.

For purposes of this Part, "endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).

VI.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, service, or program in or affecting commerce, shall disclose, clearly and prominently, and in close proximity to the endorsement, a material connection, where one exists, between a person or entity providing an endorsement of any product, service, or program, as "endorsement" is defined 16 C.F.R. 255.0 (b) and any respondent, or any other individual or entity manufacturing, labeling, advertising, promoting, offering for sale, selling, or distributing such product, service or program. For purposes of this order, "material connection" shall mean any relationship that might materially affect the weight or credibility of the endorsement and would not be reasonably expected by endorsers.

VII.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

VIII.

Nothing in this order shall prohibit respondents from making any representation for any product that is specifically permitted in

Decision and Order

labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

IX.

IT IS FURTHER ORDERED that, no later than the date this order becomes final, respondents shall pay to the Federal Trade Commission the sum of thirty thousand dollars (\$30,000), under the following terms and conditions:

- A. The payment shall be made by wire transfer to the Federal Trade Commission. In the event of any default in payment, which default continues for ten (10) days beyond the due date of payment, the amount due, together with interest as computed pursuant to 28 U.S.C. § 1961 from the date of default to the date of payment, shall immediately become due and payable.
- B. The funds paid by respondents, together with any accrued interest, shall, in the discretion of the Commission, be used by the Commission to provide direct redress to purchasers of SNORenz and to pay any attendant costs of administration. If the Commission determines, in its sole discretion, that redress to purchasers of this product is wholly or partially impracticable or is otherwise unwarranted, any funds not so used shall be paid to the United States Treasury. Respondents shall be notified as to how the funds are distributed, but shall have no right to contest the manner of distribution chosen by the Commission. No portion of the payment herein provided shall be deemed a payment of any fine, penalty or punitive assessment.
- C. Respondents relinquish all dominion, control and title to the funds paid, and all legal and equitable title to the funds vests in the Treasurer of the United States and in the designated consumers. Respondents shall make no claim to or demand

Decision and Order

for return of the funds, directly or indirectly, through counsel or otherwise; and in the event of bankruptcy of respondents, respondents acknowledge that the funds are not part of the debtor's estate, nor does the estate have any claim or interest therein.

X.

IT IS FURTHER ORDERED that respondent Med Gen, Inc., its successors and assigns, and respondent Paul B. Kravitz shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

XI.

IT IS FURTHER ORDERED that respondent Med Gen, Inc., its successors and assigns, and respondent Paul B. Kravitz shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver

Decision and Order

this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

XII.

IT IS FURTHER ORDERED that respondent Med Gen, Inc. and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

XIII.

IT IS FURTHER ORDERED that respondent Paul B. Kravitz, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

Decision and Order

XIV.

IT IS FURTHER ORDERED that respondent Med Gen, Inc. and its successors and assigns, and respondent Paul B. Kravitz shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XV.

This order will terminate on July 12, 2022, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from Med Gen, Inc. and its president, Paul Kravitz ("proposed respondents"). Proposed respondents market "Snorenz," a dietary supplement consisting of oils and vitamins that is sprayed on the back of the throat of persons who snore.

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

The Commission's complaint charges that proposed respondents failed to have a reasonable basis for claims they made about the product's efficacy in (1) reducing or eliminating snoring or the sounds of snoring, (2) reducing or eliminating snoring or the sounds of snoring for six to eight hours, and (3) treating the symptoms of sleep apnea. The complaint also alleges that proposed respondents lacked a reasonable basis to substantiate representations that testimonials from consumers who used Snorenz represented the typical and ordinary experience of users of the product. Proposed respondents are also charged with making false claims that clinical proof establishes the efficacy of Snorenz. Further, the complaint alleges that the proposed respondents failed to disclose adequately that the product is not intended to treat sleep apnea; that sleep apnea is a potentially life-threatening disorder characterized by loud snoring, frequent interruptions of sleep, and daytime tiredness; and that persons experiencing those symptoms should seek medical attention. Finally, the complaint alleges that proposed respondents failed to disclose that a material connection existed between Med Gen, Inc. and a physician who appeared in the infomercials to endorse

Analysis

Snorenz. Such claims appeared in infomercials promoting Snorenz that proposed respondents produced, or caused to be produced for them,¹ on Med Gen, Inc.'s website, and/or on labeling for the product.

Part I of the consent order requires that proposed respondents possess competent and reliable scientific evidence to substantiate representations that Snorenz or any other food, drug, or dietary supplement reduces or eliminates snoring or the sounds of snoring; reduces or eliminates snoring or the sounds of snoring for any specified period of time through a single application; or eliminates, reduces or mitigates the symptoms of sleep apnea. Part II of the order requires that, for any product that has not been shown to be effective in the treatment of sleep apnea, proposed respondents must affirmatively disclose, whenever they represent that a product is effective in reducing or eliminating snoring or the sounds of snoring, a warning statement about sleep apnea and the need for physician consultation. Part III of the order requires proposed respondents to substantiate any representation about the benefits, performance, efficacy, or safety of Snorenz or any other any other food, drug, or dietary supplement. Part IV prohibits false claims about scientific support for any product, service, or program. Part V requires that, for any consumer endorsement or testimonial proposed respondents use to promote a product, service or program, they must either possess competent and reliable scientific evidence that the testimonial represents the typical or ordinary experience of users or make an affirmative disclosure that the testimonial is not typical. Part VI requires an affirmative disclosure of any material connection between proposed respondents and any endorser of their products. Parts VII and VIII of the proposed order permit proposed respondents to make certain claims for drugs or dietary supplements,

¹ A separate consent settlement with a producer of several infomercials for Snorenz, Tru-Vantage International, L.L.C. (File No. 002-3210), is also being placed on the public record for comment.

Analysis

respectively, that are permitted in labeling under laws and/or regulations administered by the U.S. Food and Drug Administration.

The remainder of the proposed order contains standard requirements that proposed respondents maintain advertising and any materials relied upon as substantiation for any representation covered by substantiation requirements under the order; distribute copies of the order to certain company officials and employees; notify the Commission of any change in the corporation that may affect compliance obligations under the order; and file one or more reports detailing their compliance with the order. Part XIV of the proposed order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

This proposed order, if issued in final form, will resolve the claims alleged in the complaint against the named respondents. It is not the Commission's intent that acceptance of this consent agreement and issuance of a final decision and order will release any claims against any unnamed persons or entities associated with the conduct described in the complaint.

The purpose of this analysis is to facilitate public comment on the proposed order, and is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

**PHYSICIAN INTEGRATED SERVICES
OF DENVER, INC., ET AL.**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4054; File No. 0110173
Complaint, July 16, 2002--Decision, July 16, 2002*

This consent order addresses practices used by Respondent Physician Integrated Services of Denver, Inc. ("PISD") – which has 41 primary care physicians who practice in the southern part of the Denver, Colorado metropolitan area – and Respondents Michael J. Guese, M.D., and Marcia A. Brauchler, respectively the president of and an advisor to PISD. The order, among other things, prohibits the respondents from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, not to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or not to deal with any payor through an arrangement other than PISD. The order also prohibits the respondents from facilitating exchanges of information between physicians concerning whether, or on what terms, to contract with a payor. In addition, the order prohibits the respondents from attempting to engage in – or from inducing anyone to engage in – any action prohibited by the order. In addition, the order prohibits Respondent Brauchler, for a period of three years, from negotiating with any payor on behalf of any current or past member of PISD, and from advising any current or past member of PISD to accept or reject any term, condition, or requirement of dealing with any payor. The order also requires Respondent PISD to terminate – without penalty at any payor's request – current contracts with payors with respect to providing physician services.

Participants

For the Commission: *Paul J. Nolan, Steven J. Osnowitz, Constance Salemi, Robert Canterman, Christi Braun, Jessica Rosen, David R. Pender, Jeffrey W. Brennan, Rendell A. Davis, Jr., Daniel P. Ducore, Fred Martin, Louis Silvia, and Thomas Iosso.*

For the Respondents: *Larry Treece, Sherman and Howard.*

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COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Physician Integrated Services of Denver, Inc. (“Respondent PISD”), Michael J. Guese, M.D. (“Respondent Guese”), and Marcia L. Brauchler (“Respondent Brauchler”) have violated and are violating Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint, stating its charges in that respect as follows:

RESPONDENTS

PARAGRAPH 1: Respondent PISD is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 850 E. Harvard Street, Suite 455, Denver, CO 80210.

PARAGRAPH 2: Respondent Guese is a physician licensed under the laws of the State of Colorado, with his office and principal place of business located at 850 E. Harvard Street, Suite 455, Denver, CO 80210. Respondent Guese is the President and the sole director of Respondent PISD. Respondent Guese is also the principal negotiator for Respondent PISD.

PARAGRAPH 3: Respondent Brauchler is a consultant to Respondent PISD. The address of her office and principal place of business is at P.O. Box 260661, Littleton, CO 80163-0171.

JURISDICTION

PARAGRAPH 4: At all times relevant to this Complaint, all members of Respondent PISD were primary care physicians engaged in the business of providing health care services for a fee

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to patients. Except to the extent that competition has been restrained as alleged herein, members of Respondent PISD have been, and are now, in competition with each other for the provision of physician services.

PARAGRAPH 5: Respondents' general business practices, including the acts and practices alleged herein, are in or affecting "commerce" as defined in the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

PARAGRAPH 6: Respondent PISD has been organized in substantial part, and is engaged in substantial activities, for the pecuniary benefit of Respondent PISD's members and is therefore a "corporation" within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

OVERVIEW OF MARKET AND PHYSICIAN COMPETITION

PARAGRAPH 7: Respondent PISD has approximately 41 members, all of whom are primary care physicians, licensed to practice medicine in the State of Colorado, and engaged in the business of providing primary care physician services to patients. The membership of Respondent PISD consists of internists, pediatricians, family physicians, and general practitioners with offices in the southern part of the Denver metropolitan area ("South Denver area").

PARAGRAPH 8: Physicians often contract with health insurance firms and other third-party payors (hereinafter "payors"), such as preferred provider organizations. Such contracts typically establish the terms and conditions, including fees and other competitively significant terms, under which the physicians will render services to the payors' subscribers. Physicians entering into such contracts often agree to lower compensation, in order to obtain access to additional patients made available by the payors' relationship with insureds. These contracts may reduce payors' costs and enable payors to lower the

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price of insurance, and thereby result in lower medical care costs for subscribers to the payors' health insurance plans.

PARAGRAPH 9: Absent agreements among competing physicians on the terms, including price, on which they will provide services to subscribers or enrollees in health care plans offered or provided by third-party payors, competing physicians decide individually whether to enter into contracts with third-party payors to provide services to their subscribers or enrollees, and what prices they will accept pursuant to such contracts.

PARAGRAPH 10: Medicare's Resource Based Relative Value System ("RBRVS") is a system used by the Centers for Medicare and Medicaid Services to determine the amount to pay physicians for the services they render to Medicare patients. The RBRVS approach provides a method to determine fees for specific services. It is the practice of payors in the South Denver area to make contract offers to individual physicians at a fee level specified in the RBRVS for a particular year, plus a markup based on some percentage of that fee (*e.g.*, "110 percent of 2001 RBRVS").

PARAGRAPH 11: In order to be competitively marketable in the South Denver area, a payor's health insurance plan must include in its physician network a large number of primary care physicians who practice in the South Denver area. Many of the primary care physicians who practice in the South Denver area are members of Respondent PISD.

PARAGRAPH 12: Competing physicians sometimes use a "messenger" to facilitate the establishment of contracts between themselves and payors in ways that do not constitute or facilitate an unlawful agreement on fees and other competitively significant terms. Such a messenger may not, however, consistent with a competitive model, negotiate fees and other competitively significant terms on behalf of the participating physicians, or facilitate the physicians' coordinated responses to contract offers by, for example, electing not to convey a payor's offer to them

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based on the messenger's opinion on the appropriateness, or lack thereof, of the offer.

RESTRAINT OF TRADE

PARAGRAPH 13: Respondents PISD and Guese, acting as a combination of competing physicians, and Respondent Brauchler, in conspiracy with Respondent PISD and at least some of Respondent PISD's members, respectively, have acted to restrain competition by, among other things:

- A. facilitating, negotiating, entering into, and implementing agreements among Respondent PISD's members on fees and other competitively significant terms;
- B. refusing to deal with payors except on collectively agreed-upon terms; and
- C. negotiating uniform fees and other competitively significant terms in payor contracts for Respondent PISD's members, and refusing to submit payor offers to members that do not conform to Respondent PISD's standards for contracts.

FORMATION AND OPERATION OF RESPONDENT PISD

PARAGRAPH 14: Respondent Guese and others formed Respondent PISD in November 1999 to be a vehicle for physicians' collective contract negotiations with payors, in order to achieve contracts that contain higher fees and other, more advantageous terms than individual members could obtain by negotiating unilaterally with payors. Respondents sought to replace individual physician-payor contracts with a single PISD-payor contract that contained such higher fees and other terms for all members of Respondent PISD.

PARAGRAPH 15: In or about December 1999, Respondent PISD, at Respondent Guese's direction, retained Respondent Brauchler to help coordinate and manage Respondent PISD's

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payor contracting activities and to assist in renegotiating payor contracts previously entered into by members of Respondent PISD on a unilateral, rather than collective, basis. Thereafter, on behalf of Respondent PISD's collective membership, Respondent Guese and Respondent Brauchler negotiated with payors for higher fees and other, more economically advantageous contract terms.

PARAGRAPH 16: To join Respondent PISD, physicians sign an agreement that authorizes Respondent PISD to negotiate, on their behalf, fees and other contract terms with payors. Members authorize Respondent PISD to negotiate "non-risk" contracts, which are accepted only if first approved by a majority of Respondent PISD's members. Non-risk contracts do not involve sharing between physicians and payors of financial risk through arrangements such as capitation or fee withholds. Upon such approval, Respondent PISD executes a contract with a payor.

PARAGRAPH 17: Respondents have a practice – inconsistent with a messenger model arrangement – of refusing to convey to Respondent PISD's members the terms of payor offers that Respondents deem deficient. Respondents instead demand, and receive, from payors more favorable contract terms – terms that payors would not have offered to Respondent PISD's members had those members negotiated on a unilateral, rather than collective, basis. Only after payors accede to Respondents' demand for higher fees and other favorable terms do Respondents convey the contract in question to Respondent PISD's members for approval.

PARAGRAPH 18: Respondent PISD's members authorized Respondents Guese and Brauchler to act as their exclusive bargaining agents. Respondent Brauchler reported to Respondent PISD's members on the details of her negotiations with payors, including on the status of fee negotiations and the specific fee levels that were discussed. Respondents Guese and Brauchler also held general PISD membership meetings to discuss details of payor contract negotiations and overall contract strategy.

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PARAGRAPH 19: In negotiations with payors, Respondents Guese and Brauchler used a “contract-or-no-contract” strategy, through which the payor could either contract on PISD’s terms and likely have all of the members of PISD in the provider network, or not contract on PISD’s terms and have few or none of the PISD members in the network. Respondents Guese and Brauchler would either recommend that PISD members approve a negotiated contract, or, if respondents were unable to negotiate acceptable terms, refuse to convey the payor’s offer to members.

PARAGRAPH 20: Respondents Guese and Brauchler told payors that Respondent PISD’s members would deal with them only if the payor agreed to PISD’s collectively determined terms. This assertion was demonstrated when payors attempted unsuccessfully to deal individually with members of Respondent PISD – only to be told by the members that they would contract for services only through Respondent PISD. Respondents’ strategy of collective negotiations and concerted refusals to deal outside PISD left payors in the untenable position of having to pay higher fees to all members of Respondent PISD, or being denied such members’ inclusion in their respective health insurance plan’s provider networks – an outcome that would have substantially impaired payors’ ability to compete effectively.

NEGOTIATIONS WITH PACIFICARE

PARAGRAPH 21: PacifiCare Health Systems of Colorado, Inc. (“PacifiCare”) is a payor doing business in the South Denver area. In December 1999, Respondent Guese and other members of Respondent PISD signed and had delivered to PacifiCare letters demanding that the payor recognize Respondent PISD as its members’ negotiating agent for both the commercial and Medicare lines. In meetings with PacifiCare, Respondents Brauchler and Guese specified minimum fees, annual increases in such fees, and an “administrative” fee that PacifiCare had to pay in order to contract with Respondent PISD as an entity and thereby enlist Respondent PISD’s members into PacifiCare’s

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network of health plan physicians. Respondents Brauchler and Guese asserted that Respondent PISD's members would not accept, as part of any agreement, financial risk-sharing, including capitation or fee withholdings. They also emphasized to PacifiCare that Respondent PISD's members were negotiating collectively through Brauchler and Guese, and that PacifiCare had no choice but to adopt the terms that Respondent PISD was demanding in order to have individual members of Respondent PISD under contract.

PARAGRAPH 22: PacifiCare approached Respondent PISD's members individually with independent contract proposals, but the members refused to negotiate unilaterally. Respondent PISD's members told PacifiCare that it could deal with them only on a collective basis through Respondent PISD, and in particular through Respondent PISD's negotiators, Respondents Brauchler and Guese. Respondents' employment of such tactics exerted the members' collective power to obtain higher fees in a group contract than each physician might have obtained acting individually.

PARAGRAPH 23: Concerned that it otherwise would have an unmarketable health insurance plan because of a limited primary care physician network in the South Denver area, PacifiCare entered a fee-for-service contract with Respondent PISD at the higher contract rate that the members, through Respondent PISD, collectively demanded. PacifiCare also agreed to Respondent PISD's demand for annual fee increases tied to the inflation rate, the potential for bonus incentives, administrative fees to Respondent PISD, and other miscellaneous fees, all of which were concessions that PacifiCare made in response to Respondent PISD's coercive tactics. Only after Respondent PISD's collectively determined terms were met did Respondent PISD accept the PacifiCare contract and mail it to members of Respondent PISD for their acceptance.

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NEGOTIATIONS WITH AETNA

PARAGRAPH 24: Aetna U.S. Healthcare (“Aetna”) is a payor doing business in the South Denver area. In April 2000, Aetna offered individual contracts to physicians who were members of Respondent PISD. Respondent Brauchler, upon learning that Aetna was contacting Respondent PISD’s members on an individual rather than collective basis, asked each member to write a letter to Aetna, notifying it that said physician would deal only through Respondent PISD and that Aetna should direct all further contacts to Respondent Guese. Most of the members of Respondent PISD, acting on Respondent Brauchler’s request, sent the requested letter to Aetna.

PARAGRAPH 25: Aetna refused to sign a single contract with Respondent PISD that covered all its members, but negotiated with Respondent PISD in its role as the members’ exclusive bargaining agent. To obtain contracts with PISD members, Aetna agreed to offer them a contract at the higher RBRVS level that Respondent PISD had demanded; and most if not all of PISD’s members thereafter signed contracts.

NEGOTIATIONS WITH ANTHEM

PARAGRAPH 26: Anthem Blue Cross and Blue Shield of Colorado (“Anthem”) is a payor doing business in the South Denver area. In mid-2000, Respondent Brauchler contacted Anthem to initiate negotiations on behalf of Respondent PISD’s members. At that time, all members of Respondent PISD held individual contracts with Anthem at competitive market rates. Anthem at first refused to negotiate with Respondent Brauchler because it already had contracts with Respondent PISD’s individual member physicians. Respondents, however, attempted to force Anthem into dealing with Respondent PISD for new contracts for its members.

PARAGRAPH 27: Respondents Brauchler and Guese subsequently met with Anthem representatives and told them that,

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in order to reach an agreement with Respondent PISD, Anthem had to offer fees equal to a specified percentage of RBRVS. These fees were not only well above the fees that Anthem was currently paying the individual physicians, but also well above the fees contained in Respondent PISD's contract with PacifiCare. Respondents Guese and Brauchler emphasized to Anthem that they were negotiating fees for the collective benefit of the members of Respondent PISD, that the PISD contract with PacifiCare had established new "minimum" fees, and that Respondent PISD's members would not enter contracts for fees lower than the aforementioned percentage of RBRVS.

PARAGRAPH 28: On or about April 27, 2001, Anthem submitted a fee offer to Respondents that was higher than the fees contained in Anthem's contracts with individual members of Respondent PISD, but lower than the fee levels demanded by Respondents Guese and Brauchler. Anthem's offer equaled the highest fees that it was paying to any physicians in the Denver area. Respondents refused to convey Anthem's offer to Respondent PISD's members, however, because it did not meet the fee levels that Respondents Guese and Brauchler demanded.

PARAGRAPH 29: Respondents Guese and Brauchler urged Respondent PISD's members to send contract termination notices to Anthem, and to advise Anthem that it could deal with them in the future only through Respondent PISD. At least 36 of the approximately 41 members of Respondent PISD terminated their individual contracts with Anthem in this fashion. Some of those terminating members had signed their Anthem contracts only a few months earlier.

PARAGRAPH 30: Anthem attempted to bypass Respondents by sending its contract proposal directly to individual members of Respondent PISD, but this approach failed. The members again told Anthem that they would deal only through Respondent PISD, and that Anthem must negotiate for their services exclusively with Respondents Guese and Brauchler.

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PARAGRAPH 31: In the summer of 2001, Anthem continued to attempt to reach a compromise on fees with Respondents Brauchler and Guese, but was unsuccessful. Respondents rejected Anthem's offer and negotiations ended. Most members of Respondent PISD continue to refuse to enter into individual contracts with Anthem.

NEGOTIATIONS WITH OTHER PAYORS

PARAGRAPH 32: Since the inception of Respondent PISD in 1999, Respondents Guese and Brauchler have informed other payors that Respondent PISD represented the collective interest of its members, and that Respondent PISD would negotiate and sign contracts on behalf of all its members. Respondents also informed these payors of the specific fees that Respondents demanded as a condition for signing a contract, emphasizing that Respondent PISD would likely refuse any fee lower than a specified percentage of Medicare RBRVS. To exert pressure on and coerce these payors into paying higher fees, Respondent PISD's members sent termination letters to such payors, informing the payors that they would not negotiate individually, and told the payors to deal for members' services only through Respondent PISD. Respondent PISD's coercive tactics have been successful. It has obtained contracts with at least two other payors for fees matching or exceeding Respondent PISD's desired percentage of RBRVS.

LACK OF SIGNIFICANT EFFICIENCIES

PARAGRAPH 33: In collectively negotiating and entering the contracts identified above, Respondent PISD and its members refused to consider any form of financial risk-sharing and have not integrated their practices to create sufficient potential efficiencies. Respondents' joint negotiation of fees and other competitively significant terms has not been, and is not, reasonably related to any efficiency-enhancing integration.

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ANTICOMPETITIVE EFFECTS

PARAGRAPH 34: Respondents' actions described above in Paragraphs 13 through 33 have had, or have the tendency to have, the effect of restraining trade unreasonably and hindering competition in the provision of physician services in the South Denver area in the following ways, among others:

- A. fees and other forms of competition among Respondent PISD's members were unreasonably restrained;
- B. fees for physician services were increased; and
- C. competition in the purchase of physician services was restrained to the detriment of health plans, employers, and individual consumers.

PARAGRAPH 35: The combination, conspiracy, acts and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Such combination, conspiracy, acts and practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this Sixteenth day of July, 2002, issues its Complaint against Respondents PISD, Guese, and Brauchler.

By the Commission.

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DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of respondents named in the caption hereof (“Respondents”), and Respondents having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued, would charge Respondents with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the Respondents have violated the said Act, and that a Complaint should issue stating its charges in that respect, and having thereupon accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to § 2.34 of the Commission Rules, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Order:

1. Respondent Physician Integrated Services of Denver, Inc. (“PISD”) is a professional corporation organized, existing, and

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doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 850 E. Harvard Street, Suite 455, Denver, CO 80210.

2. Respondent Marcia L. Brauchler is a consultant to PISD. Her office and principal place of business is located at P.O. Box 260661, Littleton, CO 80163-0171.
3. Respondent Michael J. Guese, M.D., is a physician licensed under the laws of the State of Colorado, with his office and principal place of business located at 850 E. Harvard Street, Suite 455, Denver, CO 80210.
4. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent PISD” means Physician Integrated Services of Denver, Inc., its officers, directors, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by Physician Integrated Services of Denver, Inc., and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- B. “Respondent Brauchler” means Marcia L. Brauchler.
- C. “Respondent Guese” means Michael J. Guese, M.D.
- D. “Respondents” means Respondent PISD, Respondent Brauchler, and Respondent Guese.

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- E. “Medical group practice” means a bona fide, integrated firm in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.
- F. “Participate” in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services, to a payor through such entity. (This definition also applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”)
- G. “Payor” means any person that pays, or arranges for payment, for all or any part of any physician services for itself or for any other person.
- H. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- I. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- J. “Preexisting Contract” means a contract that was in effect prior to the receipt, by all payors that are parties to such contract, of notice sent by Respondent PISD pursuant to Paragraph IV.B. of this Order, of each such payor’s right to terminate such contract.
- K. “Principal Address” means either (1) primary business address, if there is a business address, or (2) primary residential address, if there is no business address.
- L. “Qualified clinically-integrated joint arrangement” means an arrangement to provide physician services in which:

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1. all physicians who participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the physicians who participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and
2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.

M. “Qualified risk-sharing joint arrangement” means an arrangement to provide physician services in which:

1. all physicians who participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the physicians who participate to jointly control costs and improve quality by managing the provision of physician services, such as risk-sharing involving:
 - a. the provision of physician services to payors at a capitated rate,
 - b. the provision of physician services for a predetermined percentage of premium or revenue from payors,
 - c. the use of significant financial incentives (*e.g.*, substantial withhold) for physicians who participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by physicians in different specialties offering a complementary mix of services, for a fixed, predetermined payment, where the costs of that course of

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treatment for any individual patient can vary greatly due to the individual patient's condition, the choice, complexity, or length of treatment, or other factors; and

2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.

II.

IT IS FURTHER ORDERED that Respondents, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any physicians:
 1. To negotiate on behalf of any physician with any payor,
 2. To deal, refuse to deal, or threaten to refuse to deal with any payor,
 3. Regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, including, but not limited to, price terms, or
 4. Not to deal individually with any payor, or not to deal with any payor through any arrangement other than Respondent PISD;
- B. Exchanging or facilitating in any manner the exchange or transfer of information among physicians concerning any physician's willingness to deal with a payor, or the terms or

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conditions, including price terms, on which the physician is willing to deal;

- C. Attempting to engage in any action prohibited by Paragraph II.A. or II.B., above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A. through II.C. above.

PROVIDED, HOWEVER, that nothing in this Paragraph II. shall prohibit any agreement involving or conduct by:

- (i) Respondent Brauchler that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement, or that solely involves physicians in the same medical group practice;
- (ii) Respondent Guese that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement through which he provides physician services, or that solely involves physicians in Respondent Guese's own medical group practice; or
- (iii) Respondent PISD that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement, so long as the arrangement does not restrict the ability, or facilitate the refusal, of physicians who participate in it to deal with payors on an individual basis or through any other arrangement.

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III.

IT IS FURTHER ORDERED that Respondent Brauchler, for a period of three (3) years from the date that this order is issued, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Negotiating with any payor on behalf of any physician who participates, or has participated, in Respondent PISD, notwithstanding whether such conduct also violates Paragraph II of this Order; and
- B. Advising any physician who participates, or has participated, in Respondent PISD to accept or reject any term, condition, or requirement of dealing with any payor, notwithstanding whether such conduct also violates Paragraph II of this Order.

IV.

IT IS FURTHER ORDERED that Respondent PISD shall:

- A. Within thirty (30) days after the date on which this Order is issued, send by first-class mail a copy of this Order and the Complaint to:
 1. each physician who participates, or has participated, in Respondent PISD, and
 2. each officer, director, manager, and employee of Respondent PISD;
- B. Within thirty (30) days after the date on which this Order is issued, send copies of this Order, the Complaint, and the notice specified in Appendix B to this Order, by first class mail return receipt requested, to the chief executive officer of

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each payor that is listed in Appendix A or that contracts with Respondent PISD for the provision of physician services;

- C. Terminate, without penalty or charge, any Preexisting Contract with any payor for the provision of physician services, upon receipt by Respondent PISD of a written request to terminate such contract from any payor that is a party to the contract or that pays for physician services provided through the contract;
- D. For a period of three (3) years after the date this Order is issued:
 1. Distribute by first-class mail a copy of this Order and the Complaint to:
 - a. each physician who begins participating in Respondent PISD, and who did not previously receive a copy of this Order and the Complaint from Respondent PISD, within thirty (30) days of the time that such participation begins,
 - b. each payor that contracts with Respondent PISD for the provision of physician services, and that did not previously receive a copy of this Order and the Complaint from Respondent PISD, within thirty (30) days of the time that such payor enters into such contract, and
 - c. each person who becomes an officer, director, manager, or employee of Respondent PISD, and who did not previously receive a copy of this Order and the Complaint from Respondent PISD, within thirty (30) days of the time that he or she assumes such responsibility with Respondent PISD; and
 2. Annually publish in an official annual report or newsletter sent to all physicians who participate in Respondent PISD, a

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copy of this Order and the Complaint with such prominence as is given to regularly featured articles;

- E. Notify the Commission at least thirty (30) days prior to any proposed change in Respondent PISD, such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in Respondent PISD that may affect compliance obligations arising out of this Order; and
- F. File verified written reports within sixty (60) days after the date this Order is issued, annually thereafter for three (3) years on the anniversary of the date this Order is issued, and at such other times as the Commission may by written notice require, setting forth:
 1. in detail, the manner and form in which Respondent PISD has complied and is complying with this Order, including, but not limited to, (a) information sufficient to describe, for each qualified risk-sharing arrangement established or operated by Respondent PISD, the manner in which the physicians who participate in such arrangement share financial risk, and (b) information sufficient to describe, for each qualified clinically-integrated joint arrangement established or operated by Respondent PISD, the manner in which the physicians who participate in such arrangement have integrated their practices, and
 2. the name, address, and telephone number of each payor with which Respondent PISD has had any contact.

V.

IT IS FURTHER ORDERED that Respondent Brauchler shall:

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- A. For a period of three (3) years after the date this Order is issued, distribute by first-class mail a copy of this Order and the Complaint to:
 1. all physician groups, other than any medical group practice, that Respondent Brauchler represents for the purpose of contracting, or seeking to contract, with payors for the provision of physician services, or that Respondent Brauchler advises with regard to their dealings with payors in connection with the provision of physician services, within (30) days of the time that Respondent Brauchler begins providing such representation or advice, unless such physician group previously received a copy of this Order and the Complaint from Respondent PISD or Respondent Brauchler, and
 2. each payor with which Respondent Brauchler deals, or has dealt, for the purpose of contracting, or seeking to contract, while representing any physician or any group of physicians, or while advising any physician or group of physicians with regard to their dealings regarding contracting with such payor for the provision of physician services, within thirty (30) days of such dealing, unless such payor previously received a copy of this Order and the Complaint from Respondent PISD or Respondent Brauchler; and
- B. File verified written reports within sixty (60) days after the date this Order is issued, annually thereafter for three (3) years on the anniversary of the date this Order is issued, and at such other times as the Commission may by written notice require, setting forth:
 1. in detail, the manner and form in which Respondent Brauchler has complied and is complying with this Order,
 2. the name, address, and telephone number of each physician or group of physicians that Respondent Brauchler has represented or advised with respect to their dealings with

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any payor in connection with the provision of physician services, and

3. the name, address, and telephone number of each payor with which Respondent Brauchler has dealt while representing any physician or any group of physicians in connection with the provision of physician services.

VI.

IT IS FURTHER ORDERED that Respondent Guese shall file verified written reports within sixty (60) days after the date this Order is issued, annually thereafter for three (3) years on the anniversary of the date this Order is issued, and at such other times as the Commission may by written notice require, setting forth:

- A. in detail, the manner and form in which Respondent Guese has complied and is complying with this Order, including, but not limited to, any information necessary to demonstrate such compliance;
- B. the name, address, and telephone number of each group of physicians, including any medical group practice, in which Respondent Guese has participated;
- C. the name, address, and telephone number of each person, who is not a member or employee of Respondent Guese's medical group practice, that has represented or advised Respondent Guese with respect to contracting with any payor for the provision of physician services;
- D. the name, address, and telephone number of each payor, other than individual patients, that has communicated with Respondent Guese for the purpose of contracting, or seeking to contract, for physician services; and

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- E. the name, address, and telephone number of each payor, other than individual patients, with which Respondent Guese has entered into a written agreement for the provision of physician services, and the nature of such agreement.

VII.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission of any change in its Principal Address within twenty (20) days of such change in address.

VIII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in their possession, or under their control, relating to any matter contained in this Order;
- B. Upon five (5) days' notice to Respondent PISD, and in the presence of counsel, and without restraint or interference from it, to interview officers, directors, or employees of Respondent PISD; and
- C. Upon five (5) days' notice to Respondent Brauchler or to Respondent Guese, and in the presence of counsel, and without restraint or interference from such Respondent, to interview such Respondent or the employees of such Respondent.

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IX.

IT IS FURTHER ORDERED that this Order shall terminate on July 16, 2022.

Appendix A

Aetna US Healthcare of Colorado
Anthem Blue Cross Blue Shield
CIGNA HealthCare of Colorado
Humana Health Plan
Mountain Medical Affiliates, Inc.
OneHealth Plan
PacifiCare of Colorado
Patient Choice Healthcare of Colorado
United Health Care of Colorado

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Appendix B

[letterhead of Physician Integrated Services of Denver, Inc.]

[name of payor's CEO]
[address]

Dear _____:

Enclosed is a copy of a complaint and a consent order issued by the Federal Trade Commission against Physician Integrated Services of Denver, Inc. ("PISD"). I call to your attention Paragraph IV.C. of the order, which gives you the right to terminate, without penalty or charge, any contracts with PISD that were in effect prior to your receipt of this letter.

Sincerely,

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with Physician Integrated Services of Denver, Inc. (“PISD”), Michael J. Guese, M.D., and Marcia A. Brauchler (“Respondents”). The agreement settles charges that Respondents violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by facilitating and implementing agreements among PISD’s members to fix prices and other terms of dealing with health insurance firms and other third-party payors (hereinafter, “payors”), and to refuse to deal with payors except on collectively determined terms. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by any Respondent that said Respondent violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

The Complaint

The allegations in the Commission’s proposed complaint are summarized below.

PISD has approximately 41 primary care physicians in its membership. Dr. Guese is PISD’s president and sole director. Ms. Brauchler is a consultant and advisor to PISD. Except to the extent that competition has been restrained in the manner set forth

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in the proposed complaint, PISD's members compete with each other as internists, pediatricians, family physicians, or general practitioners, in offices located in the southern part of the Denver, Colorado, metropolitan area ("South Denver area"). To be competitively marketable to employers and other purchasers in the South Denver area, a payor's health insurance plan must include in its network of participating physicians a large number of primary care physicians who practice in the South Denver area.

The physicians formed PISD as a vehicle collectively to negotiate contracts with payors, and thereby to achieve contracts containing higher fees and other, more advantageous terms than the individual physicians could obtain unilaterally. PISD members authorized PISD to negotiate for this purpose. They also authorized PISD to negotiate "non-risk" contracts, which are contracts that do not involve sharing among physicians of financial risk, through arrangements such as capitation or fee withholdings. Further, before the entire organization can accept a proposed payor contract, a majority of PISD's members must approve it.

Sometimes a network of competing physicians uses an agent to convey to payors information obtained individually from the physicians about fees or other significant contract terms that they are willing to accept. The agent may also convey to the physicians all payor contract offers, which the physicians then unilaterally decide whether to accept or reject. Such a "messenger model" arrangement, which is described in the 1996 Statements of Antitrust Enforcement Policy in Health Care jointly issued by the Federal Trade Commission and U.S. Department of Justice (*see* <http://www.ftc.gov/reports/hlth3s.htm>), can facilitate and minimize the costs involved in contracting between physicians and payors, without fostering an agreement among competing physicians on fees or fee-related terms.

PISD purported to operate as a messenger, but, in practice, it did not do so. Rather, from 1999 through 2001, Dr. Guese and Ms. Brauchler negotiated fees and other competitively significant

Analysis

terms collectively on behalf of PISD's members. Only if a payor offered a contract containing sufficiently high fees did Dr. Guese and Ms. Brauchler recommend to the members that they accept the contract. Dr. Guese and Ms. Brauchler refused to convey to PISD's members contract offers containing price and other terms that Dr. Guese and Ms. Brauchler deemed to be deficient. Instead, they demanded, and received, contract terms that were more economically advantageous, from the physicians' perspective, than the physicians themselves could have obtained by negotiating individually rather than collectively.

PISD functioned as its members' *de facto* exclusive representative. Respondents told payors that PISD had the authority to negotiate and sign contracts on behalf of all of its members, and members themselves sent letters to payors, asserting that they would deal with payors only through PISD, Dr. Guese, or Ms. Brauchler, and not unilaterally. Respondents also successfully applied coercive tactics. For example, they advised PISD members to terminate, or threaten to terminate, their pre-existing, individual contracts with payors. Many PISD members complied, to pressure payors into offering a new contract to PISD that paid fees at or above the level that the physicians, through PISD, collectively demanded. The terminations and threats of termination left payors in the untenable position of having to pay higher fees to PISD members, or being denied such members' inclusion in the payors' respective provider networks. As a consequence of this conduct, PISD or its members contracted with various payors for fees that were higher than the fees such payors had agreed to pay other primary care physicians in the area.

Respondents' joint negotiation of fees and other competitively significant terms has not been reasonably related to any efficiency-enhancing integration. PISD refused to consider any form of financial risk-sharing, and its members have not clinically integrated their practices to create sufficiently substantial potential efficiencies. Respondents' actions have restrained price and other forms of competition among the members, caused fees for

Analysis

physician services to rise, and harmed consumers, including health plans, employers, and individual patients.

The Proposed Consent Order

The proposed order is designed to prevent recurrence of these illegal concerted actions, while allowing Respondents to engage in legitimate conduct that does not impair competition. The proposed order's core prohibitions are contained in Paragraphs II and III.

Paragraph II is intended to prevent the Respondents from participating in, or creating, future unlawful physician agreements.

Paragraph II.A prohibits PISD, Dr. Guese, and Ms. Brauchler from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, not to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or not to deal with any payor through an arrangement other than PISD.

Paragraph II.B prohibits these Respondents from facilitating exchanges of information between physicians concerning whether, or on what terms, to contract with a payor. Paragraph II.C prohibits them from attempting to engage in any action prohibited by Paragraph II.A or II.B. Paragraph II.D prohibits them from inducing anyone to engage in any action prohibited by Paragraphs II.A through II.C.

Paragraph II also contains three provisos intended to clarify certain types of agreements that Paragraph II does not prohibit. The first proviso applies to Ms. Brauchler, the second to Dr. Guese, and the third to PISD. Each provides that nothing in Paragraph II prohibits the applicable Respondent from engaging in conduct that is reasonably necessary to form, participate in, or act in furtherance of, a "qualified risk-sharing joint arrangement" or a "qualified clinically-integrated joint arrangement." The proviso applies to PISD only if the physicians who participate in the

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arrangement are available to enter into payor contracts outside the arrangement, *i.e.*, the arrangement is not exclusive.

As defined in the proposed order, a “qualified risk-sharing joint arrangement” must satisfy two conditions. First, all physician participants must share substantial financial risk through the arrangement and thereby create incentives for the physician participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. The definition of financial risk-sharing tracks the discussion of that term contained in the Health Care Statements.

As defined in the proposed order, a “qualified clinically-integrated joint arrangement” also must satisfy two conditions. First, all physician participants must participate in active and ongoing programs to evaluate and modify their clinical practice patterns, creating a high degree of interdependence and cooperation among physicians, in order to control costs and ensure the quality of services provided. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. This definition also reflects the analysis contained in the Health Care Statements.

Paragraph II’s provisos, as they apply to Dr. Guese and Ms. Brauchler, also provide that Paragraph II does not prohibit them from facilitating an agreement solely between physicians who are part of the same medical group practice. The proposed order defines such a practice as a bona fide, integrated firm in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.

Paragraph III prohibits Ms. Brauchler, for a period of three years, from negotiating with any payor on behalf of any current or

Analysis

past member of PISD, and from advising any current or past member of PISD to accept or reject any term, condition, or requirement of dealing with any payor.

Ms. Brauchler is not prohibited from performing legitimate “messenger” services, including with respect to PISD. As noted above, a properly constituted messenger can efficiently facilitate the establishment of physician-payor contracts and avoid fostering unlawful agreements among the participating physicians. As set forth in the proposed complaint, however, while Ms. Brauchler purported to operate as a legitimate messenger, in practice she fostered anticompetitive physician agreements by negotiating directly with payors for higher fees on behalf of PISD’s entire membership, and by advising PISD’s members collectively to reject various payor offers and to engage in concerted refusals to deal. For this reason, Paragraph III is a necessary and appropriate supplement to Paragraph II’s provisions. Under the proposed order, Ms. Brauchler may serve as PISD’s messenger, but, pursuant to Paragraph III, may not negotiate for or advise any PISD member with respect to payor contracts.

Paragraph IV.C requires PISD to terminate, without penalty at any payor’s request, current contracts with payors with respect to providing physician services. This provision is intended to eliminate the effects of Respondents’ anticompetitive concerted actions. The remaining provisions of Paragraph IV and Paragraphs V through VIII of the proposed order impose obligations on Respondents with respect to distributing the proposed complaint and order to PISD’s members and to other specified persons, and reporting information to the Commission.

The proposed order will expire in 20 years.

Complaint

IN THE MATTER OF

**AURORA ASSOCIATED PRIMARY CARE PHYSICIANS,
L.L.C., ET AL.**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4055; File No. 0110174
Complaint, July 16, 2002--Decision, July 16, 2002*

This consent order addresses practices used by Respondent Aurora Associated Primary Care Physicians, L.L.C. (“AAPCP”) – which has approximately 45 members who are primary care physicians in the Aurora, Colorado area – Respondents Richard A. Patt, M.D. and Gary L. Gaede, M.D., respectively the chairman and an ex officio member of the board of AAPCP, and Respondent Marcia Brauchler, an advisor to AAPCP. The order, among other things, prohibits the respondents from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician’s behalf; (2) to deal, not to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or not to deal with any payor through an arrangement other than AAPCP. The order also prohibits the respondents from facilitating exchanges of information between physicians concerning whether, or on what terms, to contract with a payor. In addition, the order prohibits the respondents from attempting to engage in – or from inducing anyone to engage in – any action prohibited by the order. The order also prohibits Respondent Brauchler, for three years, from negotiating with any payor on behalf of any current or past member of AAPCP, and from advising any current or past member of AAPCP to accept or reject any term, condition, or requirement of dealing with any payor. In addition, the order requires Respondent AAPCP to terminate – without penalty at any payor’s request – current contracts with payors with respect to providing physician services.

Participants

For the Commission: *Paul Nolan, Christi Braun, Jeffrey W. Brennan, Rendell A. Davis, Jr., Daniel P. Ducore, and Louis Silvia.*

For the Respondents: *Claude Wild III, Patton Boggs LLP.*

Complaint

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U. S. C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Aurora Associated Primary Care Physicians, L.L.C. (“Respondent AAPCP”), Richard A. Patt, M.D. (“Respondent Patt”), Gary L. Gaede, M.D. (“Respondent Gaede”), and Marcia L. Brauchler (“Respondent Brauchler”) have violated and are violating Section 5 of the Federal Trade Commission Act, 15 U. S. C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint, stating its charges in that respect as follows:

RESPONDENTS

PARAGRAPH 1: Respondent AAPCP is a for-profit limited liability company, organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at P. O. Box 5183, Englewood, CO 80155.

PARAGRAPH 2: Respondent Patt is a physician licensed under the laws of the State of Colorado, with his office and principal place of business located at 1421 S. Potomac Street, Suite 320, Aurora, CO 80012. Respondent Patt is the Chairman of the Board of Managers (“Board”) of, and one of the principal negotiators for, Respondent AAPCP. The Board controls the operations of Respondent AAPCP.

PARAGRAPH 3: Respondent Gaede is a physician licensed under the laws of the State of Colorado, with his office and principal place of business located at 14991 E. Hampden Avenue, Suite 210, Aurora, CO 80014. Respondent Gaede was a member, and is now an *ex officio* member, of the Board. Respondent Gaede is also one of the principal negotiators for Respondent AAPCP.

Complaint

PARAGRAPH 4: Respondent Brauchler is a consultant to Respondent AAPCP. The address of her office and principal place of business is P.O. Box 260661, Littleton, CO 80163-0171.

JURISDICTION

PARAGRAPH 5: At all times relevant to this Complaint, all members of Respondent AAPCP were primary care physicians engaged in the business of providing health care services for a fee to patients. Except to the extent that competition has been restrained as alleged herein, members of Respondent AAPCP have been, and are now, in competition with each other for the provision of physician services.

PARAGRAPH 6: Respondents' general business practices, including the acts and practices alleged herein, are in or affecting "commerce" as defined in the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

PARAGRAPH 7: Respondent AAPCP has been organized in substantial part, and is engaged in substantial activities, for the pecuniary benefit of Respondent AAPCP's members and is therefore a "corporation" within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U. S. C. § 44.

OVERVIEW OF MARKET AND PHYSICIAN COMPETITION

PARAGRAPH 8: Respondent AAPCP has approximately 45 members, all of whom are primary care physicians, licensed to practice medicine in the State of Colorado, and engaged in the business of providing primary care physician services to patients. The membership of Respondent AAPCP consists of internists, pediatricians, family physicians, and general practitioners with offices in the Aurora, Colorado area. Aurora is an eastern suburb of Denver, Colorado.

Complaint

PARAGRAPH 9: Physicians often contract with health insurance firms and other third-party payors (hereinafter “payors”), such as preferred provider organizations. Such contracts typically establish the terms and conditions, including fees and other competitively significant terms, under which the physicians will render services to the payors’ subscribers. Physicians entering into such contracts often agree to lower compensation, in order to obtain access to additional patients made available by the payors’ relationship with insureds. These contracts may reduce payors’ costs and enable payors to lower the price of insurance, and thereby result in lower medical care cost for subscribers to the payors’ health insurance plans.

PARAGRAPH 10: Absent agreements among competing physicians on the terms, including price, on which they will provide services to subscribers or enrollees in health care plans offered or provided by third-party payors, competing physicians decide individually whether to enter into contracts with third-party payors to provide services to their subscribers or enrollees, and what prices they will accept pursuant to such contracts.

PARAGRAPH 11: Medicare’s Resource Based Relative Value System (“RBRVS”) is a system used by the Centers for Medicare and Medicaid Services to determine the amount to pay physicians for the services they render to Medicare patients. The RBRVS approach provides a method to determine fees for specific services. It is the practice of payors in the Aurora area to make contract offers to individual physicians at a fee level specified in the RBRVS for a particular year, plus a markup based on some percentage of that fee (*e.g.*, “110 percent of 2001 RBRVS”).

PARAGRAPH 12: In order to be competitively marketable in the Aurora area, a payor’s health insurance plan must include in its physician network a large number of primary care physicians who practice in the Aurora area. Many of the primary care physicians who practice in the Aurora area are members of Respondent AAPCP.

Complaint

PARAGRAPH 13: Competing physicians sometimes use a “messenger” to facilitate the establishment of contracts between themselves and payors in ways that do not constitute or facilitate an unlawful agreement on fees and other competitively significant terms. Such a messenger may not, however, consistent with a competitive model, negotiate fees and other competitively significant terms on behalf of the participating physicians, or facilitate the physicians’ coordinated responses to contract offers by, for example, electing not to convey a payor’s offer to them based on the messenger’s opinion on the appropriateness, or lack thereof, of the offer.

RESTRAINT OF TRADE

PARAGRAPH 14: Respondents AAPCP, Patt, and Gaede, acting as a combination of competing physicians, and Respondent Brauchler, in conspiracy with Respondent AAPCP and at least some of Respondent AAPCP’s members, respectively, have acted to restrain competition by, among other things:

- A. facilitating, negotiating, entering into, or implementing agreements among Respondent AAPCP’s members on fees and other competitively significant terms;
- B. refusing to deal with payors except on collectively agreed-upon terms; and
- C. negotiating uniform fees and other competitively significant terms in payor contracts for Respondent AAPCP’s members, and refusing to submit payor offers to members that do not conform to Respondent AAPCP’s standards for contracts.

FORMATION AND OPERATION OF RESPONDENT AAPCP

PARAGRAPH 15: According to its Operating Agreement, Respondent AAPCP was formed in approximately March 2000 to

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be a vehicle for physicians' collective contract negotiations with payors, in order to achieve contracts that contain higher fees and other, more advantageous terms than individual members could obtain by negotiating unilaterally with payors. Respondents sought to replace individual physician-payor contracts with a single AAPCP-payor contract that contained such higher fees and other terms for all members of Respondent AAPCP.

PARAGRAPH 16: In or about May 2000, Respondent AAPCP retained Respondent Brauchler as a consultant after she made a presentation to its Board on how AAPCP could collect fee information from members and use that information to reach a consensus on an initial fee level to demand from payors on the collective membership's behalf. The Board directed Respondent Brauchler to participate in Board meetings and to advise the Board, its committees, and Respondent AAPCP's members regarding terms of payor contracts and negotiations with payors. Thereafter, on behalf of Respondent AAPCP's collective membership, designated members of Respondent AAPCP and Respondent Brauchler negotiated with payors for higher fees and other, more economically advantageous contract terms.

PARAGRAPH 17: To join Respondent AAPCP, physicians sign an agreement that authorizes Respondent AAPCP to negotiate, on their behalf, fees and other contract terms with payors. Members authorize Respondent AAPCP to negotiate "non-risk" contracts, which are accepted only if first approved by a AAPCP's Board. Non-risk contracts do not involve sharing between physicians and payors of financial risk through arrangements such as capitation or fee withhold. Upon such approval, Respondent AAPCP executes a contract with a payor.

PARAGRAPH 18: Respondents have a practice – inconsistent with a messenger model arrangement – of refusing to convey to Respondent AAPCP's members the terms of payor offers that Respondents deem deficient. Respondents instead demand, and receive, from payors more favorable contract terms – terms that payors would not have offered to Respondent AAPCP's members

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had those members negotiated on a unilateral, rather than collective, basis. Only after payors accede to Respondents' demand for higher fees and other favorable terms do Respondents convey the contract in question to Respondent AAPCP's members for acceptance.

PARAGRAPH 19: Respondents Patt, Gaede, and Brauchler reported to Respondent AAPCP's members on the details of AAPCP's negotiations with payors, including on the status of fee negotiations and the specific fee levels that were discussed. Respondents Patt and Gaede also held general AAPCP membership meetings to discuss details of payor contract negotiations and overall contract strategy.

PARAGRAPH 20: In negotiations with payors, Respondent AAPCP's designated physician negotiators and Respondents Patt, Gaede and Brauchler used a "contract-or-no-contract" strategy, through which the payor could either contract on AAPCP's terms and likely have all of the members of AAPCP in the provider network, or not contract on AAPCP's terms and have few or none of the AAPCP members in the network. Respondents Patt, Gaede and Brauchler would either recommend that the AAPCP Board approve a negotiated contract and recommend that individual AAPCP members accept it, or, if Respondents were unable to negotiate acceptable terms, refuse to convey the payor's offer to members.

PARAGRAPH 21: Drawing from her experiences in negotiating several Respondent AAPCP contracts, Respondent Brauchler compiled a "Confidential AAPCP Play Book." In the "Play Book," she advised Respondent AAPCP's designated physician negotiators on how they could leverage the collective strength of Respondent AAPCP's members to negotiate higher fees from payors. The "Play Book" encouraged Respondent AAPCP's designated physician negotiators to threaten payors with terminations by Respondent AAPCP's members who had individual contracts with them, unless the payors agreed to the fees that Respondent AAPCP demanded. The "Play Book" also

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encouraged Respondent AAPCP's designated physician negotiators to take an aggressive and hostile stance when meeting with payors, and to reject their initial fee offers as too low. The "Play Book" cited several instances in which Respondents and other members of Respondent AAPCP used such tactics to pressure and coerce payors into making more economically favorable contract proposals to Respondent AAPCP's members.

PARAGRAPH 22: Respondents Patt, Gaede, and Brauchler and AAPCP's designated physician negotiators told payors that Respondent AAPCP's members would deal with them only if the payor agreed to terms that the Board recommended. This assertion was demonstrated when payors attempted unsuccessfully to deal individually with members of Respondent AAPCP – only to be told by the members that they would contract for services only through Respondent AAPCP. Respondents' strategy of collective negotiations and concerted refusals to deal outside AAPCP left payors in the untenable position of having to pay higher fees to all members of Respondent AAPCP, or being denied such members' inclusion in their respective health insurance plan's provider networks – an outcome that would have substantially impaired payors' ability to compete effectively.

NEGOTIATIONS WITH PACIFICARE

PARAGRAPH 23: PacifiCare Health Systems of Colorado, Inc. ("PacifiCare"), is a payor doing business in the Aurora area. In February 2000, Respondents Patt and Brauchler started contract negotiations with PacifiCare on behalf of Respondent AAPCP's members. They negotiated fees and other competitively significant terms with PacifiCare that would benefit Respondent AAPCP's members as a group. As part of their collective demands, Respondents requested a fee-for-service contract at a specified percentage of RBRVS, and an automatic annual fee increase. They also told PacifiCare that any agreement with Respondent AAPCP's members must not include any financial risk through capitation or a fee withhold.

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PARAGRAPH 24: Later in 2000, PacifiCare attempted to reach agreement with individual members of Respondent AAPCP on fee-for-service contracts. Upon learning that PacifiCare was contacting Respondent AAPCP's members on an individual rather than collective basis for contracting, Respondent Brauchler requested that all members of Respondent AAPCP not negotiate individually with PacifiCare, and allow Respondent AAPCP to continue to negotiate all agreements with PacifiCare on their collective behalf. Respondent AAPCP's members complied with this request. As a result, PacifiCare was forced to negotiate only through Respondent AAPCP.

PARAGRAPH 25: Concerned that it otherwise would have an unmarketable health insurance plan because of a limited primary care physician network in the Aurora area, PacifiCare entered a fee-for-service contract with Respondent AAPCP at the higher contract rate that the members, through Respondent AAPCP, collectively demanded. PacifiCare also agreed to Respondent AAPCP's demand for annual fee increases tied to the inflation rate, the potential for bonus incentives, administrative fees to Respondent AAPCP, and other miscellaneous fees, all of which were concessions that PacifiCare made in response to Respondent AAPCP's coercive tactics. Only after Respondent AAPCP's collectively determined terms were met did the Board accept the PacifiCare contract and mail it to members of Respondent AAPCP for their acceptance.

NEGOTIATIONS WITH CIGNA

PARAGRAPH 26: CIGNA Healthcare of Colorado, Inc. ("CIGNA"), is a payor doing business in the Aurora area. In March 2000, on behalf of Respondent AAPCP's members, Respondent Gaede and others started contract negotiations with CIGNA. When those negotiations reached an impasse, many of Respondent AAPCP's members attempted to coerce CIGNA into agreeing to Respondent AAPCP's terms by notifying CIGNA that they were terminating their individual contracts with CIGNA unless the payor dealt with Respondent AAPCP. Respondent

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Brauchler told CIGNA that Respondent AAPCP's members would agree to continue their participation with CIGNA only if it offered a contract that was acceptable to Respondents.

PARAGRAPH 27: Respondent Brauchler also told CIGNA that it would gain access to all Respondent AAPCP's members only if the Board endorsed the contract, and that the Board would not endorse a contract that did not meet Respondent AAPCP's collectively determined minimum fee levels. Respondents Brauchler and Gaede threatened that unless CIGNA agreed to contract on terms demanded by Respondent AAPCP, members would continue to terminate their individual contracts.

PARAGRAPH 28: Respondent AAPCP successfully forced CIGNA into agreeing to offer a contract that paid higher fees to Respondent AAPCP's members than it had previously agreed to pay individual primary care physicians in the Aurora area. Respondents also succeeded in forcing CIGNA to agree that fees in the future would not fall below the level established in the contract. The Board approved the CIGNA contract and mailed it to members, most of whom accepted it.

NEGOTIATIONS WITH ANTHEM

PARAGRAPH 29: Anthem Blue Cross and Blue Shield of Colorado ("Anthem") is a payor doing business in the Aurora area. Commencing in February 2000 and for many months thereafter, Anthem attempted to contract with Respondent AAPCP's members by providing Respondent AAPCP with a proposed contract to be transmitted to the individual members of Respondent AAPCP. In late 2000, the Board authorized Respondents Gaede and Brauchler to act as agents in contract negotiations with Anthem.

PARAGRAPH 30: At various times, Respondents Gaede and Brauchler met with Anthem's representatives. Respondent AAPCP, however, repeatedly refused to transmit Anthem's proposal to the members of Respondent AAPCP. Respondent

Complaint

Gaede told Anthem that its fee offer was too low and that the Board would not act on it. Respondent Gaede also told Anthem that the Board had voted to accept only a contract that contained a minimum level of fees, no requirement of financial risk to Respondent AAPCP's members, and a management fee for Respondent AAPCP. Respondent Gaede informed Anthem that Respondent AAPCP had obtained these contract terms from other payors in the market, and that only if Anthem met Respondent AAPCP's contract requirements would Respondent AAPCP's members sign a contract. Respondent Gaede further informed Anthem that Respondent AAPCP limited the number of contracts that it would accept to the four payors that offered Respondent AAPCP's members the highest fees. He threatened Anthem that it would not have a contract with any members of Respondent AAPCP unless Anthem promptly made an acceptable offer.

PARAGRAPH 31: Anthem increased its offer, but to a level that was still below Respondent AAPCP's minimum fee requirements. Because the Anthem offer did not meet Respondent AAPCP's requirements, Respondent AAPCP did not enter into a contract with Anthem.

NEGOTIATIONS WITH OTHER PAYORS

PARAGRAPH 32: Since the inception of Respondent AAPCP in 2000, Respondents Patt, Gaede, and Brauchler have informed other payors that Respondent AAPCP represented the collective interest of its members, and that Respondent AAPCP would negotiate and sign contracts on behalf of all its members. Respondents also informed these payors of the specific fees that Respondents demanded as a condition for signing a contract, emphasizing that Respondent AAPCP would likely refuse any fee lower than a specified percentage of Medicare RBRVS. To exert pressure on and coerce these payors into paying higher fees, Respondent AAPCP's members sent termination letters to such payors, informing the payors that they would not negotiate individually, and told the payors to deal for members' services only through Respondent AAPCP. Respondent AAPCP's

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coercive tactics have been successful. It has obtained contracts with at least two other payors for fees matching or exceeding Respondent AAPCP's desired percentage of RBRVS.

LACK OF SIGNIFICANT EFFICIENCIES

PARAGRAPH 33: In collectively negotiating and entering the contracts identified above, Respondent AAPCP and its members have not assumed any significant form of financial risk-sharing and have not integrated their practices to create sufficient potential efficiencies. Respondents' joint negotiation of fees and other competitively significant terms has not been, and is not, reasonably related to any efficiency-enhancing integration.

ANTICOMPETITIVE EFFECTS

PARAGRAPH 34: Respondents' actions described above in Paragraphs 14 through 33 have had, or have the tendency to have, the effect of restraining trade unreasonably and hindering competition in the provision of physician services in the Aurora area in the following ways, among others:

- A. fees and other forms of competition among Respondent AAPCP's members were unreasonably restrained;
- B. fees for physician services were increased; and
- C. competition in the purchase of physician services was restrained to the detriment of health plans, employers, and individual consumers.

PARAGRAPH 35: The combination, conspiracy, acts and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Such combination, conspiracy, acts and practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

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WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this Sixteenth day of July, 2002, issues its Complaint against Respondents AAPCP, Patt, Gaede, and Brauchler.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of respondents named in the caption hereof (“Respondents”), and Respondents having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued, would charge Respondents with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to § 2.34 of its Rules, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Order:

1. Respondent Aurora Associated Primary Care Physicians, L.L.C. (“AAPCP”), is a for-profit limited liability company, organized, existing, and doing business under and by virtue of

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the laws of the State of Colorado, with its office and principal place of business located at P. O. Box 5183, Englewood, CO 80155.

2. Respondent Marcia L. Brauchler is a consultant to AAPCP. Her office and principal place of business is located at P.O. Box 260661, Littleton, CO 80163-0171.
3. Respondent Richard A. Patt, M.D., is a physician licensed under the laws of the State of Colorado, with his office and principal place of business located at 1421 S. Potomac Street, Suite 320, Aurora, CO 80012.
4. Respondent Gary L. Gaede, M.D., is a physician licensed under the laws of the State of Colorado, with his office and principal place of business located at 14991 E. Hampden Avenue, Suite 210, Aurora, CO 80014.
5. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent AAPCP” means Aurora Associated Primary Care Physicians, L.L.C., its officers, directors, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by Aurora Associated Primary Care Physicians, L.L.C., and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- B. “Respondent Brauchler” means Marcia L. Brauchler.

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- C. “Physician Respondents” means Respondent Richard A. Patt, M.D. and Respondent Gary L. Gaede, M.D.
- D. “Respondents” means Respondent AAPCP, Respondent Brauchler, and the Physician Respondents.
- E. “Medical group practice” means a bona fide, integrated firm in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.
- F. “Participate” in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services, to a payor through such entity. (This definition also applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”)
- G. “Payor” means any person that pays, or arranges for payment, for all or any part of any physician services for itself or for any other person.
- H. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- I. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- J. “Preexisting Contract” means a contract that was in effect prior to the receipt, by all payors that are parties to such contract, of notice sent by Respondent AAPCP pursuant to Paragraph IV.B. of this Order, of each such payor’s right to terminate such contract.

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- K. “Principal Address” means either (1) primary business address, if there is a business address, or (2) primary residential address, if there is no business address.
- L. “Qualified clinically-integrated joint arrangement” means an arrangement to provide physician services in which:
 - 1. all physicians who participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the physicians who participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and
 - 2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.
- M. “Qualified risk-sharing joint arrangement” means an arrangement to provide physician services in which:
 - 1. all physicians who participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the physicians who participate to jointly control costs and improve quality by managing the provision of physician services, such as risk-sharing involving:
 - a. the provision of physician services to payors at a capitated rate,
 - b. the provision of physician services for a predetermined percentage of premium or revenue from payors,

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- c. the use of significant financial incentives (*e.g.*, substantial withholdings) for physicians who participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by physicians in different specialties offering a complementary mix of services, for a fixed, predetermined payment, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient's condition, the choice, complexity, or length of treatment, or other factors; and
2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.

II.

IT IS FURTHER ORDERED that Respondents, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any physicians:
 1. To negotiate on behalf of any physician with any payor,
 2. To deal, refuse to deal, or threaten to refuse to deal with any payor,

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3. Regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, including, but not limited to, price terms, or
 4. Not to deal individually with any payor, or not to deal with any payor through any arrangement other than Respondent AAPCP;
- B. Exchanging or facilitating in any manner the exchange or transfer of information among physicians concerning any physician's willingness to deal with a payor, or the terms or conditions, including price terms, on which the physician is willing to deal;
- C. Attempting to engage in any action prohibited by Paragraph II.A. or II.B., above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A. through II.C. above.

PROVIDED, HOWEVER, that nothing in this Paragraph II. shall prohibit any agreement involving or conduct by:

- (i) Respondent Brauchler that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement, or that solely involves physicians in the same medical group practice;
- (ii) any Physician Respondent that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement through which he provides physician services, or that solely involves physicians in such Physician Respondent's own medical group practice; or

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- (iii) Respondent AAPCP that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement, so long as the arrangement does not restrict the ability, or facilitate the refusal, of physicians who participate in it to deal with payors on an individual basis or through any other arrangement.

III.

IT IS FURTHER ORDERED that Respondent Brauchler, for a period of three (3) years from the date that this order is issued, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Negotiating with any payor on behalf of any physician who participates, or has participated, in Respondent AAPCP, notwithstanding whether such conduct also violates Paragraph II. of this Order; and
- B. Advising any physician who participates, or has participated, in Respondent AAPCP to accept or reject any term, condition, or requirement of dealing with any payor, notwithstanding whether such conduct also violates Paragraph II. of this Order.

IV.

IT IS FURTHER ORDERED that Respondent AAPCP shall:

- A. Within thirty (30) days after the date on which this Order is issued, send by first-class mail a copy of this Order and the Complaint to:

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1. each physician who participates, or has participated, in Respondent AAPCP, and
 2. each officer, director, manager, and employee of Respondent AAPCP;
- B. Within thirty (30) days after the date on which this Order is issued, send copies of this Order, the Complaint, and the notice specified in Appendix B to this Order, by first class mail return receipt requested, to the chief executive officer of each payor that is listed in Appendix A or that contracts with Respondent AAPCP for the provision of physician services;
- C. Terminate, without penalty or charge, any Preexisting Contract with any payor for the provision of physician services, upon receipt by Respondent AAPCP of a written request to terminate such contract from any payor that is a party to the contract or that pays for physician services provided through the contract;
- D. For a period of three (3) years after the date this Order is issued:
1. Distribute by first-class mail a copy of this Order and the Complaint to:
 - a. each physician who begins participating in Respondent AAPCP, and who did not previously receive a copy of this Order and the Complaint from Respondent AAPCP, within thirty (30) days of the time that such participation begins,
 - b. each payor that contracts with Respondent AAPCP for the provision of physician services, and that did not previously receive a copy of this Order and the Complaint from Respondent AAPCP, within thirty (30) days of the time that such payor enters into such contract, and

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- c. each person who becomes an officer, director, manager, or employee of Respondent AAPCP, and who did not previously receive a copy of this Order and the Complaint from Respondent AAPCP, within thirty (30) days of the time that he or she assumes such responsibility with Respondent AAPCP; and
2. Annually publish in an official annual report or newsletter sent to all physicians who participate in Respondent AAPCP, a copy of this Order and the Complaint with such prominence as is given to regularly featured articles;
- E. Notify the Commission at least thirty (30) days prior to any proposed change in Respondent AAPCP, such as dissolution, assignment, sale resulting in the emergence of a successor company or corporation, the creation or dissolution of subsidiaries, or any other change in Respondent AAPCP that may affect compliance obligations arising out of this Order; and
- F. File verified written reports within sixty (60) days after the date this Order is issued, annually thereafter for three (3) years on the anniversary of the date this Order is issued, and at such other times as the Commission may by written notice require, setting forth:
 1. in detail, the manner and form in which Respondent AAPCP has complied and is complying with this Order, including, but not limited to, (a) information sufficient to describe, for each qualified risk-sharing arrangement established or operated by Respondent AAPCP, the manner in which the physicians who participate in such arrangement share financial risk, and (b) information sufficient to describe, for each qualified clinically-integrated joint arrangement established or operated by Respondent AAPCP, the manner in which the physicians who participate in such arrangement have integrated their practices, and

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2. the name, address, and telephone number of each payor with which Respondent AAPCP has had any contact.

V.

IT IS FURTHER ORDERED that Respondent Brauchler shall:

- A. For a period of three (3) years after the date this Order is issued, distribute by first-class mail a copy of this Order and the Complaint to:
 1. all physician groups, other than any medical group practice, that Respondent Brauchler represents for the purpose of contracting, or seeking to contract, with payors for the provision of physician services, or that Respondent Brauchler advises with regard to their dealings with payors in connection with the provision of physician services, within (30) days of the time that Respondent Brauchler begins providing such representation or advice, unless such physician group previously received a copy of this Order and the Complaint from Respondent AAPCP or Respondent Brauchler, and
 2. each payor with which Respondent Brauchler deals, or has dealt, for the purpose of contracting, or seeking to contract, while representing any physician or any group of physicians, or while advising any physician or group of physicians with regard to their dealings regarding contracting with such payor for the provision of physician services, within thirty (30) days of such dealing, unless such payor previously received a copy of this Order and the Complaint from Respondent AAPCP or Respondent Brauchler; and
- B. File verified written reports within sixty (60) days after the date this Order is issued, annually thereafter for three (3) years on the anniversary of the date this Order is issued, and

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at such other times as the Commission may by written notice require, setting forth:

1. in detail, the manner and form in which Respondent Brauchler has complied and is complying with this Order,
2. the name, address, and telephone number of each physician or group of physicians that Respondent Brauchler has represented or advised with respect to their dealings with any payor in connection with the provision of physician services, and
3. the name, address, and telephone number of each payor with which Respondent Brauchler has dealt while representing any physician or any group of physicians in connection with the provision of physician services.

VI.

IT IS FURTHER ORDERED that each Physician Respondent shall file verified written reports within sixty (60) days after the date this Order is issued, annually thereafter for three (3) years on the anniversary of the date this Order is issued, and at such other times as the Commission may by written notice require, setting forth:

- A. in detail, the manner and form in which the Physician Respondent has complied and is complying with this Order, including, but not limited to, any information necessary to demonstrate such compliance;
- B. the name, address, and telephone number of each physician group, including any medical group practice, in which the Physician Respondent has participated;
- C. the name, address, and telephone number of each person, who is not a member or employee of the Physician Respondent's medical group practice, that has represented or

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advised the Physician Respondent with respect to contracting with any payor for the provision of physician services;

- D. the name, address, and telephone number of each payor, other than individual patients, that has communicated with the Physician Respondent for the purpose of contracting, or seeking to contract, for physician services; and
- E. the name, address, and telephone number of each payor, other than individual patients, with which the Physician Respondent has entered into a written agreement for the provision of physician services, and the nature of such agreement.

VII.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission of any change in its Principal Address within twenty (20) days of such change in address.

VIII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in their possession, or under their control, relating to any matter contained in this Order;
- B. Upon five (5) days' notice to Respondent AAPCP, and in the presence of counsel, and without restraint or interference from it, to interview officers, directors, or employees of Respondent AAPCP; and

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- C. Upon five (5) days' notice to Respondent Brauchler or to any Physician Respondent, and in the presence of counsel, and without restraint or interference from such Respondent, to interview such Respondent or the employees of such Respondent.

IX.

IT IS FURTHER ORDERED that this Order shall terminate on July 16, 2022.

Appendix A

Aetna US Healthcare of Colorado
Anthem Blue Cross Blue Shield
CIGNA HealthCare of Colorado
Humana Health Plan
Mountain Medical Affiliates, Inc.
OneHealth Plan
Pacificare of Colorado
Patient Choice Healthcare of Colorado
United Health Care of Colorado

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Appendix B

[letterhead of Aurora Associated Primary Care Physicians,
L.L.C.]

[name of payor's CEO]
[address]

Dear _____:

Enclosed is a copy of a complaint and a consent order issued by the Federal Trade Commission against Aurora Associated Primary Care Physicians, L.L.C. ("AAPCP"). I call to your attention Paragraph IV.C of the order, which gives you the right to terminate, without penalty or charge, any contracts with AAPCP that were in effect prior to your receipt of this letter.

Sincerely,

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with Aurora Associated Primary Care Physicians, L.L.C. (“AAPCP”), Richard A. Patt, M.D., Gary L. Gaede, M.D., and Marcia L. Brauchler (“Respondents”). The agreement settles charges that Respondents violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by facilitating and implementing agreements among AAPCP’s members to fix prices and other terms of dealing with health insurance firms and other third-party payors (hereinafter, “payors”), and to refuse to deal with payors except on collectively determined terms. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by any Respondent that said Respondent violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

The Complaint

The allegations in the Commission’s proposed complaint are summarized below.

AAPCP has approximately 45 primary care physicians in its membership. A board of managers operates AAPCP, and Dr. Patt is the board’s chairman. Except to the extent that competition has

Analysis

been restrained as alleged in the proposed complaint, AAPCP's members compete with each other as internists, pediatricians, family physicians, or general practitioners, in offices located in the Aurora, Colorado, area. To be competitively marketable to employers and other purchasers in the Aurora area, a payor's health insurance plan must include in its network of participating physicians a large number of primary care physicians who practice in the Aurora area.

The physicians formed AAPCP as a vehicle collectively to negotiate contracts with payors, and thereby to achieve contracts containing higher fees and other, more advantageous terms than the individual physicians could obtain unilaterally. AAPCP members authorized AAPCP to negotiate for this purpose. Members also agreed to accept "non-risk" contracts, which are contracts that do not involve sharing among physicians of financial risk, through arrangements such as capitation or fee withholdings. Further, before the entire organization could accept a proposed payor contract, AAPCP's board had to approve it.

In or about May 2000, AAPCP retained Ms. Brauchler, a non-physician consultant, after she had made a board presentation showing how AAPCP could collect fee information from members and use that information to reach a consensus on an initial fee level to demand from payors on the collective membership's behalf.

Sometimes a network of competing physicians uses an agent to convey to payors information obtained individually from the physicians about fees or other significant contract terms that they are willing to accept. The agent may also convey to the physicians all payor contract offers, which the physicians then unilaterally decide whether to accept or reject. Such a "messenger model" arrangement, which is described in the 1996 Statements of Antitrust Enforcement Policy in Health Care jointly issued by the Federal Trade Commission and U.S. Department of Justice (*see* <http://www.ftc.gov/reports/hlth3s.htm>), can facilitate and minimize the costs involved in contracting between physicians

Analysis

and payors, without fostering an agreement among competing physicians on fees or fee-related terms.

AAPCP purported to operate as a messenger, but, in practice, it did not do so. Rather, in 2000 and 2001, Dr. Patt and Ms. Brauchler, together with Dr. Gaede, who is an *ex-officio* member of the board, and other physicians designated by Respondent AAPCP, on behalf of Respondent AAPCP's members, used the information gathered from members to negotiate fees and other competitively significant terms collectively on behalf of AAPCP's members. Only if a payor offered a contract containing sufficiently high fees did Drs. Patt and Gaede and Ms. Brauchler recommend that the board approve the contract and that the members accept it. The Respondents refused to recommend to the board, or convey to AAPCP's members, contract offers containing price and other terms that they deemed to be deficient. Instead, they demanded, and received, contract terms that were more economically advantageous, from the physicians' perspective, than the physicians themselves could have obtained by negotiating individually rather than collectively.

AAPCP functioned as its members' *de facto* exclusive representative. Dr. Patt and Gaede and Ms. Brauchler told payors that AAPCP had the authority to negotiate and sign contracts on behalf of all of its members, and AAPCP's members themselves sent letters to payors, asserting that they would deal with payors only through AAPCP and not unilaterally. Respondents also successfully applied coercive tactics. For example, they advised AAPCP members to terminate, or threaten to terminate, their pre-existing, individual contracts with payors. Many AAPCP members complied, to pressure payors into offering a new contract to AAPCP that paid fees at or above the level that the physicians, through AAPCP, collectively demanded. The terminations and threats of termination left payors in the untenable position of having to pay higher fees to AAPCP members, or being denied such members' inclusion in the payors' respective provider networks. As a consequence of this conduct, AAPCP or its members contracted with various payors for fees that were

Analysis

higher than the fees such payors had agreed to pay other primary care physicians in the area.

Respondents' joint negotiation of fees and other competitively significant terms has not been reasonably related to any efficiency-enhancing integration. AAPCP members have not financially or clinically integrated their practices to create sufficiently substantial potential efficiencies. Respondents' actions have restrained price and other forms of competition among the members, caused fees for physician services to rise, and harmed consumers, including health plans, employers, and individual patients.

The Proposed Consent Order

The proposed order is designed to prevent recurrence of these illegal concerted actions, while allowing Respondents to engage in legitimate conduct that does not impair competition. The proposed order's core prohibitions are contained in Paragraphs II and III.

Paragraph II is intended to prevent the Respondents from participating in, or creating, future unlawful physician agreements.

Paragraph II.A prohibits AAPCP, Drs. Patt and Gaede, and Ms. Brauchler from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, not to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or not to deal with any payor through an arrangement other than AAPCP.

Paragraph II.B prohibits these Respondents from facilitating exchanges of information between physicians concerning whether, or on what terms, to contract with a payor. Paragraph II.C prohibits them from attempting to engage in any action prohibited by Paragraph II.A or II.B. Paragraph II.D prohibits them from

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inducing anyone to engage in any action prohibited by Paragraphs II.A through II.C.

Paragraph II also contains three provisos intended to clarify certain types of agreements that Paragraph II does not prohibit. The first proviso applies to Ms. Brauchler, the second to Drs. Patt and Gaede, and the third to AAPCP. Each provides that nothing in Paragraph II prohibits the applicable Respondent from engaging in conduct that is reasonably necessary to form, participate in, or act in furtherance of, a “qualified risk-sharing joint arrangement” or a “qualified clinically-integrated joint arrangement.” The proviso applies to AAPCP only if the physicians who participate in the arrangement are available to enter into payor contracts outside the arrangement, *i.e.*, the arrangement is not exclusive.

As defined in the proposed order, a “qualified risk-sharing joint arrangement” must satisfy two conditions. First, all physician participants must share substantial financial risk through the arrangement and thereby create incentives for the physician participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. The definition of financial risk-sharing tracks the discussion of that term contained in the Health Care Statements.

As defined in the proposed order, a “qualified clinically-integrated joint arrangement” also must satisfy two conditions. First, all physician participants must participate in active and ongoing programs to evaluate and modify their clinical practice patterns, creating a high degree of interdependence and cooperation among physicians, in order to control costs and ensure the quality of services provided. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. This definition also reflects the analysis contained in the Health Care Statements.

Analysis

Paragraph II's provisos, as they apply to Drs. Patt and Gaede and Ms. Brauchler, also provide that Paragraph II does not prohibit them from facilitating an agreement solely between physicians who are part of the same medical group practice. The proposed order defines such a practice as a bona fide, integrated firm in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.

Paragraph III prohibits Ms. Brauchler, for a period of three years, from negotiating with any payor on behalf of any current or past member of AAPCP, and from advising any current or past member of AAPCP to accept or reject any term, condition, or requirement of dealing with any payor.

Ms. Brauchler is not prohibited from performing legitimate "messenger" services, including with respect to AAPCP. As noted above, a properly constituted messenger can efficiently facilitate the establishment of physician-payor contracts and avoid fostering unlawful agreements among the participating physicians. As set forth in the proposed complaint, however, while Ms. Brauchler purported to operate as a legitimate messenger, in practice she fostered anticompetitive physician agreements by negotiating directly with payors for higher fees on behalf of AAPCP's entire membership, and by advising AAPCP's members collectively to reject various payor offers and to engage in concerted refusals to deal. For this reason, Paragraph III is a necessary and appropriate supplement to Paragraph II's provisions. Under the proposed order, Ms. Brauchler may serve as AAPCP's messenger, but, pursuant to Paragraph III, may not negotiate for or advise any AAPCP member with respect to payor contracts.

Paragraph IV.C requires AAPCP to terminate, without penalty at any payor's request, current contracts with payors with respect to providing physician services. This provision is intended to eliminate the effects of Respondents' anticompetitive concerted actions. The remaining provisions of Paragraph IV and

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Paragraphs V through VIII of the proposed order impose obligations on Respondents with respect to distributing the proposed complaint and order to AAPCP's members and to other specified persons, and reporting information to the Commission.

The proposed order will expire in 20 years.

Complaint

IN THE MATTER OF

BAYER AG, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT

*Docket C-4049; File No. 0110199
Complaint, May 30, 2002--Decision, July 24, 2002*

This consent order addresses the acquisition by Respondent Bayer AG of Aventis CropScience Holding S.A. (“ACS”) from Respondent Aventis S.A. The Consent Agreement is intended to resolve anticompetitive effects stemming from Bayer’s proposed acquisition of Aventis CropScience Holding S.A. (“ACS”) from Aventis. The order, among other things, requires the respondents to divest the ACS businesses that produce and market acetamiprid, fipronil, tribufos, and flucarbazone – four of a new generation of chemical insecticide active ingredients that are used in products such as non-repellent termiticides; flea control for companion animals products; a number of crop, turf, and ornamental applications; and seed treatments – that are less harmful to human health and the environment, to an acquirer or acquirers approved by the Commission. An accompanying Order to Hold Separate and Maintain Assets requires the respondents to preserve the acetamiprid, fipronil and flucarbazone operations as a viable, competitive and ongoing operation until the divestitures are completed.

Participants

For the Commission: *Wallace Easterling, Cecelia Waldeck, Susan Huber, Angelike Andrinopoulos, Kristina Martin, April Tabor, Juston Blankenship, Brian Burgess, Eric Sprauge, Linda Cunningham, Jordan Coyle, Richard Liebeskind, Jeffrey Dahnke, Naomi Licker, Daniel P. Ducore, Roger Boner, Michael Nicholson, Elizabeth Callison, and Mary T. Coleman.*

For the Respondents: *A. Douglas Melamed and Leon B. Greenfield, Wilmer, Cutler & Pickering, and Wayne D. Collins and Beau W. Buffier, Shearman & Sterling.*

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COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and of the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission (the "Commission"), having reason to believe that respondents Bayer AG ("Bayer"), a foreign corporation, and Aventis S.A. ("Aventis"), a foreign corporation, both subject to the jurisdiction of the Commission, have agreed to merge, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Bayer AG is a German corporation organized, existing, and doing business under, and by virtue of, the laws of Germany, with its office and principal place of business located at Werk Leverkusen, 51368, Leverkusen, Germany. In the United States, Bayer operates its chemical and agricultural business through its subsidiary, Bayer Corporation ("Bayer Corp"), headquartered in Kansas City, Missouri. Bayer is a global chemical and technology company that develops, manufactures, and markets a portfolio of chemical and agricultural products and services that it distributes to customers throughout the world.

2. Respondent Aventis S.A. is a French corporation organized, existing, and doing business under, and by virtue of, the laws of France, with its office and principal place of business located at Avenue de l'Europe, Espace Europeen de l'Entreprise, Schiltigheim, France. In the United States, Aventis operates its chemical and agricultural business through Aventis CropScience ("ACS"), headquartered in Lyon, France. ACS is a joint venture among its sole shareholders, Aventis, Hoechst AG, and Schering AG. ACS is a global chemical and technology company that develops, manufactures, and markets a portfolio of chemical and

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agricultural products and services that it distributes to customers throughout the world.

II. JURISDICTION

3. Bayer and Aventis are, and at all times relevant herein have been, engaged in commerce as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and are corporations whose businesses are in or affect commerce as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED TRANSACTION

4. Bayer and Aventis announced on October 2, 2001 that their respective boards of directors approved the sale of all outstanding shares of ACS stock to Bayer pursuant to the October 2, 2001, stock purchase agreements by and between Bayer, Aventis, Hoechst AG, Schering AG, and SCIC Holding, LLC.

IV. VIOLATIONS CHARGED

COUNT ONE: NEW GENERATION CHEMICAL INSECTICIDE ACTIVE INGREDIENTS

5. Paragraphs 1–4 are incorporated by reference as if fully set forth herein.

6. Relevant lines of commerce in which to analyze the effects of the proposed merger are the research, development, manufacture, and sale of new generation chemical insecticide active ingredients and related technologies (“New Generation Chemical Insecticide Active Ingredients”) for specific end use applications, including the development, manufacture and sale of insecticides for use as non-repellent termiticides, flea control for companion animals, and for use on an array of crop applications such as corn, cotton, citrus, cole crops, grapes, vegetables, for turf and ornamental uses, and as protection for seeds and seedlings

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(“seed treatments”). New Generation Chemical Insecticide Active Ingredients are chemical insecticide ingredients that are designed to kill undesirable insects and, in contrast to older chemical insecticides, are less harmful to human health and the environment. Such insecticide active ingredients include imidacloprid, acetamiprid, thiamethoxam, and other chloronicotinyls (“CNIs”); and fipronil and other phenylpyrazoles (“Pyrazoles”). CNIs and Pyrazoles are primarily used in applications where their characteristics provide significant benefits to the consumer. Those benefits include: reductions in the amount of chemical insecticides used, reduced negative impacts on the environment and human health due to lower usage rates, reduced risk to humans and beneficial insects due to the use of safer chemicals in comparison to older chemical insecticides, and superior control of certain undesirable insects. New Generation Chemical Insecticide Active Ingredients are used to make insecticide products for use on crops, for termite control and for flea control for companion animals, among other applications, as alleged further herein.

7. The related New Generation Chemical Insecticide Active Ingredients technologies include, but are not limited to, patented techniques for the commercial synthesis of New Generation Chemical Insecticide Active Ingredients molecules, patented and proprietary process technology used to manufacture such molecules, and patented formulations for chemical insecticide products based on these technologies.

8. The relevant geographic market and section of the country within which to analyze the likely effects of the proposed transaction is the United States.

9. New Generation Chemical Insecticide Active Ingredients are of increasing importance as the U.S. Environmental Protection Agency (“EPA”) removes older chemical insecticides from the market due to their harmful effects on human health and the environment. The EPA is currently evaluating the use of older chemical pesticides, particularly insecticides. Through this

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process, the EPA plans to remove or limit the use of a significant number of older chemical pesticides and is encouraging firms to replace older harmful chemicals with less harmful products.

10. As EPA regulation limits or prohibits the use of older chemical insecticides, the demand for New Generation Chemical Insecticide Active Ingredients is increasing because of, among other things, their positive environmental and health benefits as compared to older chemical insecticides, and regulatory preferences for safer chemical insecticides.

11. Competition in research and development of New Generation Chemical Insecticide Active Ingredients has led to innovations including reductions in the cost of insecticides, reduced amounts of chemical insecticides used, development of chemicals with reduced risk of harmful environmental and health impacts due to insecticide exposure, and improved product properties and performance. Consequently, innovation relating to these active ingredients provides substantial benefits to consumers. Firms that discover New Generation Chemical Insecticide Active Ingredients, including respondents, buy and sell rights to develop those molecules into insecticide applications.

12. For these reasons, New Generation Chemical Insecticide Active Ingredients and related technologies constitute relevant product markets and “lines of commerce” within the meaning of the antitrust laws.

13. Bayer is a leading developer and producer of New Generation Chemical Insecticide Active Ingredients and a leading developer, producer, and seller of end-use products based on those insecticides. Bayer competes by, among other things, developing proprietary molecules and products, and has developed proprietary processes for the production of a wide array of active ingredients and chemical insecticide products.

14. ACS is also a leading developer and producer of New Generation Chemical Insecticide Active Ingredients and a leading

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developer, producer and seller of end-use products based on those ingredients. Like Bayer, ACS competes by developing proprietary molecules and products, and has developed proprietary processes for the production of a wide array of active ingredients and resulting chemical insecticides products.

15. Bayer and ACS are the two leading firms in the development and commercialization of New Generation Chemical Insecticide Active Ingredient technologies and downstream products, and own significant and important intellectual property estates and rights relating to New Generation Chemical Insecticide Active Ingredient technologies.

16. Bayer and ACS developed New Generation Chemical Insecticide Active Ingredients and related technologies after years of analytical work and study of molecules suitable for use in pesticide applications. That work led to the identification of important molecules, techniques for commercial synthesis of those molecules, and the development of insecticide product formulations incorporating New Generation Chemical Insecticide Active Ingredients such as CNIs and Pyrazoles. In this manner, Bayer and ACS competed by, among other things, innovating and developing technology (including patents, trade secrets, and know-how) for use in the production of New Generation Chemical Insecticide Products based on CNI and Pyrazole technologies.

17. The relevant markets for New Generation Chemical Insecticide Active Ingredients are highly concentrated, and would be significantly more concentrated as a result of the merger. Bayer leads the industry in development and production of New Generation Chemical Insecticide Active Ingredients. ACS has the bulk of the remaining development and production. Syngenta is the only other firm with significant development and production of New Generation Chemical Insecticide Active Ingredients.

18. Bayer, ACS, and Syngenta have successfully developed commercial products based on New Generation Chemical Insecticide Active Ingredients for themselves and for other sellers

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of insecticides. Other firms have discovered new molecules that might have efficacy as New Generation Chemical Insecticide Active Ingredients. However, Bayer and ACS are distinguished by their ability to, among other things, take new molecules from the discovery phase to the development of production processes for commercial scale synthesis (as opposed to lab scale) of the New Generation Chemical Insecticide Active Ingredients, insecticide formulation, development of insecticide products, and successful marketing of the resulting proprietary insecticide products. Consequently, Bayer and ACS have not only developed their own New Generation Chemical Insecticide Active Ingredients, but have also been licensed by competitors to develop New Generation Chemical Insecticide Active Ingredients based on molecules discovered by other firms, in recognition of Respondents' unique product development and commercialization skills and abilities relating to New Generation Chemical Insecticide Active Ingredients.

19. Entry into New Generation Chemical Insecticide Active Ingredients and related technologies through development and marketing of commercially viable New Generation Chemical Insecticide Active Ingredients is a lengthy process. Developing New Generation Chemical Insecticide Active Ingredients requires years of chemical synthesis; laboratory and greenhouse testing; formulation; process development; pilot production; pilot trials; field trials; testing for acute, subchronic, and chronic toxicity; testing for carcinogenic and genetic effects, and incidences of birth defects that may be associated with the product; environmental toxicology testing; measurement of plant, animal, soil, water, and air residues; testing for degradation of plant, animal, soil, and water environments; data collection; active ingredient registration and EPA review; construction of production facilities; and use optimization. The difficulty and cost associated with EPA registration of active ingredients is enhanced by the fact that a firm must separately register each application in which the active ingredient will be used.

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20. The effects of the merger, if consummated, may be to substantially lessen competition and tend to create a monopoly in the New Generation Chemical Insecticide Active Ingredients markets, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45. Specifically, the merger would:
- a. eliminate actual, direct, and substantial competition between Bayer and ACS in the relevant markets;
 - b. substantially reduce competition in the markets for New Generation Chemical Insecticide Active Ingredients by giving Respondents significant control of the relevant technology, thereby impeding the ability of other firms to compete with Respondents;
 - c. eliminate potential competition between Bayer and ACS in the markets for New Generation Chemical Insecticide Active Ingredients and the technology used in their manufacture;
 - d. increase barriers to entry into the relevant markets, including enhancing patent barriers in the relevant markets resulting in increased cost of production and increased prices for chemical insecticides;
 - e. reduce innovation competition among developers of the relevant product, including the delay of, or redirection of, research and development projects in chemical insecticide technology, chemical insecticide process technology, and chemical insecticide applications;
 - f. substantially increase the level of concentration in the relevant markets and enhance the probability of coordination; and
 - g. increase Respondents' ability to exercise market power unilaterally in the relevant markets.

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21. The merger described in Paragraph 4, if consummated, would constitute a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

**COUNT TWO: NEW GENERATION CHEMICAL
INSECTICIDE PRODUCTS**

22. Paragraphs 1–21 are incorporated by reference as if fully set forth herein.

23. Additional relevant lines of commerce in which to analyze the effects of the proposed merger are insecticide products based on New Generation Chemical Insecticide Active Ingredients (“New Generation Chemical Insecticide Products”), including but not limited to (i) crop-specific end uses (including the crops identified in paragraphs 25 and 35 of this complaint); (ii) veterinary channel companion animal flea control products; and (iii) non-repellent liquid termiticides. New Generation Chemical Insecticide Products are essential and cost effective in these applications, among others, and there are no economical substitutes for them in these applications.

24. New Generation Chemical Insecticide Products are of increasing importance as the EPA removes older chemical insecticide products from the market due to their harmful effects on human health and the environment. The EPA is currently evaluating the use of older chemical pesticides, particularly insecticide products. Through this process, the EPA plans to remove or limit the use of a significant number of older chemical pesticide products and is encouraging firms to replace older harmful products with less harmful products.

25. CNIs and Pyrazoles are primarily used in insecticide products where their characteristics provide superior performance, such as non-repellent termiticides, flea control for companion animals, turf and ornamental uses, and an array of crop

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applications such as corn, cotton, citrus, cole crops, grapes, vegetables, and seed treatments. In such applications they provide benefits including reductions in the amount of chemical insecticides used, reduced negative impacts on the environment and human health due to lower usage rates, reduced risk to humans and beneficial insects due to the use of safer chemicals in comparison to older chemical insecticides, and superior control of certain undesirable insects. Annual U.S. sales of products with these technologies are approximately \$400 million.

26. Competition in research and development of New Generation Chemical Insecticide Products has led to innovations including reductions in the cost of insecticides, reduced amounts of chemical insecticides used, development of products with reduced risk of harmful environmental and health impacts due to insecticide exposure, and improved product properties and performance. Consequently, innovation relating to these products provides substantial benefits to consumers.

27. New Generation Chemical Insecticide Products include separate relevant product markets based on the specific applications in which the New Generation Chemical Insecticide Products are used. The EPA registration process requires that each New Generation Chemical Insecticide Product be registered separately for each application in which it is used. Therefore, only those New Generation Chemical Insecticide Products registered for a particular application can lawfully be used in that application. Suppliers of New Generation Chemical Insecticide Products price their products at different pricing levels dependent upon the specific application in which they are used. Consequently, New Generation Chemical Insecticide Products may constitute application-specific relevant product markets such as: termiticides, flea control for companion animals, specific crops, or for any application in which New Generation Chemical Insecticide Products are used.

28. For these reasons, New Generation Chemical Insecticide Products and specific applications including, but not limited to,

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crop protection insecticides, non-repellent termiticides, and veterinary channel companion animal flea control products, constitute relevant product markets and “lines of commerce” within the meaning of the antitrust laws.

29. The relevant geographic market and section of the country within which to analyze the likely effects of the proposed transaction is the United States.

30. Bayer is a leading developer and producer of New Generation Chemical Insecticide Products. Bayer competes by, among other things, developing proprietary products for a wide array of chemical insecticide applications.

31. ACS is also a leading developer and producer of New Generation Chemical Insecticide Products. Like Bayer, ACS competes by developing proprietary products for a wide array of chemical insecticide applications.

32. Bayer and ACS are the leading firms in the development and commercialization of New Generation Chemical Insecticide Products, and own significant and important intellectual property estates and rights relating to these products.

33. Bayer and ACS developed New Generation Chemical Insecticide Products after years of product development. That work led to the development of important product formulations incorporating New Generation Chemical Insecticide Active Ingredient technologies such as CNIs and Pyrazoles. In this manner, Bayer and ACS competed by, among other things, innovating and developing new and improved products based on CNI and Pyrazole technologies.

34. The relevant markets for New Generation Chemical Insecticide Products are highly concentrated, and would be significantly more concentrated as a result of the merger. Bayer leads the industry in development, production, and sale of New Generation Chemical Insecticide Products in agricultural and non-

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agricultural applications. Its products account for the majority of insecticide sales based on New Generation Chemical Insecticide Active Ingredients. ACS has the bulk of the remaining sales. Syngenta is the only other firm with significant sales of insecticides based on New Generation Chemical Insecticide Products with sales of less than 10 percent in the United States.

35. Bayer, ACS, and Syngenta are the only firms producing and selling a range of New Generation Chemical Insecticide Products for a range of agricultural applications, including corn, cotton, citrus, cole crops, grapes, vegetables, and seed treatments. Consequently, the number of competitors in these markets will be reduced from three to two. These markets are highly concentrated and will become more highly concentrated as a result of the merger.

36. Bayer and ACS are the only firms currently selling New Generation Chemical Insecticide Products for non-repellent liquid termiticides. The merger therefore would tend to create a monopoly in this line of commerce.

37. Bayer and ACS are the only firms that have developed and sold successful New Generation Chemical Insecticide Active Ingredients for use in veterinary channel companion animal flea control products. The merger therefore would tend to create a monopoly in this line of commerce.

38. Entry into New Generation Chemical Insecticide Products is a lengthy process. Developing a New Generation Chemical Insecticide Product requires access to a New Generation Chemical Insecticide Active Ingredient. Once a New Generation Chemical Insecticide Active Ingredient is developed or licensed, the entrant must develop products and complete EPA review with respect to those products. The difficulty and cost associated with EPA registration is enhanced by the fact that a firm must separately register each application in which the product will be used. Finally, after a product is introduced to the market, it may take several years to gain customer acceptance through demonstrated

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safety, performance, and reliability. Consequently, it would take substantial time and expense for firms to develop New Generation Chemical Insecticide Products that are closely competitive with those of the Respondents, particularly in light of the need to invent around patents controlled by the Respondents.

39. The effects of the merger, if consummated, may be to substantially lessen competition and tend to create a monopoly in each of the relevant markets for New Generation Chemical Insecticide Products in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45. Specifically, the merger would:

- a. eliminate actual, direct, and substantial competition between Bayer and ACS in the relevant markets;
- b. eliminate potential competition between Bayer and ACS in the markets for New Generation Chemical Insecticide Products and the markets for specific crop applications;
- c. increase barriers to entry into the relevant markets, including enhancing patent barriers in the relevant markets resulting in increased cost of production and increased prices for chemical insecticides;
- d. reduce innovation competition among developers of the relevant products, including the delay of, or redirection of, research and development projects in chemical insecticide products and chemical insecticide applications;
- e. substantially increase the level of concentration in the relevant markets and enhance the probability of coordination;
- f. increase Respondents' ability to exercise market power unilaterally in the relevant markets.

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40. The merger described in Paragraph 4, if consummated, would constitute a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

COUNT THREE: POST-EMERGENT GRASS HERBICIDES
FOR SPRING WHEAT

41. Paragraphs 1–40 are incorporated by reference as if fully set forth herein.

42. Another relevant line of commerce in which to analyze the effects of the proposed merger is the research, development, manufacture, and sale of post-emergent grass herbicides for spring wheat (“Spring Wheat Herbicides”). Herbicides are chemicals designed to kill or control grasses or other weeds that interfere with crop production. Separate relevant markets exist distinguished by the types of weeds, *i.e.*, broadleaf or grass, against which the herbicide is economically effective, and the stage of growth of the wheat crop, *i.e.*, pre-emergent or post-emergent, at which the herbicide is both safe for use on the crop and economically effective against the weeds to be controlled. Spring Wheat Herbicides are essential to economic production of wheat, and there are no economic substitutes for Spring Wheat Herbicides. U.S. sales of Spring Wheat Herbicides totaled over \$73 million in 2001.

43. The relevant geographic market and section of the country within which to analyze the likely effects of the proposed transaction in the market for Spring Wheat Herbicides is the United States.

44. The market for Spring Wheat Herbicides is highly concentrated. ACS’s Puma brand, which contains the active ingredient fenoxaprop, has the highest sales dollars among Spring Wheat Herbicides sold within the United States. In 2001, Puma and ACS’s other herbicides accounted for almost 70 percent of the total sales of Spring Wheat Herbicides. In 2001, Bayer introduced

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Everest, which contains the active ingredient flucarbazone. In its first year, Everest accounted for approximately 7 percent of Spring Wheat Herbicide sales.

45. Entry into the Spring Wheat Herbicide market can take seven to ten years. A substantial portion of this time is spent researching active molecules, developing promising molecules and product formulations, and implementing the studies required by the EPA to register the formulated products. The research and development activities include greenhouse and field testing of new active ingredients; developing product formulations of active ingredients; and developing production processes. The studies and resulting data required by the EPA for registration include human toxicology studies and environmental toxicology studies, including the measurement of product residues in plants, animals, soil, water, and air. Once a product is introduced to the market, it may take several years to gain customer acceptance through demonstrated safety, performance, and reliability, over a variety of weather conditions.

46. The effects of the merger, if consummated, may be to substantially lessen competition or tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45. Specifically, the merger would:

- a. eliminate the potential for increased actual, direct, and substantial price competition and cause consumers to pay higher prices for Spring Wheat Herbicides;
- b. increase the merged firm's ability to unilaterally exercise market power in the market for Spring Wheat Herbicides for post-emergent control of grasses, by combining two of the three available substitute products in the market;
- c. increase the likelihood and degree of coordinated interaction between or among competitors in the market for Spring Wheat Herbicides for post-emergent control of grasses.

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47. The merger described in Paragraph 4, if consummated, would constitute a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

COUNT FOUR: COOL WEATHER COTTON DEFOLIANTS

48. Paragraphs 1–47 are incorporated by reference as if fully set forth herein.

49. Another relevant line of commerce in which to assess the effects of the acquisition is Cool Weather Cotton Defoliants. Cotton defoliants are chemical harvest aids designed to remove leaves from cotton plants without drying them, preparing the crop for harvest. Separate markets for cotton harvest aids may be distinguished by method of action, *i.e.*, defoliation versus desiccation, and product efficacy in varying environmental conditions, *i.e.*, cool weather versus warm weather. Cool Weather Cotton Defoliants are essential to economic production of premium grades of cotton and there are no economic substitutes for Cool Weather Cotton Defoliants.

50. The relevant geographic market in which to analyze the effects of the proposed acquisition in the market for Cool Weather Cotton Defoliants is the United States.

51. The relevant market is highly concentrated. Bayer and ACS are the only two suppliers of Cool Weather Cotton Defoliants: Bayer markets DEF and ACS markets Folex. Both products contain the active ingredient Tribufos.

52. Entry into the Cool Weather Cotton Defoliant market would not be likely, timely, and sufficient to prevent anticompetitive effects in the relevant market. Despite the expiration of United States patents for Tribufos, distribution agreements, purchase and supply contracts, and EPA concerns

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relating to the safety of Tribufos have discouraged entry of generic competition.

53. The effect of the merger, if consummated, may be to lessen substantially competition and tend to create a monopoly in the relevant market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45. Specifically, the merger would:

- a. eliminate actual, direct, and substantial competition between Bayer and ACS in the market for Cool Weather Cotton Defoliants in the United States;
- b. substantially increase the level of concentration;
- c. increase the likelihood that Respondents will unilaterally exercise market power in the market for Cool Weather Cotton Defoliants;
- d. increase barriers to entry; and
- e. increase the likelihood that customers of Cool Weather Cotton Defoliants in the United States will be forced to pay higher prices.

54. The merger agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

55. The merger described in Paragraph 4, if consummated, would constitute a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

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WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirtieth day of May, 2002, issues its Complaint against said Respondents.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed acquisition by Respondent Bayer AG of the stock of Aventis CropScience Holding S.A. (“ACS”) from Respondent Aventis S.A. and Respondents having been furnished thereafter with a copy of the draft of the Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of the Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and its Order to Hold Separate and Maintain Assets and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having determined to modify the Decision and Order in certain respects, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

Decision and Order

1. Respondent Bayer AG is a German Aktiengesellschaft organized, existing, and doing business under, and by virtue of, the laws of Germany, with its office and principal place of business located at Werk Leverkusen, 51368, Leverkusen, Germany.
2. Respondent Aventis S.A. is a French société anonyme organized, existing, and doing business under, and by virtue of, the laws of France, with its office and principal place of business located at Avenue de l'Europe, Espace Européen de l'Entreprise, Schiltigheim, France.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents and the proceeding is in the public interest.

ORDER

I.

IT IS HEREBY ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Bayer” means Bayer AG, its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Bayer AG, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Aventis” means Aventis S.A., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Aventis S.A., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “ACS” means Aventis CropScience Holding S.A., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Aventis CropScience Holding S.A., and the

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respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- D. “Commission” means the Federal Trade Commission.
- E. “Acetamiprid” means the chemical compound (E)-N¹-[(6-chloro-3-pyridyl) methyl]-N²-cyano-N¹-methylacetamidine.
- F. “Acetamiprid Assets” means Aventis’s right, title, and interest in and to all assets, tangible or intangible, relating to the Acetamiprid Business, including, but not limited to:
1. All real property (together with appurtenances, licenses, and permits) owned, leased or otherwise held by Aventis;
 2. All personal property owned, leased, or otherwise held by Aventis;
 3. All inventories, stores, and supplies held by, or under the control of Aventis;
 4. All Intellectual Property relating primarily to the Acetamiprid Business owned by or licensed to Aventis, including, but not limited to, that identified in Confidential Appendix A;
 5. All rights of Aventis under any contract (other than multi-product contracts), including but not limited to licenses, leases, customer contracts, supply agreements, and procurement contracts;

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6. All pending and issued governmental approvals, registrations, consents, licenses, permits, waivers, or other authorizations held by Aventis, including foreign equivalents;
7. All rights of Aventis under any warranty and guarantee, express or implied;
8. All items of prepaid expense owned by Aventis; and
9. All separately maintained, and all relevant portions of not separately maintained, books, records, and files held by, or under the control of Aventis.

Provided, however, that the Acetamiprid Assets shall not include Aventis's right, title, and interest in and to (i) any real property (together with appurtenances, licenses, and permits) owned, leased, or otherwise held by Respondents; (ii) office space, fixtures, production equipment, vehicles, storage equipment, handling equipment, packaging equipment, office equipment, inventory equipment or systems, or furniture; (iii) personal property related exclusively to the administration, sales, and distribution operations of Aventis; (iv) management information systems, computer systems, or software that does not relate exclusively to the Acetamiprid Business; and (v) any of the Excepted Acetamiprid Assets that Respondents retain as permitted in Paragraph II.B. of this Order.

- G. “Acetamiprid Business” means Respondent Aventis’s business of researching, developing, registering, formulating, manufacturing, licensing, distributing, marketing, and selling all products containing Acetamiprid, including products in development, in any market anywhere in the world, prior to the Acquisition Date (and such business as conducted by Bayer after the Acquisition Date

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pursuant to this Order and the Order to Hold Separate); provided, however, that if Respondents retain any of the Excepted Acetamiprid Assets as permitted in Paragraph II.B. of this Order, the Acetamiprid Business shall not include the business described in this Paragraph I.G. relating exclusively to any market in Mexico, South America, Central America, or Africa.

- H. “Acetamiprid Agreements” means all agreements between Nippon Soda and Aventis relating to the Acetamiprid Business.
- I. “Acetamiprid Licensed Intellectual Property” means all Intellectual Property relating (but not relating primarily) to the Acetamiprid Business as of the date of divestiture of the Acetamiprid Assets.
- J. “Acquirer” means any Person that acquires any of the Pesticide Assets pursuant to this Order.
- K. “Acquisition” means the proposed acquisition described in (i) the Stock Purchase Agreement dated as of October 2, 2001, among Aventis Agriculture, Hoechst Aktiengesellschaft, and Bayer AG, and (ii) the Stock Purchase Agreement dated as of October 2, 2001, among Schering Aktiengesellschaft, SCIC Holdings LLC, and Bayer AG.
- L. “Acquisition Date” means the date of consummation of the Acquisition.
- M. “Additional Flucarbazone Assets” means Bayer’s right, title, and interest in and to all assets, tangible or intangible, relating to the Olympus Business, including, but not limited to:

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1. All real property (together with appurtenances, licenses, and permits) owned, leased, or otherwise held by Bayer;
2. All personal property owned, leased, or otherwise held by Bayer;
3. The Kansas City Production Assets;
4. All inventories, stores, and supplies held by, or under the control of Bayer;
5. All Intellectual Property owned by or licensed to Bayer;
6. All rights of Bayer under any contract (other than multi-product contracts), including, but not limited to, licenses, leases, customer contracts, supply agreements, and procurement contracts;
7. All pending and issued governmental approvals, registrations, consents, licenses, permits, waivers, or other authorizations held by Bayer, including foreign equivalents;
8. All rights of Bayer under any warranty and guarantee, express or implied;
9. All items of prepaid expense owned by Bayer; and

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10. All separately maintained, and all relevant portions of not separately maintained, books, records, and files held by, or under the control of Bayer.

Provided, however, that the Additional Flucarbazone Assets shall not include Bayer's right, title, and interest in and to (i) any real property (together with appurtenances, licenses, and permits) owned, leased, or otherwise held by Respondents other than the Kansas City Production Assets; (ii) office space, fixtures, vehicles, storage equipment, handling equipment, packaging equipment, office equipment, inventory equipment or systems, or furniture other than that included in the Kansas City Production Assets; (iii) personal property related exclusively to the administration, sales, and distribution operations of Bayer; and (iv) management information systems, computer systems, or software that does not relate exclusively to the Olympus Business and Flucarbazone Business (collectively).

- N. "Amvac Acquisition Agreement" means the Asset Purchase Agreement (including all related agreements, schedules, exhibits, and appendices) between Bayer and Amvac Chemical Corporation, dated April 18, 2002, as amended.
- O. "Amvac Corporation" means Amvac Chemical Corporation, a corporation organized, existing, and doing business under and by virtue of the laws of California, with its office and principal place of business located at 4695 MacArthur Court, Suite 1250, Newport Beach, California.
- P. "Animal Health Uses" means all uses of pharmaceutical, biological, and medicinal products, including in-feed products, intended to enhance the health or performance of any and all species of animals, including livestock and companion animals, excluding humans, but excluding (i) any product with a different intended utility, (ii) nutritional additives, (iii) chemical intermediates, and (iv) the inhalational anaesthetics

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Isoflurane, Halothene, Sevoflurane, and Desoflurane, as defined in the Merial Agreements.

- Q. “Consent Agreement” means the Agreement Containing Consent Orders executed by Respondents and the Commission in this matter.
- R. "Direct Cost" means (i) if in connection with Paragraph IV.E. of this Order, the actual cost of raw materials, direct labor, and reasonably allocated factory overhead in manufacturing an item, or (ii) if in connection with Paragraphs II.F., III.G., IV.F., and V.F. of this Order, the cost of direct material and labor used to provide the relevant service.
- S. “Divestiture Agreement” means any of the acquisition agreements referenced in Paragraphs II.A., III.A., IV.A., and V.A. (or V.C.) of this Order, or any acquisition agreement entered into by the Divestiture Trustee pursuant to Paragraph X of this Order.
- T. “Divestiture Trustee” means the Divestiture Trustee appointed pursuant to Paragraph X of this Order.
- U. “Elbeuf Production Facility” means the Fipronil active ingredient-related production assets located at Elbeuf, France, including, but not limited to, Building 111 and all fixtures, machinery, and equipment located in that building, and all fixtures, machinery, and equipment located in Building 121 dedicated to the production of Fipronil, and rights to shared services (such as utilities, water, and security) necessary for the production of Fipronil.
- V. “Excepted Acetamiprid Assets” means that part of the Acetamiprid Assets relating exclusively to Respondent Aventis’s business of researching, developing, registering, formulating, manufacturing, licensing, distributing, marketing, and selling all products containing Acetamiprid, including products in development, in any market in

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Mexico, South America, Central America, or Africa, prior to the Acquisition Date (and such business activities as conducted by Bayer after the Acquisition Date pursuant to this Order and the Order to Hold Separate).

- W. “Europe” means the geographical area comprising all EU Member States and Norway, Iceland, Liechtenstein, Cyprus, the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Malta, Poland, Slovakia, and Slovenia.
- X. “Fipronil” means the chemical compound (\pm)-5-amino-1-(2, 6-dichloro- α , α , α -trifluoro-p-tolyl)-4-trifluoro-methyl sulfinylpyrazole-3-carbonitrile.
- Y. “Fipronil Acquirer” means the Person that acquires the Fipronil Assets pursuant to this Order.
- Z. “Fipronil Assets” means Aventis’s right, title, and interest in and to all assets, tangible or intangible, relating to the Fipronil Business, including, but not limited to:
 - 1. All real property (together with appurtenances, licenses, and permits) owned, leased, or otherwise held by Aventis;
 - 2. All personal property owned, leased, or otherwise held by Aventis;
 - 3. The Elbeuf Production Facility;
 - 4. All inventories, stores, and supplies held by, or under the control of Aventis;

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5. All Intellectual Property relating primarily to the Fipronil Business owned by or licensed to Aventis, including, but not limited to, that identified in Confidential Appendix B;
6. All rights of Aventis under any contract (other than multi-product contracts), including, but not limited to, licenses, leases, customer contracts, supply agreements, and procurement contracts;
7. All governmental approvals, registrations, consents, licenses, permits, waivers, or other authorizations held by Aventis, including foreign equivalents (except for a co-ownership right of Bayer in the Fipronil technical registration and the underlying data packages to the extent necessary to satisfy Bayer's obligations under the Merial Agreements);
8. All rights of Aventis under any warranty and guarantee, express or implied;
9. All items of prepaid expense owned by Aventis; and
10. All separately maintained, and all relevant portions of not separately maintained, books, records, and files held by, or under the control of, Aventis.

Provided, however, that the Fipronil Assets shall not include Aventis's right, title, and interest in and to (i) any real property (together with appurtenances, licenses, and permits) owned, leased, or otherwise held by Respondents other than the Elbeuf Production Facility; (ii) office space, fixtures, formulation equipment, vehicles, storage equipment, handling equipment, packaging equipment, office equipment, inventory equipment

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or systems, or furniture other than that included in the Elbeuf Production Facility; (iii) personal property related exclusively to the administration, sales, and distribution operations of Aventis; (iv) management information systems, computer systems, or software that does not relate exclusively to the Fipronil Business; (v) the participation of Aventis in the Hangzhou Fipronil Production Joint Venture; (vi) the trademarks Chipco Choice, TopChoice, and, at the option of the Fipronil Acquirer, Firestar; (vii) the Maxforce business, including the trademark Maxforce.

- AA. “Fipronil Business” means Respondent Aventis’s business of researching, developing, registering, formulating, manufacturing, licensing, distributing, marketing, and selling all products containing Fipronil, including products in development, in any market anywhere in the world, prior to the Acquisition Date (and such business as conducted by Bayer after the Acquisition Date pursuant to this Order and the Order to Hold Separate), subject to Merial’s rights relating to Animal Health Uses under the Merial Agreements.
- BB. “Fipronil Licensed Intellectual Property” means all Intellectual Property relating (but not relating primarily) to the Fipronil Business as of the date of divestiture of the Fipronil Assets.
- CC. “Flucarbazone” means the chemical compound 4, 5-dihydro-3-methoxy-4-methyl- 5-oxo-N-[2-(trifluoromethoxy)phenylsulfonyl]-1H-1, 2, 4-triazole-1-carboxamide.
- DD. “Flucarbazone Acquirer” means the Person that acquires the Flucarbazone Assets (and Additional Flucarbazone Assets, if divested) pursuant to this Order.

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- EE. “Flucarbazone Assets” means Bayer’s right, title, and interest in and to all assets, tangible or intangible, relating to the Flucarbazone Business, including, but not limited to:
1. All real property (together with appurtenances, licenses, and permits) owned, leased, or otherwise held by Bayer;
 2. All personal property owned, leased, or otherwise held by Bayer;
 3. All inventories, stores, and supplies held by, or under the control of Bayer;
 4. All Intellectual Property relating primarily to the Flucarbazone Business owned by or licensed to Bayer, including, but not limited to, that described in Confidential Appendix C;
 5. All rights of Bayer under any contract (other than multi-product contracts), including but not limited to licenses, leases, customer contracts, supply agreements, and procurement contracts;
 6. All pending and issued governmental approvals, registrations, consents, licenses, permits, waivers, or other authorizations held by Bayer, including foreign equivalents;
 7. All rights of Bayer under any warranty and guarantee, express or implied;

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8. All items of prepaid expense owned by Bayer; and
9. All separately maintained, and all relevant portions of not separately maintained, books, records, and files held by, or under the control of Bayer.

Provided, however, that the Flucarbazone Assets shall not include Bayer's right, title, and interest in and to (i) any real property (together with appurtenances, licenses, and permits) owned, leased, or otherwise held by Respondents; (ii) office space, fixtures, production equipment, vehicles, storage equipment, handling equipment, packaging equipment, office equipment, inventory equipment or systems, or furniture; (iii) personal property related exclusively to the administration, sales, and distribution operations of Bayer; and (iv) management information systems, computer systems, or software that does not relate exclusively to the Flucarbazone Business.

- FF. "Flucarbazone Business" means Respondent Bayer's business of researching, developing, registering, formulating, manufacturing, licensing, distributing, marketing, and selling all products containing Flucarbazone, including products in development, in any market anywhere in the world.
- GG. "Flucarbazone Licensed Intellectual Property" means all Intellectual Property relating (but not relating primarily) to the Flucarbazone Business as of the date of divestiture of the Flucarbazone Assets.
- HH. "Folex Acquirer" means the Person that acquires the Folex Assets pursuant to this Order.
- II. "Folex Assets" means Aventis's right, title, and interest in and to all assets, tangible or intangible, relating to the Folex Business, including, but not limited to:

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1. All real property (together with appurtenances, licenses, and permits) owned, leased, or otherwise held by Aventis;
2. All personal property owned, leased, or otherwise held by Aventis;
3. All inventories, stores, and supplies held by, or under the control of Aventis;
4. All Intellectual Property relating primarily to the Folex Business owned by or licensed to Aventis, including, but not limited to, that described in Confidential Appendix D;
5. All rights of Aventis under any contract (other than multi-product contracts), including, but not limited to, licenses, leases, customer contracts, supply agreements, and procurement contracts;
6. All pending and issued governmental approvals, registrations, consents, licenses, permits, waivers, or other authorizations held by Aventis, including foreign equivalents;
7. All rights of Aventis under any warranty and guarantee, express or implied;
8. All items of prepaid expense owned by Aventis; and

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9. All separately maintained, and all relevant portions of not separately maintained, books, records, and files held by, or under the control of Aventis.

Provided, however, that the Folex Assets shall not include Aventis's right, title, and interest to (i) any real property (together with appurtenances, licenses, and permits) owned, leased, or otherwise held by Respondents; (ii) office space, fixtures, production equipment, vehicles, storage equipment, handling equipment, packaging equipment, office equipment, inventory equipment or systems, or furniture; (iii) personal property related exclusively to the administration, sales, and distribution operations of Aventis; and (iv) management information systems, computer systems, or software that does not relate exclusively to the Folex Business.

- JJ. "Folex Business" means Respondent Aventis's business of researching, developing, registering, formulating, manufacturing, licensing, distributing, marketing, and selling all products containing Tribufos, including products in development, in any market in the United States, prior to the Acquisition Date (and such business as conducted by Bayer after the Acquisition Date pursuant to this Order and the Order to Hold Separate).
- KK. "Folex Licensed Intellectual Property" means all Intellectual Property relating (but not relating primarily) to the Folex Business as of the date of divestiture of the Folex Assets.
- LL. "Intellectual Property" means, worldwide as of the date of the divestiture of the applicable Pesticide Assets without limitation, (i) all trade names, registered and unregistered trademarks, service marks and applications, domain names, trade dress, copyrights, copyright registrations and applications, in both published works and unpublished works; (ii) all patents, patent applications, and inventions and discoveries that may be patentable; and (iii) all know-how, trade secrets, confidential information, customer lists,

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software, technical information, data, registrations, applications for governmental approvals, processes and inventions, formulae, recipes, methods, and product and packaging specifications. For purposes of Paragraphs II.E., III.D.1., III.D.2., IV.D., and V.E. of this Order, “Intellectual Property” shall not include any trade names, registered and unregistered trademarks, service marks and applications, domain names, and trade dress.

- MM. “Kansas City Production Assets” means the Flucarbazone and Propoxycarbazone active ingredient-related production assets located at Kansas City, including but not limited to, the building housing the Bayer MKH plant, and all fixtures, machinery, and equipment located in that building, dedicated to the production of Flucarbazone and Propoxycarbazone, and rights to all shared services (such as utilities, water, and security) necessary for the production of Flucarbazone and Propoxycarbazone.
- NN. “Merial” means Merial, Limited, a corporation organized, existing, and doing business under and by virtue of the laws of England and Wales, with its office and principal place of business located at Merial Ltd., Harlow Business Park, Harlow Essex CM 195 TG, England.
- OO. “Merial Agreements” means, as amended, (i) the Fipronil and Existing Products License Agreement between ACS and Merial dated 23 May, 1997; (ii) the Fipronil Supply Agreement between ACS and Merial dated 23 May, 1997; and (iii) the Research and License Agreement for Future Products between ACS SA and Merial dated 23 May, 1997.
- PP. “Monitor” means the Monitor appointed pursuant to Paragraph IX of this Order.
- QQ. “Nippon Soda” means Nippon Soda Co. Ltd., a company organized and existing under the laws of Japan and having

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its principal place of business at 2-1, Ohtemachi 2 chome, Chiyoda-ku, Tokyo, Japan.

- RR. “Non-Agricultural Use” means the use of a product that is represented, sold, used, or intended to be used to prevent, destroy, repel, or mitigate a pest on structures, structural materials, or the environment (other than land used for professional agriculture) including, but not limited to, use in turf and ornamental, home and garden, professional pest control, vector control, locust control, forestry, public health, and industrial vegetation management.
- SS. “Non-Public Pesticide Information” means any information relating to the Pesticide Assets or the Pesticide Businesses obtained in any manner by Respondents, except for any information that Respondents demonstrate (i) was or becomes generally available to the public other than as a result of a disclosure by Respondents or (ii) was available, or becomes available, to Respondents on a non-confidential basis, but only if, to the knowledge of Respondents, the source of such information is not in breach of a contractual, legal, fiduciary, or other obligation to maintain the confidentiality of the information.
- TT. “Olympus Business” means Respondent Bayer’s business of researching, developing, registering, formulating, manufacturing, licensing, distributing, marketing, and selling all products containing Propoxycarbazone, including products in development, in any market anywhere in the world, except for Europe.
- UU. “Olympus Licensed Intellectual Property” means all Intellectual Property relating (but not relating primarily) to the Olympus Business as of the date of divestiture of the Additional Flucarbazone Assets.

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- VV. “Order to Hold Separate” means the Order to Hold Separate and Maintain Assets issued by the Commission in this matter.
- WW. “Person” means any individual, partnership, firm, corporation, association, trust, unincorporated organization or other entity.
- XX. “Pesticide Assets” means the Acetamiprid Assets, Fipronil Assets, Flucarbazone Assets, and Folex Assets, and if divested by the Divestiture Trustee pursuant to Paragraphs X, XI, or XII of this Order, the Thiacloprid Assets and Additional Flucarbazone Assets.
- YY. “Pesticide Businesses” means the Acetamiprid Business, Fipronil Business, Flucarbazone Business, and Folex Business, and if divested by the Divestiture Trustee pursuant to Paragraphs X, XI, or XII of this Order, the Thiacloprid Business and Olympus Business.
- ZZ. “Pesticide Licensed Intellectual Property” means the Acetamiprid Licensed Intellectual Property, Fipronil Licensed Intellectual Property, Flucarbazone Licensed Intellectual Property, and Folex Licensed Intellectual Property, and if divested by the Divestiture Trustee pursuant to Paragraphs X, XI, or XII of this Order, the Thiacloprid Licensed Intellectual Property and the Olympus Licensed Intellectual Property.
- AAA. “Propoxycarbazone” means the chemical compound 2-[[[(4, 5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1, 2, 4-triazol-1-yl)methylcarbonyl]amino]sulfonyl]-benzoate].
- BBB. “Respondents” means Bayer and Aventis, individually and collectively.
- CCC. “Technical Assistance” means providing expert advice, assistance, and training relating to operation of any of the

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Pesticide Businesses, including, but not limited to, providing administrative services, reasonable and timely access to Respondents' manufacturing facilities for the purpose of inspecting manufacturing operations, and reasonable access to the Pesticide Licensed Intellectual Property and to personnel familiar with such intellectual property.

- DDD. "Thiacloprid" means the chemical compound [3-[6-chloro-3-pyridinyl)methyl]2-thiazolidinylidene]-cyanamide.
- EEE. "Thiacloprid Acquirer" means the Person that acquires the Thiacloprid Assets pursuant to this Order.
- FFF. "Thiacloprid Assets" means Bayer's right, title, and interest in and to all assets, tangible or intangible, relating to the Thiacloprid Business, including, but not limited to:
1. All real property (together with appurtenances, licenses, and permits) owned, leased, or otherwise held by Bayer;
 2. All personal property owned, leased, or otherwise held by Bayer;
 3. All inventories, stores, and supplies held by, or under the control of Bayer;
 4. All Intellectual Property relating primarily to the Thiacloprid Business owned by or licensed to Bayer;
 5. All rights of Bayer under any contract (other than multi-product contracts), including, but not limited to, licenses,

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leases, customer contracts, supply agreements, and procurement contracts;

6. All pending and issued governmental approvals, registrations, consents, licenses, permits, waivers, or other authorizations held by Bayer, including foreign equivalents (except for a co-ownership right of Bayer in the Thiacloprid technical registration);
7. All rights of Bayer under any warranty and guarantee, express or implied;
8. All items of prepaid expense owned by Bayer; and
9. All separately maintained, and all relevant portions of not separately maintained, books, records, and files held by, or under the control of Bayer.

Provided, however, that the Thiacloprid Assets shall not include Bayer's right, title, and interest to (i) any assets that the Thiacloprid Acquirer does not want to acquire, provided that the Commission approves the divestiture and the manner of divestiture without such assets; (ii) personal property related exclusively to the administration, sales, and distribution operations of Bayer; and (iii) management information systems, computer systems, or software that does not relate exclusively to the Thiacloprid Business.

GGG. "Thiacloprid Business" means Respondent Bayer's business of researching, developing, registering, formulating, manufacturing, licensing, distributing, marketing, and selling all products containing Thiacloprid, including products in development, in any market anywhere in the world.

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HHH. “Tribufos” means the chemical compound S,S,S-Tributyl phosphorotriothioate.

II.**IT IS FURTHER ORDERED** that:

- A. Bayer shall divest the Acetamiprid Assets at no minimum price, absolutely and in good faith, no later than 180 days from the date the Commission accepts the Consent Agreement for public comment, to a Person that receives the prior approval of the Commission and in a manner, and pursuant to an acquisition agreement, that receives the prior approval of the Commission.
- B. Respondents shall use their best efforts to obtain the consent of Nippon Soda to the assignment of the Acetamiprid Agreements. If Nippon Soda does not consent to the assignment of the Acetamiprid Agreements relating exclusively to the Acetamiprid Business in Mexico, South America, Central America, and Africa, Bayer shall not be required to divest the Excepted Acetamiprid Assets; provided, however, that nothing in this Paragraph II.B. shall relieve Bayer of the obligation to divest the Acetamiprid Assets (with or without the Excepted Acetamiprid Assets as permitted by this Paragraph II.B.) pursuant to this Paragraph II no later than 180 days from the date the Commission accepts the Consent Agreement for public comment.
- C. Bayer shall comply with all terms of the acquisition agreement described in Paragraph II.A. of this Order, and any breach by Bayer of any term of the acquisition agreement shall constitute a violation of this Order. In the event any term of the acquisition agreement varies from or contradicts any term in Paragraphs I through XIX of this Order (“Order Term”) to the extent Bayer cannot fully comply with both terms, the Order Term shall determine Bayer’s obligations under this Order.

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- D. No later than the date Bayer divests the Acetamiprid Assets, Bayer shall grant to the Acetamiprid Acquirer (pursuant to one or more agreements that receive the prior approval of the Commission):
1. A worldwide, royalty-free, perpetual, irrevocable, sublicenseable, transferable license to Bayer's rights to the Acetamiprid Licensed Intellectual Property to invent, develop, patent, make, have made, use, sell, offer for sale and import any product (except for products containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date) anywhere in the world. Such license shall be (i) exclusive (even as to Bayer) for any product containing an existing patented molecule included in the Acetamiprid Assets or any patented molecule invented or acquired by the Acetamiprid Acquirer after the Acquisition Date and (ii) non-exclusive for any other product.
 2. An irrevocable, worldwide, perpetual immunity from suit by Bayer based on claims of infringement under all of Respondents' Intellectual Property for the developing, making, having made, using, having used, selling, offering for sale, having sold and importing of any products containing Acetamiprid for any use anywhere in the world (except for products containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date). Such immunity shall extend to any person deriving its authority from the Acetamiprid Acquirer.
- E. Nothing in this Order shall prevent Bayer from entering into an agreement with the Acetamiprid Acquirer in which the Acetamiprid Acquirer shall grant to Bayer a worldwide,

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royalty-free, perpetual, irrevocable, sublicenseable, transferable license to the Acetamiprid Acquirer's rights to any Intellectual Property included in the Acetamiprid Assets that does not relate exclusively to the Acetamiprid Business to develop, patent, make, have made, use, sell, offer for sale and import any product (except for products containing (x) an existing patented molecule included in the Acetamiprid Assets, or (y) any patented molecule invented or acquired by the Acetamiprid Acquirer after the Acquisition Date, without the consent of the Acetamiprid Acquirer) anywhere in the world. Such license (i) may be exclusive (even as to the Acetamiprid Acquirer) for any product containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date and (ii) shall be non-exclusive for any other product.

- F. Upon the request of the Acetamiprid Acquirer made at the time of divestiture of the Acetamiprid Assets, pursuant to an agreement that receives the prior approval of the Commission, Bayer shall provide Technical Assistance to the Acetamiprid Acquirer, for a period not to exceed 12 months from the date Bayer divests the Acetamiprid Assets, sufficient to enable the Acetamiprid Acquirer to operate the Acetamiprid Business in substantially the same manner as that employed by Respondents; provided, however, that Bayer shall not (i) require the Acetamiprid Acquirer to pay compensation for Technical Assistance that exceeds the Direct Cost of providing such goods and services, (ii) terminate its obligation to provide Technical Assistance because of a material breach by the Acetamiprid Acquirer of any agreement to provide such assistance, in the absence of a final order of a court of competent jurisdiction, or (iii) seek to limit the damages (such as indirect, special, and consequential damages) which the Acetamiprid Acquirer would be entitled to receive in the event of Bayer's breach of any agreement to provide Technical Assistance.

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- G. The purpose of the divestiture of the Acetamiprid Assets and of the related obligations is to ensure the continued use of the assets in the same business in which the Acetamiprid Assets were engaged by Respondents at the time of the announcement of the proposed Acquisition, including the development of new chemical insecticides and applications and the pursuit of registrations and approvals for new products and to remedy the lessening of competition alleged in the Commission's complaint.

III.

IT IS FURTHER ORDERED that:

- A. Bayer shall divest the Fipronil Assets at no minimum price, absolutely and in good faith, no later than 180 days from the date the Commission accepts the Consent Agreement for public comment, to a Person that receives the prior approval of the Commission and in a manner, and pursuant to an acquisition agreement, that receives the prior approval of the Commission.
- B. Bayer shall comply with all terms of the acquisition agreement described in Paragraph III.A. of this Order, and any breach by Bayer of any term of the acquisition agreement shall constitute a violation of this Order. In the event any term of the acquisition agreement varies from or contradicts any term in Paragraphs I through XIX of this Order ("Order Term") to the extent Bayer cannot fully comply with both terms, the Order Term shall determine Bayer's obligations under this Order.
- C. No later than the date Bayer divests the Fipronil Assets, Bayer shall grant to the Fipronil Acquirer (pursuant to one or more agreements that receive the prior approval of the Commission):
1. A worldwide, royalty-free, perpetual, sublicenseable, irrevocable, transferable license to Bayer's rights to the

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Fipronil Licensed Intellectual Property to invent, develop, patent, make, have made, use, sell, offer for sale, and import any product (except for products containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date) anywhere in the world. Such license shall be (i) exclusive (even as to Bayer) for any product containing an existing patented molecule included in the Fipronil Assets or any patented molecule invented or acquired by the Fipronil Acquirer after the Acquisition Date and (ii) non-exclusive for any other product.

2. An irrevocable, worldwide, perpetual immunity from suit by Bayer based on claims of infringement under all of Respondents' Intellectual Property for the developing, making, having made, using, having used, selling, offering for sale, having sold, and importing of any product containing Fipronil for any use anywhere in the world (except for products containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date). Such immunity shall extend to any person deriving its authority from the Fipronil Acquirer.
- D. Nothing in this Order shall prevent Bayer from entering into an agreement with the Fipronil Acquirer in which the Fipronil Acquirer shall grant to Bayer:
 1. A worldwide, royalty-free, perpetual, irrevocable, sublicenseable, transferable license to the Fipronil Acquirer's rights to any Intellectual Property included in the Fipronil Assets that does not relate exclusively to the Fipronil Business to develop, patent, make, have made, use, sell, offer for sale, and import any product (except for products containing (x) an existing patented molecule included in the Fipronil Assets, subject to Paragraph III.D.2.

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of this Order, or (y) any patented molecule invented or acquired by the Fipronil Acquirer after the Acquisition Date, without the consent of the Fipronil Acquirer) anywhere in the world. Such license (i) may be exclusive (even as to the Fipronil Acquirer) for any product containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date and (ii) shall be non-exclusive for any other product.

2. A worldwide, royalty-free, exclusive (except as to the Fipronil Acquirer), perpetual, irrevocable, sublicenseable, transferable license to the Fipronil Acquirer's rights to any Intellectual Property included in the Fipronil Assets to develop, patent, make, have made, use, sell, offer for sale, and import any product containing Fipronil for Non-Agricultural Use anywhere in the world; provided, however, that Bayer may obtain such license only if it would not impair the viability of the Fipronil Acquirer, and the Commission approves the divestiture of the Fipronil Assets with such a license.
- E. Nothing in this Order shall prevent Bayer from entering into a supply agreement with the Fipronil Acquirer (i) to supply Fipronil to Bayer on cost-plus terms in amounts necessary to cover Bayer's needs for Fipronil for Non-Agricultural Use for up to two years, which term may be extended, subject to Commission approval, and (ii) to supply Fipronil intermediates to Bayer on cost-plus terms in amounts necessary to cover Bayer's needs until expiration of any and all patents covering such intermediates.
- F. Respondents shall use their best efforts to obtain the necessary consents to assign to the Fipronil Acquirer their rights and obligations in (i) the Merial Agreements; (ii) the Scotts Fipronil Supply Agreement dated September 30, 1998, and the Scotts Research Agreement (at least to the extent relating to

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Fipronil-related research), (iii) the Amended and Restated Fipronil License Agreement with Clorox dated January 31, 2002, (iv) the U.S. Licence Agreement with TechPac dated December 13, 1999 and related agreements, and (v) the Sumitomo Fipronil Supply Agreement dated April 7, 1998; provided, however, that if Respondents are unable to obtain such consents, Bayer may enter into an agreement, subject to prior approval of the Commission, with the Fipronil Acquirer to obtain a supply of Fipronil to enable Bayer to fulfill its obligations under the supply agreements described in this Paragraph III.F.

- G. Upon the request of the Fipronil Acquirer made at the time of divestiture of the Fipronil Assets, pursuant to an agreement that receives the prior approval of the Commission, Bayer shall provide Technical Assistance to the Fipronil Acquirer, for a period not to exceed 12 months from the date Bayer divests the Fipronil Assets, sufficient to enable the Fipronil Acquirer to operate the Fipronil Business in substantially the same manner as that employed by Respondents; provided, however, that Bayer shall not (i) require the Fipronil Acquirer to pay compensation for Technical Assistance that exceeds the Direct Cost of providing such goods and services, (ii) terminate its obligation to provide Technical Assistance because of a material breach by the Fipronil Acquirer of any agreement to provide such assistance, in the absence of a final order of a court of competent jurisdiction, or (iii) seek to limit the damages (such as indirect, special, and consequential damages) which the Fipronil Acquirer would be entitled to receive in the event of Bayer's breach of any agreement to provide Technical Assistance.
- H. The purpose of the divestiture of the Fipronil Assets and of the related obligations is to ensure the continued use of the assets in the same business in which the Fipronil Assets were engaged by Respondents at the time of the announcement of the proposed Acquisition, including the

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development of new chemical insecticides and applications and the pursuit of registrations and approvals for new products and to remedy the lessening of competition alleged in the Commission's complaint.

IV.

IT IS FURTHER ORDERED that:

- A. Bayer shall divest the Flucarbazone Assets at no minimum price, absolutely and in good faith, no later than 180 days from the date the Commission accepts the Consent Agreement for public comment, to a Person that receives the prior approval of the Commission and in a manner, and pursuant to an acquisition agreement, that receives the prior approval of the Commission.
- B. Bayer shall comply with all terms of the acquisition agreement described in Paragraph IV.A. of this Order, and any breach by Respondents of any term of the acquisition agreement shall constitute a violation of this Order. In the event any term of the acquisition agreement varies from or contradicts any term in Paragraphs I through XIX of this Order ("Order Term") to the extent Bayer cannot fully comply with both terms, the Order Term shall determine Bayer's obligations under this Order.
- C. No later than the date Bayer divests the Flucarbazone Assets, Bayer shall grant to the Flucarbazone Acquirer (pursuant to one or more agreements that receive the prior approval of the Commission):
 1. A worldwide, royalty-free, perpetual, sublicenseable, irrevocable, transferable license to Bayer's rights to the Flucarbazone Licensed Intellectual Property to invent, develop, patent, make, have made, use, sell, offer for sale and import any product (except for products containing an

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existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date) anywhere in the world. Such license shall be (i) exclusive (even as to Bayer) for any product containing an existing patented molecule included in the Flucarbazone Assets or any patented molecule invented or acquired by the Flucarbazone Acquirer and (ii) non-exclusive for any other product.

2. An irrevocable, worldwide, perpetual immunity from suit by Bayer based on claims of infringement under all of Respondents' Intellectual Property for the developing, making, having made, using, having used, selling, offering for sale, having sold, and importing of any product containing Flucarbazone for any use anywhere in the world (except for products containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date). Such immunity shall extend to any person deriving its authority from the Flucarbazone Acquirer.
- D. Nothing in this Order shall prevent Bayer from entering into an agreement with the Flucarbazone Acquirer in which the Flucarbazone Acquirer shall grant to Bayer a worldwide, royalty-free, perpetual, irrevocable, sublicenseable, transferable license to the Flucarbazone Acquirer's rights to any Intellectual Property included in the Flucarbazone Assets that does not relate exclusively to the Flucarbazone Business to develop, patent, make, have made, use, sell, offer for sale, and import any product (except for products containing (x) an existing patented molecule included in the Flucarbazone Assets, or (y) any patented molecule invented or acquired by the Flucarbazone Acquirer after the Acquisition Date, without the consent of the Flucarbazone Acquirer) anywhere in the world. Such license (i) may be exclusive (even as to the Flucarbazone Acquirer) for any

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product containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date and (ii) shall be non-exclusive for any other product.

- E. Upon the request of the Flucarbazone Acquirer made at the time of divestiture of the Flucarbazone Assets, pursuant to an agreement that receives the prior approval of the Commission, Bayer shall, for a period not to exceed 30 months from the date Bayer divests the Flucarbazone Assets, provide a supply of products containing Flucarbazone, including any such products to be developed (hereinafter “Flucarbazone Products”) to the Flucarbazone Acquirer:
 1. Bayer shall provide quantities of Flucarbazone Products sufficient to enable the Flucarbazone Acquirer (i) to satisfy customer demand at substantially the same levels as Bayer prior to the Acquisition Date, (ii) to satisfy changes in customer demand that occur in the ordinary course of business, (iii) to meet customer delivery dates, and (iv) to manage the transition to an alternative means of supply upon termination of Bayer’s obligations under Paragraph IV.E. of this Order.
 2. Bayer shall (i) manufacture Flucarbazone Products that are of substantially the same quality as that achieved by Bayer prior to the Acquisition Date, (ii) manufacture the Flucarbazone Products in substantially the same manner as employed by Bayer prior to the Acquisition Date, and (iii) use its best efforts to implement any improvement in the manufacturing process of the Flucarbazone Products developed in the ordinary course of business or as a result of the Acquisition.

Provided, however, that Bayer shall not (i) require the Flucarbazone Acquirer to pay compensation for supplying

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Flucarbazone Products that exceeds the Direct Cost of providing goods and services, (ii) terminate its obligation to supply Flucarbazone Products because of a material breach by the Flucarbazone Acquirer of any agreement to provide Flucarbazone Products, in the absence of a final order of a court of competent jurisdiction, or (iii) seek to limit the damages (such as indirect, special, and consequential damages) which the Flucarbazone Acquirer would be entitled to receive in the event of Bayer's breach of any agreement to supply Flucarbazone Products.

- F. Upon the request of the Flucarbazone Acquirer at the time of divestiture of the Flucarbazone Assets, pursuant to an agreement that receives the prior approval of the Commission, Bayer shall provide Technical Assistance to the Flucarbazone Acquirer, for a period not to exceed 30 months from the date Bayer divests the Flucarbazone Assets, sufficient to enable the Flucarbazone Acquirer to operate the Flucarbazone Business in substantially the same manner as that employed by Bayer; provided, however, that Bayer shall not (i) require the Flucarbazone Acquirer to pay compensation for Technical Assistance that exceeds the Direct Cost of providing such goods and services, (ii) terminate its obligation to provide Technical Assistance because of a material breach by the Flucarbazone Acquirer of any agreement to provide such assistance, in the absence of a final order of a court of competent jurisdiction, or (iii) seek to limit the damages (such as indirect, special, and consequential damages) which the Flucarbazone Acquirer would be entitled to receive in the event of Bayer's breach of any agreement to provide Technical Assistance.
- G. The purpose of the divestiture of the Flucarbazone Assets and of the related obligations is to ensure the continued use of the assets in the same businesses in which the Flucarbazone Assets were engaged by Respondents at the time of the announcement of the proposed Acquisition, including the development of new chemical herbicides and

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applications and the pursuit of registrations and approvals for new products and to remedy the lessening of competition alleged in the Commission's complaint.

V.

IT IS FURTHER ORDERED that:

- A. Bayer shall divest the Folex Assets, absolutely and in good faith, to Amvac Corporation pursuant to the Amvac Acquisition Agreement, no later than twenty days from the date the Commission accepts the Consent Agreement for public comment.
- B. The Amvac Acquisition Agreement is incorporated by reference and made a part of this Order as Confidential Appendix E. Bayer shall comply with all terms of the Amvac Acquisition Agreement, and any breach by Bayer of any term of the Amvac Acquisition Agreement shall constitute a violation of this Order. In the event any term of the Amvac Acquisition Agreement varies from or contradicts any term in Paragraphs I through XIX of this Order ("Order Term") to the extent that Bayer cannot fully comply with both terms, the Order Term shall determine Bayer's obligations under this Order.
- C. If, at the time the Commission determines to make this Order final, the Commission determines that Amvac Corporation is not acceptable as the Folex Acquirer, or that the Amvac Acquisition Agreement is not an acceptable manner of divestiture, and so notifies Bayer, Bayer shall immediately terminate or rescind the Amvac Acquisition Agreement and divest the Folex Assets:
 1. At no minimum price, absolutely and in good faith, no later than 180 days from the date this Order becomes final, to a Person that receives the prior approval of the Commission

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and in a manner, and pursuant to an acquisition agreement, that receives the prior approval of the Commission.

2. Bayer shall comply with all terms of the acquisition agreement described in Paragraph V.C.1. of this Order, and any breach by Bayer of any term of the acquisition agreement shall constitute a violation of this Order. In the event any term of the acquisition agreement varies from or contradicts any term in Paragraphs I through XIX of this Order (“Order Term”) to the extent Bayer cannot fully comply with both terms, the Order Term shall govern Bayer’s obligations under this Order.
- D. No later than the date Bayer divests the Folex Assets, Bayer shall grant to the Folex Acquirer (pursuant to one or more agreements that receive the prior approval of the Commission):
 1. A worldwide, royalty-free, non-exclusive, perpetual, sublicenseable, irrevocable, transferable license to Bayer’s rights to the Folex Licensed Intellectual Property to invent, develop, patent, make, have made, use, sell, offer for sale, and import any product (except for products containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date) anywhere in the world. Such license shall be (i) exclusive (even as to Bayer) for any product containing an existing patented molecule included in the Folex Assets or any patented molecule invented or acquired by the Folex Acquirer and (ii) non-exclusive for any other product.
 2. An irrevocable, worldwide, perpetual immunity from suit by Bayer based on claims of infringement under all of Respondents’ Intellectual Property for the developing,

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making, having made, using, having used, selling, offering for sale, having sold, and importing of any product containing Tribufos for any use anywhere in the world (except for products containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date). Such immunity shall extend to any person deriving its authority from the Folex Acquirer.

- E. Nothing in this Order shall prevent Bayer from entering into an agreement with the Folex Acquirer in which the Folex Acquirer shall grant to Bayer a worldwide, royalty-free, non-exclusive, perpetual, irrevocable, sublicenseable, transferable license to the Folex Acquirer's rights to any Intellectual Property included in the Folex Assets that does not relate exclusively to the Folex Business to develop, patent, make, have made, use, sell, offer for sale, and import any product (except for products containing (x) an existing patented molecule included in the Folex Assets, or (y) any patented molecule invented or acquired by the Folex Acquirer after the Acquisition Date, without the consent of the Folex Acquirer) anywhere in the world. Such license (i) may be exclusive (even as to the Folex Acquirer) for any product containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date and (ii) shall be non-exclusive for any other product.
- F. Upon the request of the Folex Acquirer made at the time of divestiture of the Folex Assets, pursuant to an agreement that receives the prior approval of the Commission, Respondents shall provide Technical Assistance to the Folex Acquirer, for a period not to exceed 6 months from the date Bayer divests the Folex Assets, sufficient to enable the Folex Acquirer to operate the Folex Business in substantially the same manner as that employed by Aventis; provided, however, that Bayer shall not (i) require the Folex Acquirer to pay compensation for Technical Assistance that exceeds the Direct Cost of providing

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such goods and services, (ii) terminate its obligation to provide Technical Assistance because of a material breach by the Folex Acquirer of any agreement to provide such assistance, in the absence of a final order of a court of competent jurisdiction, or (iii) seek to limit the damages (such as indirect, special, and consequential damages) which the Folex Acquirer would be entitled to receive in the event of Bayer's breach of any agreement to provide Technical Assistance.

- G. Bayer shall not enter into any agreement with the Folex Acquirer that prohibits the Folex Acquirer from manufacturing any unmixed or mixed tribufos product, including any such product to be developed, or from arranging for a third-party to manufacture such tribufos product.
- H. The purpose of the divestiture of the Folex Assets and of the related obligations is to ensure the continued use of the assets in the same businesses in which the Folex Assets were engaged by Respondents at the time of the announcement of the proposed Acquisition, including the development of new defoliants and applications and the pursuit of registrations and approvals for new products and to remedy the lessening of competition alleged in the Commission's complaint.

VI.

IT IS FURTHER ORDERED that Bayer shall allow each Acquirer an opportunity to enter into an employment contract with any employees of Respondents identified by agreement between Respondents and the Acquirer and made a part of the relevant Divestiture Agreement (hereinafter "Pesticide Employees"):

- A. No later than thirty days before the date the applicable Pesticide Assets are divested, Respondents shall (i) provide to the Acquirer a list of all applicable Pesticide Employees, (ii) allow the Acquirer an opportunity to interview such

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Pesticide Employees, and (iii) allow the Acquirer to inspect the personnel files and other documentation relating to such Pesticide Employees, to the extent permissible under applicable laws.

- B. Respondents shall (i) not offer any incentive to any Pesticide Employee to decline employment with any Acquirer, (ii) remove any contractual impediments with Respondents that may deter any Pesticide Employee from accepting employment with any Acquirer, including, but not limited to, any non-compete or confidentiality provisions of employment or other contracts with Respondents that would affect the ability of the Pesticide Employee to be employed by the Acquirer, and (iii) not interfere with the employment by any Acquirer of any Pesticide Employee.
- C. Respondents shall (i) vest all current and accrued pension benefits as of the date of transition of employment with any Acquirer for any Pesticide Employees who accept an offer of employment from the Acquirer no later than thirty days from the date Respondents divest the applicable Pesticide Assets and (ii) pay a bonus to any Key Employee (hereinafter defined) who accepts an offer of employment from any Acquirer no later than thirty days from the date Respondents divest the applicable Pesticide Assets, pursuant to the terms set forth in Confidential Appendix F attached to this Order.
- D. For a period of one year from the date this Order becomes final, Respondents shall not, directly or indirectly, hire or enter into any arrangement for the services of any Pesticide Employee employed by any Acquirer, unless such Pesticide Employee's employment has been terminated by the Acquirer without the consent of the Pesticide Employee.

For purposes of this Paragraph VI and Confidential Appendix F, "Key Employee" means any Pesticide Employee identified by agreement between Respondents and any Acquirer and made a part of the relevant Divestiture Agreement.

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VII.

IT IS FURTHER ORDERED that:

- A. Except in the course of performing their obligations under any Divestiture Agreement or this Order, Respondents shall not (i) provide, disclose, or otherwise make available any Non-Public Pesticide Information to any Person or (ii) use any Non-Public Pesticide Information for any reason or purpose.
- B. Respondents shall disclose Non-Public Pesticide Information (i) only to those Persons who require such information for the purposes permitted under Paragraph VII.A. of this Order, (ii) only to the extent such part of the Non-Public Pesticide Information is so required, and (iii) only to those Persons who agree in writing to maintain the confidentiality of such information.
- C. Respondents shall enforce the terms of this Paragraph VII as to any Person and take such action as is necessary to cause each such Person to comply with the terms of this Paragraph VII, including training and all other actions that Respondents would take to protect their own trade secrets and proprietary information.

VIII.

IT IS FURTHER ORDERED that Bayer shall take such actions as are necessary to maintain the viability of the Pesticide Licensed Intellectual Property, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Pesticide Licensed Intellectual Property.

IX.

IT IS FURTHER ORDERED that:

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- A. RICHARD GILMORE (“Monitor”) is hereby appointed to monitor Respondents’ compliance with Paragraphs I through XIX of this Order.
- B. Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
 - 1. The Monitor shall have the power and authority to monitor Respondents’ compliance with the terms of this Order and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor pursuant to the terms of this Order and in a manner consistent with the purposes of this Order.
 - 2. Within ten days after it signs the Consent Agreement, Respondent shall execute an agreement that, subject to the approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent’s compliance with the terms of this Order in a manner consistent with the purposes of this Order. If requested by Respondents, the Monitor shall sign a confidentiality agreement prohibiting the use, or disclosure to anyone other than the Commission, of any competitively sensitive or proprietary information gained as a result of his or her role as Monitor.
 - 3. The Monitor’s power and duties under this Paragraph IX shall terminate sixty days after the Monitor has completed his or her final report pursuant to Paragraph IX.B.8.(ii), or at such other time as directed by the Commission.
 - 4. The Monitor shall have full and complete access to Respondents’ books, records, documents, personnel,

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facilities, and technical information relating to compliance with this Order, and to any other relevant information, as the Monitor may reasonably request. Respondents shall cooperate with any reasonable request of the Monitor. Respondents shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with this Order.

5. The Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for his or her services, subject to the approval of the Commission.
6. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from the Monitor's gross negligence or wilful misconduct. For purposes of this Paragraph IX.B.6., the term "Monitor" shall include all Persons retained by the Monitor pursuant to Paragraph IX.B.5. of this Order.
7. If at any time the Commission determines that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve, the Commission may appoint a

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substitute to serve as Monitor. The Commission shall select a substitute Monitor subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Monitor within ten days after notice from the staff of the Commission to Respondent of the identity of any proposed substitute Monitor, Respondent shall be deemed to have consented to the selection of the proposed substitute. Respondent shall execute the agreement required by Paragraph IX.B.2. of this Order within ten days after the Commission appoints a substitute Monitor. The substitute Monitor shall serve according to the terms and conditions of this Paragraph IX.

8. The Monitor shall report in writing to the Commission (i) every sixty days from the date this Order becomes final, (ii) no later than thirty days from the date Respondents have completed all obligations required by Paragraphs II through V of this Order, and (iii) at any other time as requested by the staff of the Commission, concerning Respondents' compliance with this Order.
- C. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.

X.

IT IS FURTHER ORDERED that:

- A. If Bayer has not divested, absolutely and in good faith any of the Acetamiprid Assets, Fipronil Assets, Flucarbazone Assets, or Folex Assets within the time and in the manner required by Paragraphs II through V of this Order, the Commission may at any time appoint one or more Persons

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as Divestiture Trustee to divest such assets to an acquirer and to execute a Divestiture Agreement that satisfies the requirements and purposes of this Order; provided, however, that if Bayer fails to divest (i) the Flucarbazone Assets, within the time and in the manner required by Paragraph IV of this Order, the Divestiture Trustee shall divest the Flucarbazone Assets and the Additional Flucarbazone Assets (to a single Acquirer) or (ii) the Acetamiprid Assets, within the time and in the manner required by Paragraph II of this Order, the Divestiture Trustee may divest either the Thiacloprid Assets or the Acetamiprid Assets.

- B. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph X shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondents to comply with this Order.
- C. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph X, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. The Commission shall select the Divestiture Trustee, subject to the consent of the Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures and may be the same Person as

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the Monitor appointed pursuant to Paragraph IX of this Order. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten business days after receipt of written notice from the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

2. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to accomplish the divestiture for which he or she has been appointed pursuant to the terms of this Order and in a manner consistent with the purposes of this Order and to enter into a Divestiture Agreement with any Acquirer.
3. Within ten days after appointment of the Divestiture Trustee, Respondents shall execute an agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed Divestiture Trustee, of the court, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to accomplish the divestiture for which he or she has been appointed.
4. The Divestiture Trustee shall have twelve months from the date the Commission approves the agreement described in Paragraph X.C.3. of this Order to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve-month period the Divestiture Trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court appointed Divestiture Trustee, by the court; provided,

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however, the Commission may extend this period only two times.

5. The Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the assets to be divested, and any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may reasonably request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
6. The Divestiture Trustee shall use his or her best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, but shall divest expeditiously at no minimum price. The divestiture shall be made only to an Acquirer that receives the prior approval of the Commission, and the divestiture shall be accomplished only in a manner that receives the prior approval of the Commission; provided, however, if the Divestiture Trustee receives bona fide offers, for a particular asset, from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity or entities selected by Respondents from among those approved by the Commission; provided, further, that Respondents shall select such entity within five business days of receiving written notification of the Commission's approval.

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7. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for his or her services, all remaining monies shall be paid at the direction of the Respondents, and the Divestiture Trustee's power shall be terminated. The Divestiture Trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the Divestiture Trustee's divesting the assets.

8. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from gross negligence or willful misconduct by the Divestiture Trustee. For purposes of this Paragraph X.C.8., the term "Divestiture Trustee" shall include all Persons retained by the Divestiture Trustee pursuant to Paragraph X.C.7. of this Order.

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9. If the Divestiture Trustee ceases to act or fails to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph X for appointment of the initial Divestiture Trustee.
 10. The Divestiture Trustee shall have no obligation or authority to operate or maintain the assets to be divested.
 11. The Divestiture Trustee shall report in writing to the Commission every sixty days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
- D. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

XI.

IT IS FURTHER ORDERED that if the Divestiture Trustee divests the Thiacloprid Assets pursuant to Paragraph X of this Order, the following additional requirements shall apply:

- A. No later than the date the Divestiture Trustee divests the Thiacloprid Assets, Bayer shall grant to the Thiacloprid Acquirer (pursuant to one or more agreements that receive the prior approval of the Commission):
1. A worldwide, royalty-free, perpetual, sublicenseable, irrevocable, transferable license to Bayer's rights to the Thiacloprid Licensed Intellectual Property to invent, develop, patent, make, have made, use, sell, offer for sale, and import any product (except for products containing an existing patented molecule of Respondents retained by

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Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date) anywhere in the world. Such license shall be (i) exclusive (even as to Bayer) for any product containing an existing patented molecule included in the Thiacloprid Assets or any patented molecule invented or acquired by the Thiacloprid Acquirer and (ii) non-exclusive for any other product.

2. An irrevocable, worldwide, perpetual immunity from suit by Bayer based on claims of infringement under all of Respondents' Intellectual Property for the developing, making, having made, using, having used, selling, offering for sale, having sold, and importing of any product containing Thiacloprid for any use anywhere in the world (except for products containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date). Such immunity shall extend to any person deriving its authority from the Thiacloprid Acquirer.

B. Nothing in this Order shall prevent the Divestiture Trustee from obtaining agreement with the Thiacloprid Acquirer in which the Thiacloprid Acquirer shall grant to Bayer:

1. A worldwide, royalty-free, perpetual, irrevocable, sublicenseable, transferable license to the Thiacloprid Acquirer's rights to any Intellectual Property included in the Thiacloprid Assets that does not relate exclusively to the Thiacloprid Business to develop, patent, make, have made, use, sell, offer for sale, and import any product (except for products containing (x) an existing patented molecule included in the Thiacloprid Assets, subject to Paragraph XI.B.2. of this Order, or (y) any patented molecule invented or acquired by the Thiacloprid Acquirer after the Acquisition Date, without the consent of the Thiacloprid Acquirer) anywhere in the world. Such license (i) may be exclusive (even as to the Thiacloprid Acquirer) for any product containing an existing patented molecule of Respondents retained by Bayer or any patented molecule

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invented or acquired by Bayer after the Acquisition Date and (ii) shall be non-exclusive for any other product.

2. A worldwide, royalty-free, exclusive (except as to the Thiacloprid Acquirer), perpetual, irrevocable, sublicenseable, transferable license to the Thiacloprid Acquirer's rights to any Intellectual Property included in the Thiacloprid Assets to develop, patent, make, have made, use, sell, offer for sale, and import any product containing Thiacloprid anywhere in the world (except for the United States, Canada, and Europe); provided, however, that Bayer may obtain such license only if it would not impair the viability of the Thiacloprid Acquirer, and the Commission approves the divestiture of the Thiacloprid Assets with such a license.
- C. Bayer may propose an agreement to allow the Thiacloprid Acquirer to supply to Bayer Thiacloprid (if Bayer obtains a license pursuant to Paragraph XI.B.2. of this Order) and Clothianidin manufactured by the Thiacloprid Acquirer; provided, however, that such agreement shall provide sufficient Thiacloprid to the Thiacloprid Acquirer to support the Thiacloprid Acquirer's good faith plans, decisions, or efforts to meet the production goals and targets in the Thiacloprid Acquirer's business plans and to expand production of Thiacloprid in a manner consistent with the purposes of this Order. If such agreement is proposed by Bayer, the Divestiture Trustee shall include such agreements among the terms offered to prospective Acquirers, and may submit a divestiture containing such agreement for the approval of the Commission. If the Divestiture Trustee is unable to enter into such agreement, or if the Commission does not approve such agreement, or does not approve a divestiture subject to such agreement, then the Commission may approve, and the Divestiture Trustee may divest, a divestiture of the Thiacloprid Assets without such agreement.

Decision and Order

XII.

IT IS FURTHER ORDERED that if the Divestiture Trustee divests the Additional Flucarbazone Assets pursuant to Paragraph X of this Order, the following additional requirements shall apply:

- A. No later than the date the Divestiture Trustee divests the Additional Flucarbazone Assets, Bayer shall grant to the Flucarbazone Acquirer (pursuant to one or more agreements that receive the prior approval of the Commission):
 1. A worldwide, royalty-free, perpetual, sublicenseable, irrevocable, transferable license to Bayer's rights to the Olympus Licensed Intellectual Property to invent, develop, patent, make, have made, use, sell, offer for sale, and import any product (except for products containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date) anywhere in the world. Such license shall be (i) exclusive (even as to Bayer) for any product containing an existing patented molecule included in the Additional Flucarbazone Assets or any patented molecule invented or acquired by the Flucarbazone Acquirer and (ii) non-exclusive for any other product.
 2. An irrevocable, worldwide, perpetual immunity from suit by Bayer based on claims of infringement under all of Respondents' Intellectual Property for the developing, making, having made, using, having used, selling, offering for sale, having sold and importing any product containing Propoxycarbazone for any use anywhere in the world (except for products containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date). Such immunity shall extend to any person deriving its authority from the Flucarbazone Acquirer.

Decision and Order

B. Nothing in this Order shall prevent the Divestiture Trustee from obtaining agreement with the Flucarbazone Acquirer in which the Flucarbazone Acquirer shall grant to Bayer a worldwide, royalty-free, perpetual, irrevocable, sublicenseable, transferable license to the Flucarbazone Acquirer's rights to any Intellectual Property included in the Additional Flucarbazone Assets that does not relate exclusively to the Olympus Business to develop, patent, make, have made, use, sell, offer for sale, and import any product (except for products containing (x) an existing patented molecule included in the Additional Flucarbazone Assets, or (y) any patented molecule invented or acquired by the Flucarbazone Acquirer after the Acquisition Date, without the consent of the Flucarbazone Acquirer) anywhere in the world. Such license (i) may be exclusive (even as to the Flucarbazone Acquirer) for any product containing an existing patented molecule of Respondents retained by Bayer or any patented molecule invented or acquired by Bayer after the Acquisition Date and (ii) shall be non-exclusive for any other product.

XIII.

IT IS FURTHER ORDERED that Respondents shall provide a copy of this Order to each of Respondents' officers, employees, or agents having managerial responsibility for any obligations under this Order, no later than ten days from the date this Order becomes final.

XIV.

IT IS FURTHER ORDERED that:

- A. Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order:

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1. No later than sixty days from the date this Order becomes final, and every sixty days thereafter (measured from the due date of the first report under this Order) until one year from the date this Order becomes final (for a total of six reports during the first year).
2. No later than ninety days from the due date of Respondents' sixth report as required by Paragraph XIV.A. of this Order and every ninety days thereafter (measured from the due date of the seventh report) until thirty months from the date this Order becomes final (for a total of twelve reports during the first thirty months).
3. No later than six months from the due date of Respondents' twelfth report as required by Paragraph XIV.A. of this Order, and annually thereafter for the next seven years, on the anniversary of the date this Order becomes final.

Provided, however, that Aventis shall be required to file the reports required by this Paragraph XIV only until the Acquisition Date; provided, further, that Respondents shall also file the report required by this Paragraph XIV at any other time as the Commission may require.

- B. For any time period during which Respondents have compliance reporting obligations pursuant to the Order to Hold Separate, Respondents shall comply with Paragraph XIV.A. of this Order by complying with the reporting requirements imposed by the Order to Hold Separate until such reporting obligations terminate. Thereafter, Respondents shall assume the reporting schedule set forth in Paragraph XIV.A. of this Order and file subsequent reports in accordance therewith.

XV.

IT IS FURTHER ORDERED that Bayer shall not acquire, directly or indirectly, through subsidiaries, partnerships, or

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otherwise, any interest in, or all or any part of, the Pesticide Assets without the prior approval of the Commission.

XVI.**IT IS FURTHER ORDERED** that:

- A. Bayer shall not, without providing advance written notification to the Commission, acquire, directly or indirectly, through subsidiaries or otherwise, any ownership, leasehold, or other interest, in whole or in part, or enter into any kind of joint venture with Merial.
- B. Bayer shall provide the prior notification required by Paragraph XVI.A. on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as “the Notification”), which shall be prepared and transmitted in accordance with the requirements of that part, except that (i) no filing fee will be required for any such notification, (ii) notification shall be filed with the Secretary of the Commission, (iii) notification need not be made to the United States Department of Justice, and (iv) notification is required only of Respondents and not of any other party to the transaction.
- C. Bayer shall provide the Notification to the Commission at least thirty days prior to consummating any such transaction (hereinafter referred to as the “first waiting period”). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Bayer shall not consummate the transaction until thirty days after submitting such additional information or documentary material. Early termination of the waiting periods in this Paragraph XVI.C. may be requested and, where appropriate, granted by letter from the Bureau of Competition.

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Provided, however, that prior notification shall not be required by this Paragraph XVI for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

XVII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty days prior to any proposed change in the corporate Respondents such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of this Order.

XVIII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of Respondents relating to any matter contained in this Order; and
- B. Upon five days' notice to Respondents and without restraint or interference from them, to interview their officers, directors, or employees, who may have counsel present, regarding any such matters.

Decision and Order

XIX.

IT IS FURTHER ORDERED that this Order shall terminate on July 24, 2012.

CONFIDENTIAL APPENDICES A-F

[Redacted From Public Record Version]

Order

ORDER TO HOLD SEPARATE AND MAINTAIN ASSETS

The Federal Trade Commission having initiated an investigation of the proposed acquisition by Respondent Bayer AG of the stock of Aventis CropScience Holding S.A. from Respondent Aventis S.A. and Respondents having been furnished thereafter with a copy of the draft of the Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, would charge Respondents with violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of the Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Hold Separate and Maintain Assets (“Hold Separate Order”):

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1. Respondent Bayer AG is an Aktiengesellschaft organized, existing, and doing business under, and by virtue of, the laws of Germany with its office and principal place of business located at Werk Leverkusen, 51368, Leverkusen, Germany.
2. Respondent Aventis S.A. is a societe anonyme organized, existing, and doing business under, and by virtue of, the laws of France, with its office and principal place of business located at Avenue de l'Europe, Espace European de l'Entreprise, Schiltigheim, France.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Hold Separate Order, the following definitions and provisions shall apply (to the extent any capitalized term appearing in this Hold Separate Order is not defined below, the term shall be defined as that same term is defined in the Decision and Order contained in the Consent Agreement):

- A. “Bayer” means Bayer AG, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Bayer AG, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Aventis” means Aventis, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Aventis and the respective

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directors, officers, employees, agents, representatives, successors, and assigns of each.

- C. “ACS Global Hold Separate Manager” means Vincent Turriès, the manager to whom the various ACS Product Hold Separate Business Managers shall report during the Hold Separate Period and who, in turn, shall report to the Hold Separate Trustee.
- D. “ACS Product Hold Separate Business Managers” means Monty Christian, the Product Hold Separate Business Manager responsible for the Acetamiprid Business and Brian Ahrens (Agriculture) and Karl Kisner (Environmental Science), the Product Hold Separate Business Managers responsible for the Fipronil Business.
- E. “Acetamiprid Assets” means the Acetamiprid Assets as defined in Paragraph I of the Decision and Order.
- F. “Acetamiprid Business” means Respondent Aventis’ business of researching, developing, registering, formulating, manufacturing, licensing, distributing, marketing, and selling all products containing Acetamiprid, as that term is defined in the Decision and Order, including products in development, in any market anywhere in the world, prior to the Acquisition Date (and such business as conducted by Bayer after the Acquisition Date pursuant to this Order and the Order to Hold Separate), and includes the Acetamiprid Assets.
- G. “Acquisition” means the proposed acquisition described in (i) the Stock Purchase Agreement dated as of October 2, 2001, among Aventis Agriculture, Hoechst Aktiengesellschaft, and Bayer AG, and (ii) the Stock Purchase Agreement dated as of October 2, 2001, among Schering Aktiengesellschaft, SCIC Holdings LLC, and Bayer AG.

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- H. “Acquisition Date” means the date of consummation of the Acquisition.
- I. “Alternative Assets” means the Additional Flucarbazone Assets, the Thiacloprid Assets, Olympus Business, the Acetamiprid Licensed Intellectual Property, the Fipronil Licensed Intellectual Property, and the Flucarbazone Licensed Intellectual Property as those terms are defined in the Decision and Order
- J. “Aventis Hold Separate Businesses” means the Acetamiprid Business and the Fipronil Business.
- K. “Bayer Global Hold Separate Manager” means Wolfgang Bieber, the manager to whom the Bayer Product Hold Separate Business Managers shall report during the Hold Separate Period and who, in turn, shall report to the Hold Separate Trustee.
- L. “Bayer Product Hold Separate Business Managers” means Gary Aagesen and Scott Fleetwood, the Product Hold Separate Business Managers responsible for the Flucarbazone Business.
- M. “Bayer Hold Separate Business” means the Flucarbazone Business.
- N. “Commission” means the Federal Trade Commission.
- O. “Consent Agreement” means the Agreement Containing Consent Orders executed by Respondents and the Commission in this matter.
- P. “Decision and Order” means:
 - 1. until the issuance of a final Decision and Order by the Commission in this matter, the proposed Decision and

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Order incorporated into and made a part of the Consent
Agreement; or

2. following the issuance of a final Decision and Order by the Commission, the Decision and Order issued by the Commission.

Q. “Effective Date of Divestiture” means the earliest date on which each and every of the divestitures required by Paragraphs II, III, IV, and V (or X, XI, and XII, if applicable) of the Decision and Order have been consummated.

R. “Fipronil Assets” means the Fipronil Assets as defined in Paragraph I of the Decision and Order.

S. “Fipronil Business” means Respondent Aventis’ business of researching, developing, registering, formulating, manufacturing, licensing, distributing, marketing, and selling all products containing Fipronil, including products in development, in any market anywhere in the world, prior to the Acquisition Date (and such business as conducted by Bayer after the Acquisition Date pursuant to this Hold Separate Order and the Decision and Order), and includes the Fipronil Assets.

T. “Flucarbazone Assets” means the Flucarbazone Assets as defined in Paragraph I of the Decision and Order.

U. “Flucarbazone Business” means Respondent Bayer’s business of researching, developing, registering, formulating, manufacturing, licensing, distributing, marketing, and selling all products containing Flucarbazone, including products in development, in any market anywhere in the world, and includes the Flucarbazone Assets.

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- V. “Hold Separate Businesses” means the Acetamiprid Business, the Fipronil Business, and the Flucarbazone Business.
- W. “Hold Separate Business Assets” means the Acetamiprid Assets, Fipronil Assets, and Flucarbazone Assets.
- X. “Hold Separate Order” means this Order to Hold Separate and Maintain Assets.
- Y. “Hold Separate Period” means the time period during which the Hold Separate is in effect, which shall begin no later than ten (10) days after the date the Hold Separate Order becomes final and terminate pursuant to Paragraph V. hereof.
- Z. “Hold Separate Trustee” means Richard Gilmore, the individual appointed pursuant to Paragraph II.D.1 of this Hold Separate Order.
- AA. “Material Confidential Information” means competitively sensitive or proprietary information not independently known to an entity from sources other than the entity to which the information pertains, and includes, but is not limited to, all customer lists, price lists, marketing methods, patents, technologies, processes, or other trade secrets.
- BB. “Product Development Managers” means the individuals appointed to manage the development of the respective products within the Hold Separate Businesses during the Hold Separate Period.
- CC. “Product Hold Separate Business Manager” means each of the three individuals, responsible for managing a different business line within the Hold Separate Businesses during the Hold Separate Period. Identified separately, the individual managers are as follows:

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Monty Christian, the Product Hold Separate Business Manager responsible for the Acetamiprid Business; Brian Ahrens (Agriculture) and Karl Kissner (Environmental Science), the Product Hold Separate Business Managers responsible for the Fipronil Business; and Gary Aagesen and Scott Fleetwood, the Product Hold Separate Business Managers responsible for the Flucarbazone Business.

DD. “Respondents” means Bayer and Aventis.

II.

IT IS FURTHER ORDERED that:

- A. During the Hold Separate Period, Respondents shall hold the Hold Separate Businesses separate, apart, and independent from Respondents as required by this Hold Separate and shall vest the Hold Separate Businesses, and the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, and each of the Product Hold Separate Business Managers with all rights, powers, and authority necessary to conduct their respective businesses. Respondents shall not exercise direction or control over, or influence directly or indirectly, the Hold Separate Businesses, the Hold Separate Trustee, the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, the Product Hold Separate Business Managers or the Hold Separate Business Assets except to the extent that Respondents must exercise direction and control over the Hold Separate Businesses as is necessary to assure compliance with this Hold Separate Order, the Consent Agreement, the Decision and Order, and with all applicable laws, including, in consultation with the Hold Separate Trustee, continued oversight of the Hold Separate Businesses’ compliance with policies and standards concerning the safety, health, and environmental aspects of their operations and the integrity of their financial controls. Respondents shall also have the right to defend any legal

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claims, investigations or enforcement actions threatened or brought against any of the Hold Separate Businesses.

- B. Until the Effective Date of Divestiture, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Hold Separate Businesses to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Hold Separate Businesses, including the Hold Separate Business Assets, except for ordinary wear and tear, including, but not limited to, continuing in effect and maintaining product registrations, proprietary trademarks, trade name, logos, trade dress, identification signs, levels of inventory appropriate for the next business cycle, and information and documents relating to formulations, field testing, research, studies, and production.
- C. The purpose of this Hold Separate Order is to:
 1. preserve the Hold Separate Businesses as viable, competitive, and ongoing businesses independent of Respondents until the Effective Date of Divestiture of the Hold Separate Business Assets;
 2. assure that no Material Confidential Information is exchanged between Respondents and the Hold Separate Businesses, except in accordance with the provisions of this Hold Separate Order;
 3. prevent interim harm to competition pending the relevant divestitures and other relief; and
 4. help remedy any anticompetitive effects of the proposed Acquisition.
- D. Respondents shall hold the Hold Separate Businesses separate, apart, and independent in the following manner:

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1. Richard Gilmore shall serve as Hold Separate Trustee, pursuant to the agreement executed by the Hold Separate Trustee and Respondents and attached as Confidential Appendix A (“trustee agreement”).
 - a. The trustee agreement shall require that, no later than ten (10) days after this Hold Separate Order becomes final, Respondents transfer to the Hold Separate Trustee all rights, powers, and authorities necessary to permit the Hold Separate Trustee to perform his/her duties and responsibilities, pursuant to this Hold Separate Order and consistent with the purposes of the Decision and Order.
 - b. No later than ten (10) days after this Hold Separate Order becomes final, Respondents shall, pursuant to the trustee agreement, transfer to the Hold Separate Trustee all rights, powers, and authorities necessary to permit the Hold Separate Trustee to perform his/her duties and responsibilities, pursuant to this Hold Separate Order and consistent with the purposes of the Decision and Order.
 - c. The Hold Separate Trustee shall have the responsibility, consistent with the terms of this Hold Separate Order and the Decision and Order, for monitoring the organization of the Hold Separate Businesses; for maintaining the independence of the Hold Separate Businesses; and for monitoring Respondents’ compliance with their obligations pursuant to this Hold Separate Order and the Decision and Order.
 - d. The Hold Separate Trustee shall have full and complete access to all personnel, books, records, documents and facilities of the Hold Separate Businesses or to any other relevant information as the Hold Separate Trustee may reasonably request,

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including, but not limited to, all documents and records kept by Respondents in the ordinary course of business that relate to the Hold Separate Businesses. Respondents shall develop such financial or other information as the Hold Separate Trustee may request and shall cooperate with the Hold Separate Trustee. Respondents shall take no action to interfere with or impede the Hold Separate Trustee's ability to monitor Respondents' compliance with this Hold Separate Order and the Decision and Order or otherwise to perform his/her duties and responsibilities consistent with the terms of this Hold Separate Order.

- e. The Hold Separate Trustee shall have the authority to employ, at the cost and expense of Bayer, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Hold Separate Trustee's duties and responsibilities.
- f. The Commission may require the Hold Separate Trustee to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with performance of the Hold Separate Trustee's duties.
- g. Respondents may require the Hold Separate Trustee to sign a confidentiality agreement prohibiting the disclosure of any Material Confidential Information gained as a result of his or her role as Hold Separate Trustee to anyone other than the Commission.
- h. Thirty (30) days after the Hold Separate Order becomes final, and every thirty (30) days thereafter until the Hold Separate terminates, the Hold Separate Trustee shall report in writing to the Commission concerning the efforts to accomplish the purposes of this Hold Separate Order and the Decision and Order

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and Respondents' compliance with its obligations under the Hold Separate Order and the Decision and Order. Included within that report shall be the Hold Separate Trustee's assessment of the extent to which the Hold Separate Businesses are meeting (or exceeding) their projected goals as are reflected in operating plans, budgets, projections or any other regularly prepared financial statements.

- i. If the Hold Separate Trustee ceases to act or fails to act diligently and consistent with the purposes of this Hold Separate Order, the Commission may appoint a substitute Hold Separate Trustee consistent with the terms of this paragraph, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of the substitute Hold Separate Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any substitute Hold Separate Trustee, Respondents shall be deemed to have consented to the selection of the proposed substitute trustee. Respondents and the substitute Hold Separate Trustee shall execute a trustee agreement, subject to the approval of the Commission, consistent with this paragraph.
2. No later than five (5) days after this Hold Separate Order becomes final, Respondents shall, subject to the approval of the Commission, enter into separate agreements with the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, and each of the Product Hold Separate Business Managers (collectively "Global Hold Separate Management Agreements"). No later than ten (10) days after this Hold Separate Order becomes final, and consistent with the terms of the Global Hold Separate Management Agreements, Respondents shall transfer to the ACS Global Hold Separate Manager and

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the Bayer Global Hold Separate Manager, all rights, powers, and authorities necessary to permit them to perform their duties and responsibilities, pursuant to the Hold Separate Order and consistent with the purposes of the Hold Separate Order and the Decision and Order.

- a. The ACS Global Hold Separate Manager shall be responsible for the Aventis Hold Separate Businesses and shall report directly to the Hold Separate Trustee. The ACS Global Hold Separate Manager shall have the responsibility, consistent with the terms of this Hold Separate Order and the Decision and Order, to manage the Aventis Hold Separate Businesses. The ACS Global Hold Separate Manager shall not have any access to Material Confidential Information of Bayer other than Material Confidential Information relating to the Aventis Hold Separate Businesses. During the term of this Hold Separate, the ACS Global Hold Separate Manager shall not be involved, in any way, in the operations of the other businesses of Respondents.
- b. The Bayer Global Hold Separate Manager shall be responsible for the Bayer Hold Separate Business and shall report directly to the Hold Separate Trustee. The Bayer Global Hold Separate Manager shall have the responsibility, consistent with the terms of this Hold Separate Order and the Decision and Order, to manage the Bayer Hold Separate Business. The Bayer Global Hold Separate Manager shall not have any access to Material Confidential Information of Bayer other than Material Confidential Information relating to the Bayer Hold Separate Business. During the term of this Hold Separate, the Bayer Global Hold Separate Manager shall not be involved, in any way, in the operations of the other businesses of Respondents.

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- c. The Product Hold Separate Business Managers responsible for the Acetamiprid Business and for the Fipronil Business shall report directly and exclusively to the ACS Global Hold Separate Manager; the Product Hold Separate Business Managers responsible for the Flucarbazone Business shall report directly and exclusively to the Bayer Global Hold Separate Manager. Each of the Product Hold Separate Business Managers shall manage his or her part of the Hold Separate Businesses independently of the management of Respondents. During the term of this Hold Separate, the Product Hold Separate Business Managers shall not be involved, in any way, in the operations of the other businesses of Respondents.
- d. In the event the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, or any of the Product Hold Separate Business Managers cease to act as the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, or the Product Hold Separate Business Manager, the Hold Separate Trustee shall select a substitute manager, after consultation with the staff of the Commission, and transfer to the substitute manager all rights, powers and authorities necessary to permit the substitute manager to perform his/her duties and responsibilities, pursuant to this Hold Separate Order.
- e. The ACS Global Hold Separate Manager and the Bayer Hold Separate Manager shall have no financial interests affected by Respondents' revenues, profits or profit margins, except that the individual manager's compensation for managing the respective Hold Separate Businesses may include economic incentives dependent on the financial performance of their respective businesses if there are also sufficient incentives for the ACS Global Hold Separate Manager and the Bayer Hold Separate Manager to operate the

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business at no less than current rates of operation (including, but not limited to, current rates of production and sales) and to achieve the objectives of this Hold Separate Order.

- f. The Product Hold Separate Business Managers shall have no financial interests affected by Respondents' revenues, profits or profit margins, except that the individual Product Hold Separate Business Manager's compensation for managing his/her part of the Hold Separate Businesses may include economic incentives dependent on the financial performance of their respective business line if there are also sufficient incentives for the Product Hold Separate Business Managers to operate the business at no less than current rates of operation (including, but not limited to, current rates of production and sales) and to achieve the objectives of this Hold Separate Order.
- g. The ACS Global Hold Separate Manager and the Bayer Global Hold Separate Manager shall make no material changes in the present operation of the Hold Separate Businesses except with the approval of the Hold Separate Trustee.
- h. The ACS Global Hold Separate Manager and the Bayer Global Hold Separate Manager shall have the authority, with the approval of the Hold Separate Trustee, to remove employees and replace them with others of similar experience or skills. If any person ceases to act or fails to act diligently and consistent with the purposes of the Hold Separate Order, the ACS Global Hold Separate Manager and the Bayer Global Hold Separate Manager, in consultation with the Hold Separate Trustee, may request Respondents to, and Respondents shall, appoint a substitute person, which person the respective manager and the Hold

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Separate Trustee shall have the right to approve or disapprove.

- i. The ACS Global Hold Separate Manager and the Bayer Global Hold Separate Manager may employ, in addition to those employees within the Hold Separate Businesses, such employees as are reasonably necessary to assist them in managing and operating the Hold Separate Businesses, including, without limitation, those providing administrative services, such as finance personnel, information technology personnel, employee relations personnel, legal services personnel, public relations personnel, regulatory personnel, supply personnel, earnings consolidation and analysis personnel, business performance personnel, and customer relations personnel.
- j. Each Product Hold Separate Business Manager shall have the responsibility and resources to implement existing sales, marketing, research and development, product registration, and product development plans relating to their products or to modify, with the concurrence of the respective ACS Global Hold Separate Manager or the Bayer Global Hold Separate Manager, and the approval of the Hold Separate Trustee, existing plans consistent with previously approved goals and objectives. The managers shall not have access to any other of Respondents' confidential marketing materials, including without limitation, Bayer CropScience confidential marketing materials, during the Hold Separate Period.
- k. Each Product Hold Separate Business Manager, with the concurrence of the respective ACS Global Hold Separate Manager or Bayer Global Hold Separate Manager, shall appoint the relevant Product Development Managers for each of the Hold Separate

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Businesses as identified in Confidential Appendix B. In all instances, the manager appointed shall be an individual with the necessary experience and expertise in the particular product. This individual shall have the responsibility to oversee development of products within the individual Hold Separate Businesses during the Hold Separate Period. This person shall not have access to the ongoing research and development operations of Bayer that are not related to the Hold Separate Businesses during the Hold Separate Period.

- l. During the Hold Separate Period, the Bayer and Aventis sales forces will continue to operate in substantially the same manner as they were prior to closing of the Acquisition. Provided, however, that Respondents may integrate their crop protection sales forces after August 1, 2002; provided further, however, that: (1) the individual Product Hold Separate Business Managers will be responsible for overseeing sales of the products in the Hold Separate Businesses; (2) sales representatives responsible for sales in the Aventis Hold Separate Businesses shall have no access to Material Confidential Information relating to the Bayer Hold Separate Business; and (3) sales representatives responsible for sales in the Bayer Hold Separate Business shall have no access to Material Confidential Information relating to the Aventis Hold Separate Businesses. For crop protection and Non-Agricultural Use products, however, Respondents may initiate cross-training for their sales forces starting at the time of closing of the Acquisition; provided, however, that no training will be provided on the products of the Hold Separate Businesses or their competing products.
- m. The Hold Separate Trustee shall be permitted, in consultation with the Commission staff, to remove any of the managers for cause. Within fifteen (15)

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days after such removal, Respondents shall appoint a replacement manager, subject to the approval of the Hold Separate Trustee, on the same terms and conditions as provided in paragraph II.D.1. of this Hold Separate.

3. The Hold Separate Businesses shall be staffed with sufficient employees to maintain the viability and competitiveness of the Hold Separate Businesses. Employees of the Hold Separate Businesses shall include (i) all personnel performing responsibilities primarily in connection with any of the Hold Separate Businesses as of the date Respondents executed the Consent Agreement, and (ii) any persons hired from other sources. To the extent that any employees of the Hold Separate Businesses leave or have left the Hold Separate Businesses prior to the Effective Date of Divestiture, the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, or Product Hold Separate Business Managers, as applicable, with the approval of the Hold Separate Trustee, may replace departing or departed employees with persons who have similar experience and expertise or may determine not to replace such departing or departed employees.
4. In connection with support services or products not included within the Hold Separate Businesses, Respondents shall continue to provide, or offer to provide, the same support services to the Hold Separate Businesses as are being provided to such businesses by Respondents as of the date the Consent Agreement is signed by Respondents. For services that Bayer or Aventis previously provided to the Hold Separate Businesses, Respondents shall not charge more than the same fees, if any, charged by Respondents for such services as of the date this Consent Agreement is signed by Respondents. For any other services or products that Respondents may provide the Hold Separate Businesses,

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Respondents shall not charge more than the same price they charge others for the same services or products. Respondents' personnel providing such services or products must retain and maintain all Material Confidential Information of the Hold Separate Businesses on a confidential basis, and, except as is permitted by this Hold Separate Order, such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any person whose employment involves any of Respondents' businesses, other than the Hold Separate Businesses. Such personnel shall also execute confidentiality agreements prohibiting the disclosure of any Material Confidential Information of Hold Separate Businesses.

- a. Respondents shall offer and the Hold Separate Businesses shall obtain the following services and products solely from Respondents:
 - (1) National brand advertising and promotion programs;
 - (2) Federal and state regulatory policy development and compliance;
 - (3) Human resources administrative services, including but not limited to labor relations support;
 - (4) Environmental health and safety services, which develops corporate policies and ensures compliance with federal and state regulations and corporate policies;
 - (5) Security services;
 - (6) Preparation of tax returns; and
 - (7) Audit services.
- b. Respondents shall offer to the Hold Separate Businesses any services and products that Respondents provide to their other businesses directly or through third-party contracts, or that they have

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provided directly or through third-party contracts to the businesses constituting the Hold Separate Businesses at any time since January 1, 2002. The Hold Separate Businesses may, at the option of the respective Global or Product Hold Separate Business Managers, with the approval of the Hold Separate Trustee, obtain such services and products from Respondents. The services and products that Respondents shall offer the Hold Separate Businesses shall include, but shall not be limited to, the following:

- (1) Information systems, which constructs, maintains, and supports all SAP and other computer systems;
 - (2) Public affairs, which provides media and community relations services;
 - (3) Processing of accounts payable;
 - (4) Technical support;
 - (5) Financial accounting services;
 - (6) Procurement of goods and services utilized in the ordinary course of business by the Hold Separate Business;
 - (7) Legal services; and
 - (8) Real estate services.
- c. In connection with services and products other than those listed in a. above, and including but not limited to those listed in b. above, the Hold Separate Businesses shall have, at the option of the ACS Global Hold Separate Manager or the Bayer Global Hold Separate Manager, as applicable, with the approval of the Hold Separate Trustee, the ability to acquire services and products from third parties unaffiliated with Respondents.
5. Bayer shall cause the Hold Separate Trustee, the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, the Product Hold Separate Business

Order

Managers, and each employee of the Hold Separate Businesses having access to Material Confidential Information to submit to the Commission a signed statement that the individual will maintain the confidentiality required by the terms and conditions of this Hold Separate. These individuals must retain and maintain all Material Confidential Information relating to the Hold Separate Businesses on a confidential basis and, except as is permitted by this Hold Separate Order, such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any other person whose employment involves any of Respondents' businesses other than the Hold Separate Business. These persons shall not be involved in any way in the management, production, distribution, sales, marketing, and financial operations of the competing products of Respondents.

6. No later than ten (10) days after the date this Hold Separate becomes final, Bayer shall establish written procedures, subject to the approval of the Hold Separate Trustee, covering the management, maintenance, and independence of the Hold Separate Businesses consistent with the provisions of this Hold Separate Order.
7. No later than five (5) days after the date this Hold Separate Order becomes final, Bayer shall circulate to employees of the Hold Separate Businesses a notice of this Hold Separate Order and Decision and Order, and shall circulate to its employees a notice in the form attached as Attachment A.
8. The Hold Separate Trustee, the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, and the Product Hold Separate Business Managers shall serve, without bond or other security, at the cost and expense of Bayer, on reasonable and

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customary terms commensurate with the person's experience and responsibilities.

9. Bayer shall indemnify the Hold Separate Trustee, the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, and the Product Hold Separate Business Managers and hold each harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Hold Separate Trustee's, the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, or the Product Hold Separate Business Managers' duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Hold Separate Trustee, the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, or the Product Hold Separate Business Managers.
10. Bayer shall provide the Hold Separate Businesses with sufficient financial resources:
 - a. as are appropriate in the judgment of the ACS Global Hold Separate Manager and the Bayer Global Hold Separate Manager (in connection with the respective Hold Separate Businesses), with the concurrence of the Hold Separate Trustee, to operate the Hold Separate Businesses at least at current rates of operation to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities found in the Hold Separate Businesses most recent budget; provided that failure to achieve production or sales goals projected in the Hold

Order

Separate Businesses respective budgets shall not be deemed to be a violation of this Hold Separate;

- b. to continue, at least at their scheduled pace, any additional expenditures for the Hold Separate Businesses authorized prior to the date the Consent Agreement was signed by Respondents;
 - c. to perform all maintenance to, and replacements of, the assets of the Hold Separate Businesses; and
 - d. to maintain the viability, competitive vigor, and marketability of the Hold Separate Businesses.
 - e. Such financial resources to be provided to the Hold Separate Businesses shall include, but shall not be limited to, (i) general funds, (ii) capital, (iii) working capital, and (iv) reimbursement for any operating losses, capital losses, or other losses; provided, however, that, consistent with the purposes of the Decision and Order, the ACS Global Hold Separate Manager or the Bayer Global Hold Separate Manager, as appropriate, may reduce in scale or pace any capital or research and development project, or substitute any capital or research and development project for another of the same cost.
11. Except for the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, the Product Hold Separate Business Managers, employees of the Hold Separate Businesses, and support services employees involved in providing services to the Hold Separate Businesses pursuant to Paragraph II.D.4., and except to the extent provided in Paragraph II.A., Respondents shall not permit any other of its employees, officers, or directors to be involved in the operations of the Hold Separate Businesses.

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12. Respondents shall not, during the Hold Separate Period, offer employees of any of the Hold Separate Businesses positions with Respondents. The acquirer approved by the Commission pursuant to the Decision and Order shall have the option of offering employment to any employees of any of the Hold Separate Businesses. Respondents shall not interfere with the employment, by the Commission-approved acquirer, of such employees; shall not offer any incentive to such employees to decline employment with the Commission-approved acquirer or to accept other employment with the Respondents; and shall remove any impediments that may deter such employees from accepting employment with the Commission-approved acquirer including, but not limited to, any non-compete or confidentiality provisions of employment or other contracts that would affect the ability of such employees to be employed by the Commission-approved acquirer, and the payment, or the transfer for the account of the employee, of all current and accrued bonuses, pensions and other current and accrued benefits to which such employees would otherwise have been entitled had they remained in the employment of the Respondents.
13. For a period of one (1) year commencing on the Effective Date of Divestiture, Respondents shall not employ or make offers of employment to employees of any of the Hold Separate Businesses who have accepted offers of employment with the Commission-approved acquirer unless the individual employee has been terminated by the acquirer.
14. Notwithstanding the requirements of Paragraph II.D.12., Respondents shall offer a bonus or severance to employees included in the Hold Separate Businesses that continue their employment with the

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Hold Separate Businesses until termination of the Hold Separate Period (in addition to any other bonus or severance to which the employees would otherwise be entitled).

15. Bayer shall assure that employees of the Hold Separate Businesses receive, during the Hold Separate Period, their salaries, all current and accrued bonuses, pensions and other current and accrued benefits to which those employees would otherwise have been entitled.
16. Except as required by law, and except to the extent that necessary information is exchanged in the course of consummating the Acquisition, negotiating agreements to divest assets pursuant to the Decision and Order and engaging in related due diligence; complying with this Hold Separate Order or the Decision and Order; overseeing compliance with policies and standards concerning the safety, health and environmental aspects of the operations of the Hold Separate Businesses and the integrity of the Hold Separate Businesses' financial controls; defending legal claims, investigations or enforcement actions threatened or brought against the Hold Separate Businesses; or obtaining legal advice, Respondents' employees (excluding support services employees involved in providing support to the Hold Separate Businesses pursuant to Paragraph II.D.4.) shall not receive, or have access to, or use or continue to use any Material Confidential Information, not in the public domain, of the Hold Separate Businesses. Nor shall the ACS Global Hold Separate Manager, the Bayer Global Hold Separate Manager, the Product Hold Separate Business Managers, or employees of the Hold Separate Businesses receive or have access to, or use or continue to use, any Material Confidential Information not in the public domain

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about Respondents and relating to Respondents' businesses, except such information as is related to the Hold Separate Businesses. Respondents may receive aggregate financial and operational information relating to the Hold Separate Businesses only to the extent necessary to allow Respondents to prepare consolidated financial reports, tax returns, reports required by securities laws, and personnel reports, or otherwise meet reporting obligations imposed by law. Any such information that is obtained pursuant to this subparagraph shall be used only for the purposes set forth in this subparagraph.

17. Respondents and the Hold Separate Businesses shall jointly implement, and at all times during the Hold Separate Period maintain in operation, a system, as approved by the Hold Separate Trustee, of access and data controls to prevent unauthorized access to or dissemination of Material Confidential Information of the Hold Separate Businesses, including, but not limited to, the opportunity by the Hold Separate Trustee, on terms and conditions agreed to with Respondents, to audit Respondents' networks and systems to verify compliance with this Hold Separate Order.

III.

IT IS FURTHER ORDERED that from the date this Hold Separate Order becomes final, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Alternative Assets to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Alternative Assets, except for ordinary wear and tear, including, but not limited to, continuing in effect and maintaining product registrations, proprietary trademarks, trade names, logos, trade dress, identification signs, levels of inventory appropriate for the next

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business cycle, and information and documents relating to formulations, field testing, research, studies, and production.

IV.

IT IS FURTHER ORDERED that Bayer shall notify the Commission at least thirty (30) days prior to any proposed change in Bayer such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of this Hold Separate Order.

V.

IT IS FURTHER ORDERED that

- A. Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Hold Separate Order and the Decision and Order, no later than thirty days from the date this Hold Separate Order becomes final and every thirty days thereafter (measured from the due date of the first report) until the date this Hold Separate Order terminates.
- B. Respondents shall also include in their compliance reports a full description of the efforts being made to comply with Paragraphs II. through V. of the Decision and Order, including a description of all substantive contacts or negotiations for the divestiture and the identity of all parties contacted. Respondents shall include in their compliance reports copies of all written communications to and from such parties, all internal memoranda, all reports and recommendations concerning divestiture, the date of divestiture, and a statement that the divestiture has been accomplished in the manner approved by the Commission.

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VI.

IT IS FURTHER ORDERED that for the purposes of determining or securing compliance with the Hold Separate Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents, Respondents shall permit any duly authorized representatives of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities, and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of the Respondents relating to compliance with this Hold Separate Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Hold Separate shall terminate at the earlier of:

- A. three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. the day after the Effective Date of Divestiture; provided, however, that Respondents' obligations in this Hold Separate Order as to any of the individual Hold Separate Businesses and the respective Hold Separate Business Assets contained therein will terminate the day after Respondents comply with their obligation to divest the particular Hold Separate Business Assets contained within

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the individual Hold Separate Business consistent with their obligations in the Decision and Order.

By the Commission.

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ATTACHMENT A

**NOTICE OF DIVESTITURE AND REQUIREMENT FOR
CONFIDENTIALITY**

Bayer AG intends to acquire certain assets of Respondent Aventis S.A. Bayer and Aventis have entered into an Agreement Containing Consent Orders (“Consent Agreement”) with the Federal Trade Commission relating to the divestiture of certain assets and other relief.

As used herein, the term “Held Separate Business” means the businesses defined in Paragraph I.V. of the Order to Hold Separate and Maintain Assets (the “Hold Separate Order”) contained in the Consent Agreement. Under the terms of the Decision and Order contained in the Consent Agreement, Respondents must divest certain assets, which are included within the Held Separate Business, 180 days from the date the Commission accepts the Consent Agreement for public comment.

During the Hold Separate Period (which begins after the Hold Separate Order becomes final and ends after Respondents have completed the required divestitures), the Held Separate Business shall be held separate, apart, and independent of Respondents’ businesses. The Held Separate Business must be managed and maintained as a separate, ongoing business, independent of all other businesses of Respondents until Respondents have completed the required divestitures. All competitive information relating to the Held Separate Business must be retained and maintained by the persons involved in the operation of the Held Separate Business on a confidential basis, and such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any other person whose employment involves any other of Respondents’ businesses, except as otherwise provided in the Hold Separate Order. These persons involved in the operation of the Held Separate Business shall not be involved in any way in the management, production, distribution, sales, marketing, or

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financial operations of Respondents relating to competing products. Similarly, persons involved in similar activities in Respondents' businesses shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any similar information to or with any other person whose employment involves the Held Separate Business, except as otherwise provided in the Hold Separate Order.

Any violation of the Consent Agreement may subject Respondents to civil penalties and other relief as provided by law.

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Confidential Appendix A

TRUSTEE AGREEMENT

[Redacted From Public Record Version]

Confidential Appendix B

[Redacted From Public Record Version}

Analysis

Analysis of the Complaint and Proposed Consent Order to Aid Public Comment**I. Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Bayer AG (“Bayer”) and Aventis S.A. (“Aventis”) (collectively “Respondents”). The Consent Agreement is intended to resolve anticompetitive effects stemming from Bayer’s proposed acquisition of Aventis CropScience Holding S.A. (“ACS”) from Aventis. The Consent Agreement includes a proposed Decision and Order (the “Order”), which would require Respondents to divest ACS’s acetamiprid, fipronil and tribufos businesses, including its fipronil production facility in Elbeuf, France, and Bayer’s flucarbazone business, to an acquirer or acquirers approved by the Commission and in a manner approved by the Commission. The Consent Agreement also includes an Order to Hold Separate and Maintain Assets, which requires Respondents to preserve the acetamiprid, fipronil and flucarbazone operations as a viable, competitive and ongoing operation until the divestitures are completed.

The Consent Agreement, if finally accepted by the Commission, would settle charges that Bayer’s proposed acquisition of ACS may have substantially lessened competition in the markets for New Generation Chemical Insecticide Active Ingredients; New Generation Chemical Insecticide Products (including but not limited to (i) crop specific end uses, (ii) veterinary channel companion animal flea and tick control products and (iii) non-repellent liquid termiticides); Post-Emergent Grass Herbicides for Spring Wheat; and Cool Weather Cotton Defoliants. The Commission has reason to believe that Bayer’s proposed acquisition of ACS would have violated Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act, as alleged in the Commission’s proposed complaint.

Analysis

II. The Proposed Complaint

According to the Commission's proposed complaint, there are several relevant lines of commerce in which to analyze the effects of Bayer's proposed acquisition of ACS, including: 1) New Generation Chemical Insecticide Active Ingredients; 2) New Generation Chemical Insecticide Products; 3) Post-Emergent Grass Herbicides for Spring Wheat; and 4) Cool Weather Cotton Defoliants.

The proposed complaint alleges that the United States is the relevant geographic market and section of the country within which to analyze the likely effects the combination of Bayer and ACS.

New Generation Chemical Insecticide Active Ingredients

The proposed complaint alleges that relevant lines of commerce in which to analyze the effects of the proposed merger are new generation chemical insecticide active ingredients and related technologies ("New Generation Chemical Insecticide Active Ingredients") for specific end use applications, including the development, manufacture and sale of insecticides for use as non-repellent termiticides, flea control for companion animals, and for use on an array of crop applications such as corn, cotton, citrus, cole crops, grapes, vegetables, for turf and ornamental uses, and as protection for seeds and seedlings ("seed treatments"). New Generation Chemical Insecticide Active Ingredients are chemicals that are designed to kill undesirable insects but that, unlike older insecticide active ingredients, are less harmful to human health and the environment. These New Generation Chemical Insecticide Active Ingredients include imidacloprid, acetamiprid, thiamethoxam, and other chloronicotinyls; and fipronil and other phenylpyrazoles.

According to the Commission's proposed complaint, New Generation Chemical Insecticide Active Ingredients are used in applications where their characteristics provide superior

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performance and where they offer advantages as compared to older chemical insecticides. These advantages include reductions in the amount of chemical insecticides used (resulting in reduced negative impacts on the environment and human health), reduced risk to humans and beneficial insects due to the use of safer chemicals in comparison to older chemical insecticides, and superior control of certain undesirable pests. The proposed complaint alleges that many of these advantages are a result of competition in research and development. The proposed complaint also alleges that New Generation Chemical Insecticide Active Ingredients are of increasing importance as the EPA removes older insecticides from the market because of harmful effects on human health and the environment.

The proposed complaint alleges that Bayer and Aventis are the firms that have been significant competitors in developing and commercializing New Generation Chemical Insecticide Active Ingredients; Syngenta Corporation is the only other firm with significant development and production of New Chemical Insecticide Active Ingredients.

According to the Commission's proposed complaint, Bayer and Aventis are distinguished by their unique product development and commercialization skills relating to New Generation Chemical Insecticide Active Ingredients. The proposed complaint alleges that these unique skills have prompted competitors, through licensing, to allow Bayer and Aventis to develop products based on molecules other firms have discovered.

The proposed complaint alleges that the acquisition would reduce actual, direct, and substantial competition, eliminate potential competition, increase barriers to entry, reduce innovation competition, increase Respondents' ability to exercise unilateral market power and substantially increase the level of concentration and enhance the probability of coordination in the relevant markets.

Analysis

A. New Generation Chemical Insecticide Products

The proposed complaint alleges that insecticide products based on New Generation Chemical Insecticide Active Ingredients (“New Generation Chemical Insecticide Products”) constitute relevant lines of commerce in which to analyze the effects of the proposed merger. New Generation Chemical Insecticide Products include, but are not limited to, (i) crop specific end uses, such as corn, cotton, citrus, cole crops, grapes, vegetables and seed treatments; (ii) veterinary channel companion animal flea control products; and (iii) non-repellent liquid termiticides.

The proposed complaint alleges that New Generation Chemical Insecticide Active Ingredients provide New Generation Chemical Insecticide Products with advantages over older chemical insecticide products. The proposed complaint alleges that New Generation Chemical Insecticide Products are displacing older insecticide products as the EPA removes or limits the use of a significant number of these older harmful products.

The proposed complaint alleges that New Generation Chemical Insecticide Products include separate relevant markets based on the specific applications in which the relevant products are used because the EPA requires a separate registration for each application in which the products will be used and suppliers price their products at different levels depending on the specific end use application. The proposed complaint further alleges that New Generation Chemical Insecticide Products may constitute application specific relevant product markets such as: termiticides, flea control for companion animals, specific crops or any application in which New Generation Chemical Insecticide Products are used.

According to the proposed complaint, Bayer and Aventis are the leading firms in the development and commercialization of New Generation Chemical Insecticide Products and own significant intellectual property estates relating to these products. The proposed complaint alleges that Syngenta is the only other

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firm with significant sales of New Generation Chemical Insecticide Products.

According to the Commission's proposed complaint, the proposed transaction would reduce the number of firms – from two to one in two relevant markets, and from three to two in other relevant markets. The proposed complaint alleges that Bayer and Aventis are the only firms currently selling New Generation Chemical Insecticide Products for non-repellent liquid termiticides. The proposed complaint also alleges that Bayer and Aventis are the only firms that have developed and sold successful New Generation Chemical Insecticide Products for use in the veterinary channel companion animal flea control application. The proposed complaint further alleges that Bayer, Aventis and Syngenta are the only firms producing and selling a range of New Generation Chemical Insecticide Products for a range of crop specific end uses.

According to the proposed complaint, the acquisition would eliminate competition (including potential competition), increase barriers to entry, reduce innovation competition among developers of relevant products, increase Respondents' ability to exercise unilateral market power and substantially increase the level of concentration and enhance the probability of coordination in the relevant markets.

B. Post-Emergent Grass Herbicides for Spring Wheat

According to the proposed complaint, herbicides are chemicals designed to kill or control grasses that interfere with crop production. The proposed complaint alleges that separate markets for herbicides may be distinguished by the type of weed controlled (grassy weed versus broadleaf weed) and the growth stage at which the herbicide is applied (pre-emergent versus post-emergent). The proposed complaint further alleges that post-emergent grass herbicides for spring wheat ("Spring Wheat Herbicides") is a relevant product market in which to analyze the effects of Bayer's proposed acquisition of ACS.

Analysis

According to the Commission's proposed complaint, Aventis is the largest supplier of Spring Wheat Herbicides, accounting for almost 70 percent of sales in 2001. The proposed complaint alleges that Aventis' leading product for post-emergent grass control for spring wheat is Puma, which contains the active ingredient fenoxaprop. The proposed complaint also alleges that in 2001, Bayer introduced Everest, which contains the active ingredient flucarbazone, and that Everest accounted for approximately 7 percent of sales in the market in that year.

The Complaint alleges that the acquisition would eliminate price competition, increase the Respondents' ability to unilaterally raise price and increase the likelihood and degree of coordinated interaction among competitors in the market for Spring Wheat Herbicides.

C. Cool Weather Cotton Defoliants

According to the Commission's proposed complaint, cotton defoliants are chemical harvest aids designed to remove leaves from cotton plants without drying them. The proposed complaint alleges that separate markets for cotton defoliants may be distinguished by method of action (defoliation versus desiccation) and by product efficacy in varying environmental conditions (cool weather versus warm weather). The Commission's proposed complaint further alleges that Cool Weather Cotton Defoliants are necessary for economical harvesting of premium grade cotton and constitutes a relevant product market in which to analyze the effects of the proposed acquisition.

The proposed complaint alleges that Bayer and Aventis are the only two suppliers of Cool Weather Cotton Defoliants. The proposed complaint also alleges that both Bayer and Aventis offer products containing the active ingredient tribufos for cool weather cotton defoliation; Bayer offers the DEF product and Aventis offers the Folex product.

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The Commission's proposed complaint alleges that Bayer's proposed acquisition of ACS would eliminate competition between Bayer and Aventis in the market for Cool Weather Cotton Defoliants in the U.S., substantially increase the level of concentration, increase the likelihood that Respondents will unilaterally exercise market power and increase barriers to entry. The proposed complaint also alleges that the proposed acquisition would increase the likelihood that customers of Cool Weather Cotton Defoliants in the U.S. would be forced to pay higher prices.

D. Barriers to Entry Into the Relevant Product Markets

The proposed complaint alleges that entry into the relevant markets for New Generation Chemical Insecticide Active Ingredients would require years of research, development, testing, registration and commercial scale production synthesis. The proposed complaint alleges that entry into the New Generation Chemical Insecticide Products market is an expensive and lengthy process that requires access to a New Generation Chemical Insecticide Active Ingredient, product development and EPA review, among other things. The proposed complaint further alleges that entry into the Spring Wheat Herbicides market can take seven to ten years, in part because a potential entrant would spend substantial time researching active molecules, developing promising molecules, and implementing the studies required by the EPA. The proposed complaint alleges that barriers to entry into the Cool Weather Cotton Defoliant market include distribution barriers, existing purchase and supply contracts and EPA regulations.

III. Terms of the Proposed Order

The proposed Order is designed to remedy the alleged anti-competitive effects of the proposed acquisition by requiring the divestiture of assets relating to four businesses: 1) acetamiprid; 2) fipronil; 3) flucarbazone; and 4) Folex (tribufos). The proposed Order requires Respondents to divest the acetamiprid, fipronil,

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and flucarbazone businesses to acquirer(s) approved by the Commission, at no minimum price, not later than 180 days from the date that the Commission accepts the proposed Order for public comment. If this divestiture does not occur by that date, the proposed Order allows the Commission to appoint a trustee to sell the divestiture assets or additional assets, to acquirer(s) approved by the Commission.

A. Acetamiprid

Section II. of the proposed Order requires Respondents to divest ACS's worldwide assets relating to the acetamiprid business. However, the proposed Order does not require Bayer to divest the acetamiprid business in Mexico, South America, Central America or Africa in the event that Nippon Soda, the acetamiprid licensor, does not consent to the assignment of the acetamiprid agreements relating exclusively to these regions.

Paragraph II.E. of the proposed Order permits the Commission-approved acquirer, at its discretion, to license back to Bayer any intellectual property that is not related primarily to the acetamiprid business. This provision ensures that the Order will not prevent Bayer from obtaining exclusive rights to develop, make, sell or import any new insecticide products that are in the same chemical family as acetamiprid. Thus, both the acquirer and Bayer will have the right to invent, patent, and develop new compounds in the chemical family to which acetamiprid belongs.

The proposed Order also provides that if Bayer fails to divest its assets relating to the acetamiprid business within the time and manner described above, the Commission may appoint a divestiture trustee to divest those assets in a manner acceptable to the Commission, or may require divestiture of Bayer's assets relating to the thiacloprid business at no minimum price. The proposed Order provides that while Bayer may obtain a cross-license to any intellectual property included in the thiacloprid business (provided that Bayer's license does not impair the viability of the thiacloprid business), this provision creates an

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additional thiacloprid supplier to compete directly with Bayer. The proposed Order provides that if Bayer obtains this cross-license, Bayer can obtain a supply agreement of thiacloprid from the acquirer. Bayer may also obtain a supply of clothianidin from the acquirer because this chemical is produced in the same plant that produces thiacloprid. The Commission must approve all such supply agreements, licenses, and divestitures.

B. Fipronil

Section III. of the proposed Order requires Respondents to divest all assets relating to ACS's fipronil business, including intellectual property, ACS's production facility in Elbeuf, France, and other assets.

Paragraph III.D.2. of the proposed Order allows Bayer to license back any intellectual property included in the fipronil assets for non-agricultural use, as described in Definition RR. This license back increases competition in the non-repellant liquid termiticide market as it enables both Bayer and the fipronil acquirer to bring products containing fipronil to the market.

Paragraph III.E. of the proposed Order permits Bayer to enter into a supply agreement with the Commission-approved acquirer. The supply agreement allows the acquirer to supply fipronil to Bayer for non-agricultural use for a term of two years, which may be extended subject to Commission approval. This supply arrangement may be necessary because of current supply contracts that obligate ACS to supply fipronil to third parties. The supply agreement may also allow the acquirer to supply intermediates to Bayer until the expiration of patents covering such intermediates. This may be necessary because Bayer may require the use of those intermediates in the production of its own chemicals.

C. Flucarbazone

The proposed Order provides that Respondents will divest the flucarbazone assets, including tangible and intangible assets

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relating to the business of developing, manufacturing and selling all products containing the active ingredient flucarbazone worldwide. The divested assets exclude the manufacturing facility in Kansas City where flucarbazone is manufactured. This facility is also used to manufacture other Bayer herbicides that are not sold in the Spring Wheat Herbicide market.

So long as Bayer divests the Everest assets to a Commission-approved acquirer by the deadline described above, the proposed Order permits Bayer to exclusively retain its intellectual property rights that relate primarily to its Olympus (propoxycarbazone) business. Under the license grant in Paragraph IV.C. of the proposed Order, both the Commission-approved acquirer and Bayer will have the right to invent, patent, and develop new compounds in the chemical family to which Everest (flucarbazone) and Olympus (propoxycarbazone) belong.

In order to guarantee that Bayer will not block the Commission-approved acquirer from operating the Everest (flucarbazone) business, Paragraph IV.C.2. of the proposed Order prohibits Bayer from suing the acquirer for patent infringement relating to the acquirer's actions in developing, making, selling or importing any product containing flucarbazone, except for those products containing propoxycarbazone (*i.e.* Bayer's Olympus business).

Paragraph IV.E. of the proposed Order permits Bayer to supply the Commission-approved acquirer with flucarbazone products for an interim period of 30 months from the date Bayer divests the Everest (flucarbazone) business. This supply arrangement may be necessary because the acquirer is unlikely to have sufficient time to set-up an independent capability for manufacturing flucarbazone and formulating flucarbazone-based products in time for the 2003 spring wheat crop. The proposed Order sets up parameters for the supply relationship between Bayer and the acquirer, including requiring Bayer to supply the acquirer with sufficient quantities of flucarbazone in a timely manner and requiring Bayer to charge a reasonable price that is based on its

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direct costs of providing the acquirer with flucarbazone and other related services.

Finally, in the event Bayer does not divest its Everest (flucarbazone) business by the deadline described above, Sections X. and XII. of the proposed Order require Bayer to additionally divest its Olympus (propoxycarbazone) business, and the plant in Kansas City where it manufactures flucarbazone and propoxycarbazone, to a Commission-approved acquirer that may not license the business back to Bayer. Additionally, Paragraph XII.A.2. of the proposed order prohibits Bayer from suing the acquirer for patent infringement relating to the acquirer's actions in developing, making, selling or importing any product containing propoxycarbazone.

D. Folex

The provisions in Section V. of the proposed Order requires Respondent to divest assets relating to Folex, which contains the active ingredient tribufos, and to assign ACS's rights under the tribufos supply agreement to Amvac Corporation ("Amvac") no later than twenty days from the date the Commission accepts the Consent for public comment. Amvac is a manufacturer that purchases proprietary molecules from discovery firms and commercializes these molecules. Under the supply agreement, Amvac may purchase tribufos from Bayer. Amvac also has the capability to manufacture its own tribufos.

If the Commission, at the time that it makes the Order final, notifies Bayer that it does not approve of the proposed divestiture to Amvac, or of the manner of the divestiture, the proposed Order provides that Bayer would terminate or rescind the sale to Amvac and divest the Folex business within 180 days, at no minimum price, to a Commission-approved acquirer.

Analysis

E. Other Elements of the Order

According to the proposed Order, Bayer shall provide technical assistance to the acquirer(s) of the assets relating to the acetamiprid, fipronil, flucarbazone and Folex businesses upon their request. Because Respondents' employees have likely developed expertise in the manufacture of these chemicals and other operations of the businesses, this technical assistance provision ensures that the acquirer(s) can obtain the capability to operate the businesses as efficiently as Respondents.

Section VI. of the proposed Order contains various provisions which aid the Commission-approved acquirers in hiring Respondents' employees with experience in the divested businesses. Respondents must provide the acquirers with the names of these employees and access to personnel files and other documents relating to the employees' performance. Moreover, for a subset of employees considered to have a "key" role in the divested businesses, Respondents must pay such employees a bonus if they accept an employment offer from the acquirers within the first thirty days after the relevant divestiture.

The proposed Order also provides for the Commission to appoint a monitor trustee to oversee Bayer's compliance with the terms of the proposed Order and the divestiture agreements that Bayer enters pursuant to the proposed Order.

The proposed Order requires Respondents to provide the Commission, within sixty days from the date the Order becomes final, a verified written report setting forth in detail the manner and form in which the Respondents intend to comply, is complying, and has complied with the provisions relating to the proposed Order and the Order to Hold Separate and Maintain Assets. The proposed Order further requires Respondent to provide the Commission with a report of compliance with the Order every sixty days after the date when the Order becomes final until the divestitures have been completed.

Analysis

According to the proposed Order, Bayer shall provide the Commission with advance written notice prior to acquiring any interest of or entering into a joint venture with Merial unless such transaction requires notification pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a. Merial is a joint venture between Aventis S.A. and Merck. Prior to the proposed transaction, ACS supplied fipronil to Merial for use in its Frontline flea and tick control product. ACS also provided a crop protection pipeline of new insecticide molecules that may have application in animal health. Following the proposed transaction, Merial may wish to reform the existing research and development agreement, or form a research and development technology venture with Bayer. Prior notification will allow the Commission to investigate whether such a partnership would have appropriate safeguards to obtain the benefits of joint development without negatively impacting competition in downstream animal health products.

F. The Order to Hold Separate and Maintain Assets

The proposed Order to Hold Separate and Maintain Assets that is also included in the Consent Agreement requires that Respondent hold separate and maintain the viability of the acetamiprid, fipronil, and flucarbazone businesses.

IV. Opportunity for Public Comment

The proposed Order has been placed on the public record for thirty days to receive comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the Consent Agreement and comments received and will decide whether to withdraw its agreement or make final the Consent Agreement's proposed Order and Order to Hold Separate and Maintain Assets.

The purpose of this analysis is to facilitate public comment on the proposed Order. This analysis is not intended to constitute an official interpretation of the Consent Agreement, the proposed

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Order, or the Order to Hold Separate and Maintain Asset or in any way to modify the terms of the Consent Agreement, the proposed Order, or the Order to Hold Separate and Maintain Assets.

Statement

**STATEMENT OF COMMISSIONER MOZELLE W.
THOMPSON****In the Matter of Bayer/Aventis AG, File No. 011 0199**

Today, I have joined in the Commission's vote to accept for public comment a proposed consent agreement and order resolving competitive issues stemming from Bayer AG's proposed acquisition of Aventis CropScience Holding S.A. Although I believe that in this matter the proposed consent agreement and order adequately address the Commission's concerns, I write separately to underscore that consent order divestiture provisions for which a buyer has not yet been identified will continue to be closely scrutinized in order to ensure that the asset package is sufficient and that a qualified buyer will likely be found.

The value of having "up front" buyers is explained in the Commission's 1999 Divestiture Study,¹ which reviews Commission divestiture orders issued between 1990 and 1994. This value has only increased as we review more complex

¹ *A Study of the Commission's Divestiture Process*, Staff of the Bureau of Competition (1999), available at <http://www.ftc.gov/os/1999/9908/divestiture.pdf>. "The 'up front' divestiture not only reduces the opportunity for interim competitive harm by expediting the divestiture process, but it assures at the outset that there will be an acceptable buyer for the to-be-divested assets." *Id.* at 39.

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transactions in interconnected markets. In cases where there are questions about asset sufficiency or buyer qualifications, or where the Commission determines that there are other risks to the proposed divestiture, I believe that presentation of an up front buyer will be required.²

² Indeed, it is the Commission's prerogative to require an up front buyer in any merger warranting divestiture(s), and it will do so when it has less than complete confidence that all risks to the efficacy of the proposed relief have been minimized. For more information regarding "up front" buyers, please see "Frequently Asked Questions About Merger Consent Order Provisions," available at <http://www.ftc.gov/bc/mergerfaq.htm>.

Complaint

IN THE MATTER OF

BIOVAIL CORPORATION, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4057; File No. 0110132

Complaint, August 15, 2002--Decision, August 15, 2002

This consent order addresses practices used by Respondents Biovail Corporation and Elan Corporation – respectively Canadian and Irish manufacturers of branded and generic pharmaceutical products – which were the first firms to file Abbreviated New Drug Applications (“ANDAs”) to market generic versions (in different dosage levels) of Adalat CC, a once-a-day anti-hypertension medication. The order, among other things, requires the respondents to terminate an agreement executed in 1999 – involving all four of the respondents’ generic Adalat products – under which Elan appointed Biovail as the exclusive distributor of Elan’s two generic Adalat products. The order also prohibits the respondents from entering into certain price, output, or distribution agreements with other generic drug companies concerning any generic drug for which both parties to the agreement have filed for FDA approval of an ANDA referencing the same pioneer drug product. In addition, the order prohibits Elan from distributing its generic Adalat products – with certain exceptions – through Teva Pharmaceuticals, Inc., which distributes some of Biovail’s products under a long-standing commercial relationship. The order also requires the respondents to use best efforts to market their respective 30 mg and 60 mg versions of generic Adalat products through separate distributors. In addition, the order requires the respondents to give the Commission notice of two prescribed types of agreements with other pharmaceutical manufacturers.

Participants

For the Commission: *Randall David Marks, Garry R. Gibbs, Ellen Connelly, Dara J. Diomande, Emily Jones, Timothy Abbott, Michael Kades, David R. Pender, Jeffrey W. Brennan, Rendell A. Davis, Jr., Roberta S. Baruch, and David J. Balan.*

For the Respondents: *Steven Newborn, Clifford Chance Rogers & Wells LLP, Ken Cancellara, Biovail, Charles Gilman, Larry Sorkin and Kristen Emigholz, Cahill, Gordon & Reindel, Marc Schildkraut, Howrey Simon Arnold & White LLP, and Libby Murphy, Elan.*

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that an agreement between Biovail Corporation (“Biovail”) and Elan Corporation, plc (“Elan”), hereinafter sometimes referred to as Respondents, has violated and violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint, stating its charges in that respect as follows:

Respondents

1. Respondent Biovail is a corporation organized under the laws of the Province of Ontario, Canada, with its principal place of business at 2488 Dunwin Drive, Mississauga, Ontario, Canada. Biovail’s subsidiary, Biovail Technologies, Ltd., has offices in the United States located at 3701 Concorde Parkway, Chantilly, Virginia 20151. Biovail is a manufacturer of branded and generic pharmaceutical products, and it is engaged in all stages of pharmaceutical development, from research, through clinical testing and regulatory filings, to full-scale manufacturing. Biovail’s 2001 world-wide revenues were over \$583 million.

2. Respondent Elan is a corporation organized under the laws of Ireland, with its principal place of business at Lincoln House, Lincoln Place, Dublin 2, Ireland. Elan’s subsidiary, Elan Pharmaceutical Research Corporation, has offices in the United States located at 1300 Gould Drive, Gainesville, Georgia 30504. Elan is a manufacturer of branded and generic pharmaceutical products, and it is engaged in all stages of pharmaceutical development, from research, through clinical testing and regulatory filings, to full-scale manufacturing. Elan’s 2001 world-wide revenues were \$1.7 billion.

3. Respondents are, and at all relevant times herein have been, engaged in commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

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4. Respondents are, and at all relevant times herein have been, corporations, as “corporation” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

Respondents’ Market Power

5. Adalat CC (“Adalat”), a prescription drug used to treat hypertension, is marketed in the United States in 30 mg, 60 mg, and 90 mg dosage forms. Bayer AG (“Bayer”) launched Adalat as a branded pharmaceutical product in 1993. In 1999, before the first entry of generic equivalents to Adalat (“generic Adalat”) in 2000, Bayer’s United States sales of the 30 mg and 60 mg dosages of Adalat were approximately \$270 million.

6. The relevant product markets within which to assess the effects of Respondents’ conduct described herein are the sale of 30 mg dosages of generic Adalat and the sale of 60 mg dosages of generic Adalat.

7. The relevant geographic market within which to assess the effects of Respondents’ conduct described herein is the United States.

8. In April 1997, Elan was the first company to file an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”) for approval to market a 30 mg generic Adalat product. In December 1997, Biovail became the second company to file an ANDA for approval to market a 30 mg generic Adalat product. In March 2000, the FDA granted final approval to Elan’s 30 mg product. The same month, pursuant to the agreement described hereinafter, Elan entered the market with its 30 mg product. In December 2000, the FDA granted final approval to Biovail’s 30 mg product. Biovail has never entered the market with its own 30 mg product.

9. In April 1998, Biovail was the first company to file an ANDA for approval to market a 60 mg generic Adalat product. In June 1999, Elan became the second company to file an ANDA for

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approval to market a 60 mg generic Adalat product. In December 2000, the FDA granted final approval to Biovail's 60 mg product. The same month, Biovail entered the market with its 60 mg product. In October 2001, the FDA granted final approval to Elan's 60 mg product. Elan has never entered the market with its own 60 mg product.

10. Biovail and Elan are the only manufacturers with FDA approval to market 30 mg and 60 mg generic Adalat products. No other manufacturer has applied for FDA approval of either a 30 mg or 60 mg generic Adalat product.

11. Biovail and Elan have market power in the United States markets for sales of the 30 mg and 60 mg dosages of generic Adalat (collectively the "relevant markets").

Respondents' Agreement

12. Biovail and Elan entered into an agreement in October 1999 whereby Elan appointed Biovail the exclusive distributor of Elan's 30 mg and 60 mg generic Adalat products. In exchange, Biovail agreed to make specified payments to Elan. Biovail also shares with Elan in the profits on the two Elan products. The agreement has a minimum term of 15 years.

13. At the time of the agreement, neither Elan nor Biovail distributed its own generic drugs in the United States. Teva Pharmaceuticals, Inc. ("Teva"), a distributor of Biovail products in the United States, participated in the negotiations leading up to the agreement. Respondents' agreement provided that Teva would become Biovail's sub-distributor of Elan's 30 mg generic Adalat product. The agreement further provided that, upon notice from Elan that Elan's 60 mg product was ready for commercial launch, Biovail would appoint either Teva or another firm as sub-distributor for that product. Respondents thus created an arrangement whereby Teva could distribute Elan's 30 mg and Biovail's 60 mg product, some other sub-distributor of Biovail

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could distribute Elan's 60 mg product and Biovail's 30 mg product, and Biovail would receive profits from all four products.

14. Respondents modified their agreement in December 2000 and June 2001, but these modifications did not lessen any of the agreement's anticompetitive features. The June 2001 modification affected only Elan's 60 mg product.

15. Pursuant to its agreement with Elan, Biovail has paid Elan approximately \$33 million in connection with Teva's distribution of Elan's 30 mg generic Adalat product, and \$12.75 million in connection with the right to distribute Elan's 60 mg generic Adalat product. Under the agreement, Biovail will continue to make payments to Elan, and share in profits from sales of Elan's generic Adalat products, at least until the year 2014.

Respondents' Incentives Under Their Agreement

16. Respondents' agreement gave Biovail substantial incentives not to launch its own 30 mg product. Respondents knew that Elan, as the first ANDA filer for a 30 mg generic Adalat product, would be the first to enter the market with that product, and that Biovail, as the second and only other ANDA filer for that product, would be the second to enter. Biovail's launch of its own 30 mg product could be expected to cause a reduction in the price of Elan's incumbent 30 mg product by a significant amount and generate for Elan's product lower total profits, which Biovail shares with Elan. Biovail, therefore, had a substantially reduced commercial interest in launching its own 30 mg product. For the same reasons, the agreement also diminished Biovail's incentives to exercise maximum efforts at eliminating the technological obstacles, if any, that Biovail asserts impeded its ability to launch a self-manufactured 30 mg product.

17. Respondents knew that Biovail, as the first ANDA filer for a 60 mg generic Adalat product, would be the first to enter the market with that product, and that Elan, as the second and only other ANDA filer for that product, would be the second to enter.

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Elan's launch of its own 60 mg product could be expected to cause a reduction in the price of Biovail's incumbent 60 mg product by a significant amount and generate lower total profits for Biovail's product. It was in Biovail's strategic interest, therefore, for Elan not to launch its 60 mg product.

18. Respondents' agreement gave Elan substantial incentives not to launch its own 60 mg product. Under the agreement, in exchange for receiving a large up-front payment, Elan, in effect, stood to receive no royalties upon launch of its 60 mg product until that product generated certain profits for Biovail. It would take several years of sales before Elan's 60 mg product would generate such profits. Once that triggering event happened, moreover, Elan's royalty was only to be 6% of profits. Accordingly, the agreement compensated Elan for its 60 mg product up-front and pre-entry, while substantially diminishing that product's value to Elan thereafter. For the same reasons, the agreement also diminished Elan's incentives to exercise maximum efforts at eliminating the technological obstacles, if any, that Elan asserts impeded its ability to launch a self-manufactured 60 mg product.

19. Respondents' agreement contained provisions that purportedly compelled Biovail to exercise "reasonable commercial endeavors" to launch "with reasonable dispatch" a self-manufactured 30 mg product in competition with Elan's 30 mg product, and compelled Elan to launch, through Biovail and Biovail's sub-distributor, a 60 mg product in competition with Biovail's product of that dosage. These provisions are ineffective. Neither Biovail nor Elan has any incentive to enforce these provisions against the other and, in fact, neither has done so, because to do so would have the effect of forcing competing products onto the market against their respective incumbent products and lowering each Respondent's profits.

20. Even if Biovail had launched its 30 mg product and Elan had launched its 60 mg product, the agreement allows Biovail to control or influence pricing and other competitive features of both

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its and Elan's 30 mg and 60 mg generic Adalat products. Biovail was thus in a position to profit by suppressing competition between its and Elan's products.

Respondents' Implementation of Their Agreement

21. After the FDA approved Elan's 30 mg generic Adalat product in March 2000, Biovail, pursuant to its agreement with Elan, began selling that product through Teva. Although Biovail obtained FDA approval to market its 30 mg generic Adalat product in December 2000, it has not entered the relevant market with that product. Had Biovail entered, and had the agreement's anticompetitive provisions not existed, Biovail's 30 mg product would have competed freely with Elan's 30 mg product.

22. After the FDA approved Biovail's 60 mg generic Adalat product in December 2000, Biovail immediately began selling that product through Teva. Although Elan obtained FDA approval to market its 60 mg generic Adalat product in October 2001, it has not entered the relevant market with that product. Had Elan entered, and had the agreement's anticompetitive provisions not existed, Elan's 60 mg product would have competed freely with Biovail's 60 mg product.

23. As a result of Biovail's failure to launch its own 30 mg generic Adalat product and Elan's failure to launch its 60 mg generic Adalat product, Teva is the only firm selling generic Adalat to consumers in the United States.

Effects of Respondents' Agreement

24. Respondents' acts and practices herein alleged have had either the purpose or effect of restraining, or the tendency to restrain, competition unreasonably and injuring consumers in the following ways, among others:

- a. By denying consumers, pharmacies, hospitals, insurers, wholesalers, government agencies, managed care

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organizations, and others the benefits of having competing generic Adalat products on the market;

- b. By forcing pharmacies, hospitals, insurers, wholesalers, government agencies, managed care organizations, and others to pay artificially high prices for generic Adalat products; and
- c. By forcing individual consumers to pay artificially high prices for generic Adalat products or to forgo purchasing such products by reason of an inability to afford them.

Unfair Methods of Competition

25. Respondents have agreed not to compete and thereby unreasonably restrained competition between the only two producers of generic Adalat products.
26. Respondents' anticompetitive agreement is not justified by any countervailing efficiencies.
27. Respondents' agreement and related acts and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. The acts and practices, as herein alleged, are continuing and will continue in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this fifteenth day of August, 2002, issues its complaint against said respondents.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission ("Commission"), having initiated an investigation of certain acts and practices of Biovail Corporation ("Biovail") and Elan Corporation, plc ("Elan"), hereinafter sometimes referred to as Respondents, and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), containing an admission by the Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that the Respondents have violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to section 2.34 of its Rules, hereby issues its Complaint, makes the following jurisdictional findings, and issues the following Order:

1. Respondent Biovail is a corporation organized under the laws of the Province of Ontario, Canada, with its principal

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place of business at 2488 Dunwin Drive, Mississauga, Ontario, Canada. Biovail's subsidiary, Biovail Technologies, Ltd., has offices in the United States located at 3701 Concorde Parkway, Chantilly, Virginia 20151.

2. Respondent Elan is a corporation organized under the laws of Ireland, with its principal place of business at Lincoln House, Lincoln Place, Dublin 2, Ireland. Elan's subsidiary, Elan Pharmaceutical Research Corporation, has offices in the United States located at 1300 Gould Drive, Gainesville, Georgia 30504.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent Biovail” means Biovail Corporation and its officers, directors, employees, agents and representatives, successors, and assigns; subsidiaries, divisions, groups, and affiliates controlled by Biovail; and the officers, directors, employees, agents and representatives, successors, and assigns of each.
- B. “Respondent Elan” means Elan Corporation, plc, and its officers, directors, employees, agents and representatives, successors, and assigns; subsidiaries, divisions, groups, and affiliates controlled by Elan; and the officers, directors, employees, agents and representatives, successors, and assigns of each.

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- C. "Respondents" means Respondent Biovail and Respondent Elan.
- D. "Commission" means the Federal Trade Commission.
- E. "Adalat CC Agreement" means the "License, Distribution & Supply Agreement" covering generic Adalat CC that Biovail and Elan executed on October 4, 1999; the subsequently modified separate agreements executed on December 29, 2000, and titled "Amended and Restated Licensing and Supply Agreement (30 mg Nifedipine O.D.)" and "Amended and Restated Licensing and Supply Agreement (60 mg Nifedipine O.D.); and all other agreements and understandings that relate to or modify the agreements executed on October 4, 1999, and December 29, 2000. The October 4, 1999, "License, Distribution & Supply Agreement" is attached to this Order as a Confidential Appendix.
- F. "Agreement" means anything that would constitute an agreement under Section 1 of the Sherman Act or Section 5 of the Federal Trade Commission Act.
- G. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j), *et seq.*
- H. "Cost" means Elan's actual manufacturing cost. In no case shall Cost exceed fully allocated cost, which is the sum total of all production-related costs, packaging, and labeling for the product (direct labor, direct materials, facility overhead, and other overhead and expenses, including manufacturing charges for material adjustments, handling losses, physical adjustments, salvage and start-up costs, quality assurance, quality control, analytical charges, packaging, and regulatory compliance costs for the product including stability and FDA fees), together with insurance costs accounted for in accordance with United States Generally Accepted Accounting Principles and in a manner consistent with expenses and overhead allocated to other products

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manufactured by Elan. “Cost” shall *not* include any costs associated with (a) Elan’s or Biovail’s litigation against Bayer (including, but not limited to, attorneys’ fees, court fees, and actual or expected financial settlements with or payments to Bayer) and (b) compliance with this Order (including, but not limited to, attorneys’ fees and allocations for time spent by Respondents’ employees in complying with this Order).

- I. “Drug Delivery Technology” means a technology that controls the release rate, or enhances the absorption or utilization, of a pharmaceutical compound. “Drug Delivery Technology” does not include a Drug Product.
- J. “Drug Product” means a finished dosage form (*e.g.*, tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients, as defined in 21 C.F.R. § 314.3(b).
- K. “FDA” means the United States Food and Drug Administration.
- L. “Generic Adalat CC” means the Drug Products that include Biovail ANDAs 75-269 and 75-359 and Elan ANDAs 75-128 and 75-659.
- M. “Launch” means the delivery of commercial quantities of Generic Adalat CC to a viable pharmaceutical distributor pursuant to a commercially reasonable multi-year contract.
- N. “NDA” means a New Drug Application, as defined under 21 U.S.C. § 355(b), *et seq.*
- O. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- P. “Teva” means Teva Pharmaceuticals, Inc.

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- Q. "Therapeutic Class" means a class of drugs categorized at the fourth-level (xxxx-0) or, if no fourth-level exists for such class of drugs, then at the third-level (xxx-00) in the Unified System of Classification (USC) contained in the most recent version of the IMS Health Incorporated publication *Market Research Database: Product Directory*.

II.

IT IS FURTHER ORDERED that each Respondent, directly or indirectly, or through any corporate or other device, in connection with the manufacture or sale of a Drug Product in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, forthwith cease and desist from entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or facilitating any Agreement with any other person on the price, production, volume, marketing, distribution, or sale of a Drug Product where the ANDAs for that Drug Product of Respondent and of the other person reference the same NDA.

III.

IT IS FURTHER ORDERED that no later than the date on which this Order becomes final, Respondents shall terminate all rights, under the Adalat CC Agreement, of Respondent Biovail to import, use, offer for sale, sell, or distribute Respondent Elan's Generic Adalat CC, and restore such rights to Respondent Elan. The purpose of the reallocation of rights is to restore competitive incentives to the Generic Adalat CC market and to remedy any lessening of competition resulting from the alleged anticompetitive practices stated in the Commission's complaint.

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PROVIDED that, without affecting the foregoing, Respondents may resolve financial issues, if any, connected with the termination of the Adalat CC Agreement on mutually agreeable terms. Such resolution shall not be measured directly or indirectly by sales, revenues, or profits generated by Generic Adalat CC or any other Drug Product, and shall not include compensation in the form of the United States rights relating to any Drug Product.

IV.

IT IS FURTHER ORDERED that Respondent Elan shall not sell, directly or indirectly, commercial quantities of Generic Adalat CC to Respondent Biovail or to Teva.

PROVIDED that Respondent Elan shall supply, to Respondent Biovail, Respondent Elan's 30 mg Generic Adalat CC for sale through Teva in the United States, subject to each of the following conditions:

- (1) Respondent Elan shall supply to Respondent Biovail amounts of 30 mg Generic Adalat CC requested by Respondent Biovail, up to the amounts to which Respondent Biovail would be entitled under Clause 7.6 of the October 4, 1999, Generic Adalat CC "License, Distribution & Supply Agreement," but in no event shall Respondent Elan, in any quarter, supply to Respondent Biovail more than 125 per cent of the quantity of 30 mg Generic Adalat CC than it supplied during the corresponding quarter of the previous year;
- (2) Respondents Biovail and Elan shall order and deliver, respectively, Respondent Elan's 30 mg Generic Adalat CC product in accordance with the procedures in the October 4, 1999, Generic Adalat CC "License, Distribution & Supply Agreement;"
- (3) Respondent Elan shall charge Respondent Biovail no more than Respondent Elan's Cost;

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- (4) On the day Respondent Biovail begins manufacturing sufficient commercial quantities of 30 mg Generic Adalat CC to supply Teva, Respondent Biovail shall notify Respondent Elan in writing of that fact;
- (5) Respondent Elan shall not fill any order from Respondent Biovail or Teva for 30 mg Generic Adalat CC more than thirty (30) days after it receives the notice pursuant to clause (4) above;
- (6) In no event shall Respondent Elan supply Respondent Biovail with 30 mg Generic Adalat CC later than May 31, 2003;
- (7) Respondent Elan shall permit Respondent Biovail to verify that it is charging Respondent Biovail no more than Respondent Elan's Cost, but only if Respondent Biovail uses an independent auditing firm that does not disclose to Respondent Biovail or any other person, confidential, proprietary information about Respondent Elan's costs; however, the independent auditing firm may reveal confidential, proprietary information only for the purpose of prosecuting a bona fide court or arbitration action regarding a dispute on the price charged Respondent Biovail for Respondent Elan's 30 mg Generic Adalat CC, and then only pursuant to a protective order or confidentiality agreement assuring that such information will be used only for the purpose of resolving the dispute; and
- (8) In the event that a Court of competent jurisdiction holds that Respondent Biovail's sale of Respondent Elan's 30 mg Generic Adalat CC infringes any patent, Respondents shall resolve issues of indemnification in accordance with the October 4, 1999, Generic Adalat CC "License, Distribution & Supply Agreement," unless Respondents

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mutually agree otherwise and so long as their agreement complies with all other provisions of this Order.

V.

IT IS FURTHER ORDERED that:

- A. Respondent Elan shall use best efforts to manufacture and launch, as promptly as possible, its 30 mg and 60 mg Generic Adalat CC for sale and distribution in the United States through a distributor other than Respondent Biovail or Teva.
- B. Respondent Biovail shall use best efforts to manufacture and launch, as promptly as possible, its 30 mg Generic Adalat CC for sale and distribution in the United States through a distributor other than Respondent Elan's Generic Adalat CC distributor. Respondent Biovail shall use best efforts to continue to manufacture and distribute its 60 mg Generic Adalat CC for sale and distribution in the United States through a distributor other than Respondent Elan's Generic Adalat CC distributor.
- C. The purpose of Paragraphs V.A and V.B is to restore competitive incentives in the market for Generic Adalat CC and to remedy any lessening of competition resulting from the alleged anticompetitive practices stated in the Commission's complaint.

VI.

IT IS FURTHER ORDERED that:

- A. Each Respondent shall notify the Commission of any agreement with another person relating to the price, production, volume, marketing, distribution, or sale of a Drug Product:
 - (1) Where, at the time of the agreement:

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- (a) Respondent and the other party to the agreement each own, control, or license a Drug Product that:
 - (i) Respondent knows, after diligent inquiry, is the subject of an NDA or ANDA pending with or approved by the FDA; and
 - (ii) Are in the same Therapeutic Class; and
 - (b) The agreement covers one or both such Drug Products.
- (2) For which, at the time of the agreement, Respondent or the other party has an ANDA for the Drug Product that references an NDA that the other party owns, controls, or licenses.

PROVIDED that Paragraph VI.A.1 does not apply to any agreement that only transfers a Drug Delivery Technology solely in exchange for a commercially reasonable cash royalty not to exceed 5 per cent of revenue.

B. Such notice to the Commission shall occur no later than five (5) days after execution of said agreement.

C. Such notice to the Commission shall include:

- (1) The agreement;
- (2) The names of the parties to the agreement, including the name, address, and phone number of the chief executive officer of each party;
- (3) The name, address, and phone number of each person who has filed an ANDA with the FDA for any Drug Product to which the agreement relates and, to the extent known, the status of such ANDA; and

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- (4) The last two annual marketing plans for the Drug Product(s) that the agreement covers and any documents that Respondent's board of directors received concerning the agreement.

VII.

IT IS FURTHER ORDERED that:

- A. Each Respondent shall distribute a copy of this Order and the Complaint, within thirty (30) days after the date on which this Order becomes final, to each of its officers, members of its board of directors, and managers with responsibility for prescription drug business development, licensing, sales, and marketing.
- B. Respondent Biovail shall provide to Teva a copy of this Order and the Complaint, within five (5) days after the date on which this Order becomes final.
- C. Respondent Elan shall provide to each person Respondent Elan appoints as a distributor of its Generic Adalat CC a copy of this Order and the Complaint, within five (5) days of such appointment.
- D. Each Respondent shall distribute a copy of this Order and the Complaint, for a period of five (5) years after the date this Order becomes final, within five (5) days of appointment, to: (1) each new officer, member of its board of directors, and manager with responsibility for prescription drug business development, licensing, sales, or marketing; and (2) each person Respondent appoints as a United States distributor of its Generic Adalat CC.

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VIII.

IT IS FURTHER ORDERED that:

A. Within thirty (30) days after the date this Order becomes final, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with Paragraphs III, IV, and V of this Order. Each Respondent shall submit such a compliance report every thirty (30) days until it has complied fully with Paragraphs III, IV, and V of this Order. Each Respondent shall include in such compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with Paragraphs III, IV, and V of this Order.

B. As part of its obligation under Paragraph VIII.A:

- (1) Respondent Elan shall include in its compliance reports (a) a description of all substantive contacts or negotiations concerning the launches provided for in Paragraph V and the identity of all parties contacted, and (b) copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning the launches provided for in Paragraph V. Respondent Elan's final compliance report under Paragraph VIII.A shall include a statement that the launches provided for in Paragraph V have been accomplished and shall include the date they were accomplished.
- (2) Respondent Biovail shall include in its compliance reports (a) a description of all substantive contacts with suppliers and/or Teva regarding obstacles to launch, and (b) copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning obstacles to launch. Respondent Biovail's final compliance report under Paragraph VIII.A shall

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include a statement that the launch provided for in Paragraph V of this Order has been accomplished and shall include the date it was accomplished.

C. One year (1) from the date this Order becomes final, annually for the next four (4) years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, each Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with this Order.

IX.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty days prior to (1) any dissolution, assignment, or sale resulting in the emergence of a successor corporation, or (2) the creation or dissolution of subsidiaries or any other change in the Respondent that may affect compliance obligations arising out of the Order.

X.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, each Respondent shall permit any duly authorized representative of the Commission, in the presence of Respondent's counsel:

A. Access, during office hours, to all facilities and to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of each Respondent relating to compliance with this Order; and

B. Without restraint or interference from each Respondent, to interview officers, directors, or employees of each Respondent relating to compliance with this Order.

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PROVIDED that each Respondent:

- (1) Shall receive five (5) days' written notice;
- (2) May assert any legally authorized privilege; and
- (3) May have counsel present during any inspection or interview.

XI.

IT IS FURTHER ORDERED that this Order shall terminate on August 15, 2012.

By the Commission.

Decision and Order

**Confidential Appendix Containing
October 4, 1999 "License, Distribution & Supply Agreement"**

[Redacted from Public Record Version]

Analysis

Analysis to Aid Public Comment

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with Biovail Corporation (“Biovail”) and Elan Corporation, plc (“Elan”), settling charges that the two companies illegally agreed to restrain competition in the market for generic Adalat CC. The Commission has placed the proposed consent order on the public record for thirty days to receive comments by interested persons. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by either Biovail or Elan that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

Background

Biovail is a Canadian manufacturer of branded and generic pharmaceutical products. Elan is an Irish manufacturer of branded and generic pharmaceutical products. Biovail and Elan are the only two sellers of generic forms of Adalat CC (“generic Adalat”), a once-a-day anti-hypertension medication. No other company has even sought Food and Drug Administration (“FDA”) approval to sell a 30 mg or a 60 mg dosage form of generic Adalat. Bayer AG (“Bayer”) manufactures branded Adalat CC. In 1999, before the entry of generic equivalents to Adalat CC, Bayer’s United States sales of the 30 mg and 60 mg dosages of Adalat CC were in excess of \$270 million.

Biovail was the first to file an Abbreviated New Drug Application (“ANDA”) for FDA approval on the 60 mg dosage, and Elan was the first to file an ANDA for FDA approval on the 30 mg dosage. Thus, Elan had 180 days of exclusivity for the 30 mg product upon receiving final FDA approval, and Biovail had the 180-day exclusivity on the 60 mg product upon receiving final FDA approval. Each was the second to file on the other dosage.

In October 1999, after both Biovail and Elan (hereinafter sometimes referred to as “Respondents”) had filed for FDA

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approval of their 30 mg and 60 mg generic Adalat products, they entered into an agreement involving all four of their generic Adalat products. That agreement (the “Agreement”), and the Respondents’ conduct arising out of that Agreement, are the subject of the Commission’s complaint. The complaint alleges that, by entering the Agreement, Respondents illegally created market power in the United States market for sales of 30 mg and 60 mg dosages of generic Adalat. There is little prospect of new entry in the near future, because no other companies have applied for FDA approval of a 30 mg or a 60 mg generic Adalat product.

The Challenged Conduct

Under Respondents’ Agreement, Elan appointed Biovail as the exclusive distributor of Elan’s 30 mg and 60 mg generic Adalat products. At the time of the Agreement, neither Elan nor Biovail distributed its own generic drugs in the United States. Teva Pharmaceuticals, Inc. (“Teva”), a distributor of some of Biovail’s products, participated in the negotiations leading up to the Agreement. The Agreement provided that Biovail appoint Teva to sub-distribute Elan’s 30 mg generic Adalat product in the United States. With respect to Elan’s 60 mg product, the Agreement provided that, upon notice from Elan that Elan’s 60 mg product was ready for commercial launch, Biovail would appoint either Teva or another company as a sub-distributor of that product. The Agreement has a minimum term of 15 years.

The FDA approved Elan’s 30 mg generic Adalat product in March 2000 and its 60 mg product in October 2001. It approved Biovail’s 30 mg and 60 mg generic Adalat products in December 2000. Biovail began selling Elan’s 30 mg product immediately after receiving final FDA approval. Biovail began selling its own 60 mg product through Teva immediately after the FDA gave final approval to that product. Neither Elan’s 60 mg product nor Biovail’s 30 mg product, however, has ever been launched commercially. Thus, although two 30 mg generic Adalat products and two 60 mg generic Adalat products have had FDA approval

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for many months, consumers can purchase only one product at each strength.

The complaint alleges that, in exchange for the right to distribute Elan's products and share in the profits of those products, Biovail agreed to make specified payments to Elan. To date, Biovail has paid Elan approximately \$33 million in connection with its distribution of Elan's 30 mg generic Adalat product, and \$12.75 million in connection with the right to distribute Elan's 60 mg generic Adalat product.

As the complaint alleges, the Agreement gave Biovail substantial incentives not to launch its own 30 mg product. Although Biovail has had final FDA approval to market its 30 mg product for over one year, and the Agreement purports to require Biovail to use "reasonable commercial endeavors" to launch that product "with reasonable dispatch," Biovail has not yet launched that product. Biovail's launch of its own 30 mg product could be expected to cause a significant reduction in the price of Elan's incumbent 30 mg product, and generate for Elan's product lower total profits, which Biovail shares with Elan. For the same reasons, the Agreement diminished Biovail's incentives to exercise maximum efforts at eliminating the technological obstacles, if any, that Biovail asserts have impeded its ability to launch a self-manufactured 30 mg product. Elan also does not have any incentive to enforce the Agreement's provision requiring that Biovail use reasonable efforts to launch its 30 mg product in competition with Elan's product.

Similarly, the complaint alleges that the Agreement gave Elan substantial incentives not to launch its 60 mg product. Under the Agreement, in exchange for receiving a large up-front payment, Elan, in effect, stood to receive no royalties upon launch of its 60 mg product, until that product generated certain profits for Biovail. It would take several years of sales before Elan's 60 mg product would generate such profits, and once that triggering event happened, Elan's royalty was to be only 6% of profits. Accordingly, the complaint alleges that the Agreement

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compensated Elan for its 60 mg product up-front and pre-entry, while substantially diminishing that product's value to Elan thereafter. The Agreement also diminished Elan's incentives to exercise maximum efforts at eliminating any technological obstacles to launching its 60 mg product, if any, that Elan has asserted to exist. Moreover, neither Elan nor Biovail had any financial incentives to enforce the provision requiring launch of Elan's 60 mg product. As with the launch of Biovail's 30 mg product, Respondents knew that Elan's launch of its own 60 mg product could be expected to cause a reduction in the price of Biovail's incumbent 60 mg product by a significant amount and generate lower total profits for Biovail's product. It was in Biovail's strategic interest, therefore, for Elan not to launch its 60 mg product.

The complaint further alleges that even if Biovail had launched its 30 mg product and Elan had launched its 60 mg product, the Agreement allows Biovail to control or influence pricing and other competitive features of both its and Elan's 30 mg and 60 mg generic Adalat products. Biovail was thus in a position to profit by suppressing competition between its and Elan's products.

For the above reasons, the complaint alleges that Respondents' Agreement is an agreement not to compete between the only two producers of the 30 mg and 60 mg generic Adalat products. As a result, Teva, Biovail's distributor, is the only firm selling generic Adalat to consumers in the United States, and consumers have had access to only one of two approved generic Adalat products at each strength. Moreover, the Agreement is not justified by any countervailing efficiency.

The Proposed Order

The proposed order remedies the Respondents' anticompetitive conduct by requiring them to end their anticompetitive Agreement and barring them from engaging in similar conduct in the future. It maintains supply of the incumbent generic Adalat products while Respondents unwind their anticompetitive Agreement and

Analysis

eliminates the anticompetitive obstacles to entry of a second 30 mg and a second 60 mg generic Adalat product.

Paragraph I of the proposed order contains definitions, one of which defines the “Adalat CC Agreement” as the “License, Distribution & Supply Agreement” covering generic Adalat that Biovail and Elan executed on October 4, 1999, and all modifications and amendments thereto. We discuss other definitions below, as needed to explain the substantive provisions of the proposed order.

Paragraph II of the proposed order is a core provision, prohibiting Biovail or Elan from repeating the instant conduct by entering anticompetitive price, output, or distribution agreements with other generic drug companies. This provision targets agreements between either Respondent and other persons concerning a generic drug for which both parties to the agreement have filed for FDA approval of an ANDA referencing the same pioneer drug product. It aims to prohibit agreements between competing generic drug manufacturers that restrict the marketing of competing generic drugs.

Paragraph III of the proposed order requires Biovail and Elan to terminate their agreement on generic Adalat no later than the date on which the order becomes final. Paragraph 13 of the Agreement Containing Consent Order required them to start the termination process upon their execution of that document. The proviso to Paragraph III allows Biovail and Elan to resolve financial issues connected to the termination of their agreement on generic Adalat on mutually agreeable terms; however, they cannot resolve those financial issues by using sales, revenues, or profits generated by generic Adalat or any other drug product, or by transferring rights connected to any drug product. This limitation is intended to ensure that, in resolving the financial issues, Respondents do not perpetuate the anticompetitive effects of the Agreement by continuing the entanglements between them on generic Adalat or on other drug products.

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Paragraph IV of the proposed order prohibits Elan from distributing its generic Adalat products through Teva. This prohibition is necessary because Biovail and Teva have a long-standing commercial relationship, whereby Teva distributes some of Biovail's products. Forbidding Elan from distributing its generic Adalat products through Teva will minimize the risk of inappropriate information exchanges among Biovail, Elan, and Teva regarding generic Adalat, by eliminating any legitimate reason for all three companies to discuss their marketing of the products. Thus, it will help ensure that the termination of the Agreement fully restores the proper competitive incentives for each company.

The proviso to Paragraph IV requires Elan to supply Teva, through Biovail, with Elan's 30 mg product, until the earlier of Biovail's launch of its own 30 mg product or May 31, 2003 (the "Interim Supply Agreement"). This provision eliminates any disruption of supply of the 30 mg product to consumers while Elan makes alternate arrangements for the distribution of its products. Once Elan begins to distribute its own product through an independent distributor, the Interim Supply Agreement will assure that consumers have access to two generic 30 mg Adalat products. The Interim Supply Agreement may continue for up to a year, to give consumers the continued benefit of two 30 mg generic Adalat products while Biovail solves its purported manufacturing difficulty. Biovail has assured the Commission that it expects to overcome any manufacturing problems it has and launch its 30 mg generic Adalat product within a year. (Paragraph V further addresses Biovail's launch of its own 30 mg product, as we discuss below.)

Paragraph IV prohibits Elan from charging Biovail more than Elan's "Cost" for the product. Paragraph I of the proposed order defines "Cost" to mean Elan's actual manufacturing cost. The cost definition is narrow, to minimize Elan's ability to profit from the Interim Supply Agreement through manipulation of the definition. Preventing Elan from profiting by supplying Biovail with the Elan 30 mg generic Adalat product gives Elan a strong

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incentive to launch its own 30 mg product through an independent distributor as quickly as possible. Only through that launch will Elan begin to earn a profit on its 30 mg product. Because, under the Interim Supply Agreement, Biovail will receive Elan's 30 mg product at Elan's manufacturing cost, Biovail will be in the same competitive position with respect to the cost of the 30 mg product as will Elan. In addition, Biovail will have to compete with Elan's new distributor to gain and maintain market share. Thus, the narrow cost definition will also give consumers the benefit of immediate price competition between the 30 mg product marketed by Teva and the 30 mg product marketed by Elan's independent distributor.

Paragraph V of the proposed order requires Elan to use best efforts to launch its 30 mg and 60 mg generic Adalat products as promptly as possible through a distributor other than Teva. It also requires Biovail to use best efforts to manufacture and distribute its 30 mg generic Adalat product, and to use best efforts to continue to manufacture and distribute its 60 mg generic Adalat product through a distributor other than Elan's generic Adalat distributor. Paragraph V.C states that the purpose of these requirements is to restore competitive incentives in the market for generic Adalat, and to remedy the lessening of competition resulting from the anticompetitive practices alleged in the Commission's complaint. This provision covers all four generic Adalat products, to ensure that Biovail and Elan market their 30 mg and 60 mg products through separate distributors. The proposed order defines "Launch" to require Biovail and Elan to deliver commercial quantities of their generic Adalat products to a viable pharmaceutical distributor pursuant to a commercially reasonable, multi-year contract. This definition will ensure that the launch of Elan's 60 mg product and of Biovail's 30 mg product is on a competitive scale.

The Commission will closely monitor Respondents' efforts to market their products. To facilitate this, the proposed order includes reporting requirements. Paragraph VIII requires Biovail and Elan to submit to the Commission verified written reports

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detailing each of their efforts to comply with the proposed order. Biovail and Elan must submit these reports every thirty days until they have complied with the proposed order.

Paragraph VI of the proposed order requires Biovail and Elan to give the Commission notice of two types of agreements with other pharmaceutical manufacturers. First, Paragraph VI.A requires Biovail and Elan to give notice of agreements where, at the time of the agreement, the parties to the agreement each own, control, or license another product that is in the same “Therapeutic Class” as the product covered by the agreement. (The proposed order defines “Therapeutic Class” as a class of drugs categorized by the Unified System of Classification contained in the most recent version of the IMS Health Incorporated publication *Market Research Database: Product Directory*.) A proviso excepts from the reporting requirement agreements that only transfer “Drug Delivery Technology” in exchange for a commercially reasonable cash royalty not to exceed five per cent of revenue. (The proposed order defines “Drug Delivery Technology” to mean technology that controls the release rate, or enhances the absorption or utilization, of a pharmaceutical compound.)

Second, Paragraph VI.B requires Biovail and Elan to give notice of agreements involving a product for which one party to the agreement has an ANDA that references a New Drug Application (“NDA”) that the other party owns, controls, or licenses. The notification provisions contained in Paragraph VI are necessary, because the core prohibition in Paragraph II only reaches agreements involving ANDAs that reference the same branded drug. Paragraph VI ensures that the Commission will receive notice of potentially anticompetitive agreements not covered by Paragraph II (*i.e.*, agreements involving potentially competitive branded products, and agreements regarding a brand product and its generic equivalent.)

Paragraphs VII, VIII, IX, and X of the proposed order contain reporting and other standard Commission order provisions designed to assist the Commission in monitoring compliance with

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the order. Paragraph XI provides that the order will expire in ten years.

Opportunity for Public Comment

The proposed order has been placed on the public record for thirty days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed order and the comments received and will decide whether it should withdraw from the agreement containing the proposed order or make the proposed order final.

By accepting the proposed order subject to final approval, the Commission anticipates that the competitive issues alleged in the complaint will be resolved. The purpose of this analysis is to facilitate public comment on the agreement. It is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.

Complaint

IN THE MATTER OF

AMGEN INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT

Docket C-4056; File No. 0210059

Complaint, July 12, 2002--Decision, September 3, 2002

This consent order addresses the merger of Respondent Amgen Inc. and Respondent Immunex Corporation, two pharmaceutical manufacturers. The order, among other things, requires the respondents to divest all of Respondent Immunex's assets relating to Leukine – a neutrophil regeneration factor used to treat neutropenia (the suppression of production of certain white blood cells known as “neutrophils”), which often results from chemotherapy – to Schering AG. The order also requires the respondents to license certain Amgen patents relating to its tumor necrosis factor (“TNF”) receptor to Serono S.A. In addition, the order requires the respondents to license certain Amgen and Immunex patents relating to the development of Interleukin-1 (“IL-1”) receptors to Regeneron Pharmaceuticals Inc., thereby enabling Regeneron to continue to develop its IL-1 Trap product – an IL-1 inhibitor used to treat rheumatoid arthritis – in competition with the respondents.

Participants

For the Commission: *Elizabeth A. Jex, James J. Hegarty, Kari A. Wallace, David von Nirschl, Jennifer Lee, Kristen M. Gorzelany, Stephanie Richard, Ann Malester, Christina Sarris, Elizabeth A. Piotrowski, Hajime Hadeishi, and Michael G. Vita.*

For the Respondents: *John M. Nannes, Skadden, Arps, Slate, Meagher & Flom, and Daniel M. Wall and J. Thomas Rosch, Latham & Watkins.*

Complaint

COMPLAINT

The Federal Trade Commission (“Commission”), having reason to believe that Respondent Amgen Inc. (“Amgen”), a corporation subject to the jurisdiction of the Commission, has agreed to merge with Respondent Immunex Corporation (“Immunex”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. DEFINITIONS

1. “Abbott” means Abbott Laboratories, a corporation organized, existing, and doing business under and by virtue of the laws of the state of Illinois, with its offices and principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064.
2. “Celltech” means Celltech Group plc, a corporation organized, existing, and doing business under and by virtue of the laws of the United Kingdom, with its offices and principal place of business located at 208 Bath Road, Slough, Berkshire, SL1 3WE, UK.
3. “FDA” means the United States Food and Drug Administration.
4. “IL-1 Inhibitor” or “IL-1 Inhibitor product” means any molecule capable of binding to human Interleukin-1 (“IL-1”), thereby reducing the binding of IL-1 to the target cell membrane receptors, which molecule is comprised of all of, or an IL-1 binding portion of, an IL-1 receptor (Type I or Type II) and all of, or an active portion of, the IL-1 accessory protein.

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5. "Johnson & Johnson" means Johnson & Johnson, a corporation organized, existing, and doing business under and by virtue of the laws of the state of New Jersey, with its offices and principal place of business located at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

6. "Merger Agreement" means the Amended and Restated Agreement and Plan of Merger by and among Amgen, AMS Acquisition Inc., and Immunex dated December 16, 2001.

7. "Neutrophil Regeneration Product" means a colony stimulating factor produced, at least in part, by recombinant DNA technology, that stimulates the proliferation and differentiation of human neutrophil cells, commonly referred to as white blood cells, including, but not limited to, granulocytes and macrophages.

8. "Pharmacia" means Pharmacia Corporation, a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its offices and principal place of business located at 100 Route 206 North, Peapack, New Jersey 07977.

9. "RA" means rheumatoid arthritis.

10. "Regeneron" means Regeneron Pharmaceuticals Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the state of New York, with its offices and principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

11. "Serono" means Serono International S.A., a corporation organized, existing, and doing business under and by virtue of the laws of the Swiss Confederation, with its offices and principal place of business located at 15bis, Chemin des Mines, Case Postale 54, CH-1202 Geneva, Switzerland.

12. "TNF Inhibitor" or "TNF Inhibitor product" means any recombinant human tumor necrosis factor ("TNF") binding

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protein that binds to TNF, thereby reducing the binding of TNF to target cell membrane receptors.

II. RESPONDENTS

13. Respondent Amgen is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen, among other things, is engaged in the research, development, manufacture, and sale of human pharmaceutical products, including, among other things, Neutrophil Regeneration Products, TNF Inhibitors, and IL-1 Inhibitors.

14. Respondent Immunex is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Washington, with its office and principal place of business located at 51 University Street, Seattle, Washington 98101. Immunex, among other things, is engaged in the research, development, manufacture, and sale of human pharmaceutical products, including, among other things, Neutrophil Regeneration Products, TNF Inhibitors, and IL-1 Inhibitors.

15. Respondents are, and at all times relevant herein have been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C.

§ 12, and are corporations whose business is in or affects commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED MERGER

16. On December 16, 2001, Amgen and Immunex entered into a Merger Agreement whereby Amgen agreed to acquire, through its wholly-owned subsidiary, AMS Acquisition Inc., 100 percent of all issued and outstanding shares of Immunex ("Merger"). Amgen intends to pay consideration such that each issued and outstanding share of Immunex common stock will be converted

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into the right to receive 0.44 shares of Amgen common stock and about \$4.50 in cash. The parties estimate the aggregate value of the transaction to be approximately \$16 billion. After the completion of the transaction, Amgen will be the surviving corporate entity.

IV. THE RELEVANT MARKETS

17. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Merger are:

- a. the research, development, manufacture, and sale of Neutrophil Regeneration Products;
- b. the research, development, manufacture, and sale of TNF Inhibitors; and
- c. the research, development, manufacture, and sale of IL-1 Inhibitors.

18. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Merger in the relevant lines of commerce.

V. THE STRUCTURE OF THE MARKETS

19. Amgen and Immunex are the only two companies competing in the \$1.2 billion neutrophil regeneration market. Amgen is developing and marketing Neupogen, a granulocyte colony stimulating factor (“G-CSF”) that stimulates the production of granulocytes to treat cancer chemotherapy patients suffering from neutropenia, as well as for other indications. Amgen is also marketing Neulasta, a new, longer-lasting formulation of the G-CSF product for those same indications. Immunex is developing and marketing Leukine, a granulocyte macrophage colony stimulating factor that stimulates the production of macrophages and granulocytes to treat cancer chemotherapy patients (especially acute myelogenous leukemia

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cancer patients) suffering from neutropenia, as well as for other indications.

20. In the United States, Amgen and Immunex are the only companies clinically developing or marketing soluble TNF receptor products, two of only four companies clinically developing subcutaneously delivered TNF Inhibitors, and two of only five companies clinically developing TNF Inhibitors to treat RA and other autoimmune diseases by blocking the activity of the pro-inflammatory cytokine TNF. There are two TNF Inhibitors approved by the FDA for the treatment of RA: (1) Enbrel, Immunex's soluble TNF receptor; and (2) Remicade, Johnson & Johnson's chimeric monoclonal antibody targeting the TNF cell surface receptor. In the United States, there are three TNF Inhibitors in clinical development: (1) Amgen is in late Phase II trials with PEG-sTNFr, a soluble receptor product very similar to Immunex's Enbrel; (2) Abbott recently submitted a Biologic License Application to the FDA for its humanized monoclonal antibody, D2E7, targeting the TNF cell surface receptor; and (3) Pharmacia and Celltech are jointly in Phase II trials with a humanized monoclonal antibody, CDP 870, targeting the TNF cell surface receptor. Serono also is developing a soluble TNF receptor, Onercept, for use in Europe, but it does not possess the patent rights necessary to market the product in the United States.

21. Amgen and Immunex are two of only three companies clinically developing or marketing IL-1 Inhibitor products to treat RA and other autoimmune diseases by blocking the activity of the pro-inflammatory cytokine IL-1. Amgen's product, Kineret, was the first IL-1 Inhibitor approved by the FDA. Amgen also has research and development efforts directed at second generation IL-1 Inhibitors. Immunex is in Phase I trials of its IL-1 Inhibitor product, known as IL-I Type II. Regeneron, the only other company in clinical development of an IL-1 Inhibitor, is about to begin Phase II trials of its IL-1 Inhibitor product called IL-1 Trap. It appears that Immunex is likely to succeed in its efforts to preclude Regeneron's successful commercialization of its IL-1 Trap product through patent infringement litigation for the

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following reasons: (1) Immunex has the ability to block Regeneron by using patent litigation; (2) Regeneron has indicated that such litigation, even were it to ultimately yield a favorable outcome for Regeneron, could foreclose its ability to commercialize its IL-1 Trap; and (3) the likelihood of threatened patent litigation by Immunex will jeopardize and could effectively preclude commercialization of Regeneron's IL-1 Trap.

VI. ENTRY CONDITIONS

22. Amgen and Immunex each control substantial proprietary rights necessary to commercialize Neutrophil Regeneration Products, TNF Inhibitor products, and IL-1 Inhibitor products in the United States, and possess the technological, manufacturing, clinical and regulatory expertise, and manufacturing capability to commercially develop Neutrophil Regeneration Products, TNF Inhibitor products, and IL-1 Inhibitor products.

23. Entry into the United States neutrophil regeneration, TNF Inhibitor, and IL-1 Inhibitor product markets would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the merger. FDA regulations covering these products create long lead times for the introduction of new products. Additionally, patents and other intellectual property create large and potentially insurmountable barriers to entry.

24. Entry into the neutrophil regeneration, TNF Inhibitor, and IL-1 Inhibitor product markets requires lengthy preclinical and clinical trials, data collection and analysis, and expenditures of significant resources over many years to qualify manufacturing facilities with the FDA. Clinical development and FDA approval can extend from 6 to 10 years and cost over \$200 million. The FDA must approve all phases of development, including extensive preclinical and clinical work. The most significant barriers to entry include technical, regulatory, patent, clinical and production barriers. No company can reach advanced stages of development in the relevant market without: (1) scientific research that

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requires years to complete; (2) patent rights sufficient to provide the company with reasonable assurances of freedom to operate; (3) commercial scale product manufacturing expertise and capacity, regulatory approvals; and (4) clinical expertise. The necessary intellectual property includes the respective DNA sequences, methods of making and using neutrophil regeneration, TNF Inhibitor, and IL-1 Inhibitor products.

VII. EFFECTS OF THE MERGER

25. The effects of the Merger, if consummated, may be to lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Amgen and Immunex in the neutrophil regeneration market;
- b. by increasing the merged firm's ability to exercise market power unilaterally in the neutrophil regeneration market;
- c. by reducing innovation competition in the research, development, and commercialization of (a) neutrophil regeneration, (b) TNF Inhibitor, and (c) IL-1 Inhibitor products; and
- d. by eliminating potential competition in the (a) TNF Inhibitor and (b) IL-1 Inhibitor product markets.

VIII. VIOLATIONS CHARGED

26. The Merger Agreement described in Paragraph 16 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

Complaint

27. The Merger described in Paragraph 16, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twelfth day of July, 2002, issues its Complaint against said Respondents.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed merger of Respondent Amgen Inc. (“Amgen”) and Respondent Immunex Corporation (“Immunex”), hereinafter referred to as “Respondents,” and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

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1. Respondent Amgen is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at One Amgen Center Drive, Thousand Oaks, California 91320-1799.
2. Respondent Immunex is a corporation organized, existing and doing business under and by virtue of the laws of the State of Washington, with its office and principal place of business located at 51 University Street, Seattle, Washington 98101-2936.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Amgen” means Amgen Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Amgen Inc. (including, but not limited to, AMS Acquisition, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Immunex” means Immunex Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Immunex Corporation (including, but not limited to, Immunex Manufacturing Corporation), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

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- C. "Respondents" means Amgen and Immunex, individually and collectively.
- D. "Merger" means the proposed merger of AMS Acquisition Inc., a wholly-owned subsidiary of Amgen, and Immunex by means of an Amended and Restated Agreement and Plan of Merger dated as of December 16, 2001, by and among Amgen, AMS Acquisition Inc., and Immunex.
- E. "Commission" means the Federal Trade Commission.
- F. "Regeneron" means Regeneron Pharmaceuticals Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its offices and principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591.
- G. "Schering" means Schering Aktiengesellschaft, a stock corporation organized under the laws of The Federal Republic of Germany with its offices and principal place of business located at Mullerstrasse 178, 13353 Berlin, Germany.
- H. "Serono" means Serono International, S.A., a corporation organized, existing and doing business under and by virtue of the laws of the Swiss Confederation, with its offices and principal place of business located at 15bis, Chemin des Mines, Case Postale 54, CH-1202 Geneva, Switzerland.
- I. "Agency(ies)" means any governmental regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s) or permit(s) for any aspect of the research, development, manufacture, marketing, distribution or sale of a Product. The term "Agency" includes, but is not limited to, the United States Food and Drug Administration ("FDA").

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- J. “BLA” means the Biologic License Application or Establishment License Application/Product License Application filed or to be filed with the FDA for Leukine pursuant to 21 C.F.R. 601.2, et seq., and Section 351 of the Public Health Service Act, or its foreign Agency equivalent, and all supplements, amendments, revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondents and the FDA or other Agency relative thereto.
- K. “Bothell Facility” means that portion of the Immunex facility located at 21511 23rd Drive SE, Bothell, Washington that is described in Exhibits A-2 and B (and which constitutes a portion of the larger facility that is legally described in Exhibit A-1) of the Lease by and among Immunex and Schering, which Lease is attached as Exhibit H to the Leukine Asset Purchase Agreement.
- L. “Business Day” means any day excluding Saturday, Sunday and any United States Federal holiday.
- M. “Closing Date” means the date on which Respondents and a Commission-approved Acquirer close on a transaction to divest, license, or otherwise convey relevant assets pursuant to this Order.
- N. “Commission-approved Acquirer” means an entity approved by the Commission to acquire the Leukine Assets.
- O. “Confidential Business Information” means all information owned by Respondents that is not in the public domain related to the research, development, manufacture, marketing, commercialization, distribution, importation, cost, pricing, supply, sales, sales support, or use of Leukine.
- P. “Divestiture Agreement” means any agreement between Respondents and a Commission-approved Acquirer (or between a trustee appointed pursuant to Paragraph VI of this

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Order and a Commission-approved Acquirer) and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Leukine Assets to be divested that have been approved by the Commission to accomplish the requirements of this Order.

- Q. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph VI.A. of this Order.
- R. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any entity or authority who issues and maintains the domain name registration. “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Leukine Trademarks required to be divested.
- S. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to Leukine.
- T. “Effective Date” means the date the Merger is consummated by filing articles of merger with the Secretary of State of the State of Washington.
- U. “Governmental Entity” means any Federal, state, local or non-U.S. government or any court, legislature, governmental agency or governmental commission or any judicial or regulatory authority of any government.
- V. “IL-1 Inhibitor” means any recombinant human Interleukin-1 (“IL-1”) binding protein that binds to IL-1, thereby reducing the binding of IL-1 to the target cell membrane receptors.
- W. “IL-1 Trap” means a molecule capable of binding to IL-1, thereby reducing the binding of IL-1 to the target cell membrane receptors, which molecule is comprised of all of, or an IL-1 binding portion of, an IL-1 receptor (Type I or

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Type II) and all of, or an active portion of, the IL-1 accessory protein.

- X. “IL-1 License Agreement” means the license agreement between Immunex and Regeneron dated June 26, 2002, attached hereto as non-public Appendix IV.
- Y. “IND” means an Investigational New Drug Application filed with the FDA for Leukine pursuant to 21 C.F.R. 312.1, et seq., for which Immunex is the “Sponsor” (as defined in 21 C.F.R. 312.3), and all supplements, amendments and revisions thereto.
- Z. “Leukine” means the Product that contains the active ingredient generically known as sargramostim, *i.e.*, a certain modified human granulocyte-macrophage colony stimulating factor produced by recombinant DNA technology, that is or was researched, developed, manufactured, marketed and sold by Respondent Immunex prior to the divestiture of the Leukine Assets. The term “Leukine” also includes Products in development by Respondent Immunex on or before the Effective Date that have a similar amino acid sequence and mechanism of action to that of Leukine, *i.e.*, that stimulate production of granulocytes and macrophages.
- AA. “Leukine Assets” means all of Respondent Immunex’s rights, title and interest, in the United States and Canada, in and to all assets related to Leukine to the extent legally transferable, including the research, development, manufacture, distribution, marketing or sale of Leukine including, without limitation, the following:
 - 1. all Leukine Intellectual Property;
 - 2. the Product and Product Registrations;
 - 3. the Leukine Trade Dress;

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4. the existing lists of all current customers for Leukine and the pricing of Leukine for such customers;
5. at the Commission-approved Acquirer's option, each of the Leukine Assumed Contracts;
6. all Leukine Marketing Materials;
7. all Website(s) related to Leukine;
8. rights to use the NDC Numbers related to Leukine;
9. rights of reference to the Drug Master Files;
10. rights of reference (if such rights exist) to information similar to the Drug Master Files submitted to any Agency (including any Agency outside the United States and Canada) other than the FDA;
11. Leukine Scientific and Regulatory Material;
12. all unfilled customer orders for finished goods as of the Closing Date (a list of such orders is to be provided to the Commission-approved Acquirer within two Business Days after the Closing Date);
13. Leukine Manufacturing Technology, and Leukine manufacturing and manufacturing processes;
14. at the Commission-approved Acquirer's option, all inventories in existence as of the Closing Date, including, but not limited to, raw materials, goods in process, finished goods, and Leukine specific packaging and labels;
15. the cell bank inventories related to Leukine owned by Respondent Immunex, including, but not limited to, Master Cell Bank Lot BVL-0002; Working Cell Bank Lot: BAG/010138; Working Cell Bank Lot: BAG/A03184;

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Original Host Source Material: XV2181 diploid; and one (1) vial of yeast haploid strain named: 79 containing the same plasmid PIXY15;

16. the Leukine Microbial Manufacturing Facility, *provided, however,* that, in lieu of a sale of this facility to the Commission-approved Acquirer, the Respondents may offer a lease to the facility, for a term of not less than three (3) years from the Closing Date and renewable, at the Commission-approved Acquirer's option, for at least five (5) additional terms of one (1) year each;
17. all manufacturing and other equipment located at the Leukine Microbial Manufacturing Facility that was used in, or suitable for use in, the research, development or manufacture of Leukine;
18. at the Commission-approved Acquirer's option, the Bothell Facility including the real property and buildings; *provided, however,* if the Commission-approved Acquirer so elects, the Respondents may provide a long-term lease to the Bothell Facility in lieu of a sale of the facility to the Commission-approved Acquirer;
19. at the Commission-approved Acquirer's option, all quality control equipment used or held for use for the manufacture of Leukine that is located at the Bothell Facility;
20. all permits from any Governmental Entity that are required to manufacture or sell Leukine, to the extent transferable; and
21. all Respondents' books, records and files related to the foregoing, including, but not limited to, the following specified documents: the Product Registrations; rights of reference to Drug Master Files, including, but not limited to, the pharmacology and toxicology data contained in all INDs and BLAs; all data submitted to and all

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correspondence with the FDA and other Agencies; all validation documents and data; all market studies; all sales histories, including, without limitation, clinical data, sales force call activity, and physician prescription activity (to the extent Respondents have the right to transfer such information), for Leukine on a per-physician basis from January 1, 1997, through the Closing Date, and quality control histories pertaining to Leukine owned by Respondents, in each case such as is in existence, and in the possession or control of Respondents, as of the Closing Date.

Provided, however, that in cases in which documents or other materials included in the Leukine Assets contain information that (i) relates both to Leukine and to other Products or businesses of Respondent Immunex, and (ii) cannot be segregated in a manner that preserves the usefulness of the information as it relates to Leukine, the Respondent Immunex shall be required only to provide copies of the documents and materials containing this information. In instances where such copies are provided to the Commission-approved Acquirer, the Commission-approved Acquirer shall have access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondents provide the Commission-approved Acquirer with the above-described information without requiring Respondents completely to divest themselves of information that, in content, also relates to Products and businesses other than Leukine.

- BB. “Leukine Asset Purchase Agreement” means the “Asset Purchase Agreement by and between Immunex Corporation as Seller, and Schering Aktiengesellschaft as Purchaser” dated May 2, 2002, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Leukine Assets to be divested that have been approved by the Commission to accomplish the requirements of this

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Order. The Leukine Asset Purchase Agreement is attached to this Order as non-public Appendix II.

- CC. “Leukine Assumed Contracts” means all contracts or agreements:
1. pursuant to which any third party purchases Leukine from Immunex;
 2. pursuant to which Immunex purchases any materials from any third party for use in connection with the manufacture of Leukine;
 3. relating to any clinical trial involving Leukine;
 4. constituting the material transfer agreements involving the transfer of Leukine;
 5. relating to the marketing of Leukine or educational matters relating to the Leukine business;
 6. relating to the manufacture (including finish or fill) of Leukine;
 7. constituting confidentiality agreements involving Leukine;
 8. involving any royalty, licensing or similar arrangement involving Leukine;
 9. pursuant to which any services are provided to Immunex with respect to Leukine or the Leukine business, including consultation arrangements; and/or
 10. pursuant to which any third party collaborates with Immunex in performance of research or development of Leukine or the Leukine business.

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Provided, however, that where any such contract or agreement also relates to Product(s) of Respondent Immunex other than Leukine, Respondents shall assign the Commission-approved Acquirer all such rights under the contract or agreement as are related to Leukine, but concurrently may retain similar rights for the purposes of the other Product(s).

- DD. “Leukine Bothell Microbial Facility Project Employees” means all employees of Respondent Immunex who directly participated (irrespective of the portion of working time involved) in the planning, engineering, procurement, or analysis of the means to produce Leukine at Immunex’s facility in Bothell, Washington within the eighteen (18) month period immediately prior to the Closing Date. These employees are identified in non-public Appendix I.
- EE. “Leukine Copyrights” means rights to all original works of authorship of any kind related to Leukine and any registrations and applications for registrations thereof, including, but not limited to, the following: all promotional materials for healthcare providers; all promotional materials for patients; educational materials for the sales force; copyrights in all pre-clinical, clinical and process development data and reports relating to the research and development of Leukine or of any materials used in the research, development, manufacture, marketing or sale of Leukine, including all raw data relating to clinical trials of Leukine, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; customer information, promotional and marketing materials, Leukine sales forecasting models, medical education materials, sales training materials, Website content and advertising and display materials; all records relating to employees that accept employment with the Commission-approved

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Acquirer (excluding any personnel records the transfer of which is prohibited by applicable law); all records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all data contained in laboratory notebooks relating to Leukine or relating to its biology; all adverse experience reports and files related thereto (including source documentation) and all periodic adverse experience reports and all data contained in electronic data bases relating to adverse experience reports and periodic adverse experience reports; all analytical and quality control data; and all correspondence with the FDA.

- FF. “Leukine Core Employees” means the Leukine Bothell Microbial Facility Project Employees, Leukine Manufacturing Employees, Leukine Marketing Employees, Leukine Patent Attorneys, and Leukine Research and Development Employees.
- GG. “Leukine Intellectual Property” means all of the following related to Leukine:
1. Patents;
 2. Leukine Copyrights;
 3. Leukine Software;
 4. Leukine Trademarks, including the goodwill of the business symbolized thereby and associated therewith;
 5. trade secrets, know-how, techniques, data, inventions, practices, methods and other confidential or proprietary technical, business, research, development and other information, and all rights in any jurisdiction to limit the use or disclosure thereof;

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6. rights to obtain and file for Patents and registrations thereof; and
7. rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation or breach of any of the foregoing.

Provided, however, “Leukine Intellectual Property” does not include the name “Immunex” or related logos to the extent used on other of Respondent Immunex’s Products.

- HH. “Leukine Manufacturing Employees” means all employees of Respondent Immunex who directly participated (irrespective of the portion of working time involved) in the manufacture of Leukine, including, but not limited to, those involved in the quality assurance and quality control of Leukine, within the eighteen (18) month period immediately prior to the Closing Date. These employees are identified in non-public Appendix I.
- II. “Leukine Manufacturing Technology” means all technology, trade secrets, know-how, and proprietary information related to the manufacture, validation, packaging, release testing, stability and shelf life of Leukine, including Leukine’s formulation, in existence and in the possession of Respondents as of the Closing Date, including, but not limited to, manufacturing records, sampling records, standard operating procedures and batch records related to the manufacturing process, and supplier lists.
- JJ. “Leukine Marketing Employees” means all executives of Respondent Immunex who directly participated (irrespective of the portion of working time involved) in the marketing, contracting, or promotion of Leukine in the United States and Canada within the eighteen (18) month period immediately prior to the Closing Date. These employees include, without limitation, all executives having any responsibilities in the areas of sales management, brand

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management, sales training, market research, managed care contracting, hospital market and other specialty markets, but excluding administrative assistants. These employees are identified in non-public Appendix I.

- KK. “Leukine Marketing Materials” means all marketing materials used anywhere in the world related to Leukine as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, price lists, mailing lists, sales materials (e.g., detailing reports; vendor lists; sales data; reimbursement data), marketing information (e.g., competitor information; research data; market intelligence reports; statistical programs (if any) used for marketing and sales research; customer information, including customer sales information; sales forecasting models; medical educational materials; Website content and advertising and display materials; speaker lists), promotional and marketing materials, artwork for the production of packaging components, television masters and other similar materials related to Leukine.
- LL. “Leukine Microbial Manufacturing Facility” means the third floor of Immunex’s facility located at 51 University Street, Seattle, Washington that has been used by Immunex to research and develop Leukine and to manufacture Leukine bulk drug substance.
- MM. “Leukine Patent Attorneys” means all employees of Respondent Immunex who are attorneys and who performed legal work (irrespective of the portion of working time involved) on Patents related to Leukine within the eighteen (18) month period immediately prior to the Closing Date. These employees are identified in non-public Appendix I.
- NN. “Leukine Research and Development Employees” means all employees of Respondent Immunex who directly participated (irrespective of the portion of working time involved) in the research, development, regulatory approval

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process, or clinical studies of Leukine within the eighteen (18) month period immediately prior to the Closing Date. These employees are identified in non-public Appendix I.

- OO. “Leukine Sales Employees” means all of Respondent Immunex’s worldwide oncology sales force personnel, including all sales representatives, sales managers, national account managers, reimbursement managers, oncology medical associates and oncology nurse educators. These employees are identified in non-public Appendix I.
- PP. “Leukine Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and clinical trial materials and information related to Leukine, and all rights thereto, in any and all jurisdictions.
- QQ. “Leukine Seller Disclosure Letter” means the disclosure letter from Immunex to Schering dated May 2, 2002, and signed by Edward V. Fritzky, Chief Executive Officer of Immunex, and referred to in the Leukine Asset Purchase Agreement. This letter is attached to this Order and contained in non-public Appendix II.
- RR. “Leukine Software” means computer programs, including all software implementations of algorithms, models, and methodologies whether in source code or object code form, databases and compilations, including any and all data and collections of data, all documentation, including user manuals and training materials, related to any of the foregoing and the content and information contained on any Website; *provided, however,* that “Leukine Software” does not include software that is readily purchasable or licensable and which has not been modified in a manner material to the use or function thereof (other than through user preference settings).

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- SS. “Leukine Trade Dress” means the current trade dress of Leukine, including, but not limited to, product packaging associated with the sale of Leukine worldwide and the lettering of Leukine’s trade name or brand name.
- TT. “Leukine Trademarks” means all trademarks, trade names and brand names including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for Leukine.
- UU. “NDC Numbers” means the National Drug Code numbers(s) assigned by the FDA to a Product.
- VV. “Neupogen” or “Neulasta” means the Neutrophil Regeneration Products developed and marketed by Respondent Amgen.
- WW. “Neutrophil Regeneration Product” means a Product that is a colony stimulating factor produced, at least in part, by recombinant DNA technology, that stimulates the proliferation and differentiation of human neutrophil cells, commonly referred to as white blood cells, including, but not limited to, granulocytes and macrophages.
- XX. “Ownership Interest” means any and all rights, present or contingent, of Respondents to hold any voting or nonvoting stock, share capital, equity or other interests or beneficial ownership in an entity.
- YY. “Patents” mean all patents, patent applications and statutory invention registrations, in each case existing as of the Effective Date, and including all reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all

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rights to obtain and file for patents and registrations thereto in the world, related to any Product of or owned by Respondents as of the Closing Date.

- ZZ. “Product” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically or genetically active ingredient.
- AAA. “Product Registrations” means all registrations, permits, licenses, consents, authorizations and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, development, manufacture, distribution, finishing, packaging, marketing or sale of the Product worldwide, including all INDs or BLAs in existence for the Product as of the Closing Date.
- BBB. “TNFbp-I” means a molecule capable of binding to tumor necrosis factor (“TNF”), thereby reducing the binding of TNF to target cell membrane receptors, which molecule is comprised of the soluble portion of TNF Receptor Type-I, and which is also known as soluble TNF Receptor Type-I.
- CCC. “TNF Settlement and Cross-License Agreement” means the license agreement between Serono and Amgen dated June 28, 2002, attached hereto as non-public Appendix III.
- DDD. “Washington University” means Washington University located in Saint Louis, Missouri.
- EEE. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by Respondents. “Website” shall not include content owned by third parties and other Leukine Intellectual Property not owned by Respondents that are incorporated in such Website(s), such as stock photographs used in the Website(s), except to the

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extent that Respondents can transfer their rights, if any, therein.

II.

IT IS FURTHER ORDERED that:

- A. Not later than ten (10) Business Days after the Effective Date, Respondents shall divest the Leukine Assets as an ongoing business to Schering pursuant to and in accordance with the Leukine Asset Purchase Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Schering or to reduce any obligations of Respondents under such agreement), and such agreement, if approved by the Commission as the Divestiture Agreement for the Leukine Assets, is incorporated by reference into this Order and made part hereof as non-public Appendix II. If Respondents do not divest the Leukine Assets to Schering within ten (10) Business Days after the Effective Date, the Commission may appoint a Divestiture Trustee to divest the Leukine Assets. *Provided, however,* that if Respondents have divested the Leukine Assets to Schering prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Schering is not an acceptable purchaser of the Leukine Assets or that the manner in which the divestiture was accomplished is not acceptable, then Respondents shall immediately rescind the transaction with Schering and the Commission may appoint a Divestiture Trustee to divest the Leukine Assets to a Commission-approved Acquirer.
- B. Failure to comply with all terms of the Leukine Asset Purchase Agreement, if approved by the Commission, shall constitute a failure to comply with this Order. Any Divestiture

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Agreement between Respondents (or a Divestiture Trustee) and a Commission-approved Acquirer of the Leukine Assets shall be deemed incorporated by reference into this Order, and any failure by Respondents to comply with the terms of such Divestiture Agreement shall constitute a failure to comply with this Order.

C. Respondents shall include in any Divestiture Agreement related to the Leukine Assets the following provisions, and Respondents shall commit that, upon reasonable notice and a request from the Commission-approved Acquirer to the Respondents, Respondents shall provide in a timely manner:

1. assistance and advice to enable the Commission-approved Acquirer to obtain all necessary permits and approvals from any Agency or Governmental Entity to manufacture and sell Leukine;
2. assistance to the Commission-approved Acquirer to manufacture Leukine in substantially the same manner and quality employed or achieved by Respondent Immunex; and
3. consultation with knowledgeable employees of Respondents and training, at the request of the Commission-approved Acquirer and at a facility chosen by the Commission-approved Acquirer, until the Commission-approved Acquirer receives certification from the FDA for the manufacture of Leukine at the Leukine Microbial Manufacturing Facility (if such certification is required), sufficient to satisfy management of the Commission-approved Acquirer that its personnel are adequately trained in the manufacture of Leukine.

D. Respondents shall not seek or obtain, directly or indirectly, alone or in collaboration with a third party, an assignment or exclusive license right under any Patent relating to the use of Leukine for the treatment of Crohn's disease (including,

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but not limited to, Patent Application WO 00/47195 “Stimulating Neutrophil Function to Treat Inflammatory Bowel Disease”), that is owned or controlled by Washington University as of the Closing Date. In addition, Respondents shall not interfere with the Commission-approved Acquirer’s ability to acquire rights under such Patent(s) and shall remove any impediments within the control of Respondents that may inhibit the Commission-approved Acquirer’s ability to secure such rights.

- E. Respondents shall submit to the Commission-approved Acquirer, at Respondents’ expense, all Confidential Business Information related to Leukine. *Provided, however,* this provision shall not apply to any Confidential Business Information related to Leukine that Respondent Amgen can demonstrate it obtained without the assistance of Respondent Immunex prior to the Effective Date.
- F. Respondents shall not use, directly or indirectly, any Confidential Business Information related to the research, development, manufacturing, marketing, or sale of Leukine, and shall not disclose or convey such Confidential Business Information, directly or indirectly, to any person except the Commission-approved Acquirer. This provision shall not apply to any Confidential Business Information related to Leukine that Respondent Amgen can demonstrate it obtained without the assistance of Respondent Immunex prior to the Effective Date.
- G. Respondents shall provide the Commission-approved Acquirer with the opportunity to enter into employment contracts with the Leukine Sales Employees and the Leukine Core Employees for a period of six (6) months from the Closing Date (“the Access Period”), provided that such contracts are contingent upon the Commission’s approval of the Divestiture Agreement.

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- H. Respondents shall provide the Commission-approved Acquirer an opportunity to inspect the personnel files and other documentation related to the Leukine Sales Employees and the Leukine Core Employees, to the extent permissible under applicable laws, at the request of the Commission-approved Acquirer, at any time after execution of the Divestiture Agreement until the end of the Access Period.
- I. During the Access Period, Respondents shall not interfere with the hiring or employing by the Commission-approved Acquirer of Leukine Sales Employees or Leukine Core Employees, and shall remove any impediments within the control of Respondents that may deter these employees from accepting employment with the Commission-approved Acquirer, including, but not limited to, any non-compete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by the Commission-approved Acquirer. In addition, Respondents shall not make any counteroffer to a Leukine Sales Employee or Leukine Core Employee who receives a written offer of employment from the Commission-approved Acquirer.

Provided, however, that this Paragraph II.I. does not prohibit the Respondents from making offers of employment to or employing any Leukine Sales Employee or Leukine Core Employee during the Access Period where the Commission-approved Acquirer has notified the Respondents in writing that the Commission-approved Acquirer does not intend to make an offer of employment to that employee.

Provided further, that if the Respondents notify the Commission-approved Acquirer in writing of their desire to make an offer of employment to a particular Leukine Core Employee or Leukine Sales Employee, and the Commission-approved Acquirer does not make an offer of employment to that employee within twenty (20) Business Days of the date the Commission-approved Acquirer receives such notice, the

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Respondents may make an offer of employment to that employee.

- J. Respondents shall provide all Leukine Core Employees and all Leukine Sales Employees with reasonable financial incentives to continue in their positions until the Closing Date in accordance with Section 3.13(a)(i) of the Leukine Seller Disclosure Letter, which identifies employees and their respective coverage under the Immunex Corporation Retention Plan, as adopted December 16, 2001 ("Retention Plan"). Such incentives shall include a continuation of all employee benefits offered by Respondents until the Closing Date for the divestiture of the Leukine Assets has occurred, including regularly scheduled raises and bonuses, and a vesting of all pension benefits (as permitted by law). In addition to the foregoing, Respondents shall provide to each Leukine Manufacturing Employee who (i) is not included in levels one through six of the Retention Plan as disclosed in Section 3.13(a)(i) of the Leukine Seller Disclosure Letter and (ii) accepts employment with the Commission-approved Acquirer, an incentive equal to three (3) months of such employee's base annual salary to be paid upon the employee's completion of one (1) year of employment with the Commission-approved Acquirer.

Provided, however, that nothing in this Paragraph II.J. or in this Order requires or shall be construed to require the Respondents to terminate the employment of any employee.

- K. For a period of one (1) year following the date the divestiture is accomplished, Respondents shall not, directly or indirectly, solicit or otherwise attempt to induce any employees of the Commission-approved Acquirer with any amount of responsibility related to Leukine to terminate their employment relationship with the Commission-approved Acquirer; *provided, however,* a violation of this provision will not occur if: (i) Respondents advertise for employees in newspapers, trade publications or other media

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not targeted specifically at the employees, or (ii) Respondents hire employees who apply for employment with Respondents, as long as such employees were not solicited by Respondents in violation of this paragraph. During the one-year period following the divestiture, Respondents shall not, directly or indirectly, hire or enter into any arrangement for the services of any employee employed by the Commission-approved Acquirer with any amount of responsibility related to Leukine, unless the individual's employment has been terminated by the Commission-approved Acquirer.

- L. Respondents shall secure, prior to divestiture, all consents and waivers from all private entities that are necessary for the divestiture of the Leukine Assets to the Commission-approved Acquirer, or for the continued research, development, manufacture, sale, marketing or distribution of Leukine by the Commission-approved Acquirer.
- M. For the periods as set forth in this Paragraph II. M. (collectively, the "Moratorium/Waiting Period"), Respondents will not market or promote Neupogen or Neulasta or any other Neutrophil Regeneration Product in the United States or Canada using the services of any employee who has directly participated in the marketing, contracting, promotion or sale of Leukine, regardless of the portion of work time expended on Leukine, within the eighteen (18) month period immediately prior to the Closing Date. The Moratorium/Waiting Period shall be as follows:
 - (i) six (6) months from the Closing Date with respect to Leukine Sales Employees; and (ii) twelve (12) months from the Closing Date for all Leukine Marketing Employees.
- N. Respondents shall require, as a condition of continued employment post-divestiture, that each Leukine Sales Employee and each Leukine Core Employee sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Leukine Confidential

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Business Information (including, without limitation, all field experience) strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondents.

- O. Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to Leukine by Respondents' personnel and of the restrictions on the sale of Neupogen or Neulasta or any other Neutrophil Regeneration Product by certain Immunex personnel to all of Respondents' employees who (i) are or were involved in the research, development, manufacturing, distribution, sale or marketing of Leukine, (ii) are involved in the research, development, manufacturing, distribution, sale or marketing of Neupogen or Neulasta or any other Neutrophil Regeneration Product and/or (iii) may have Confidential Business Information related to Leukine. Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondents shall provide a copy of such notification to the Commission-approved Acquirer. Respondents shall also obtain from each employee covered by this Paragraph II. O. an agreement to abide by the applicable restrictions. Such agreement and notification shall be in substantially the form set forth in the "Notice of Divestiture and Employee Agreement to Maintain Non-Public Business Information Related to Leukine Confidential" attached as Appendix V to this Order and as Appendix A to the Order to Maintain Assets. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters and shall provide an officer's certification to the Commission, stating that such acknowledgment program has been implemented and is being complied with. Respondents shall monitor the implementation by their sales forces of all applicable restrictions, including the provision of written reminders to all such sales personnel at three (3) month

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intervals until the expiration of the time periods set forth in all Divestiture Agreements, including those in the Leukine Asset Purchase Agreement, and take corrective actions for the failure of sales personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order. Respondents shall provide the Commission-approved Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

- P. At the time of divestiture, Respondents shall make available to the Commission-approved Acquirer such personnel, assistance and training as the Commission-approved Acquirer might reasonably need to transfer the Leukine Assets, and shall continue providing such personnel, assistance and training, at the request of the Commission-approved Acquirer, until the Commission-approved Acquirer is fully validated, qualified, and approved by the FDA, and able to manufacture Leukine. At the time of divestiture, Respondents shall also divest any additional, incidental assets of Respondents and make any further arrangements for transitional services within the first twelve (12) months after divestiture that may be reasonably necessary to assure the viability and competitiveness of the Leukine Assets.
- Q. Pending divestiture of the Leukine Assets, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Leukine Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Leukine Assets except for ordinary wear and tear.
- R. Counsel for Respondents (including in-house counsel under appropriate confidentiality arrangements) may retain unredacted copies of all documents or other materials provided to the Commission-approved Acquirer and may have access to original documents (under circumstances where copies of

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documents are insufficient or otherwise unavailable) provided to the Commission-approved Acquirer in order to:

1. comply with any Divestiture Agreement, this Order, any law, (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable Governmental Entity, or any taxation requirements; or
2. defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Leukine Assets or Leukine business; *provided, however,* that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement.

Provided further, however:

1. Respondents shall require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Commission-approved Acquirer; *provided, however,* that Respondents shall not be deemed to have violated this Paragraph if the Commission-approved Acquirer withholds such agreement unreasonably; and
 2. Respondents shall use their best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.
- S. The purpose of the divestiture of the Leukine Assets is to ensure the continued use of the Leukine Assets in the same business in which the Leukine Assets were engaged at the time of the announcement of the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's Complaint.

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III.

IT IS FURTHER ORDERED that:

- A. Not later than ten (10) Business Days after the Effective Date, Respondents shall grant to Serono rights and immunities under certain Patents controlled by Respondents sufficient to allow Serono freedom to practice in the research, development, manufacture, use, import, export, distribution and sale of TNFbp-I Products and certain glycosylated and non-glycosylated fragments, derivatives and analogs thereof in the United States in accordance with the TNF Settlement and Cross-License Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order), which is incorporated by reference into this Order and made part hereof as non-public Appendix III.
- B. The purpose of the requirements in Paragraph III.A. is to ensure the continuation of TNFbp-I research and development for additional TNFbp-I Products to be approved by the FDA for sale in the United States and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's Complaint.

IV.

IT IS FURTHER ORDERED that:

- A. Not later than ten (10) Business Days after the Effective Date, Respondents shall grant to Regeneron rights and immunities under certain Patents controlled by Respondents sufficient to allow Regeneron freedom to practice in the research, development, manufacture, use, import, export, distribution and sale of IL-1 Trap Products in the United States in accordance with the IL-1 License Agreement (which agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order),

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which is incorporated by reference into this Order and made part hereof as non-public Appendix IV.

- B. Not later than four (4) years from the Effective Date, Respondents shall divest all their Ownership Interest in Regeneron, including, but not limited to, all of the shares of Regeneron common stock owned by Respondent Amgen prior to the Effective Date, pursuant to the following conditions (the purpose of which is to insure that the Respondents dispose of such Ownership Interest in a manner that avoids disruption of the market for Regeneron stock or share capital):
1. during the first and second years following the Effective Date, Respondents shall not sell more than 250,000 shares of Regeneron common stock during any calendar quarter; *provided, however,* during the first year, Respondents shall not sell more than a total of 500,000 of such shares;
 2. thereafter, Respondents shall not sell more than the greater of (1) 500,000 shares or (2) the average weekly reported volume of Regeneron common stock traded over the National Association of Securities Dealers Automated Quotation System during any calendar quarter; and
 3. any public announcement made by Respondents regarding such sales shall state that such sales are being made pursuant to the divestiture requirements of this Order.

Provided, however, that the limitation on the number of shares of Regeneron common stock that the Respondents may sell in any period shall be adjusted to reflect any Regeneron stock split.

Provided further, however, that nothing in this Paragraph shall be construed to prohibit the Respondents from (1) accepting a general offer made for all of the issued stock or share capital of Regeneron; (2) selling stock in a private sale to which Regeneron has consented in writing; or (3) after the second

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year following the Effective Date, selling such stock in an underwritten public offering that was initiated by Regeneron.

C. Respondents shall not, directly or indirectly:

1. exercise dominion or control over, or otherwise seek to influence, the management, direction or supervision of the business of Regeneron, including, but not limited to, any participation in the formulation, determination or direction of any business decisions of Regeneron;
2. propose corporate action requiring the approval of Regeneron shareholders;
3. nominate candidates for, or in any other way seek to or obtain representation on, the Board of Directors of Regeneron;
4. have any of their directors, officers or employees serve simultaneously as an officer or director of Regeneron;
5. exercise any voting rights attached to any Ownership Interest in Regeneron; *provided, however,* that in any matter to be voted on by the shareholders of Regeneron, Respondents shall cast the votes related to their Ownership Interest in each class of Regeneron stock in an amount and manner proportional to the vote of all other votes cast by other Regeneron shareholders entitled to vote on such matter;
6. seek or obtain access to any confidential, proprietary, or other non-public information of Regeneron relating to the research or development of IL-1 and not otherwise necessary to comply with this Order; *provided, however,* that this shall not be construed to prohibit Respondents from seeking or obtaining discovery in any litigation or other proceeding to resolve a claim between Respondents and Regeneron in accordance with the procedures of the forum

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before which the dispute is pending. With respect to any such discovery, Respondents shall enter into a protective order to prevent any information from being used for any purpose other than providing legal representation or evidence as to the particular dispute and to prevent any information from being disclosed to any person(s) not necessary to the resolution of such dispute; or

7. take any action or omit to take any action in a manner that would be incompatible with the status of Respondents as passive investors in Regeneron.

The requirements of this Paragraph IV.C. shall continue and remain in effect so long as Respondents retain any Ownership Interest in Regeneron.

- D. For a period commencing on the date this Order becomes final and continuing for ten (10) years, Respondents shall not, without providing advance written notification to the Commission, acquire, directly or indirectly, through subsidiaries or otherwise, any additional or greater Ownership Interest in Regeneron than that which exists as of the Closing Date, or any other interest(s), in whole or in part, in any Patents owned by Regeneron and related to IL-1 Trap. Said notification shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as "the Notification"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such notification, notification shall be filed with the Secretary of the Commission, notification need not be made to the United States Department of Justice, and notification is required only of the Respondents and not of any other party to the transaction. Respondents shall provide two (2) complete copies (with all attachments and exhibits) of the Notification to the Commission at least thirty (30) days prior to consummating any such transaction

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(hereinafter referred to as the “first waiting period”). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents shall not consummate the transaction until thirty (30) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition. *Provided, however,* that prior notification shall not be required by this Paragraph for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

- E. The purpose of the requirements of Paragraph IV is to ensure the continuation of IL-1 Inhibitor research and development for additional IL-1 Inhibitor Products to be approved by the FDA for sale in the United States and to remedy the lessening of competition resulting from the Merger as alleged in the Commission’s Complaint.

V.

IT IS FURTHER ORDERED that:

- A. At any time after Respondents sign the Consent Agreement, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order and by the Order to Maintain Assets (collectively, “the Orders”).
- B. If an Interim Monitor is appointed pursuant to this Paragraph or pursuant to Paragraph III.A. of the Order to Maintain Assets in this matter, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

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1. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If neither Respondent has opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
2. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the terms of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
3. Within ten (10) days after appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant terms of the Orders in a manner consistent with the purposes of the Orders.
4. The Interim Monitor shall serve until the later of:
 - a. when the Leukine Assets have been divested in a manner that fully satisfies the requirements of the Orders and the Commission-approved Acquirer is fully capable of, independently of Respondents, producing Leukine acquired pursuant to a Divestiture Agreement; or
 - b. when the last obligation under the Orders pertaining to the Interim Monitor's service has been fully performed.

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Provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

5. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Orders, including, but not limited to, their obligations related to the Leukine Assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
6. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities. The Interim Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission. The Commission may, among other things, require the Interim Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

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7. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
8. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph or Paragraph III.A. of the Order to Maintain Assets in this matter.
9. The Commission may on its own initiative or at the request of the Interim Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
10. Respondents shall report to the Interim Monitor in accordance with the requirements of Paragraph VII.A. of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondents' obligations under the Orders or the Divestiture Agreement. Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning compliance by Respondents with the provisions of the Orders.

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11. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- C. The Interim Monitor appointed pursuant to Paragraph III.A. of the Order to Maintain Assets in this matter may be the same Person appointed as Divestiture Trustee pursuant to Paragraph VI.A. of this Order.

VI.**IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations specified in Paragraph II of this Order, the Commission may appoint a trustee to divest the assets required to be divested pursuant to Paragraph II in a manner that satisfies the requirements of Paragraph II. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to divest the relevant assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.
- B. If a Divestiture Trustee is appointed by the Commission or a court pursuant to Paragraph VI.A. of this Order, Respondents shall consent to the following terms and conditions regarding

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the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
2. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to divest the assets that are required by this Order to be divested.
3. Within ten (10) days after appointment of the Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed Divestiture Trustee, of the court, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by the Order.
4. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in Paragraph VI.B.3. to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve-month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed Divestiture Trustee, by the court; *provided,*

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however, the Commission may extend the divestiture period only two (2) times.

5. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be divested by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
6. The Divestiture Trustee shall use best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an acquirer as required by this Order; *provided, however,* if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; *provided further, however,* that Respondents shall select such entity within five (5) Business Days after receiving notification of the Commission's approval.
7. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the

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Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

8. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
9. If the Divestiture Trustee ceases to act or fails to act diligently, a substitute Divestiture Trustee shall be appointed in the same manner as provided in Paragraph VI.A. of this Order.
10. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or

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at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

11. In the event that the Divestiture Trustee determines that he or she is unable to divest the relevant assets required to be divested in a manner that preserves their marketability, viability and competitiveness and ensures their continued use in the research, development, manufacture, distribution, marketing, promotion, sale, or after-sales support of Leukine, the Divestiture Trustee may divest such additional assets of Respondents and effect such arrangements as are necessary to satisfy the requirements of this Order.
 12. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
 13. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
 14. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- C. The Divestiture Trustee appointed pursuant to Paragraph VI.A. of this Order may be the same Person appointed as Interim Monitor pursuant to Paragraph III.A. of the Order to Maintain Assets in this matter.

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IT IS FURTHER ORDERED that:

- A. Within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondents have fully complied with Paragraph II.A., Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. Respondents shall submit at the same time a copy of their report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with Paragraph II.A. of the Order, including a description of all substantive contacts or negotiations related to the divestiture of the Leukine Assets and the identity of all parties contacted. Respondents shall include in their reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing the obligations.
- B. One (1) year from the date this Order becomes final, annually for the next nine (9) years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with this Order.

VIII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in either corporate Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any

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other change in the corporation that may affect compliance obligations arising out of the Order.

IX.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents related to compliance with this Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order will terminate on September 3, 2012.

By the Commission.

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**APPENDIX I (non-public)
Leukine Core Employees**

[Redacted From Public Record Version]

**APPENDIX II (non-public)
Leukine Asset Purchase Agreement**

[Redacted From Public Record Version]

**APPENDIX III (non-public)
TNF Settlement and Cross-License Agreement**

[Redacted From Public Record Version]

**APPENDIX IV (non-public)
IL-1 License Agreement**

[Redacted From Public Record Version]

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**APPENDIX A
TO THE ORDER TO MAINTAIN ASSETS****APPENDIX V
TO THE DECISION AND ORDER****NOTICE OF DIVESTITURE AND EMPLOYEE
AGREEMENT TO MAINTAIN NON-PUBLIC BUSINESS
INFORMATION RELATED TO LEUKINE
CONFIDENTIAL**

On [date], Amgen Inc. (“Amgen”) and Immunex Corporation (“Immunex”), hereinafter referred to collectively as “Respondents,” entered into an Agreement Containing Consent Orders (“Consent Agreement”) with the Federal Trade Commission (“FTC”) relating to the divestiture of certain assets. That Consent Agreement includes two orders: (i) the Decision and Order, and (ii) the Order to Maintain Assets. The Decision and Order requires the divestiture of assets relating to the Leukine business of Immunex. These assets are hereinafter referred to as the “Leukine Assets.” The Order to Maintain Assets requires Respondents to maintain the Leukine Assets pending divestiture of these assets. Both the Decision and Order and the Order to Maintain Assets require Respondents to commit that no Confidential Business Information relating to the Leukine Assets will be disclosed to or used by any employee of the combined entity formed by the merger of Amgen and Immunex (“Combined Entity”), except under specified circumstances. In particular, this restriction is to protect such information from being used in any way for the research, development, sale or manufacture of Neupogen or Neulasta or any other Neutrophil Regeneration Product that may be commercialized by the Combined Entity after the proposed merger. The Decision and Order also requires the divestiture of documents (including electronically stored material) that contain Confidential Business Information related to the Leukine Business. Accordingly, no employee of the Combined Entity may maintain copies of documents containing such information.

Decision and Order

Under the Decision and Order, the Respondents are required to divest all of the Leukine Assets to an acquirer that must be approved by the FTC. Schering Aktiengesellschaft has been proposed to the FTC as the acquirer for these assets. Until the divestiture of all of the Leukine Assets occurs, the requirements of the second order – the Order to Maintain Assets – are in place to insure the continued marketability, viability and competitive vigor of the Leukine Assets. This includes preserving the work force that performs functions related to the Leukine Assets.

You are receiving this notice because you (i) have work responsibilities related to Leukine, (ii) have work responsibilities related to Neulasta or Neupogen, or (iii) might have Confidential Business Information in your possession related to Leukine.

All Confidential Business Information related to Leukine must be retained and maintained by the persons involved in the operation of that business on a confidential basis. Such persons must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment involves responsibilities unrelated to the Leukine Assets (such as persons with job responsibilities related to Amgen's Neupogen or Neulasta businesses). In addition, any person who possesses such Confidential Business Information related to the Leukine Assets and who becomes involved in the Combined Entity's business related to Neupogen, Neulasta or any other Neutrophil Regeneration Product must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment relates to such businesses. Finally, if you have documents that you believe might be considered Confidential Business Information related to Leukine and have not received specific instructions as to how the documents in your possession should be disposed of, you should contact the contact person identified at the end of this notice.

For the purposes herein, "Confidential Business Information" means all information owned or controlled by Immunex that is not in the public domain related to the research, development,

Decision and Order

manufacturing, marketing, commercialization, distribution, importation, cost, pricing, supply, sales, sales support or use of Leukine.

Any violation of the Decision and Order or the Order to Maintain Assets may subject Amgen, Immunex, or the Combined Entity to civil penalties and other relief as provided by law.

CONTACT PERSON

If you have questions regarding the contents of this notice, the confidentiality of information, the Decision and Order or the Order to Maintain Assets, you should contact

_____ at _____, e-mail address:_____.

ACKNOWLEDGMENT

I, _____ (print name), hereby acknowledge that I have read the above notification and agree to abide by its provisions.

Order

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed merger between Respondent Amgen Inc. (“Amgen”) and Respondent Immunex Corporation (“Immunex”), hereinafter referred to as “Respondents,” and the Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing the proposed Decision and Order, an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

Order

1. Respondent Amgen is a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at One Amgen Center Drive, Thousand Oaks, California 91320-1799.
2. Respondent Immunex is a corporation organized, existing and doing business under and by virtue of the laws of the state of Washington, with its office and principal place of business located at 51 University Street, Seattle, Washington 98101.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order to Maintain Assets, the definitions used in the Consent Agreement and the attached Decision and Order shall apply.

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final:

- A. Respondents shall take such actions as are reasonably necessary to maintain the viability, marketability, and competitive vigor of the Leukine Assets, and shall prevent the destruction, removal, wasting, deterioration, sale, disposition, transfer or impairment of the Leukine Assets, except for ordinary wear and tear and as otherwise would occur in the ordinary course of business.

Order

- B. Respondents shall maintain the operations of the Leukine Assets in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the Leukine Assets) and shall use their best efforts to preserve the existing relationships with suppliers, vendors, customers, employees, and others having business relations with the Leukine Assets. Respondents' responsibilities shall include, but are not limited to:
1. providing the Leukine Assets with sufficient working capital to operate the Leukine Assets at least at current rates of operation, to meet all capital calls with respect to the Leukine Assets and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Leukine Assets;
 2. continuing, at least at their scheduled pace, any additional expenditures for the Leukine Assets authorized prior to the date the Consent Agreement was signed by Respondents;
 3. making available for use by the Leukine Assets funds sufficient to perform all necessary routine maintenance to, and replacements of, the Leukine Assets;
 4. providing the Leukine Assets with such funds as are necessary to maintain the viability, competitive vigor, and marketability of the Leukine Assets;
 5. providing such support services to the Leukine Assets as are being provided to this business by Respondent Immunex as of the date the Consent Agreement was signed by Respondents.
- C. Respondents shall maintain a work force equivalent in size, training, and expertise to what has been associated with the Leukine Assets.

Order

- D. Respondents shall provide all Leukine Core Employees and all Leukine Sales Employees with reasonable financial incentives to continue in their positions until the Closing Date in accordance with Section 3.13(a)(i) of the Leukine Seller Disclosure Letter, which identifies employees and their respective coverage under the Immunex Corporation Retention Plan, as adopted December 16, 2001 (“Retention Plan”). Such incentives shall include a continuation of all employee benefits offered by Respondents until the Closing Date for the divestiture of the Leukine Assets has occurred, including regularly scheduled raises and bonuses, and a vesting of all pension benefits (as permitted by law). In addition to the foregoing, Respondents shall provide to each Leukine Manufacturing Employee who (i) is not included in levels one through six of the Retention Plan as disclosed in Section 3.13(a)(i) of the Leukine Seller Disclosure Letter and (ii) accepts employment with the Commission-approved Acquirer, an incentive equal to three (3) months of such employee’s base annual salary to be paid upon the employee’s completion of one (1) year of employment with the Commission-approved Acquirer.

Provided, however, this Paragraph shall not be construed to require the Respondents to terminate the employment of any employee.

- E. Prior to the Closing Date, Respondents shall not interfere with the hiring or employing of Leukine Sales Employees and Leukine Core Employees by Schering, or any entity subsequently proposed by the Respondents or a Divestiture Trustee to the Commission as an acquirer of the Leukine Assets (“Proposed Acquirer”), and shall remove any impediments within the control of Respondents that may deter these employees from accepting employment related to the Leukine Assets with Schering or the Proposed Acquirer, including, but not limited to, any non-compete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be

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employed by either Schering or the Proposed Acquirer. In addition, Respondents shall not make any counteroffer to a Leukine Sales Employee or Leukine Core Employee who receives a written offer of employment from Schering or the Proposed Acquirer.

Provided, however, that this Paragraph II.E. does not prohibit the Respondents from making offers to any Leukine Sales Employee or Leukine Core Employee where either Schering or the Proposed Acquirer has notified the Respondents in writing that it does not intend to make an offer of employment to that employee.

Provided further, that if the Respondents notify Schering or the Proposed Acquirer in writing of their desire to make an offer of employment to a particular Leukine Core Employee or Leukine Sales Employee, and Schering or the Proposed Acquirer does not make an offer of employment to that employee within twenty (20) Business Days of the date Schering or the Proposed Acquirer receives such notice, the Respondents may make an offer of employment to that employee.

F. Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to Leukine by Respondents' personnel and of the restrictions on the sale of Neupogen or Neulasta or any other Neutrophil Regeneration Product by certain Immunex personnel to all of Respondents' employees who (i) are involved in the research, manufacturing, distribution, sale or marketing of Leukine, (ii) are involved in the research, manufacturing, distribution, sale or marketing of Neupogen or Neulasta or any other Neutrophil Regeneration Product and/or (iii) may have Confidential Business Information related to Leukine. Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondents shall provide a copy of such notification to Schering or the Proposed Acquirer.

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Respondents shall also obtain from each employee covered by this Paragraph II. F. an agreement to abide by the applicable restrictions. Such agreement and notification shall be in substantially the form set forth in the “Notice of Divestiture and Employee Agreement to Maintain Non-Public Business Information Related to Leukine Confidential” attached as Appendix A to this Order and as Appendix V to the Decision and Order. Respondents shall maintain complete records of all such agreements at Respondents’ corporate headquarters and shall provide an officer’s certification to the Commission, stating that such acknowledgment program has been implemented and is being complied with. Respondents shall monitor the implementation by their sales forces of all applicable restrictions, including the provision of written reminders to all such sales personnel at three (3) month intervals until the expiration of the time periods set forth in all Divestiture Agreements, including those in the Leukine Asset Purchase Agreement, and take corrective actions for the failure of sales personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order. Respondents shall provide Schering or the Proposed Acquirer with copies of all certifications, notifications and reminders sent to Respondents’ personnel.

- G. Respondents shall adhere to and abide by the Divestiture Agreement incorporated by reference into this Order to Maintain Assets and made a part hereof.

III.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as

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required by this Order to Maintain Assets and by the Decision and Order (collectively, “the Orders”).

- B. If an Interim Monitor is appointed pursuant to Paragraph III.A. of this Order to Maintain Assets or Paragraph V.A. of the Decision and Order in this matter, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
 1. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If neither Respondent has opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
 2. The Interim Monitor shall have the power and authority to monitor the Respondents’ compliance with the terms of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
 3. Within ten (10) days after appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents’ compliance with the relevant terms of the Orders in a manner consistent with the purposes of the Orders.
 4. The Interim Monitor shall serve until the later of:

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- a. when the Leukine Assets have been divested in a manner that fully satisfies the requirements of the Orders and the Commission-approved Acquirer is fully capable of, independently of Respondents, producing Leukine acquired pursuant to a Divestiture Agreement; or
- b. when the last obligation under the Orders pertaining to the Interim Monitor's service has been fully performed.

Provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

5. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and any other relevant information as the Interim Monitor may reasonably request, relating to Respondents' compliance with their obligations under the Orders, including, but not limited to, their obligations relating to the Leukine Assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
6. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities. The Interim Monitor shall account for all

Order

expenses incurred, including fees for services rendered, subject to the approval of the Commission. The Commission may, among other things, require the Interim Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

7. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
8. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in Paragraph III.A. of this Order to Maintain Assets or Paragraph V.A. of the Decision and Order in this matter.
9. The Commission may on its own initiative or at the request of the Interim Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
10. Respondents shall report to the Interim Monitor in accordance with the requirements of Paragraph VII.A. of the Decision and Order and/or as otherwise provided in

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any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondents' obligations under the Orders or the Divestiture Agreement. Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning compliance by Respondents with the provisions of the Orders.

11. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- C. The Interim Monitor appointed pursuant to Paragraph III.A. of this Order to Maintain Assets may be the same Person appointed as Divestiture Trustee pursuant to Paragraph VI.A. of the Decision and Order in this matter.

IV.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in either corporate Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of this Order to Maintain Assets.

V.

IT IS FURTHER ORDERED that, for the purposes of determining or securing compliance with this Order to Maintain

Order

Assets, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representatives of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents relating to compliance with this Order to Maintain Assets; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

VI.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the earlier of:

- A. Three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The day after the divestiture of all of the Leukine Assets, as described in and required by the attached Decision and Order, is completed.

By the Commission.

Order

**APPENDIX A
TO THE ORDER TO MAINTAIN ASSETS**

**APPENDIX V
TO THE DECISION AND ORDER**

**NOTICE OF DIVESTITURE AND EMPLOYEE
AGREEMENT TO MAINTAIN NON-PUBLIC BUSINESS
INFORMATION RELATED TO LEUKINE
CONFIDENTIAL**

On [date], Amgen Inc. (“Amgen”) and Immunex Corporation (“Immunex”), hereinafter referred to collectively as “Respondents,” entered into an Agreement Containing Consent Orders (“Consent Agreement”) with the Federal Trade Commission (“FTC”) relating to the divestiture of certain assets. That Consent Agreement includes two orders: (i) the Decision and Order, and (ii) the Order to Maintain Assets. The Decision and Order requires the divestiture of assets relating to the Leukine business of Immunex. These assets are hereinafter referred to as the “Leukine Assets.” The Order to Maintain Assets requires Respondents to maintain the Leukine Assets pending divestiture of these assets. Both the Decision and Order and the Order to Maintain Assets require Respondents to commit that no Confidential Business Information relating to the Leukine Assets will be disclosed to or used by any employee of the combined entity formed by the merger of Amgen and Immunex (“Combined Entity”), except under specified circumstances. In particular, this restriction is to protect such information from being used in any way for the research, development, sale or manufacture of Neupogen or Neulasta or any other Neutrophil Regeneration Product that may be commercialized by the Combined Entity after the proposed merger. The Decision and Order also requires the divestiture of documents (including electronically stored material) that contain Confidential Business Information related to the Leukine Business. Accordingly, no employee of the Combined Entity may maintain copies of documents containing such information.

Order

Under the Decision and Order, the Respondents are required to divest all of the Leukine Assets to an acquirer that must be approved by the FTC. Schering Aktiengesellschaft has been proposed to the FTC as the acquirer for these assets. Until the divestiture of all of the Leukine Assets occurs, the requirements of the second order – the Order to Maintain Assets – are in place to insure the continued marketability, viability and competitive vigor of the Leukine Assets. This includes preserving the work force that performs functions related to the Leukine Assets.

You are receiving this notice because you (i) have work responsibilities related to Leukine, (ii) have work responsibilities related to Neulasta or Neupogen, or (iii) might have Confidential Business Information in your possession related to Leukine.

All Confidential Business Information related to Leukine must be retained and maintained by the persons involved in the operation of that business on a confidential basis. Such persons must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment involves responsibilities unrelated to the Leukine Assets (such as persons with job responsibilities related to Amgen's Neupogen or Neulasta businesses). In addition, any person who possesses such Confidential Business Information related to the Leukine Assets and who becomes involved in the Combined Entity's business related to Neupogen, Neulasta or any other Neutrophil Regeneration Product must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment relates to such businesses. Finally, if you have documents that you believe might be considered Confidential Business Information related to Leukine and have not received specific instructions as to how the documents in your possession should be disposed of, you should contact the contact person identified at the end of this notice.

For the purposes herein, "Confidential Business Information" means all information owned or controlled by

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Immunex that is not in the public domain related to the research, development, manufacturing, marketing, commercialization, distribution, importation, cost, pricing, supply, sales, sales support or use of Leukine.

Any violation of the Decision and Order or the Order to Maintain Assets may subject Amgen, Immunex, or the Combined Entity to civil penalties and other relief as provided by law.

CONTACT PERSON

If you have questions regarding the contents of this notice, the confidentiality of information, the Decision and Order or the Order to Maintain Assets, you should contact

_____ at _____, e-mail address:_____.

ACKNOWLEDGMENT

I, _____ (print name), hereby acknowledge that I have read the above notification and agree to abide by its provisions.

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a proposed Consent Order from Amgen Inc. (“Amgen”) and Immunex Corporation (“Immunex”) that is designed to remedy the anticompetitive effects of the merger of Amgen and Immunex. Under the terms of the agreement, the companies would be required to: (1) divest all of Immunex’s assets relating to Leukine (a neutrophil regeneration factor) to Schering AG (“Schering”); (2) license certain Amgen patents relating to its tumor necrosis factor (“TNF”) receptor to Serono S.A. (“Serono”); and (3) license certain Amgen and Immunex patents relating to the development of Interleukin-1 (“IL-1”) receptors to Regeneron Pharmaceuticals Inc. (“Regeneron”).

The proposed Consent Order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and any comments received and will decide whether it should withdraw from the agreement or make final the agreement’s proposed Consent Order.

In their merger agreement of December 16, 2001, Amgen and Immunex propose to combine their two companies in a transaction valued at approximately \$16 billion. Thereafter, the merged entity will be called Amgen Inc. The proposed Complaint alleges that the proposed merger, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the markets for: (1) neutrophil regeneration factors; (2) TNF inhibitors; and (3) IL-1 inhibitors. The proposed Consent Order would remedy the alleged violations by replacing the lost competition in each of these markets that would result from the merger.

Analysis

Neutrophil Regeneration Factors

Neutrophil regeneration factors are used to treat neutropenia, the suppression of production of certain white blood cells (known as “neutrophils”) which often results from chemotherapy. Immunex’s product, Leukine, stimulates the production of both granulocytes and macrophages, two types of neutrophils, while Amgen’s products, Neupogen and Neulasta, stimulate the production of granulocytes. The use of these products to stimulate neutrophil regeneration allows patients to maintain a robust immune system while continuing with their chemotherapy regimens. Annual U.S. sales of neutrophil regeneration factors total approximately \$1.2 billion.

The market for neutrophil regeneration factors is highly concentrated. Amgen and Immunex are the only companies with neutrophil regeneration factors approved for sale in the United States. Amgen’s Neupogen is the leading product in this market, with 2001 sales of approximately \$1.05 billion in the United States. In January 2002, Amgen launched Neulasta, an extended-release version of Neupogen. Immunex’s 2001 sales for Leukine were \$109 million.

Entry into the neutrophil regeneration factor market requires lengthy preclinical and clinical trials, data collection and analysis, and expenditures of significant resources over many years to qualify manufacturing facilities with the Food and Drug Administration (“FDA”). Clinical development and FDA approval can extend from 6 to 10 years and cost over \$200 million. The FDA must approve all phases of development, including extensive preclinical and clinical work. The most significant barriers to entry include technical, regulatory, patent, clinical and production barriers. No company can reach advanced stages of development in the relevant market without: (1) clinical trial expertise; (2) patent rights sufficient to provide the company with reasonable assurances of freedom to operate; (3) commercial scale product manufacturing expertise and capacity; and (4) regulatory approvals.

Analysis

The proposed merger of Amgen and Immunex would cause significant anticompetitive effects in the U.S. neutrophil regeneration market by eliminating actual, direct, and substantial competition between the only two firms in the market. As a result, cancer patients that need these drugs would likely pay higher prices for neutrophil regeneration factors.

The proposed Consent Order maintains competition in the market for neutrophil regeneration factors by requiring that Immunex sell its Leukine business to Schering so that Schering can maintain the present competition against Amgen as well as the continued research and development of Leukine for future competition.

TNF Inhibitors

TNF is a cytokine that promotes the inflammation of human tissues. TNF inhibitors may be used to prevent the binding of TNF proteins with TNF receptors, thereby blocking the triggering of the inflammation cascade. TNF inhibitors are used primarily to treat rheumatoid arthritis, Crohn's disease, and psoriatic arthritis, but they also are being examined for a host of other autoimmune diseases. Annual U.S. sales of TNF inhibitors total approximately \$1.4 billion.

The market for TNF inhibitors is highly concentrated. Immunex, which makes Enbrel, and Johnson & Johnson ("J&J"), which makes Remicade, are the only companies with TNF inhibitors on the market. In 2001, Immunex sold over \$760 million of Enbrel in the United States and Canada, while Remicade accounted for the rest of the market in the United States. There are only three other companies with TNF inhibitors in clinical development in the United States. Amgen has a TNF inhibitor similar to Enbrel in clinical development that it expects to launch in 2005. Abbott recently submitted a Biologic License Application to the FDA for its D2E7 product. Pharmacia and Celltech are jointly in Phase II trials for their TNF inhibitor, CDP870. Additionally, Serono is developing a TNF inhibitor for

Analysis

use in Europe, but it does not possess the patent rights necessary to market the product in the United States.

New entry into the research, development, manufacture, and sale of TNF inhibitors is difficult, expensive, and time-consuming. As with other pharmaceutical markets, entry requires identifying a preclinical compound, performing animal safety tests, clinically developing the product in humans, securing FDA approval of commercial scale production facilities, and obtaining FDA approval to market the drug in the United States. In order to enter the market, a firm must incur substantial sunk costs to research, develop, manufacture, and sell a TNF inhibitor. *De novo* entry has been estimated to take from 8 to 10 years and cost over \$400 million. New entry sufficient to deter or counteract the anticompetitive effects of the proposed merger would not occur in a timely manner.

The proposed merger of Amgen and Immunex would cause significant anticompetitive effects in the U.S. TNF inhibitor market by eliminating potential competition from Amgen's TNF inhibitor in development. Immunex and Amgen are the only two firms that market or are developing soluble TNF receptor products in the United States and two of only five firms that are developing any type of TNF inhibitor for the U.S. market. As a result of the merger, consumers of these drugs would likely pay higher prices and have fewer alternatives for TNF inhibitors for the treatment of rheumatoid arthritis and other diseases.

The proposed Consent Order maintains competition in the TNF inhibitor market by requiring that Amgen license certain patents to Serono, a Swiss biotechnology company with a soluble TNF inhibitor in clinical development that otherwise likely would not be sold in the United States due to blocking patents held by Amgen. This license would assure Serono that it has the freedom of operation necessary to market its TNF inhibitor in the U.S. Amgen retains the rights to pursue development of its TNF inhibitor either as a monotherapy or in combination with an IL-1 inhibitor.

Analysis

IL-1 Inhibitors

IL-1 is another cytokine that promotes the inflammation of human tissues. IL-1 inhibitors prevent the binding of IL-1 proteins with IL-1 receptors, thereby blocking the triggering of the inflammation cascade. IL-1 inhibitors are used to treat rheumatoid arthritis.

The market for IL-1 inhibitors is highly concentrated. Amgen's Kineret, approved by the FDA in November of 2001, is the only IL-1 inhibitor on the U.S. market. Sales to date have exceeded \$2.4 million. Immunex and Regeneron are the only other companies with IL-1 inhibitors in clinical trials in the United States. Regeneron's development and commercialization of its IL-1 Trap, however, may be delayed or foreclosed by patents owned by Immunex. It appears that Immunex is likely to succeed in its efforts to preclude Regeneron's successful commercialization of its IL-1 Trap product through patent infringement litigation for the following reasons: (1) Immunex has indicated that it will seek to block Regeneron by using patent litigation; (2) Regeneron has indicated that such litigation, even were it to yield an outcome favorable to Regeneron, could foreclose its ability to commercialize its IL-1 Trap; and (3) the likelihood of threatened patent litigation by Immunex will jeopardize and could effectively preclude commercialization of Regeneron's IL-1 Trap.

New entry into the research, development, manufacture, and sale of IL-1 inhibitors is difficult, expensive, and time-consuming. As with other pharmaceutical markets, entry requires identifying a preclinical compound, performing animal safety tests, clinically developing the product in humans, securing FDA approval of commercial scale production facilities, and obtaining FDA approval to market the drug in the United States. In order to enter the market, a firm must incur substantial sunk costs to research, develop, manufacture, and sell an IL-1 inhibitor. *De novo* entry has been estimated to take between 6 to 10 years and cost over \$200 million. New entry sufficient to deter or counteract the

Analysis

anticompetitive effects of the merger would not occur in a timely manner.

The proposed merger of Amgen and Immunex would cause significant anticompetitive effects in the U.S. IL-1 inhibitor market by eliminating Amgen's most significant (and likely only) potential competitor, Immunex. By consolidating the IL-1 patents of both companies, Amgen would be more likely to use its combined patents to block Regeneron from marketing an IL-1 inhibitor. Furthermore, Amgen and Immunex are the only companies actively engaged in the development of TNF/IL-1 combination therapies, which may prove more efficacious for the treatment of rheumatoid arthritis in many patients than using either drug alone. The proposed merger, therefore, is likely to lead to unilateral anticompetitive effects in the IL-1 inhibitor market by eliminating potential competition between Amgen and Immunex as well as the ongoing research and development competition between the companies.

The proposed Consent Order remedies the merger's anticompetitive effects by requiring that Immunex license certain patents to Regeneron, giving Regeneron the freedom of operation necessary to bring its IL-1 Trap product to the market and compete against Amgen in this market.

The purpose of this analysis is to facilitate public comment on the proposed Consent Order, and it is not intended to constitute an official interpretation of the proposed Consent Order or to modify its terms in any way.

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IN THE MATTER OF

BIOVAIL CORPORATION

**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT**

Docket C-4060; File No. 0110094

Complaint, October 2, 2002--Decision, October 2, 2002

This consent order addresses practices used by Respondent Biovail Corporation – a Canadian manufacturer of branded and generic pharmaceutical products – with respect to an Abbreviated New Drug Application filed by Andrx Pharmaceuticals, Inc. to make and sell a generic version of Tiazac, a once-a-day diltiazem-based prescription drug used to treat high blood pressure and to reduce the occurrence of chronic chest pain. The order, among other things, requires the respondent to divest to DOV Pharmaceuticals, Inc. the exclusive rights to the ‘463 patent – which the respondent listed in the United States Food and Drug Administration Orange Book as claiming Tiazac – previously acquired from DOV. The order also prohibits the respondent from taking any actions that would result in an additional 30-month stay of final FDA approval for a generic form of Tiazac, and from wrongfully listing any patents in the Orange Book in violation of applicable law. In addition, the order prohibits the respondent from participating in any lawsuits to enforce the ‘463 patent in the Tiazac Field, and requires the respondent to dismiss a pending patent infringement claim against Andrx. The order also requires the respondent to give the Commission prior notice before it acquires an exclusive license to any patent that it plans to list in the Orange Book for a product for which it already has an FDA-approved New Drug Application.

Participants

For the Commission: *Markus H. Meier, Bradley S. Albert, Oscar Voss, George Bellack, David Dudley, Jerod Klein, Mary Connelly-Draper, Daniel Bress, Rendell A. Davis, Jr., Roberta S. Baruch, Abraham Wickelgren, Leslie Farber, and Mary T. Coleman.*

For the Respondent: *Ron Rauchberg, Proskauer Rose LLP, and Ken Cancellara, Biovail.*

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COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission, having reason to believe that respondent Biovail Corporation has engaged in conduct that violates Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

I. Nature of the Case

1. This matter concerns Biovail Corporation's illegal acquisition of an exclusive patent license and its wrongful listing of the patent with the U.S. Food and Drug Administration. Each of these actions independently had the potential to block the entry of any bioequivalent generic drug capable of competing with Biovail's lucrative branded Tiazac product and deprives consumers of the substantial benefits of lower-priced generic Tiazac that might have occurred absent Biovail's conduct.

II. Respondent Biovail Corporation

2. Respondent Biovail Corporation ("Biovail") is a corporation organized under the laws of the Province of Ontario, Canada, with its principal place of business at 2488 Dunwin Drive, Mississauga, Ontario, Canada. Biovail has offices in the United States located at 3701 Concorde Parkway, Chantilly, Virginia.

3. Biovail manufactures branded and generic pharmaceutical products, and is involved in all stages of pharmaceutical development, from research and development, through clinical testing and regulatory filings, to full-scale manufacturing. For the first six months of 2001, Biovail had product sales of over \$237 million, and revenues of nearly \$253 million. Tiazac, the drug at

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issue in this matter, is an extended-release, diltiazem-based drug that is one of Biovail's largest selling products.

III. DOV Pharmaceuticals, Inc.

4. DOV Pharmaceuticals, Inc. ("DOV") was formed in 1995. It is incorporated under the laws of the State of Delaware, with its principal place of business in New Jersey. DOV develops drugs to advanced stages in preclinical and clinical development, and then seeks strategic partnerships, joint ventures, or sub-licensing arrangements with larger pharmaceutical companies for the final development and marketing of products. DOV has no commercial manufacturing capability or experience, and, to date, it has not generated revenue from the sale of any pharmaceutical products.

5. DOV owns the rights to U.S. Patent Number 6,162,463 ("the '463 patent"), the patent at issue in this matter, which it has licensed to Biovail on an exclusive basis. The pharmaceutical product described in the '463 patent is a unique formulation of diltiazem (the active pharmaceutical ingredient in Biovail's Tiazac) that combines both an immediate-release and an extended-release form of diltiazem.

IV. Jurisdiction and Interstate Commerce

6. Biovail is, and at all relevant times herein has been, a corporation within the meaning of Section 4 of the FTC Act, 15 U.S.C. § 44.

7. Biovail's general business activities, its acquisition of exclusive rights to the '463 patent from DOV, and its unfair methods of competition alleged below, are "in or affecting commerce" within the meaning of Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

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V. Statutory and Regulatory Background

8. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, *codified* at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), commonly known as the “Hatch-Waxman Act,” requires approval by the U.S. Food and Drug Administration (“FDA”) before a company may market or sell a pharmaceutical product in the United States. A company may obtain approval to make and sell a new or branded drug by filing a New Drug Application (“NDA”) with the FDA.

9. A generic drug is one that the FDA has found to be “bioequivalent” to a branded drug. Two drugs are considered bioequivalent if they contain the same active pharmaceutical ingredient and if there is no significant difference in the rate, and extent to which, the products are absorbed in the human body under similar experimental conditions, when administered at the same dose. *See* Food, Drug and Cosmetic Act, 21 U.S.C. § 505(j)(8)(B).

10. Although therapeutically identical to their branded counterparts, generic drugs are typically sold at substantial discounts from the price of the branded drug. In fact, the first generic drug to enter the market often does so at a price 25 percent or more below that of the branded product.

11. The Hatch-Waxman Act establishes a procedure for a branded-drug company to identify to prospective generic competitors all patents that it believes claim the branded drug. The Act also establishes a process for addressing potential claims of patent infringement against the manufacturer of a proposed generic product.

12. The FDA makes public the patents identified by branded-drug companies as claiming a given product in a publication entitled “Approved Drug Products with Therapeutic Equivalence

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Evaluations,” which is commonly referred to as the “Orange Book.”

13. The FDA views its role in listing patents in the Orange Book as “purely ministerial,” because it has neither the expertise nor the resources to resolve complex patent coverage issues. 59 Fed. Reg. 50338, 50345 (Oct. 3, 1994). Consequently, the FDA does not scrutinize a party’s bases for listing patents in the Orange Book, as long as all the information required by statute has been submitted. Should one company challenge the validity of another’s Orange Book listing, the FDA requests only that the NDA holder provide written confirmation that the patent is properly listed.

14. A company may obtain approval to make and sell a generic version of a branded drug by filing an Abbreviated New Drug Application (“ANDA”) with the FDA. If a company seeks to market a generic version of a branded drug prior to the expiration of one or more of the patents listed in the Orange Book as relating to that drug, the generic applicant must provide a certification to the FDA with respect to each such patent.

15. One type of certification a generic applicant may make to the FDA is a “Paragraph IV Certification,” in which the applicant claims that the branded-drug company’s patent is invalid or will not be infringed by the manufacture, use, or sale of the generic product. This is the form of certification at issue in this matter.

16. When making a Paragraph IV Certification, the generic applicant must provide notice to each patent owner and the branded-drug company listed in the Orange Book.

17. The Hatch-Waxman Act contains provisions that allow a branded-drug company to delay the entry of a generic drug for which a Paragraph IV Certification has been filed, depending on whether a patent infringement suit is initiated. If neither the patent holder nor the branded-drug company files a patent infringement suit against the generic drug applicant within forty-

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five days of receipt of notification of a Paragraph IV Certification, the FDA review and approval process may proceed. Upon final FDA approval of the ANDA, the generic applicant is free to market its product. If, however, a patent infringement suit is filed against the generic drug applicant within the forty-five day period, then final FDA approval of the ANDA is automatically stayed until the earliest of: (a) patent expiration; (b) a final determination by a court of non-infringement or patent invalidity; or (c) the expiration of a thirty month period from the time the patent holder receives the Paragraph IV Certification. This thirty month period, which effectively is an automatic statutory injunction, is commonly referred to as the “30-month stay.”

VI. Tiazac Sold in the United States is the Relevant Market in which to Assess Biovail’s Conduct

18. The relevant antitrust product market in which to assess the anticompetitive effects of Biovail’s conduct is Tiazac and generic bioequivalent versions of Tiazac. Tiazac is a diltiazem-based prescription drug taken once a day. It is used to treat high blood pressure (hypertension) and chronic chest pain (angina).

19. In addition to Tiazac, other therapeutic agents can be used to treat high blood pressure and chronic chest pain, including several branded and generic formulations of once-a-day diltiazem, but these other therapeutic agents do not significantly constrain Tiazac’s pricing.

20. In contrast, entry of a generic bioequivalent version of Tiazac likely would result in a significant, immediate decrease in the sales of branded Tiazac, and lead to a significant reduction in the average market price paid for Tiazac and its generic bioequivalents.

21. The relevant antitrust geographic market in which to assess the anticompetitive effects of Biovail’s conduct is the United States. This is so given the FDA’s elaborate regulatory process for approving drugs for sale in the United States, and the

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fact that the marketing, sales, and distribution of pharmaceuticals occur on a nationwide basis.

VII. Biovail Has Monopoly Power in the Relevant Market

22. At all times germane to this complaint, Biovail, through its U.S. distributor Forest Laboratories, Inc., of New York, has had 100 percent of the sales in the Tiazac market in the United States.

VIII. The Threat of Generic Tiazac Entry

23. The FDA approved Tiazac for sale in the United States in September 1995. Shortly thereafter, Biovail, through Forest Laboratories, Inc., began marketing Tiazac in the United States.

24. Tiazac is an important product for Biovail. In 2000, Tiazac's U.S. sales reached almost \$200 million, accounting for approximately 38 percent of the total gross sales of products owned by Biovail.

25. On or about June 22, 1998, Andrx Pharmaceuticals, Inc. ("Andrx"), a Florida-based company that develops generic versions of extended-release, branded pharmaceuticals, submitted an ANDA to the FDA to market a generic version of Tiazac. Andrx's application included a Paragraph IV Certification asserting that its generic product would not infringe any patent claiming Tiazac. At the time, the only patent listed in the Orange Book as claiming Tiazac was U.S. Patent Number 5,529,791 ("the '791 patent"), which covers aspects of the extended-release formulation of Tiazac. The basic patent on diltiazem, Tiazac's active pharmaceutical ingredient, expired long before any date relevant to this complaint.

26. On October 7, 1998, Biovail filed a patent infringement lawsuit against Andrx in the U.S. District Court for the Southern District of Florida, alleging that Andrx's proposed generic bioequivalent version of Tiazac would infringe the '791 patent.

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By filing this lawsuit, Bovail triggered a provision under the Hatch-Waxman Act preventing the FDA from granting final approval of Andrx's ANDA for up to thirty months.

27. On March 6, 2000, the federal district court ruled in Andrx's favor, finding that its generic bioequivalent version of Tiazac did not infringe the '791 patent. Bovail appealed this decision, and the United States Court of Appeals for the Federal Circuit affirmed the district court's ruling on February 13, 2001.

28. The FDA tentatively approved Andrx's ANDA for generic Tiazac on September 29, 2000, and informed Andrx that the ANDA would be eligible for final approval upon expiration of the 30-month stay, which, because of the decision of the Court of Appeals for the Federal Circuit, would have ended around February 13, 2001. Final FDA approval of Andrx's ANDA, however, was not granted on February 13 or at any other time as of the date of this complaint.

IX. Bovail's Anticompetitive Conduct

a. Bovail Acquired an Exclusive License to the '463 Patent

29. On December 19, 2000, the U.S. Patent and Trademark Office issued the '463 patent to its inventor, Dr. Arnold Lippa, the founder and CEO of DOV Pharmaceuticals, Inc. Dr. Lippa subsequently assigned the patent to DOV.

30. The product described in the '463 patent is a unique formulation of diltiazem (the same active pharmaceutical ingredient as in Bovail's Tiazac), which combines both an immediate-release and an extended-release form of diltiazem.

31. Within days of the patent's issuance, Bovail approached and met with Dr. Lippa in order to negotiate an exclusive license to the '463 patent.

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32. Biovail insisted on completing the license agreement with DOV by no later than January 19, 2001. A patent claiming a pharmaceutical product must be listed in the FDA's Orange Book within thirty days of issuance by the U.S. Patent and Trademark Office in order to trigger Hatch-Waxman Act provisions that could result in a 30-month stay. As a result, January 19 was the last day on which Biovail could list the '463 patent and still be eligible to obtain a second 30-month stay, precluding the FDA from granting final approval of Andrx's application to sell a generic version of Tiazac.

33. On January 12, 2001, Biovail and DOV executed the exclusive license agreement for the '463 patent.

b. Biovail Listed the '463 Patent in the FDA's Orange Book

34. On January 8, 2001, Biovail listed the '463 patent in the Orange Book. In its certification to the FDA supporting the listing, Biovail attested that the '463 patent covers the currently approved formulation of Tiazac.

35. On January 30, 2001, Biovail publicly disclosed that it had listed the '463 patent in the Orange Book. Biovail's press release stated that as a result of this listing, FDA approval of any generic version of Tiazac could be delayed for up to thirty months:

The effect of Biovail's listing of this Patent in the Orange Book is that the FDA will require every filer of an ANDA for a generic version of Tiazac to also submit a Notice of Certification to Biovail on this Patent. As a result, Biovail will consider whether such ANDA formulation infringes on its listed Patent and will have the legal right to commence a lawsuit against the owner of such ANDA. If Biovail determines to commence such suit within 45 days from receipt of the Notice of Certification, the Hatch Waxman provisions of the [FDCA] will be triggered

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and the ANDA owner will not be able to obtain final approval for up to 30 months.

36. At the time of listing, Biovail was aware that the ‘463 patent did not cover the formulation of Tiazac it was marketing. Further, Biovail knew that absent its exclusive license with DOV, it would not have listed the ‘463 patent in the Orange Book. The product described in the ‘463 patent contains at least 1 percent of uncoated or “free” immediate-release diltiazem in addition to extended-release diltiazem in the form of coated beads. By contrast, the only Tiazac formulation that Biovail has ever sold contains only negligible amounts – that is, less than 1 percent – of uncoated immediate-release diltiazem outside the extended-release coated beads. Accordingly, Biovail did not need the ‘463 patent in order to manufacture and sell its existing FDA-approved formulation of Tiazac, and it could have continued to do so without infringing the ‘463 patent.

37. Because Biovail listed the ‘463 patent in January 2001, the FDA was no longer permitted to grant Andrx final approval to launch its generic Tiazac product in February 2001. Instead, Andrx was required to make a new certification to the FDA concerning the ‘463 patent, potentially further delaying Andrx’s entry into the Tiazac market.

c. Andrx Challenged – and the FDA Questioned – the Propriety of Biovail’s Listing of the ‘463 Patent

38. After Biovail’s January 30, 2001, press release announcing that it had listed the ‘463 patent in the Orange Book, Andrx contacted DOV in order to seek a license for the patent. Citing its exclusive agreement with Biovail, DOV refused to discuss such an arrangement with Andrx.

39. On February 1, 2001, Andrx petitioned the FDA to require Biovail to de-list the ‘463 patent, alleging, among other things, that the ‘463 patent did not cover the Tiazac product Biovail currently marketed.

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40. On February 7, 2001, and again on February 22, 2001, the FDA, consistent with its limited “ministerial role” in listing patents in the Orange Book, sought confirmation from Biovail that the ‘463 patent was properly listed for Tiazac.

41. On February 26, 2001, as the result of a court filing by Biovail in a federal lawsuit by Andrx to force Biovail to de-list the ‘463 patent, the FDA learned that Biovail’s position was that the ‘463 patent covered a new formulation of Tiazac that Biovail developed only after it acquired the exclusive license to, and listed, the ‘463 patent, rather than covering the version of Tiazac that Biovail had been marketing.

42. On March 20, 2001, the FDA notified Biovail that its new formulation of Tiazac was not approved by the FDA under the Tiazac NDA, and that the FDA would de-list the ‘463 patent from the Orange Book unless Biovail amended its certification to indicate that the ‘463 patent claimed the version of Tiazac that the FDA had approved.

43. On March 26, 2001, Biovail submitted a signed declaration to the FDA stating that “Biovail hereby confirms its belief that the ‘463 patent is eligible for listing in the FDA’s Orange Book in connection with Biovail’s drug product Tiazac.” This declaration did not clarify whether the term “Tiazac” as used by Biovail meant FDA-approved Tiazac (as the FDA required) or Biovail’s revised form of the product, which practices the ‘463 patent.

44. As revealed in papers filed by the FDA in the federal lawsuit by Andrx to force Biovail to de-list the ‘463 patent, it is clear that the FDA understood Biovail’s March 26, 2001, declaration as “affirming the ‘463 patent covers the *currently approved* Tiazac product” (emphasis added), and, on that basis, decided not to de-list the ‘463 patent from the Orange Book. Biovail, however, continued to assert that listing the ‘463 patent in the Orange Book was justified because it covers a revised form of

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Tiazac that Biovail believes falls within the Tiazac NDA, but which the FDA does not.

**d. Biovail Initiated a Patent Infringement
Lawsuit against Andrx Based on the ‘463 Patent**

45. On February 16, 2001, Andrx filed a Paragraph IV certification with the FDA, certifying either that its generic Tiazac product does not infringe the ‘463 patent or that the patent is not valid. Sometime thereafter, Andrx notified Biovail of this certification.

46. On April 5, 2001, Biovail filed a lawsuit against Andrx alleging infringement of the ‘463 patent, thereby triggering a second 30-month stay under the Hatch-Waxman Act, and precluding the FDA from granting final approval to Andrx’s ANDA for generic Tiazac.

X. The Anticompetitive Effects of Biovail’s Conduct

47. As a result of Biovail’s conduct as alleged herein, consumers have been deprived of the benefits of lower-priced generic competition that might have occurred had the FDA granted final approval to Andrx’s generic Tiazac in February 2001. Andrx’s generic Tiazac was expected to enter the market at a substantial discount to branded Tiazac, and it was expected to take almost all of its market share from branded Tiazac. In fact, Biovail’s own forecasts projected that generic Tiazac would capture 40 percent of branded Tiazac sales within the first year.

48. The purpose or effect of Biovail’s actions was to block Andrx or any other manufacturer of generic Tiazac from entering the relevant market and thereby lowering the price consumers pay for the drug.

49. Biovail’s anticompetitive actions are not justified by any countervailing efficiencies.

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XI. Violations Alleged

Count 1 – Unlawful Asset Acquisition in Violation of Clayton Act § 7 and FTC Act § 5

50. Biovail's acquisition of an exclusive license to the '463 patent constitutes an asset acquisition within the meaning of Section 7 of the Clayton Act, 15 U.S.C. § 18.

51. Prior to Biovail's acquisition of an exclusive license to the '463 patent, Biovail had monopoly power in the relevant market.

52. Biovail did not need a license – much less an exclusive license – to the '463 patent in order to make and sell its FDA-approved Tiazac product.

53. Biovail's acquisition of the exclusive license to the '463 patent raised substantial barriers to entry into the relevant market and gave Biovail the power to exclude competition, thereby protecting Biovail's monopoly in the relevant market, in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45.

Count 2 – Unlawful Monopolization in Violation of FTC Act § 5

54. Biovail has, and at all times relevant to this complaint has had, monopoly power in the market for Tiazac and generic bioequivalent versions of Tiazac in the United States.

55. Biovail engaged in acts to willfully maintain its Tiazac monopoly. These acts included, but were not limited to: (a) acquiring an exclusive license to the '463 patent for the purpose of listing it in the Orange Book; (b) wrongfully listing the '463 patent in the Orange Book as claiming Tiazac, in order to be eligible for an automatic 30-month stay of FDA approval for any generic Tiazac product; and (c) giving non-responsive answers to

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questions raised by the FDA about the propriety of listing the '463 patent in the Orange Book so as to avoid de-listing.

56. Biovail's monopolization raised substantial barriers to entry into the relevant market and gave Biovail the power to exclude competition, thereby depriving consumers of the benefits of lower-priced generic competition that might have occurred had the FDA not been precluded from granting final approval to Andrx's generic Tiazac.

57. Biovail's acts and practices described above are anticompetitive in nature and tendency, and constitute an unfair method of competition in violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this second day of October, 2002, issues its complaint against said respondent.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices by Respondent Biovail Corporation, hereinafter referred to as “Respondent,” and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having modified the Decision and Order in certain respects, now in further conformity with the procedure prescribed in Commission Rule § 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

Decision and Order

1. Respondent Biovail Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the Province of Ontario, Canada, with its office and principal place of business located at 2488 Dunwin Drive, Mississauga, Ontario, Canada and offices in the United States at 3701 Concorde Parkway, Chantilly, Virginia.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent” means Biovail Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Biovail Corporation; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “Assets To Be Divested” means all Exclusive Licenses to the DOV ‘463 patent in the Tiazac Field.
- D. “ANDA” means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j) *et seq.*
- E. “Divestiture Date” means the date on which the Respondent has fully completed the divestiture, pursuant to this Order, of the Assets To Be Divested to DOV.

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- F. “DOV” means DOV Pharmaceuticals, Inc., a Delaware corporation which has its principal place of business at 433 Hackensack Avenue, Hackensack, New Jersey 07601.
- G. “DOV ‘463 Patent” means U.S. Patent No. 6,162,463 issued by the U.S. Patent and Trademark Office on December 19, 2000.
- H. “Exclusive License” means a license of intellectual property that (a) restricts the right of the licensor to license the intellectual property to others or (b) grants to the licensee the right to enforce the intellectual property rights against others.
- I. “FDA” means the U.S. Food and Drug Administration.
- J. “NDA” means a New Drug Application, as defined under 21 U.S.C. § 355(b) *et seq.*
- K. “Notification and Report Form” means the form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended.
- L. “Person” means any natural person, partnership, corporation, company, association, trust, joint venture or other business or legal entity, including any governmental agency.
- M. “Orange Book” means the U.S. Food and Drug Administration publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations.”
- N. “30-Month Stay” means the period of time established by 21 U.S.C. § 355(j)(5)(B)(iii) during which the FDA may not grant approval to an ANDA.
- O. “Tiazac Field” means any extended release formulation of diltiazem that has been approved by the FDA for sale pursuant to NDA 20-401, or that is described in any ANDA for which approval is sought by referencing NDA 20-401.

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- P. "Dismissal Date" means the day after the date of the dismissal with prejudice of all of Respondent's claims relating to enforcement of the DOV '463 Patent, including those claims in *Biovail Corporation v. Andrx Pharmaceuticals, Inc.*, Civ. No. 01-CV-6548 (S.D. Fla.).

II.**IT IS FURTHER ORDERED** that:

- A. No later than thirty (30) days after this Order becomes final, Respondent shall divest, absolutely, in good faith, and only in a manner that receives the prior approval of the Commission, the Assets To Be Divested to DOV.
- PROVIDED HOWEVER, Respondent shall not divest the Assets To Be Divested to DOV prior to the Dismissal Date.
- B. Any consideration received by Respondent in exchange for the Assets To Be Divested must be a fixed amount. In particular, such consideration cannot be a function of any revenue generated for DOV by the Assets To Be Divested. Respondent shall not accept any share of royalties or other fees paid by licensees of the DOV '463 Patent in the Tiazac Field.
- C. Respondent shall not enter into any agreement with DOV or any other Person that restricts the ability of such Person to provide information to the Commission.
- D. Respondent shall place no restrictions on DOV's use of the Assets To Be Divested, and shall not assist in, advise regarding, or act so as to affect in any manner DOV's (1) enforcement of the DOV '463 Patent in the Tiazac Field, (2) licensing of the DOV '463 Patent in the Tiazac Field, or (3) determination of royalties or other fees paid by others for the DOV '463 Patent in the Tiazac Field.

Decision and Order

- E. Respondent shall not initiate, maintain, or be a party to any legal action to enforce the DOV ‘463 Patent in the Tiazac Field against any other Person.
- F. In order to comply with Paragraph II.E., Respondent shall, within 5 days of signing this Agreement Containing Consent Order, use its best efforts, including by moving for appropriate judicial relief and attaching this Order, to achieve dismissal with prejudice of any and all claims relating to enforcement of the DOV ‘463 Patent in the Tiazac Field, including, but not limited to, any and all claims asserted in *Biovail Corporation v. Andrx Pharmaceuticals, Inc.*, Civ. No. 01-CV-6548 (S.D. Fla.).

III.

IT IS FURTHER ORDERED that:

- A. If Respondent has not divested, absolutely and in good faith and with the Commission’s prior approval, the Assets To Be Divested within the time and in the manner required by Paragraph II. of this Order, the Commission may appoint a trustee to divest those assets to DOV. In the event that the Commission or the Attorney General brings an action pursuant to Section 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a trustee in such action. Neither the appointment of a trustee nor a decision not to appoint a trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to Section 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.
- B. If a trustee is appointed by the Commission or a court pursuant to Paragraph III.A. of this Order, Respondent shall

Decision and Order

consent to the following terms and conditions regarding the trustee's powers, duties, authority, and responsibilities:

1. The Commission shall select the trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after receipt of written notice by the staff of the Commission to Respondent of the identity of any proposed trustee, Respondent shall be deemed to have consented to the selection of the proposed trustee.
2. Subject to the prior approval of the Commission, the trustee shall have the exclusive power and authority to divest the Assets To Be Divested.
3. Within ten (10) days after appointment of the trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed trustee, of the court, transfers to the trustee all rights and powers necessary to permit the trustee to effect the divestiture required by this Order.
4. The trustee shall have twelve (12) months from the date the Commission or court approves the trust agreement described in Paragraph III.B.3. to accomplish the divestiture. If, however, at the end of the twelve-month period, the trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed trustee, by the court; provided, however, the Commission may extend the period for no more than two (2) additional periods of twelve (12) months each.

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5. The trustee shall have full and complete access to the personnel, books, records, and facilities related to the Assets To Be Divested, the Tiazac Field, or to any other relevant information, as the trustee may request. Respondent shall develop such financial or other information as such trustee may request and shall cooperate with the trustee. Respondent shall take no action to interfere with or impede the trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed trustee, by the court.
6. The trustee shall use his or her best efforts to negotiate the most favorable price and terms available, subject to Respondent's absolute and unconditional obligation to divest expeditiously at no minimum price. The divestiture shall be made only in a manner that receives the prior approval of the Commission, and only to an acquirer that receives the prior approval of the Commission.
7. The trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for his or her services, all remaining monies shall be paid at the

Decision and Order

direction of Respondent, and the trustee's power shall be terminated.

8. Respondent shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for or defense of any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.
9. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in Paragraph III.A. of this Order.
10. The Commission or, in the case of a court-appointed trustee, the court, may on its own initiative or at the request of the trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.
11. The trustee shall have no obligation or authority to administer or maintain the Assets To Be Divested.
12. The trustee shall report in writing to the Commission every thirty (30) days concerning the trustee's efforts to accomplish the divestiture required by this Order.
13. Respondent may require the trustee to sign a customary confidentiality agreement; provided, however, such agreement shall not restrict the trustee from providing any information to the Commission.

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IV.

IT IS FURTHER ORDERED that Respondent shall cease and desist from taking any action that initiates, maintains, or causes to be initiated or maintained, a 30-Month Stay of FDA Final Approval of ANDA No. 75-401.

V.

IT IS FURTHER ORDERED that Respondent shall not seek, certify to, or take any action in furtherance of, the listing or continued listing of any patent in the Orange Book in violation of applicable law, including, but not limited to, 21 U.S.C. § 355(b) and (c)(2) and 21 C.F.R. § 314.53 (b)-(c), as interpreted by the FDA and the courts.

VI.

IT IS FURTHER ORDERED that Respondent shall not, without providing prior written notification to the Commission in the manner described in Paragraph VII. (“Notification”), acquire a patent or an Exclusive License to a patent (hereinafter, the “Transaction”), if Respondent seeks or secures the patent’s listing in the Orange Book for an NDA which has received FDA approval.

VII.

IT IS FURTHER ORDERED that Respondent shall provide the Notification required by Paragraph VI. in the form of a letter (“Notification Letter”) submitted to the Secretary of the Commission and containing the following information: (1) the docket number and caption name of this Order; (2) a statement that the purpose of the letter is to give the Commission prior notification of a Transaction as required by Paragraph VI. of this Order; (3) identification of the parties participating in the Transaction; (4) a copy of each patent acquired pursuant to the Transaction (“Acquired Patent”); (5) for each Acquired Patent,

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identification of the Approved NDA(s) in respect to which the Acquired Patent is, or will be, submitted for listing in the Orange Book; (6) for each such Approved NDA identified in the previous subpart, identification of all Persons who have filed with the FDA an ANDA which references the Approved NDA; (7) a copy of all transactional documents; and (8) a copy of all documents which were prepared by or for any officer(s) or director(s) of Respondent for the purpose of evaluating or analyzing the Transaction.

Respondent shall submit the Notification Letter to the Secretary of the Commission at least thirty (30) days prior to consummating any such Transaction (hereinafter referred to as the "First Waiting Period"). If, prior to expiration of the First Waiting Period, representatives of the Commission make a written request for additional information or documentary material (as if within the meaning of 16 C.F.R. § 803.20), Respondent shall not consummate the Transaction until expiration of thirty (30) days following submission of such additional information or documentary material. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Commission's Bureau of Competition.

PROVIDED, HOWEVER, that, if the Transaction is subject to the reporting obligations of Section 7A of the Clayton Act, 15 U.S.C. 18a ("HSR Act"), and if a complete and accurate Notification Letter for such Transaction is appended to, and submitted with, a Notification and Report Form filed pursuant to the HSR Act for such Transaction, then Respondent shall not be required to comply further with Paragraph VI. of this Order with respect to such Transaction; except that nothing in this Order shall be construed to relieve Respondent of any obligation to comply with any requirement of the HSR Act.

VIII.

IT IS FURTHER ORDERED that:

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- A. Within sixty (60) days after Respondent has divested the Assets To Be Divested pursuant to Paragraph II.A. of this Order, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it has complied with Paragraph II.A. of this Order. Respondent shall include in this compliance report copies of all written communications to and from parties to the divestiture, all internal memoranda, and all reports and recommendations concerning the divestiture.
- B. Within sixty (60) days after the date this Order becomes final and every sixty (60) days thereafter until all applicable courts have dismissed with prejudice any and all claims of Respondent relating to enforcement of the DOV '463 Patent in the Tiazac Field, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with Paragraph II.F. of this Order.
- C. One (1) year from the date this Order becomes final, annually thereafter on the anniversary of the date of this Order becoming final, and at such other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it is complying, and has complied, with Paragraphs II., IV., and V. of this Order.

IX.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent, such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of this Order.

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X.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, upon written request, Respondent shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondent relating to any matters contained in this Order; and
- B. Upon five (5) days' notice to Respondent and without restraint or interference from it, to interview officers, directors, employees, agents or independent contractors of Respondent relating to any matters contained in this Order.

XI.

IT IS FURTHER ORDERED that this Order will terminate on October 2, 2012.

By the Commission.

Analysis

Analysis to Aid Public Comment

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with Biovail Corporation, settling charges that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent with the U.S. Food and Drug Administration. The Commission has placed the proposed consent order on the public record for thirty days in order to receive comments by interested persons. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by Biovail Corporation that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

Background

Biovail Corporation is a Canadian manufacturer of branded and generic pharmaceutical products, including Tiazac. Tiazac, a once-a-day diltiazem-based prescription drug that is at issue in this case, is used to treat high blood pressure and to decrease the occurrence of chronic chest pain. In 2000, Tiazac's sales reached almost \$200 million, accounting for 38 percent of Biovail's gross sales.

Andrx Pharmaceuticals, Inc., a Florida-based company that develops generic versions of branded pharmaceuticals, was the first company to submit an application to the U.S. Food and Drug Administration (“FDA”) to make and sell a generic version of Tiazac. Andrx’s application to the FDA included a certification asserting that its generic product would not infringe any patent claiming Tiazac. At that time, the only patent known to claim Tiazac was U.S. Patent Number 5,529,791 (“the ‘791 patent”), which covers aspects of Tiazac’s once-a-day formulation.

As in several recent Commission matters, the facts of this case are set against the backdrop of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as “the Hatch-Waxman Act.” Congress enacted the Hatch-Waxman Act

Analysis

to facilitate the entry of lower priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs. In particular, the Hatch-Waxman Act established certain rights and procedures in situations where a company seeks approval from the FDA to market a generic product prior to the expiration of a patent or patents relating to the branded drug upon which the generic is based.

A generic drug is a pharmaceutical product that the FDA has determined to be bioequivalent to a branded drug. Generic drugs are chemically identical to their branded counterparts, but they typically are sold at substantial discounts from the branded drug's price. A Congressional Budget Office Report estimates that U.S. consumers saved an estimated \$8-10 billion on prescriptions at retail pharmacies in 1994 by purchasing generic drugs instead of the branded product.¹

Under the provisions of the Hatch-Waxman Act, a company seeking approval from the FDA to market a new drug must file a New Drug Application ("NDA") demonstrating the safety and efficacy of its product. As part of this process, the NDA applicant also is required to submit to the FDA information on any patent claiming the approved drug and for which a claim of patent infringement could reasonably be asserted against another party. The FDA then lists the approved drug and its related patents in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book."

¹Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* at xiii & 13 (July 1998).

Analysis

The Hatch-Waxman Act also allows the listing of patents that are issued by the U.S. Patent and Trademark Office after an NDA has been approved.²

In order to receive FDA approval to market a generic version of a branded drug, a company must file an Abbreviated New Drug Application (“ANDA”) demonstrating that its product is bioequivalent to its branded counterpart. As part of the ANDA application process, the ANDA applicant also must provide a certification to the FDA regarding its generic product and any patents listed in the Orange Book that claim the reference branded drug. Under one form of certification, known as a “Paragraph IV certification,” the ANDA applicant certifies that the patents listed in the Orange Book either are invalid or will not be infringed by the manufacture, use, or sale of the drug products for which the ANDA is submitted.

The Hatch-Waxman Act further provides that notice of the Paragraph IV certification must be provided to each patent owner and the NDA holder for the listed drug. After receiving notice of a Paragraph IV certification, if the branded drug owner does not initiate a patent infringement suit within forty-five days, then the FDA’s review and generic approval process may proceed according to the FDA’s schedule. If, however, a patent infringement suit is filed within the forty-five day window, the FDA’s approval of the ANDA is automatically stayed until the earliest of: (1) the date the patents expire; (2) a final determination of non-infringement or patent invalidity by a court in the patent litigation; or (3) the expiration of thirty months from the receipt of notice of the Paragraph IV certification (the “30-month stay”).

Andrx filed the first ANDA for a generic version of Tiazac in June 1998. At that time, it provided a Paragraph IV certification to the FDA regarding the only patent then claiming Tiazac, the ‘791 patent. Within forty-five days of receiving Andrx’s notice of

²21 U.S.C. § 355(c)(2).

Analysis

certification, Biovail filed a patent infringement lawsuit, alleging that Andrx's generic Tiazac product would infringe the '791 patent. This lawsuit triggered a 30-month stay of final regulatory approval of Andrx's ANDA, which was to expire on February 26, 2001 (or earlier, if an appellate court decision was granted in Andrx's favor before that date).

On March 6, 2000, the U.S. District Court presiding over the patent infringement suit found that Andrx's product did not infringe the '791 patent.³ Biovail appealed this decision to the U.S. Court of Appeals for the Federal Circuit. On September 29, 2000, while the appeal was still pending, the FDA tentatively approved Andrx's ANDA and informed Andrx that it would be eligible to receive final FDA approval upon expiration of the 30-month stay. This stay would have expired on February 13, 2001, the day the Federal Circuit affirmed the district court's ruling that Andrx's product did not infringe Biovail's '791 patent.

Before the Federal Circuit issued its decision, however, Biovail, on January 8, 2001, listed a second patent in the Orange Book as claiming Tiazac. Biovail acquired this patent, U.S. Patent No. 6,162,463 ("the '463 patent"), from DOV Pharmaceuticals, Inc., of New Jersey, through an exclusive licensing arrangement that also included plans to jointly develop new diltiazem products using the '463 patent. Because of this listing, Andrx was required to submit a second Paragraph IV certification asserting non-infringement of the '463 patent. After receiving Andrx's certification, Biovail filed a second patent infringement suit, triggering a second 30-month stay of the final approval of Andrx's ANDA, and further delaying the potential entry of Andrx's generic Tiazac product.

³*Biovail Corp. Int'l v. Andrx Pharm. Inc.*, 2000 WL 33354427 (S.D. Fla. March 6, 2000).

Analysis

The Challenged Conduct

The Commission's complaint alleges that Biovail acquired exclusive rights to the '463 patent from DOV Pharmaceuticals, Inc., for the purpose of listing it in the FDA's Orange Book and thereby blocking Andrx's entry into the Tiazac market.

Two days after the U.S. Patent and Trademark Office issued the '463 patent, Biovail met with DOV to discuss a potential licensing agreement. Biovail sought to complete an exclusive licensing agreement with DOV by no later than January 19, 2001, the last date on which it could list the patent in the Orange Book and still be eligible to trigger Hatch-Waxman provisions that could result in a 30-month stay. Biovail listed the '463 patent in the Orange Book on January 8, four days before it actually completed the exclusive license agreement with DOV.

In its certification to the FDA supporting the listing of the patent, Biovail attested that the '463 patent claimed FDA-approved Tiazac. According to the complaint, however, Biovail was aware that the '463 patent did not claim the formulation of Tiazac that it had been marketing. The product described in the '463 patent contains at least 1 percent of uncoated or "free" immediate-release diltiazem, in addition to extended-release diltiazem in the form of coated beads. By contrast, the only form of Tiazac that Biovail has ever sold contains only negligible amounts – that is, well below 1 percent – of uncoated immediate-release diltiazem. Accordingly, Biovail did not need the '463 patent in order to make or sell its existing FDA-approved formulation of Tiazac, and it could have continued to do so without infringing the '463 patent. Moreover, in prosecuting the patent before the U.S. Patent and Trademark Office, Dr. Lippa of DOV was required to distinguish the '463 patent from the prior art – including Biovail's Tiazac – before the patent examiner approved the patent. This suggests that the '463 patent could not simultaneously be valid and properly listed in the Orange Book for Tiazac.

Analysis

After learning that DOV was unable to give it a license to the ‘463 patent because of Biovail’s exclusive license, Andrx petitioned the FDA to require Biovail to de-list the ‘463 patent from the Orange Book. Although the FDA has publicly stated that it lacks the resources and the expertise to review patents submitted with NDAs and that it has only a limited “ministerial role” in listing patents,⁴ a party may dispute the propriety of a patent listing, as Andrx did, by notifying the FDA. The FDA will then request that the NDA holder confirm that the listed patent information is correct. Unless the NDA holder voluntarily withdraws or amends its listing, however, the FDA will not change the patent information in the Orange Book. As one court has observed, the FDA’s listing of a patent does “not create any presumption that [a] patent was correctly listed” in the Orange Book.⁵

On February 7, 2001, and again on February 22, 2001, the FDA, consistent with its limited “ministerial role” in listing patents in the Orange Book, sought confirmation from Biovail that the ‘463 patent was properly listed. The complaint alleges that on February 26, 2001, as a result of a court filing by Biovail in a federal lawsuit brought by Andrx to force Biovail to de-list the ‘463 patent,⁶ the FDA learned that Biovail’s position was that the ‘463 patent covered a new formulation of Tiazac that Biovail had developed only after it acquired and listed the ‘463 patent, rather than the version of Tiazac that the FDA had approved and that

⁴59 Fed. Reg. 50338, 50345 (Oct. 3, 1994).

⁵*Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 10 F. Supp. 2d 446, 456 (D.N.J. 1998).

⁶The federal district court eventually ruled that there is no private right of action under the Food, Drug, and Cosmetic Act for one company to require another to de-list a patent from the Orange Book. *Andrx Pharm., Inc. v. Biovail Corp.*, 175 F. Supp. 2d 1362, 1373 (S.D. Fla. 2001).

Analysis

Biovail had been marketing. The FDA notified Biovail on March 20, 2001, that its new formulation of Tiazac was not approved by the FDA under the Tiazac NDA. Accordingly, the FDA would de-list the ‘463 patent from the Orange Book unless Biovail amended its certification to indicate that the patent claimed the version of Tiazac the FDA had approved.

In response to the FDA’s inquiries, Biovail submitted a signed declaration stating that the ‘463 patent was eligible for listing in the FDA’s Orange Book as claiming Tiazac. The complaint alleges that this declaration was misleading because it did not clarify whether the term “Tiazac” as used by Biovail meant the form of Tiazac the FDA had approved for marketing (as the FDA intended) or Biovail’s revised form of the product. The FDA understood Biovail’s March 26, 2001, declaration as affirming that the ‘463 patent covers the currently approved Tiazac product. On that basis, the FDA decided not to de-list the ‘463 patent from the Orange Book. According to the complaint, however, Biovail continued to assert that listing the ‘463 patent in the Orange Book was justified because it covers a revised form of Tiazac that Biovail believed fell within the Tiazac NDA, but which the FDA did not.

The complaint concludes that as a result of Biovail’s conduct, consumers of Tiazac have been deprived of the benefits of lower-priced generic competition that might have been possible had Biovail not acquired exclusive rights to, and then listed, the ‘463 patent, thereby precluding the FDA from granting final approval to Andrx’s generic Tiazac in February 2001.

Competitive Analysis

The complaint alleges that the relevant product market in which to assess the anticompetitive effects of Biovail’s conduct is Tiazac and generic bioequivalent versions of Tiazac. Although other therapeutic agents can be used to treat high blood pressure and chronic chest pain, including several other branded and generic formulations of once-a-day diltiazem, these other

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therapeutic agents do not significantly constrain Tiazac's pricing. In contrast, entry of a generic bioequivalent version of Tiazac likely would result in a significant, immediate decrease in the sales of branded Tiazac, and lead to a significant reduction in the average market price paid for Tiazac and its generic bioequivalents. In fact, Biovail's own sales forecasts projected that generic Tiazac would have captured 40 percent of branded Tiazac sales within the first year alone.

The relevant geographic market in which to assess the competitive effects of Biovail's conduct is the United States, given the FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals, like Tiazac, occur on a nationwide basis.

The complaint thus alleges that, at all times relevant to this case, Biovail's market share of the relevant antitrust market has been 100 percent.

Biovail's conduct as described above, and as alleged in the complaint, violated the antitrust laws in two ways. First, Biovail's acquisition of an exclusive license to the '463 patent substantially lessened competition in the U.S. market for Tiazac and its generic equivalents. As stated in the complaint, Biovail's acquisition of the exclusive license to the '463 patent raised substantial barriers to Andrx's entry into the relevant market and gave Biovail the power to exclude competition, thereby protecting Biovail's monopoly in the Tiazac market, in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45.

The complaint also alleges that Biovail violated Section 5 of the FTC Act by engaging in acts that willfully maintained its Tiazac monopoly. These acts included: (a) acquiring an exclusive license to the '463 patent for the purpose of listing it in the Orange Book; (b) wrongfully listing the '463 patent in the Orange Book as claiming Tiazac, in order to be eligible for an automatic 30-

Analysis

month stay of FDA approval for any generic Tiazac product; and (c) giving non-responsive answers to questions raised by the FDA about the propriety of listing the ‘463 patent in the Orange Book, so as to avoid the possibility of de-listing. As the complaint states, Biovail’s illegal monopolization raised substantial barriers to entry into the relevant market and gave Biovail the power to exclude competition. Biovail thereby deprived consumers of the benefits of lower-priced generic competition that might have been possible had the FDA not been precluded from granting final approval to Andrx’s generic Tiazac. These acts and practices are anticompetitive in nature and tendency, and constitute an unfair method of competition in violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

The Proposed Order

The proposed order is designed to address the anticompetitive effects of Biovail’s illegal conduct charged above, by requiring Biovail to divest part of its exclusive rights to the ‘463 patent and by providing other relief, on a prospective basis, to prevent or discourage recurrence of such conduct in the future. In essence, the proposed order:

- Requires that Biovail divest to DOV the exclusive rights to the ‘463 patent, as it applies for use in making any form of the currently marketed and FDA-approved Tiazac product.
- Prevents Biovail from taking any actions that would result in an additional 30-month stay of final FDA approval for a generic form of Tiazac.
- Prohibits Biovail from wrongfully listing any patents in the Orange Book in violation of applicable law.
- Requires that Biovail give the Commission prior written notice before it acquires an exclusive license to any patent that it plans to list in the Orange Book for a product for which Biovail already has an FDA-approved NDA.

Analysis

By requiring that Biovail divest its exclusive rights in the ‘463 patent in the “Tiazac Field,” that is, for use in making any form of the currently FDA-approved Tiazac, Paragraph II returns the market for Tiazac products to the status quo as it existed before the patent acquisition occurred. Paragraph II.A requires that Biovail divest to DOV its exclusive interest in the ‘463 patent as it relates to the Tiazac Field. Paragraph II.B prevents Biovail from structuring the divestiture in such a way that it would be able to continue reaping the benefits of its acquisition of the patent. Paragraph II.C proscribes the creation of a confidentiality agreement that could hinder future Commission enforcement actions against Biovail under the order or the antitrust laws. Paragraph II.D prohibits Biovail from having any input into the future utilization of the patent in the Tiazac Field. Paragraph II.E prevents Biovail from participating in any lawsuits to enforce the ‘463 patent in the Tiazac Field. Paragraph II.F requires Biovail to dismiss its patent infringement claim against Andrx.

Taken as a whole, Paragraph II removes Biovail’s possession of exclusive rights in the ‘463 patent (through which it was able to erect barriers to Andrx’s potential entry), while preserving Biovail’s and DOV’s ability to innovate and develop new products using that same patent. Paragraph II allows Biovail to continue to use the ‘463 patent, on an exclusive basis, to develop new diltiazem products that may result in the filing of an NDA with the FDA. Moreover, nothing in the paragraph prevents Biovail from holding non-exclusive rights to the ‘463 patent to develop improved forms of the currently marketed Tiazac product.

If Biovail fails to complete the divestiture required in Paragraph II.A within ninety days of signing the Agreement Containing Consent Order in this matter, Paragraph III of the Proposed Order requires Biovail to enter into a trust agreement and transfer the assets set forth in Paragraph II.A to a trustee appointed by the Commission. The trustee will then have the sole and exclusive power to divest the assets required in Paragraph II.A, subject to the prior approval of the Commission. The trustee

Analysis

will have twelve months to accomplish the divestiture, at no minimum price, to a buyer or buyers approved by the Commission.

Paragraph IV is intended to remedy Biovail's allegedly illegal monopolization. By preventing Biovail from engaging in strategies that pharmaceutical companies have used to exploit the Hatch-Waxman Act to thwart generic entry, Paragraph IV seeks to ensure the entry of a generic Tiazac product at the earliest possible moment.

Paragraph V is intended to deter Biovail from listing patents in the Orange Book that do not actually claim the drug product at issue, and thus prevent the triggering of procedures under the Hatch-Waxman Act that could improperly block generic entry. The Commission is concerned that improper patent listings may be a recurring problem in the pharmaceutical industry, and that such listings have a significant potential to affect competition and harm consumers. NDA holders have the ability unilaterally to list patents in the Orange Book – and thus exclude potential generic competitors from entering the market and competing for up to thirty months – whether or not the patent they list actually claims the product approved under the NDA. Because the FDA views its role in listing patents as “purely ministerial,” and because there is no private right of action to challenge a patent listing under the Food, Drug, and Cosmetic Act,⁷ it is possible for NDA holders, such as Biovail in this case, to obtain an additional thirty months free from generic competition by listing inappropriate patents in the Orange Book.

The Commission believes that the operative provisions in Paragraphs II through V of the proposed order strike an appropriate balance between Biovail's interests in acquiring

⁷*Mylan v. Bristol-Myers Squibb Co.*, 268 F.3d 1323, 1331-32 (Fed. Cir. 2001). See also *Andrx Pharm., Inc. v. Biovail Corp.*, 175 F. Supp. 2d 1362, 1373 (S.D. Fla. 2001).

Analysis

patents for legitimate business purposes, such as developing new products using that intellectual property, and the Commission's intention to remedy an NDA holder's creation of barriers to generic competition through strategic patent acquisitions and the misuse of the Hatch-Waxman regulatory framework. By not imposing broad prohibitions on Biovail's ability to develop new products based on the '463 patent, and by not preventing Biovail from legitimately acquiring and listing patents for other NDAs it may hold, the order maintains Biovail's incentive to develop and sell new drug products, while curbing the potential for Hatch-Waxman Act abuse.

Paragraph VI requires that Biovail submit written notification to the Commission before acquiring any patent or exclusive license on a patent, if Biovail also intends to seek the patent's listing in the Orange Book. Biovail will thus be free to continue acquiring intellectual property for legitimate business purposes, but the Commission will be notified in situations where there is a possibility that the acquisition of an exclusive license may serve to protect Biovail's dominant position in a relevant pharmaceutical market.

Paragraph VII sets forth the form of notice that Biovail must provide to the Commission under Paragraph VI of the order. In addition to supplying a copy of the patents to be acquired, Paragraph VII requires Biovail to provide certain other information to assist the Commission in assessing the potential competitive effect of the patent acquisition. Accordingly, the order requires Biovail to identify, among other things, the parties participating in the acquisition, the approved NDA(s) with respect to which the acquired patent will be submitted for listing in the Orange Book, and all persons who have filed an ANDA referencing the identified NDAs. In addition, Biovail must provide the Commission with copies of all transactional documents and other documents that evaluate the proposed licensing agreement.

Analysis

Paragraphs VIII, IX, and X of the proposed order contain certain reporting and other standard Commission order provisions designed to assist the Commission in monitoring compliance with the order.

The order will expire in ten years.

Opportunity for Public Comment

The proposed order has been placed on the public record for thirty days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed order and the comments received and will decide whether it should withdraw from the agreement containing the proposed order or make the proposed order final.

By accepting the proposed order subject to final approval, the Commission anticipates that the competitive issues alleged in the complaint will be addressed. The purpose of this analysis is to facilitate public comment on the agreement. It is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.

Complaint

IN THE MATTER OF

LIBBEY INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT

*Docket 9301; File No. 0110194
Complaint, May 9, 2002--Decision, October 7, 2002*

This consent order addresses the acquisition by Respondent Libbey Inc. – the largest maker and seller of food service glassware in the United States – of Anchor Hocking Corporation, the third largest maker and seller of food service glassware in the United States, and a wholly-owned subsidiary of Respondent Newell Rubbermaid Inc. The order, among other things, requires the respondents to provide the Commission with prior notice of the acquisition, sale, transfer, or other conveyance of all or part of Anchor or Anchor's Food Service Business. The order also requires Respondent Libbey to provide the Commission with prior notice of its acquisition of any interest in Anchor's stock or in the assets of Anchor's Food Service Business. In addition, the order requires Respondent Newell, for ten years, to provide the Commission with prior notice if it sells, transfers, or otherwise conveys any part of Anchor's Food Service Business to Libbey or Vitrocrisa, and to provide such prior notice for five years with respect to such transactions in all other circumstances.

Participants

For the Commission: *Richard Liebeskind, Chul Pak, Rhett Krulla, Morris Bloom, Brian Burgess, William Diaz, Lisa A. Rosenthal, April Tabor, Robert Tovsky, Robert Williams, Mary Forster, Art Strong, Elizabeth A. Piotrowski, Debra J. Holt, Christopher Garmon, Joseph Breedlove, Leslie Farber, and Mary T. Coleman.*

For the Respondents: *Bruce J. Prager and E. Marcellus Williamson, Latham & Watkins, Richard C. Weisberg, Libbey, and William S. D'Amico, Chadbourne & Parke.*

Complaint

COMPLAINT

The Federal Trade Commission (“Commission”), having reason to believe that respondents Libbey Inc. (“Libbey”), a corporation, and Newell Rubbermaid, Inc. (“Newell Rubbermaid”), a corporation, entered into (1) an agreement, dated as of June 17, 2001, for the acquisition by Libbey of the stock of Anchor Hocking Corporation (“Anchor”) from Newell Rubbermaid, and (2) an amended agreement, dated as of January 21, 2002, for the acquisition by Libbey of the stock of Anchor from Newell Rubbermaid, both in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, which acquisitions, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, and that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

RESPONDENT LIBBEY

1. Respondent Libbey is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 300 Madison Avenue, Toledo, Ohio 43699-0060.
2. Libbey is the largest maker and seller of food service glassware in the United States, with substantially more than half of the sales. Libbey produces and sells food service glassware, a line of products that includes many different styles of tumblers and stemware for beverages, and other glassware products ranging from serving platters to candle holders. Libbey produces and sells glassware, among other segments, to food service customers, including distributors who resell soda-lime glassware to restaurants, hotels and other food service establishments.

RESPONDENT NEWELL RUBBERMAID

3. Respondent Newell Rubbermaid is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 29 East Stephenson Street, Freeport, Illinois 61032. Anchor is an indirect, wholly-owned subsidiary of Newell Rubbermaid.

Complaint

4. Anchor is the third largest maker and seller of food service glassware in the United States. Anchor is Libbey's most formidable competitor in the food service glassware market.

JURISDICTION

5. Libbey is, and at all times relevant herein has been, engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

6. Newell Rubbermaid is, and at all times relevant herein has been, engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

THE ACQUISITION AND THE AMENDED MERGER
AGREEMENT

7. Pursuant to a Stock Purchase Agreement dated June 17, 2001, Libbey proposed to acquire all of the stock of Anchor from Newell Rubbermaid (the "acquisition").

8. On December 18, 2001, the Commission authorized the commencement of an action under Section 13(b) of the FTC Act to seek a preliminary injunction barring the acquisition during the pendency of administrative proceedings. Thereafter, on January 14, 2002, the FTC commenced such an action in the United States District Court for the District of Columbia, and on April 22, 2002, the district court granted the FTC's motion for a preliminary injunction pending the completion of administrative adjudication.

Complaint

9. On or about January 21, 2002, after the preliminary injunction action was commenced, respondents amended their merger agreement (the “amended merger agreement”). Respondents amended their merger agreement in response to the Commission’s vote to challenge the acquisition. Pursuant to the amended merger agreement, Libbey would still acquire all of the stock of Anchor, but prior to closing Anchor would transfer to Newell Rubbermaid’s Rubbermaid Commercial Products (“RCP”) division less than 10% of the assets of Anchor, and the consideration to be paid by Libbey for Anchor would be reduced by less than 10%.

10. Under the amended merger agreement, the assets to be transferred to RCP are most (not all) of the molds, customer relationships and certain other assets used in Anchor’s food service glassware business. Anchor would keep, and Libbey would still acquire, key assets used by Anchor in the food service glassware business, most significantly Anchor’s two glassware manufacturing plants. Newell would not retain any capability to manufacture glassware.

11. After the district court granted the Commission’s motion for a preliminary injunction, respondents told the court that Libbey would not solicit certain Anchor employees. At approximately the same time, Newell and a third party modified the price term under a supply agreement for RCP.

12. The amended merger agreement and the changes described in Paragraph 11 do not materially change the acquisition or its likely effect on competition.

RELEVANT MARKET

13. A relevant line of commerce in which to assess the effects of the acquisition and the amended merger agreement is food service glassware.

GEOGRAPHIC MARKET

Complaint

14. The relevant geographic area in which to assess the effects of the acquisition and the amended merger agreement is the United States.

Complaint

MARKET STRUCTURE

15. The United States food service glassware market is highly concentrated.

16. Libbey is the largest maker and seller of food service glassware in the United States, with substantially more than half of the sales.

17. Anchor is the third largest maker and seller of food service glassware in the United States.

18. Libbey and Anchor are direct and actual competitors in the manufacture and sale of food service glassware. They compete with each other on price by, among other things, offering discounts and other promotions on the sale of their food service glassware. Anchor prices and discounts its food service glassware in response to Libbey's pricing, and in order to take sales from Libbey. Anchor has succeeded in taking food service glassware sales from Libbey by offering lower prices to food service customers and distributors.

19. The acquisition and the amended merger agreement would combine the largest and third largest manufacturers and sellers of food service glassware in the United States, substantially increasing concentration in the food service glassware market, would result in a highly concentrated market, would eliminate the existing substantial competition between Libbey and Anchor, would impair the competitive viability of Newell Rubbermaid, and would substantially reduce competition and tend to create a monopoly in the market for food service glassware in the United States.

ANTICOMPETITIVE EFFECTS OF THE ACQUISITION
AND THE AMENDED MERGER AGREEMENT

20. The amended merger agreement, if consummated, would impair the competitive viability of Newell Rubbermaid as a competitor in the sale of food service glassware in the United States, and would reduce competition in the food service glassware market.

Complaint

21. The acquisition and the amended merger agreement may substantially lessen competition in the following ways, among others:

- a. they would eliminate actual, direct and substantial competition between Libbey and Anchor;
- b. they would increase the level of concentration in the relevant market;
- c. they may lead to increases in price for the relevant product;
- d. they may increase barriers to entry into the relevant market;
- e. they may give Libbey market power in the relevant market; and
- f. they may allow Libbey to exercise market power in the relevant market either unilaterally or in coordination with others.

ENTRY CONDITIONS

22. Entry into the relevant product market would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract anticompetitive effects of the acquisition and the amended merger agreement.

VIOLATIONS CHARGED

COUNT I – ILLEGAL ACQUISITION

23. The allegations contained in Paragraphs 1-22 are repeated and realleged as though fully set forth here.

Complaint

24. The effect of the acquisition may be substantially to lessen competition or tend to create a monopoly in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

COUNT II – ILLEGAL ACQUISITION AGREEMENT

25. The allegations contained in Paragraphs 1-22 are repeated and realleged as though fully set forth here.

26. Libbey and Newell Rubbermaid, through the Stock Purchase Agreement described in Paragraph 7, have engaged in unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

**COUNT III – ILLEGAL ACQUISITION
AMENDED MERGER AGREEMENT**

27. The allegations contained in Paragraphs 1-22 are repeated and realleged as though fully set forth here.

28. The effect of the amended merger agreement may be substantially to lessen competition or tend to create a monopoly in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

**COUNT IV – ILLEGAL ACQUISITION AGREEMENT
AMENDED MERGER AGREEMENT**

29. The allegations contained in Paragraphs 1-22 are repeated and realleged as though fully set forth here.

30. Libbey and Newell Rubbermaid, through the amended merger agreement described in Paragraph 9 and the changes thereto described in Paragraph 11, have engaged in unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

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NOTICE

Proceedings on the charges asserted against you in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You may file an answer to this complaint. Any such answer must be filed within 20 days after service of the complaint on you. If you contest the complaint's allegations of fact, your answer must concisely state the facts constituting each ground of defense, and must specifically admit, deny, explain, or disclaim knowledge of each fact alleged in the complaint. You will be deemed to have admitted any allegations of the complaint that you do not so answer.

If you elect not to contest the allegations of fact set forth in the complaint, your answer shall state that you admit all of the material allegations to be true. Such an answer will constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the ALJ will file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. Such an answer may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice.

If you do not answer within the specified time, you waive your right to appear and contest the allegations of the complaint. The ALJ is then authorized, without further notice to you, to find that the facts are as alleged in the complaint and to enter an initial decision and a cease and desist order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 14 days after the last answer is filed by any party named as a respondent in the complaint. Unless

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otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

A hearing on the complaint will begin on August 12, 2002, at 10:00 A.M. in Room 532, or such other date as determined by the ALJ. At the hearing, you will have the right to contest the allegations of the complaint and to show cause why a cease and desist order should not be entered against you.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Stock Purchase Agreement described in Paragraph 7 or the amended merger agreement described in Paragraph 9 violates Section 5 of the Federal Trade Commission Act, as amended, or that the proposed acquisition or the proposed amended merger agreement challenged in this proceeding would, if consummated, violate Section 7 of the Clayton Act, as amended, or Section 5 of the Federal Trade Commission Act, as amended, the Commission may order such relief against respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. An order to cease and desist from any action to effect the acquisition and the amended merger agreement by Libbey of any assets or securities of Newell Rubbermaid.
2. Rescission of the Stock Purchase Agreement and the amended merger agreement between respondents.

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3. Divestiture of an ongoing, operating business, including all assets, tangible and intangible, including, but not limited to, all intellectual property, knowhow, trademarks, trade names, research and development, and customer contracts, and including all improvements to existing products and new products developed by Newell Rubbermaid.

4. Such other or additional relief as is necessary to ensure the creation of one or more viable, competitive, independent entities to compete against Libbey in the manufacture and sale of food service glassware.

5. A requirement, for a ten (10) year period, that Libbey and Newell Rubbermaid provide the Commission with notice in advance of acquiring the assets or securities of, or any other combination with, any person engaged in the manufacture or sale of food service glassware in the United States.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C. this ninth day of May, 2002.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having heretofore issued its complaint charging the Respondents named in the caption hereof with violations of Section 5 of the Federal Trade Commission Act, as amended, and Section 7 of the Clayton Act, as amended, and Respondents having been served with a copy of that complaint, together with a notice of contemplated relief, and Respondents having answered the complaint denying said charges and asserting affirmative defenses but admitting the jurisdictional allegations set forth therein; and

The Respondents, their attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the Respondents of all the jurisdictional facts set forth in the complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission’s Rules; and

The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with § 3.25(c) of its Rules; and

The Commission having thereafter considered the matter and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure prescribed in § 3.25(f) of its Rules, the Commission hereby makes the following jurisdictional findings and enters the following Order:

1. Respondent Libbey Inc. (“Libbey”) is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 300 Madison Avenue, Toledo, Ohio 43604.

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2. Respondent Newell Rubbermaid Inc. ("Newell") is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 29 East Stephenson Street, Freeport, Illinois 61032. Anchor Hocking Inc. and Anchor Hocking Consumer Glass Corporation, corporations organized, existing and doing business under and by virtue of the laws of the State of Delaware, with their offices and principal places of business located at 519 Pierce Avenue, Lancaster, Ohio 43130, are indirect, wholly-owned subsidiaries of Newell. Newell Holdings Delaware, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal places of business located at 29 E. Stephenson Street, Freeport, Illinois 61032, is an indirect, wholly-owned subsidiary of Newell.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the Commission has determined that this proceeding is in the public interest.

ORDER

I

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

A. "Libbey" means Libbey Inc., its directors, officers, employees, agents, representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates, controlled by Libbey, and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

B. "Newell" means Newell Rubbermaid Inc., its directors, officers, employees, agents, representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates, controlled by Newell (including, but not limited to,

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Anchor and RCP), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

C. "Commission" means the Federal Trade Commission.

D. "Anchor" means Anchor Hocking Inc. and Anchor Hocking Consumer Glass Corporation, two Delaware corporations organized, existing and doing business under and by virtue of the laws of the State of Delaware, with their offices and principal places of business located at 519 Pierce Avenue, Lancaster, Ohio 43130, and assets of Anchor's Food Service Business held by Newell Holdings Delaware, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 29 E. Stephenson Street, Freeport, Illinois 61032.

E. "RCP" means Rubbermaid Commercial Products LLC, a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 3124 Valley Avenue, Winchester, Virginia 22601.

F. "Vitrocrisa" means Vitrocrisa, S. de R.L. de C.V., a joint venture between Libbey and Vitro, S.A., organized, existing and doing business under and by virtue of the laws of Mexico, with its office and principal place of business located at Doblado Norte 1627, Col. Terminal, 64580 Monterrey, Mexico.

G. "Anchor's Food Service Business" means all of Anchor's rights, title, and interest in and to all assets and businesses, tangible or intangible, anywhere in the world, used in the research, development, manufacture, distribution, licensing, marketing, or sale of glassware products to Food Service Customers in the United States, including, but not limited to:

1. Real property (together with appurtenances, licenses, and permits) owned, leased or otherwise held by Anchor, including,

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but not limited to, the Lancaster, Ohio and Monaca, Pennsylvania glassware manufacturing plants, and related machinery, fixtures, equipment, furniture, tools and other tangible property, including, but not limited to, glassware molds;

2. Personal property owned, leased, or otherwise held by Anchor;
3. Inventories, stores, and supplies held by, or under the control of, Anchor;
4. Intellectual property rights owned by or licensed to Anchor, including, but not limited to, trademarks, patents, copyrights, and trade secrets;
5. Rights of Anchor under any contract, including, but not limited to, licenses, leases, customer contracts (including, but not limited to, contracts with Food Service Customers), supply agreements and procurement contracts;
6. Pending and issued governmental approvals, registrations, consents, licenses, permits, waivers, or other authorizations held by Anchor, including foreign equivalents;
7. Rights of Anchor under any warranty or guarantee, express or implied;
8. Items of prepaid expense owned by Anchor; and
9. Separately maintained, and relevant portions of not separately maintained, books, records, and files held by, or under the control of, Anchor.

PROVIDED, HOWEVER, that Anchor's Food Service Business shall not include:

- i. Rights of Anchor to warehouse space;
- ii. Office equipment, furniture and accessories;

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- iii. Computer hardware and accessories;
- iv. Motor vehicles, forklifts, overhead cranes, and other transportation equipment;
- v. Raw materials, including, but not limited to, electricity, natural gas, water, sand, soda lime, cullet, corrugate and other packaging materials and metal, ceramic and plastic accessories;
- vi. Scrap metal and other scrap materials;
- vii. Machine replacement parts;
- viii. Decorating equipment;
- ix. Packaging equipment;
- x. Hand tools;
- xi. Machine tools;
- xii. Sandblasting equipment; and
- xiii. Bakeware, candles, floral items and storage jars, and the molds used to form these items.

Anchor's Food Service Business expressly includes any and all assets of Anchor's Food Service Business sold or transferred to any other Person, including RCP or any other Person or business unit included within Newell, on or after June 10, 2002, except in the ordinary course of business.

H. "Food Service Customers" means restaurants, hotels and other food service establishments, whether private or public, that use or sell glassware in the course of serving or selling food or beverages to consumers, and includes distributors or resellers of glassware to such establishments; PROVIDED, HOWEVER, that

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Food Service Customers shall not include retail stores, original equipment manufacturers, and warehouse clubs.

I. "Person" means any natural person, partnership, corporation, company, association, trust, joint venture or other business or legal entity, including any governmental agency.

J. "Respondents" means Libbey and Newell, individually and collectively.

II

IT IS FURTHER ORDERED that Libbey shall not, without prior written notification to the Commission, acquire, directly or indirectly, through subsidiaries or otherwise, any ownership, leasehold, or other interest, in whole or in part, in the stock of Anchor or the assets of the Anchor Food Service Business.

III

IT IS FURTHER ORDERED that Newell shall not, without prior written notification to the Commission, sell, transfer, or otherwise convey, directly or indirectly, through subsidiaries or otherwise, any ownership, leasehold, or other interest, in all or any part of Anchor's Food Service Business:

A. to Libbey or to Vitrocrisa, for a period commencing on the date this Order becomes final and continuing for ten (10) years; and

B. to any Person other than to Libbey or to Vitrocrisa, for a period commencing on the date this Order becomes final and continuing for five (5) years;

PROVIDED, HOWEVER, that such notification shall not be required for sales, transfers or other conveyances by Newell: (i) to a Person or business unit included within Newell; (ii) in the ordinary course of business; (iii) of inventory to liquidators; or

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(iv) of accounts receivable in connection with financing transactions.

IV

IT IS FURTHER ORDERED that Respondent Libbey and Respondent Newell shall provide the respective prior written notifications required by Paragraphs II and III of this Order, as applicable, on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as the "Notification"), which Notification shall be prepared and transmitted in accordance with the requirements of that part, except that (i) no filing fee will be required for any such Notification, (ii) Notification shall be filed with the Secretary of the Commission, (iii) Notification need not be made to the United States Department of Justice, and (iv) Notification is required only of the applicable Respondent and not of any other party to the relevant transaction. Notification shall be provided to the Commission at least thirty (30) days prior to consummating any transaction covered by the respective requirements of Paragraph II or Paragraph III, as applicable (hereinafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), the applicable Respondent shall not consummate the transaction until thirty (30) days after submitting such additional information or documentary material. Early termination of the waiting periods in Paragraphs II and III may be requested and, where appropriate, granted by letter from the Commission's Bureau of Competition. PROVIDED, HOWEVER, that prior notification shall not be required by Paragraphs II and III for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

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V

IT IS FURTHER ORDERED that:

- A. Within sixty (60) days after the date this Order becomes final, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they have complied and are complying with this Order; and
- B. One (1) year from the date this Order becomes final, annually for the next nine (9) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with this Order.

VI

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate Respondents such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of this Order.

VII

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, upon written request, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and

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documents in the possession or under the control of Respondents relating to any matters contained in this Order; and

B. Upon five (5) days' notice to Respondents and without restraint or interference from them, to interview officers, directors, employees, agents or independent contractors of Respondents, who may have counsel present, relating to any matters contained in this Order.

VIII

IT IS FURTHER ORDERED that this Order shall terminate on October 7, 2012.

By the Commission.

Analysis

**Analysis to Aid Public Comment on Agreement Containing
Consent Order****I. Introduction**

The Federal Trade Commission has accepted for public comment a Decision and Order (“Proposed Order”), pursuant to an Agreement Containing Consent Order (“Consent Agreement”), against Libbey Inc. and Newell Rubbermaid Inc. (collectively “Respondents”). The Proposed Order is intended to resolve anticompetitive effects in the United States food service glassware market stemming from the proposed acquisition by Libbey of Anchor Hocking Corporation, a wholly-owned subsidiary of Newell. Under the Proposed Order, Libbey cannot acquire any stock of Anchor or the assets of Anchor’s food service glassware business without prior notice to the Commission. Additionally, Newell cannot sell or transfer all or a substantial part of the assets of Anchor’s food service business without prior notice to the Commission.

**II. The Parties, the Transaction and the History of the
Litigation**

Libbey is the largest maker and seller of food service glassware in the United States, with substantially more than half of the sales, and has plants located in Ohio, Louisiana and California. Libbey produces and sells food service glassware, a line of products that includes many different styles of tumblers and stemware for beverages. Libbey sells food service glassware to customers that use glassware in the course of serving or selling food or beverages to consumers, including distributors who resell glassware to restaurants, hotels and other such establishments. Besides food service glassware, Libbey produces and sells glassware products ranging from serving platters to candle holders for the retail and industrial segments.

Newell is a diversified company based in Illinois. Anchor is an indirect, wholly-owned subsidiary of Newell, with manufacturing

Analysis

facilities in Ohio and Pennsylvania. Anchor is the third largest maker and seller of food service glassware in the United States, and, as found by a District Court, is Libbey's most formidable competitor in food service. Besides food service glassware, Anchor produces and sells glassware products ranging from bakeware to candle holders for the retail and industrial segments.

Pursuant to an agreement dated June 17, 2001, Libbey proposed to acquire all of the stock of Anchor from Newell (the "acquisition"). On December 18, 2001, the Commission authorized the commencement of an action under Section 13(b) of the FTC Act to seek a preliminary injunction barring the acquisition during the pendency of administrative proceedings. On January 14, 2002, the FTC commenced such an action against Respondents in the United States District Court for the District of Columbia.

Pursuant to an agreement dated January 21, 2002, after the preliminary injunction action was commenced and in response to the Commission's vote to challenge the acquisition, Libbey and Newell amended their merger agreement (the "amended merger agreement"). The amended merger agreement provided that Libbey would acquire all of the stock of Anchor, but prior to closing Anchor would transfer to Newell's Rubbermaid Commercial Products ("RCP") division less than 10 percent of the assets of Anchor, and the consideration to be paid by Libbey for Anchor would be reduced by less than 10 percent. Under the amended merger agreement, the assets to be transferred to RCP were most (not all) of the molds, customer relationships and certain other assets used in Anchor's food service glassware business. Anchor would have kept, and Libbey would still have acquired, key assets used by Anchor in the food service glassware business—most significantly, Anchor's two glassware manufacturing plants. Newell would not retain any capability to manufacture glassware.

In its Amended Complaint, filed February 22, 2002, the FTC alleged that the acquisition pursuant to the amended merger

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agreement would substantially lessen competition. The proposed merger would eliminate Anchor as a competitor from the food service glassware market and RCP would be unable to replace Anchor as a viable competitor. The Commission later issued a statement on April 2, 2002, in which it reaffirmed its position that the amended merger would result in a lessening of competition in violation of the Clayton and FTC Acts. Statement of the Federal Trade Commission Regarding *FTC v. Libbey Inc., et al.*, Apr. 2, 2002.

On April 22, 2002, the District Court granted the FTC's motion for a preliminary injunction pending the completion of administrative adjudication. Memorandum Opinion ("Op.") (*FTC v. Libbey Inc., et al.*, 2002 U.S. Dist. LEXIS 8867 (D.D.C., Apr. 22, 2002)).

In granting the FTC's motion, the Court found that Libbey dominates the food service glassware market with a 65 percent share, while Anchor, with seven percent of the market, has the third largest share. Op. at 3. Although Libbey's market share dwarfs Anchor's, the Court found that "Anchor is Libbey's most formidable competitor in the food service glassware market," because it is "the largest seller of Libbey look-alikes," *id.* at 18, and because its prices "are frequently 10 to 20 percent lower than Libbey's prices," *id.* at 5.

The Court concluded that both the acquisition and the amended merger likely would reduce competition in the food service glassware market; the food service glassware market was highly concentrated, and, "if what is now Anchor were eliminated from the market, there are no other viable alternatives to Libbey's food service glassware that consumers could [rely] upon to acquire their glassware at the lower prices now offered by Anchor." *Id.* at 28. Moreover, the Court held that RCP would not replace Anchor as an effective competitor. Because RCP would not retain important assets, such as Anchor's manufacturing plants, brand name, customer relationships, and key employees, the Court held

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that the amended merger would have the same anti-competitive effect as if Libbey had acquired all of Anchor. *Id.* at 23.

On May 2, 2002, Respondents moved to vacate the preliminary injunction order on the ground that Newell and a third party supplier had modified the price term under a glassware supply agreement for RCP. On May 17, 2002, the District Court denied Respondents' motion because of the numerous other cost components that would likely make RCP's costs substantially higher than Anchor's costs and, therefore, not a viable competitive alternative to Anchor. *FTC v. Libbey Inc.*, Order Denying Defendants' Motion to Vacate, May 17, 2002. Reiterating the reasons in its earlier opinion, the Court stated that "the FTC's concerns remain[ed] plausible" and noted that the appropriate venue to fully evaluate the amended merger was at a full administrative hearing before the FTC. *Id.* at 3.

Following the District Court's preliminary injunction order, on May 9, 2002, the Commission issued its complaint against Respondents. Shortly after answering the complaint, on June 10, 2002, Respondents announced that they had withdrawn plans for Libbey to acquire Anchor from Newell. On July 23, 2002, Respondents entered into the Consent Agreement. Pursuant to Rule 3.25 of the Commission's Rules of Practice, 16 C.F.R. § 3.25, a motion was filed to withdraw the matter from adjudication, and on July 25, 2002, the matter was withdrawn from adjudication for the purpose of considering the Consent Agreement.

III. The Complaint

In its administrative complaint, the FTC charged that both the acquisition and the amended merger violated the Clayton and FTC Acts. The complaint alleges that the acquisition and the amended merger would eliminate competition between Libbey and Anchor, increase market concentration, and increase barriers to entry. The complaint also alleges that the amended merger would impair the

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viability of Newell as a competitor in the sale of food service glassware.

IV. Terms of the Proposed Order

The Proposed Order (“Order”) is effective for 10 years and requires Libbey and Newell to provide the Commission with written notice prior to the acquisition, sale, transfer, or other conveyance of all or part of Anchor or Anchor’s Food Service Business. Under the terms of the Order, Libbey is required to provide the Commission with prior written notice of its acquisition of any interest in Anchor’s stock or in the assets of Anchor’s Food Service Business. Order ¶ II. In addition, Newell must provide the Commission with prior written notice if it sells, transfers, or otherwise conveys any part of Anchor’s Food Service Business to any entity not included within Newell. Order ¶ III. If Newell sells, transfers or otherwise conveys Anchor’s Food Service Business to Libbey or Vitrocrisia, Newell’s obligation to notify the Commission extends for 10 years. *Id.* In all other circumstances, Newell is obligated to provide notice for five years. *Id.*

Anchor’s Food Service Business is defined as “all of Anchor’s rights, title, and interest in and to all assets and businesses, tangible or intangible, anywhere in the world, used in the research, development, manufacture, distribution, licensing, marketing, or sale of glassware products to Food Service Customers in the United States,” and expressly includes assets that Newell may have internally transferred to other divisions on or after June 10, 2002. Order ¶ I.G. Anchor’s Food Service Business does not include items that are generally available, are not unique to the glassware industry, or are minimally used in the production of food service glassware, such as sand, scrap metal, and office equipment. *Id.*

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V. Opportunity for Public Comment

The Proposed Order has been placed on the public record for 30 days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Consent Agreement and the comments received and will decide whether to make the Proposed Order final. By accepting the Consent Agreement subject to final approval, the Commission anticipates that the competitive problems alleged in the Complaint will be resolved.

The Commission invites public comment to aid the Commission in determining whether it should make final the Proposed Order contained in the Consent Agreement. The Commission does not intend this analysis to constitute an official interpretation of the Proposed Order, nor does this analysis modify in any way the terms of the Proposed Order.

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IN THE MATTER OF**R. T. WELTER AND ASSOCIATES, INC., ET AL.**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4063; File No. 0110175**Complaint, October 8, 2002--Decision, October 8, 2002*

This consent order addresses practices used by Respondents R.T. Welter and Associates, Inc. ("RTWA"), R. Todd Welter – a non-physician consultant who through his company, RTWA, represented a group of approximately 88 physicians specializing in obstetrics and gynecology known as Professionals in Women's Care ("PIWC") – and eight medical group practices in the Denver, Colorado metropolitan area. The order, among other things, prohibits the respondents from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, not to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or to deal with any payor only through an arrangement involving the respondents. The order also prohibits the respondents from facilitating exchanges of information between physicians concerning whether, or on what terms, to contract with a payor. In addition, the order prohibits the respondents from attempting to engage in – or from inducing anyone to engage in – any action prohibited by the order. In addition, the order prohibits Respondents RTWA and Welter, for three years, from negotiating with any payor on behalf of any PIWC physician, and from advising any PIWC physician to accept or reject any term, condition, or requirement of dealing with any payor. The order also requires Respondent RTWA to distribute the complaint and order to all physicians who participated in PIWC – and to the payors that negotiated contracts with RTWA or Respondent Welter on behalf of any of the eight respondent practice groups – and requires the Respondent Practice Groups to terminate – without penalty at any payor's request – current contracts, with respect to providing physician services, negotiated by Respondent Welter with payors.

Participants

For the Commission: *Paul J. Nolan, Christi J. Braun, David R. Pender, Jeffrey W. Brennan, Rendell A. Davis, Jr., Daniel P. Ducore, Fred Martin, Thomas Iosso and Louis Silvia.*

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For the Respondents: *Colleen Rea, Stromberg Cleveland Crawford & Schmidt, P.C., Claude Wild, III, Patton Boggs LLP, and Neil Peck, Snell & Wilmer.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U. S. C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that the corporations, partnership, and individual named in the caption hereof, hereinafter collectively referred to as "Respondents," have violated and are violating Section 5 of the Federal Trade Commission Act, 15 U. S. C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges in that respect as follows:

RESPONDENTS AND JURISDICTION

PARAGRAPH 1: Respondent R.T. Welter and Associates, Inc. (hereinafter "Respondent RTWA") is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 655 Broadway, Suite 500, Denver, CO 80203. Respondent RTWA is a consulting firm that offers services to physician clients, in Denver and elsewhere, including the service of representing physicians in contract negotiations with health insurance firms and other third-party payors.

PARAGRAPH 2: R. Todd Welter (hereinafter "Respondent Welter") is president of Respondent RTWA. His office and principal place of business is 655 Broadway, Suite 500, Denver, CO 80203. Respondent Welter is a consultant, operating through RTWA, who represents physicians in contract negotiations with health insurance firms and other third-party payors.

PARAGRAPH 3: In October 1999, Respondents RTWA and Welter organized numerous physicians into a concerted

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arrangement for the purpose of collective contract negotiations with health insurance firms and other third-party payors. These physicians specialize in the practices of obstetrics and gynecology (“OB/GYNs”) in the Denver metropolitan area. Respondents named their concerted arrangement “Professionals in Women’s Care” (hereinafter “PIWC”). Aside from the name itself, PIWC lacked any indicia of a formal entity, such as officers, directors, or by-laws. Nonetheless, Respondents Welter and RTWA routinely referred to PIWC’s participating physicians as “members” in correspondence.

PARAGRAPH 4: The medical group practice firms listed below (hereinafter “Respondent Practice Groups”), among the largest OB/GYN medical group practices in the Denver metropolitan area, are participants in PIWC. Each contracted with Respondent RTWA for the purpose of negotiating contracts with health insurance firms and other third-party payors. Respondent Practice Groups are and have been, at all times relevant to this complaint, organized for profit within the meaning of Section 4 of the Federal Trade Commission Act. They are:

- A. Respondent Cohen and Womack, M.D., P.C., a professional corporation with its office and principal place of business located at 255 Union Boulevard, Suite 200, Lakewood, CO 80228.
- B. Respondent Consultants in Obstetrics and Gynecology, P.C., a professional corporation with its office and principal place of business located at 4500 East 9th Ave, Suite 300, Denver, CO 80220.
- C. Respondent Mid Town Obstetrics & Gynecology, P.C., a professional corporation with its office and principal place of business located at 2005 Franklin Street, Midtown II, Suite 440, Denver, CO 80205.
- D. Respondent Mile High OB/GYN Associates, P.C., a professional corporation with its office and principal place

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of business located at 455 South Hudson St., Level 2,
Denver, CO 80246.

- E. Respondent The OB-GYN Associates Professional Corporation, a professional corporation with its office and principal place of business located at 3773 Cherry Creek North Drive, Suite 100, Denver, CO 80209.
- F. Respondent Rocky Mountain OB-GYN, P.C., a professional corporation with its office and principal place of business located at 4500 East 9th Ave., Suite 200-S, Denver, CO 80220.
- G. Respondent The Women's Health Group, P.C., a professional corporation with its office and principal place of business located at 9195 Grant Street, Suite 300, Thornton, CO 80229.
- H. Respondent Westside Women's Care, L.L.P., a partnership of professional corporations with its office and principal place of business located at 7950 Kipling Street, Suite 201, Arvada, CO 80005.

PARAGRAPH 5: At all times relevant to this Complaint, Respondents RTWA and Welter were engaged in the business of providing consulting services in the Denver metropolitan area to OB/GYNs who provide health care services for a fee to patients. All members of the Respondent Practice Groups, and all other PIWC participants, are physicians engaged in the business of providing obstetrical and gynecological services for a fee to patients, are licensed to practice medicine in the State of Colorado, and have offices located in the Denver metropolitan area. Except to the extent that competition has been restrained as alleged herein, Respondent Practice Groups have been, and are now, in competition with each other, with other PIWC participants, and with other OB/GYNs for the provision of physician services.

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PARAGRAPH 6: The Respondents' general business practices, including the acts and practices alleged herein, are in or affecting "commerce" as defined in the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

OVERVIEW OF MARKET AND PHYSICIAN COMPETITION

PARAGRAPH 7: Approximately 88 OB/GYNs participate in PIWC. These PIWC participants constitute a significant percentage of the OB/GYNs practicing in the Denver metropolitan area. About one-half of the participants in PIWC are OB/GYNs who practice medicine through one of the Respondent Practice Groups.

PARAGRAPH 8: Physicians often contract with health insurance firms and other third-party payors (hereinafter "payors"), such as preferred provider organizations. Such contracts typically establish the terms and conditions, including fees and other competitively significant terms, under which the physicians will render services to the payors' subscribers. Physicians entering into such contracts often agree to lower compensation, in order to obtain access to additional patients made available by the payors' relationship with insureds. These contracts may reduce payors' costs and enable payors to lower the price of insurance, and thereby result in lower medical care costs for subscribers to the payors' health insurance plans.

PARAGRAPH 9: Absent agreements among competing physicians on the terms, including price, on which they will provide services to subscribers or enrollees in health care plans offered or provided by third-party payors, competing physicians decide individually whether to enter into contracts with third-party payors to provide services to their subscribers or enrollees, and what prices they will accept pursuant to such contracts.

PARAGRAPH 10: Medicare's Resource Based Relative Value System ("RBRVS") is a system used by the Centers for Medicare

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and Medicaid Services to determine the amount to pay physicians for the services they render to Medicare patients. The RBRVS approach provides a method to determine fees for specific services. It is the practice of payors in the Denver metropolitan area to make contract offers to individual physicians at a fee level specified in the RBRVS for a particular year, plus a markup based on some percentage of that fee (*e.g.*, “110 percent of 2001 RBRVS”). Most gynecological services and some obstetrical services are reimbursed according to this system.

PARAGRAPH 11: Obstetrical professional services include services for childbirth and related prenatal and postnatal services. In most payor contracts for such services in the Denver metropolitan area, obstetricians receive a “global” fee for attending a normal delivery, regardless of the number of visits or associated services the physician provides to the patient.

PARAGRAPH 12: In order to be competitively marketable in the Denver metropolitan area, a payor’s health insurance plan must include in its physician network a large number of OB/GYNs who practice in the Denver metropolitan area. A significant percentage of the OB/GYNs who practice in the Denver metropolitan area participate in PIWC.

PARAGRAPH 13: Competing physicians sometimes use a “messenger” to facilitate the establishment of contracts between themselves and payors in ways that do not constitute or facilitate an unlawful agreement on fees and other competitively significant terms. Such a messenger may not, however, consistent with a competitive model, negotiate fees and other competitively significant terms on behalf of the participating physicians, or facilitate the physicians’ coordinated responses to contract offers by, for example, electing not to convey a payor’s offer to them based on the messenger’s opinion on the appropriateness, or lack thereof, of the offer.

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RESTRAINT OF TRADE

PARAGRAPH 14: The Respondent Practice Groups, acting as a combination of competing physicians through PIWC, and Respondents RTWA and Welter, in conspiracy with the Respondent Practice Groups, have acted to restrain competition by, among other things:

- A. facilitating, negotiating, entering into, or implementing agreements on fees and other competitively significant terms;
- B. refusing to deal with payors except on collectively agreed-upon terms; and
- C. negotiating uniform fees and other competitively significant terms in payor contracts for PIWC's participants, and refusing to submit payor offers to PIWC participants that do not conform to Respondents' standards for contracts.

FORMATION AND OPERATION OF PIWC

PARAGRAPH 15: Respondent Welter and Respondent Practice Groups organized collectively under the name "PIWC" in October 1999 to engage in collective contract negotiations with payors. Respondent Welter and the Respondent Practice Groups encouraged other OB/GYNs to participate in PIWC for the purpose of acting as a united front to demand and receive higher fees and other, more advantageous terms from payors. Respondent Welter enlisted participation in PIWC by promising to "stop the downward slide of reimbursement from managed care insurance companies."

PARAGRAPH 16: In or about October 1999, Respondent Welter and representatives of the Respondent Practice Groups created the "Steering Committee," as a means to manage the collusive arrangement known as PIWC. The Steering Committee

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was composed of one representative from each of the Respondent Practice Groups. The PIWC Steering Committee was responsible for adoption of a general strategy that Respondent Welter would use to negotiate higher fees from payors on behalf of PIWC's participating physicians. Respondent Welter advised Steering Committee members that they "must meet periodically to discuss the [PIWC's] operations, set managed care targets, and to discuss and agree on strategy."

PARAGRAPH 17: The OB/GYNs who participate in PIWC do not pay membership fees or make capital contributions. Instead, they jointly pay Respondent Welter an hourly fee to represent them in contract negotiations with payors. OB/GYNs participating in PIWC, or the medical group practices in which they were members, signed an agreement authorizing Respondent Welter to negotiate, on their behalf, fees and other terms of "non-risk" managed care contracts with payors. In non-risk contracts, physicians and payors do not share financial risk through arrangements such as capitation or fee withhold.

PARAGRAPH 18: Respondent Practice Groups and other PIWC participants collectively decided to authorize Respondent Welter to renegotiate fee terms contained in existing payor contracts, advised Respondent Welter to reject payor fee offers that were too low, and determined whether Respondent Welter should deal with a particular payor. As contract negotiations with particular payors progressed, Respondent Welter regularly held Steering Committee meetings and general meetings among all PIWC participants to discuss details of his payor contract negotiations, including the status of fee negotiations, the specific fee levels that were discussed, and overall contract strategy.

PARAGRAPH 19: Respondent Welter has a practice, inconsistent with a messenger model arrangement, of not conveying to PIWC participants the terms of payor offers that Respondent Welter and the Respondent Practice Groups deem deficient. The Respondent Practice Groups, and the PIWC participants more generally, understood and jointly agreed that

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Respondent Welter would first negotiate with payors for favorable contract terms. Respondents understood that the payors would offer more advantageous terms to PIWC participants if the physicians negotiated on a collective, rather than unilateral, basis. Only after engaging in such jointly authorized negotiations did Respondent Welter convey the payor contract in question to PIWC participants for approval.

PARAGRAPH 20: PIWC participants knew from Respondent Welter's regular reports and updates that he was simultaneously representing all of the PIWC participants in contract negotiations with payors, and that he represented them all for the common purpose of attaining higher fees for them. Respondent Welter, with the approval of the Respondent Practice Groups, solicited *de facto* exclusivity among PIWC participants, by requesting that they terminate their relationships with independent practice associations ("IPAs") and practice management groups ("PMGs") in the Denver metropolitan area. He urged the PIWC participants to "terminate their IPA affiliations so that the payors can only access them through one direct agreement negotiated through Professionals in Women's Care," stating that "[i]n this way maximum leverage can be made." Many PIWC participants, including most Respondent Practice Groups, terminated their affiliations with such other physician organizations.

PARAGRAPH 21: Respondent Practice Groups exploited PIWC's collective power to exact higher fees and more favorable price-related terms in payor contracts, by using Respondents Welter and RTWA to demand that payors provide PIWC participants with a new contract offer containing more lucrative terms. Many PIWC participants, on whose behalf Respondent Welter made these demands, were already under contract with these payors for a considerable period into the future. Respondent Welter advised PIWC participants, including Respondent Practice Groups, to terminate existing contracts with payors that refused to deal with Respondent RTWA, and Respondent Practice Groups and other PIWC participants followed Respondent Welter's advice by terminating existing payor contracts. Respondent

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Practice Groups knew that Respondent Welter was representing the PIWC participants as a group, and telling payors that the PIWC Participants were united in bargaining for higher contract fees.

PARAGRAPH 22: Respondents' strategy of collective contract negotiations and concerted refusals to deal individually left payors in the untenable position of having to pay higher fees to the PIWC participants or being denied the OB/GYNs' inclusion in the payors' provider networks – an outcome that would have substantially impaired the payors' ability to compete effectively.

PARAGRAPH 23: In the first year after PIWC was organized, Respondent Welter presented PIWC participants with data that Respondent Welter characterized as showing that their jointly negotiated payor contracts paid each PIWC participant, on average, an 11% increase in fees over the previous year's contracts.

NEGOTIATIONS WITH PACIFICARE

PARAGRAPH 24: PacifiCare Health Systems of Colorado (“PacifiCare”) is a payor doing business in the Denver metropolitan area. In the late summer and fall of 1999, PacifiCare made contract offers to numerous OB/GYNs in the Denver metropolitan area. In its contracts, PacifiCare proposed a fee-for-service arrangement based on a percentage of RBRVS; the percentage could be adjusted downward if the physicians' expenses exceeded a pre-determined budgeted amount. Respondent Practice Groups objected to these terms, and collectively retained Respondents RTWA and Welter to negotiate for a different agreement on their behalf.

PARAGRAPH 25: On October 21, 1999, in what would be the first coming together of the arrangement later named “PIWC,” Respondent Welter and the Respondent Practice Groups convened a meeting among themselves and OB/GYNs from 7 Denver area hospitals to discuss and jointly respond to PacifiCare's contract

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offer. At this meeting, the OB/GYNs voted unanimously to authorize Respondent Welter to represent them and negotiate for higher fees on their behalf with PacifiCare. A few days later, Respondent Welter informed PacifiCare that the OB/GYNs had reached a “unanimous decision” to request a meeting with PacifiCare representatives regarding PacifiCare’s contract offer, and had unanimously “decided not to sign the current agreement.”

PARAGRAPH 26: Respondent Welter advised the PIWC participants, including Respondent Practice Groups, to refuse to sign individual PacifiCare agreements, to refer any communications they may receive from PacifiCare on to Respondent Welter, and to terminate their relationships with IPAs and PMGs under contract with PacifiCare. The purpose of this strategy was to ensure that PacifiCare could only have the PIWC participants in its physician network if it negotiated exclusively with Respondent Welter. PIWC participants, including Respondent Practice Groups, complied with this strategy. Respondent Welter told the PIWC participants that the “termination process” would lead to “payor panic,” an outcome that would create bargaining leverage for the collection of PIWC participants. Respondent Welter and the Respondent Practice Groups knew that unless PacifiCare acquiesced in their demands for higher fees, PacifiCare would have no contract with PIWC participants after January 1, 2000.

PARAGRAPH 27: Respondent Welter told PacifiCare’s representatives that the PIWC participants had joined together for the purpose of securing higher fees and better contract terms from payors. He told PacifiCare that he was the agent for all of the OB/GYNs participating in PIWC, that they demanded higher fees from PacifiCare, and that the OB/GYNs had instructed him to tell PacifiCare that they would not agree to PacifiCare’s current contract offer.

PARAGRAPH 28: In response to Respondent Welter’s threat that none of the PIWC participants would sign individual agreements under the current contract proposal, PacifiCare

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increased its fee offer, both with respect to global delivery fees and RBRVS for OB/GYN services. In March 2000, Respondent Welter informed the PIWC participants that he had succeeded in convincing PacifiCare to offer higher fees. Subsequently, on behalf of PIWC participants, including the Respondent Practice Groups, Respondents RTWA and Welter continued to negotiate fee-related contract language with PacifiCare. When the negotiations were completed, Respondent Welter sent to each PIWC participant an individual PacifiCare contract reflecting the higher fees that he had negotiated. The PIWC participants, including the Respondent Practice Groups, thereafter signed individual agreements.

NEGOTIATIONS WITH AETNA U.S. HEALTHCARE

PARAGRAPH 29: In 2000, Respondent Practice Groups, in their capacity as the PIWC Steering Committee, convened a meeting to consider actions against another payor doing business in the Denver metropolitan area, Aetna U.S. Healthcare (“Aetna”). At that time, Aetna’s standard contract with OB/GYNs contained terminology aimed at controlling the cost of routine care. Respondent Practice Groups and Respondent Welter collectively demanded that Aetna rewrite the OB/GYNs’ contracts, to eliminate all cost control measures and to agree to the specified fees. Aetna refused these demands and informed Respondent Welter that the OB/GYNs could renegotiate with Aetna on an individual basis.

PARAGRAPH 30: Following Aetna’s rejection, Respondent Welter, together with the Respondent Practice Groups, coordinated a response. He informed all PIWC participants that “we have had [a] very unsatisfactory response from Aetna regarding your concerns for proper payment.” Respondent Welter requested that the PIWC participants notify him or his assistant should Aetna request that the OB/GYNs sign an individual contract, so that he could negotiate with Aetna on all the OB/GYNs’ behalf.

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PARAGRAPH 31: In or about August, 2000, on the collective behalf of the PIWC participants, Respondent Welter issued to Aetna a September 15, 2000, “deadline for Aetna’s response to our contract issues.” On October 11, 2000, after Aetna refused to meet Respondent Welter’s demands, Respondent Welter told the PIWC participants that due to the “inadequate results the current course of action is having,” “your only option may be to terminate with Aetna.” Around the same time, Respondent Welter told the Respondent Practice Groups that “we are unable to leverage contracts if the members are un-willing to: say NO to bad rates [and] get OUT of other entanglements,” such as IPAs and PMGs, and align themselves exclusively as a group through PIWC. Respondent Welter threatened to resign as the PIWC participants’ agent, unless PIWC participants were willing to hold out for higher fees and terminate their IPA and PMG affiliations. In order to ensure solidarity in their contracting actions, Respondent Welter, with the authority of the Steering Committee, advised the PIWC participants to terminate their IPA and PMG affiliations, which most did.

PARAGRAPH 32: Soon after the efforts of Respondent Welter and the Respondent Practice Groups to ensure “solidarity” among PIWC participants, more than thirty PIWC Participants sent termination notices to Aetna. Concerned that a boycott among PIWC participants would damage its ability to compete, Aetna delivered to Respondent Welter new contracts that raised fees to the higher level that Respondents were demanding. Respondent Welter forwarded the Aetna contracts containing the higher fees to PIWC participants, all of whom signed them.

NEGOTIATIONS WITH ANTHEM BLUE CROSS & BLUE SHIELD

PARAGRAPH 33: Anthem Blue Cross & Blue Shield of Colorado (“Anthem”) is a payor doing business in the Denver metropolitan area. Beginning in or about June 2000 and extending through 2001, Respondent Welter met with Anthem representatives to negotiate better contract terms, including higher

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fees, for PIWC participants. At the time of these negotiations, Anthem had individual contracts with all PIWC participants.

PARAGRAPH 34: In or about early September 2000, Anthem made a contract offer to the PIWC participants, which they all rejected. Anthem made a second contract offer in late September 2000, which contained higher fees for gynecological services than the prior offer. On October 12, 2000, Respondent Welter sent a letter to Anthem, in which he stated that "we represent approximately 85 OB/GYNs in the Denver area," that 70 of those physicians rejected Anthem's most recent offer, that Anthem "should consider the attached rejections as [termination] notice from these physicians," and that the terminating physicians would "begin to immediately notify their patients that they are not on Anthem's panel."

PARAGRAPH 35: In response to Respondent Welter's letter, which expressly or impliedly threatened a group boycott, Anthem submitted a revised contract offer to the PIWC participants. Anthem's new offer contained the highest fees that it was currently paying to any OB/GYNs in the Denver area, including to some of the PIWC participants, who had renewed their individual contracts at these same fee levels. The fees contained in Anthem's latest offer, however, were still lower than what the Respondent Practice Groups and other PIWC participants, through Respondent Welter, had demanded. Accordingly, Respondent Welter advised the PIWC participants to reject the Anthem offer, and more than 30 of them did so. Subsequently, many PIWC participants, including some of the Respondent Practice Groups, wrote letters to Anthem, stating that Respondent Welter was their negotiator and that they were terminating their individual contracts. Respondent Welter personally delivered these letters to Anthem.

PARAGRAPH 36: The simultaneous loss of many OB/GYNs from its health care plan physician network would have adversely affected Anthem's ability to compete in the Denver metropolitan area. Accordingly, to avoid losing numerous PIWC participants

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from its network, Anthem increased its fee offer to the level that Respondents and the PIWC participants demanded, and all participants signed contracts with Anthem.

NEGOTIATIONS WITH OTHER PAYORS

PARAGRAPH 37: Since PIWC's inception in 1999, Respondents RTWA and Welter have informed other payors that they represented between 85 and 88 OB/GYNs in the Denver metropolitan area. With the advice and consent of representatives of the Respondent Practice Groups, Respondent Welter has informed these payors of the fees that the PIWC participants collectively demanded as a condition for contracting with these payors. The Respondent Practice Groups authorized Respondent Welter to tell these payors that PIWC participants would refuse any contract offering fees that were below a specified percentage of Medicare RBRVS and a specified global fee for obstetrical care. Respondent Welter has negotiated contracts with at least two other payors for fees matching or exceeding the levels that Respondents collectively demanded. At all times applicable herein, the Respondent Practice Groups have assisted Respondents RTWA and Welter in developing and coordinating strategy for negotiating terms and rates with particular payors, prior to and during the course of contract negotiations.

LACK OF EFFICIENCIES

PARAGRAPH 38: In collectively negotiating and entering the contracts identified above, the Respondent Practice Groups and other PIWC participants refused to consider any form of financial risk-sharing and have not integrated their practices to create sufficient potential efficiencies. Respondents' joint negotiation of fees and other competitively significant terms has not been, and is not, reasonably related to any efficiency-enhancing integration.

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ANTICOMPETITIVE EFFECTS

PARAGRAPH 39: Respondents' actions described above in Paragraphs 14 through 38 have had, or have the tendency to have, the effect of restraining trade unreasonably and hindering competition in the provision of physician services in the Denver metropolitan area in the following ways, among others:

- A. fees and other forms of competition among the Respondent Practice Groups and other PIWC participants were unreasonably restrained;
- B. fees for obstetrical and gynecological services were increased; and
- C. competition in the purchase of physician services was restrained to the detriment of health plans, employers, and individual consumers.

PARAGRAPH 40: The combination, conspiracy, acts and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Such combination, conspiracy, acts and practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this eighth day of October, 2002, issues its Complaint against Respondents R. T. Welter and Associates, Inc.; R. Todd Welter; Cohen and Womack, M.D., P.C.; Consultants in Obstetrics and Gynecology, P.C.; Mid Town Obstetrics & Gynecology, P.C.; Mile High OB/GYN Associates, P.C.; The OB-GYN Associates Professional Corporation; Rocky Mountain OB-GYN, P.C.; The Women's Health Group, P.C.; and Westside Women's Care, L.L.P.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of respondents named in the caption hereof (“Respondents”), and Respondents having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued, would charge Respondents with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received from an interested person pursuant to Section 2.34 of its Rules, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Order:

1. Respondent R.T. Welter and Associates, Inc. is a for-profit corporation, organized, existing, and doing business under

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and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 655 Broadway, Suite 500, Denver, CO 80203.

2. Respondent R. Todd Welter, an individual, is president of R.T. Welter and Associates, Inc. His principal office or place of business is 655 Broadway, Suite 500, Denver, CO 80203.
3. Respondent Cohen and Womack, M.D., P.C. is a professional corporation, organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 255 Union Boulevard, Suite 200, Lakewood, CO 80228.
4. Respondent Consultants in Obstetrics and Gynecology, P.C. is a professional corporation, organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 4500 East 9th Ave, Suite 300, Denver, CO 80220.
5. Respondent Mid Town Obstetrics & Gynecology, P.C. is a professional corporation, organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 2005 Franklin Street, Midtown II, Suite 440, Denver, CO 80205.
6. Respondent Mile High OB/GYN Associates, P.C. is a professional corporation, organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 455 South Hudson St., Level 2, Denver, CO 80246.
7. Respondent The OB-GYN Associates, Professional Corporation is a professional corporation, organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of

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business located at 3773 Cherry Creek North Drive, Suite 100, Denver, CO 80209.

8. Respondent Rocky Mountain OB-GYN, P.C. is a professional corporation, organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 4500 East 9th Ave., Suite 200-S, Denver, CO 80220.
9. Respondent The Women's Health Group, P.C. is a professional corporation, organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 9195 Grant Street, Suite 300, Thornton, CO 80229.
10. Respondent Westside Women's Care, L.L.P. is a partnership of professional corporations. The partnership is organized, existing, and doing business under and by virtue of the laws of the State of Colorado, with its office and principal place of business located at 7950 Kipling Street, Suite 201, Arvada, CO 80005.
11. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. "Respondent RTWA" means Respondent R.T. Welter and Associates, Inc., its officers, directors, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by R.T. Welter and Associates, Inc.

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- B. “Respondent Welter” means R. Todd Welter.
- C. “Respondent Practice Groups” means the following corporations and partnership: Cohen and Womack, M.D., P.C.; Consultants in Obstetrics and Gynecology, P.C.; Mid Town Obstetrics & Gynecology, P.C.; Mile High OB/GYN Associates, P.C.; The OB-GYN Associates, Professional Corporation; Rocky Mountain OB-GYN, P.C.; Westside Women’s Care, L.L.P.; and The Women’s Health Group, P.C. “Respondent Practice Groups” also means the officers, directors, partners, employees, agents, representatives, successors, and assigns of each such corporation and partnership; and the subsidiaries, divisions, groups, and affiliates controlled by each such corporation and partnership.
- D. “Respondents” means Respondent RTWA, Respondent Welter, and the Respondent Practice Groups.
- E. “Medical group practice” means a bona fide, integrated firm in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.
- F. “Participate” in an entity means (1) to be a partner, shareholder, owner, member or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services, to a payor through such entity. (This definition also applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”)
- G. “Payor” means any person that pays, or arranges for payment, for all or any part of any physician services for itself or for any other person.

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- H. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- I. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- J. “PIWC Physician or Practice Group” means any physician or medical group practice identified by Respondent Welter as a participant in “Professionals in Women’s Care.”
- K. “Preexisting Contract” means a contract with any payor for the provision of physician services, where
 - 1. at least one Respondent Practice Group, or physician participating in any Respondent Practice Group, is a party to the contract, and
 - 2. the contract was in effect prior to the receipt, by all payors that are parties to such contract, of notice sent pursuant to Paragraph IV.B. of this Order of each such payor’s right to terminate such contract.
- L. “Principal Address” means either (1) primary business address, if there is a business address, or (2) primary residential address, if there is no business address.
- M. “Qualified clinically-integrated joint arrangement” means an arrangement to provide physician services in which:
 - 1. all physicians who participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the physicians who participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and

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2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.
- N. “Qualified risk-sharing joint arrangement” means an arrangement to provide physician services in which:
1. all physicians who participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the physicians who participate to jointly control costs and improve quality by managing the provision of physician services, such as risk-sharing involving:
 - a. the provision of physician services to payors at a capitated rate,
 - b. the provision of physician services for a predetermined percentage of premium or revenue from payors,
 - c. the use of significant financial incentives (*e.g.*, substantial withhold) for physicians who participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by physicians in different specialties offering a complementary mix of services, for a fixed, predetermined payment, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient’s condition, the choice, complexity, or length of treatment, or other factors; and

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2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.

II.

IT IS FURTHER ORDERED that Respondents, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any physicians:
 1. To negotiate on behalf of any physician with any payor,
 2. To deal, refuse to deal, or threaten to refuse to deal with any payor,
 3. Regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, including, but not limited to, price terms, or
 4. Not to deal individually with any payor, or to deal with any payor only through an arrangement involving Respondent(s);
- B. Exchanging or facilitating in any manner the exchange or transfer of information among physicians concerning any physician's willingness to deal with a payor, or the terms or conditions, including price terms, on which the physician is willing to deal;

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- C. Attempting to engage in any action prohibited by Paragraph II.A. or II.B., above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A. through II.C. above.

PROVIDED, HOWEVER, that nothing in this Paragraph II shall prohibit any agreement involving or conduct by:

- (i) Respondent RTWA or Respondent Welter that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement, or that solely involves physicians in the same medical group practice; or
- (ii) any Respondent Practice Group that is reasonably necessary to form, participate in, or take any action in furtherance of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement through which it provides physician services, or that solely involves physicians in the same medical group practice.

III.

IT IS FURTHER ORDERED that Respondent RTWA and Respondent Welter, for a period of three (3) years from the date that this order is issued, directly or indirectly, or through any corporate or other device, in connection with the provision of physician services in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Negotiating with any payor on behalf of any PIWC Physician or Practice Group, notwithstanding whether such conduct also violates Paragraph II. of this Order; and

Decision and Order

- B. Advising any PIWC Physician or Practice Group to accept or reject any term, condition, or requirement of dealing with any payor, notwithstanding whether such conduct also violates Paragraph II. of this Order.

IV.

IT IS FURTHER ORDERED that Respondent RTWA shall:

- A. Within thirty (30) days after the date on which this Order is issued, send by first-class mail a copy of this Order and the Complaint to:
1. each PIWC Physician or Practice Group; and
 2. each employee of Respondent RTWA.
- B. Within thirty (30) days after the date on which this Order is issued, send copies of this Order, the Complaint, and the notice specified in Appendix B to this Order, by first class mail return receipt requested, to the chief executive officer of each payor that
1. is listed in Appendix A, or
 2. engaged in negotiations with any Respondent Practice Group for a contract for the provision of physician services, where the Respondent Practice Group was represented by Respondent RTWA or Respondent Welter in such negotiations;
- C. For a period of three (3) years after the date this Order is issued, distribute by first-class mail a copy of this Order and the Complaint to:
1. each physician, medical group practice, and other group of physicians that Respondent RTWA represents for the purpose of contracting, or seeking to contract, with payors

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for the provision of physician services, or that Respondent RTWA advises with regard to its dealings with payors in connection with the provision of physician services, within (30) days of the time that Respondent RTWA begins providing such representation or advice, unless such physician or physician group previously received a copy of this Order and the Complaint from Respondent RTWA or Respondent Welter;

2. each payor with which Respondent RTWA deals, or has dealt, for the purpose of contracting, or seeking to contract, while representing any physician or any group of physicians, or while advising any physician or group of physicians with regard to their dealings regarding contracting with such payor for the provision of physician services, within thirty (30) days of such dealing, unless such payor previously received a copy of this Order and the Complaint from Respondent RTWA or Respondent Welter
 3. each employee of Respondent RTWA within (30) days of the time that their employment with Respondent RTWA commences;
- D. Notify the Commission at least thirty (30) days prior to any proposed change in Respondent RTWA, such as dissolution, assignment, sale resulting in the emergence of a successor company or corporation, the creation or dissolution of subsidiaries, or any other change in Respondent RTWA that may affect compliance obligations arising out of this Order; and
- E. File verified written reports within sixty (60) days after the date this Order is issued, annually thereafter for three (3) years on the anniversary of the date this Order is issued, and at such other times as the Commission may by written notice require, setting forth, in detail, the manner and form in which

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Respondent RTWA has complied and is complying with this Order.

V.

IT IS FURTHER ORDERED that Respondent Welter shall:

- A. For a period of three (3) years after the date this Order is issued, distribute by first-class mail a copy of this Order and the Complaint to:
 1. each physician, medical group practice, and other group of physicians that Respondent Welter represents for the purpose of contracting, or seeking to contract, with payors for the provision of physician services, or that Respondent Welter advises with regard to its dealings with payors in connection with the provision of physician services, within (30) days of the time that Respondent Welter begins providing such representation or advice, unless such physician or physician group previously received a copy of this Order and the Complaint from Respondent RTWA or Respondent Welter;
 2. each payor with which Respondent Welter deals, or has dealt, for the purpose of contracting, or seeking to contract, while representing any physician or any group of physicians, or while advising any physician or group of physicians with regard to their dealings regarding contracting with such payor for the provision of physician services, within thirty (30) days of such dealing, unless such payor previously received a copy of this Order and the Complaint from Respondent RTWA or Respondent Welter; and
- B. File verified written reports within sixty (60) days after the date this Order is issued, annually thereafter for three (3) years on the anniversary of the date this Order is issued, and at such other times as the Commission may by written notice

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require, setting forth, in detail, the manner and form in which Respondent Welter has complied and is complying with this Order.

VI.

IT IS FURTHER ORDERED that each Respondent Practice Group shall:

- A. Terminate, without penalty or charge, in accordance with applicable state law, any Preexisting Contract negotiated on behalf of the Respondent Practice Group by Respondent RTWA or Respondent Welter with any payor, upon receipt by the Respondent Practice Group of a written request to terminate such contract from any payor that is a party to the contract or that pays for physician services provided through the contract;
- B. File verified written reports within sixty (60) days after the date this Order is issued, annually thereafter for three (3) years on the anniversary of the date this Order is issued, and at such other times as the Commission may by written notice require, setting forth, in detail, the manner and form in which the Respondent Practice Group has complied and is complying with this Order; and
- C. Notify the Commission at least thirty (30) days prior to any proposed change in any Respondent Practice Group, such as dissolution, assignment, or sale resulting in the emergence of a successor company or corporation, the creation or dissolution of subsidiaries, or any other change in the Respondent Practice Group that may affect compliance obligations arising out of this Order.

Decision and Order

VII.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission of any change in its Principal Address within twenty (20) days of such change in address.

VIII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in their possession, or under their control, relating to any matter contained in this Order;
- B. Upon five (5) days' notice to Respondent RTWA, and without restraint or interference from it, to interview officers, directors, or employees of Respondent RTWA in the presence of counsel for such officers, directors, or employees;
- C. Upon five (5) days' notice to Respondent Welter, to interview Respondent Welter or, without restraint or interference from Respondent Welter, to interview employees of Respondent Welter in the presence of counsel for such employees; and
- D. Upon five (5) days' notice to any Respondent Practice Group and without restraint or interference from such Respondent, to interview such Respondent or the officers, directors, partners, or employees of such Respondent in the presence of counsel for such officers, directors, partners, or employees.

Decision and Order

IX.

IT IS FURTHER ORDERED that this Order shall terminate on October 8, 2022.

Appendix A

Aetna US Healthcare of Colorado
Anthem Blue Cross Blue Shield of Colorado
CIGNA HealthCare of Colorado
Community Health Plan of the Rockies
Humana Health Plan
Mountain Medical Affiliates, Inc.
OneHealth Plan
PacifiCare of Colorado
Patient Choice Healthcare of Colorado
United Health Care of Colorado

Decision and Order

Appendix B

[letterhead of Respondent RTWA]

[name of payor's CEO]
[address]

Dear _____:

Enclosed is a copy of a Complaint and a Consent Order issued by the Federal Trade Commission against R.T. Welter and Associates, Inc., and others. I call to your attention Paragraph VI.A. of the Order, which gives you the right to terminate, without penalty or charge, in accordance with applicable state law, any preexisting contract negotiated on behalf of any Respondent Practice Group by R.T. Welter and Associates, Inc. or R. Todd Welter for the provision of physician services. If you choose to exercise your right to terminate any such contract, you will need to send the notice of termination, by first class mail return receipt requested, to the person(s) or entit(ies) named in the contract.

Sincerely,

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with R.T. Welter and Associates, Inc. (“RTWA”), R. Todd Welter, and the following medical group practices (hereinafter “Respondent Practice Groups”): Cohen and Womack, M.D., P.C.; Consultants in Obstetrics and Gynecology, P.C.; Mid Town Obstetrics & Gynecology, P.C.; Mile High OB/GYN Associates, P.C.; The OB-GYN Associates Professional Corporation; Rocky Mountain OB-GYN, P.C.; Westside Women’s Care, L.L.P.; and The Women’s Health Group, P.C. Mr. Welter, RTWA and the Respondent Practice groups are collectively referred to as “Respondents.” The agreement settles charges that Respondents violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by facilitating and implementing agreements among the obstetricians and gynecologists represented by Mr. Welter to fix prices and other terms of dealing with health insurance firms and other third-party payors (hereinafter, “payors”), and to refuse to deal with payors except on collectively determined terms. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by any Respondent that said Respondent violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

Analysis

The Complaint

The allegations in the Commission's proposed complaint are summarized below.

Mr. Welter is a non-physician consultant who, through his company RTWA, organized approximately 88 physicians specializing in obstetrics and gynecology ("OB/GYNs") into a concerted group for the purpose of negotiating as a bloc with payors over contract terms. Respondents called their group "Professionals in Women's Care" ("PIWC"). About half of PIWC's physicians practice medicine through one of the eight Respondent Practice Groups, all but one of which are corporations (the other is a partnership), consisting of OB/GYNs practicing medicine. Except to the extent that competition has been restrained in the manner set forth in the proposed Complaint, the Respondent Practice Groups and other physicians who participated in PIWC compete with each other in the provision of OB/GYN services in the Denver, Colorado metropolitan area.

PIWC came together in 1999 in response to a proposed contract that PacifiCare Health Systems of Colorado ("PacifiCare"), a payor doing business in the Denver area, offered to OB/GYNs in the region. The Respondent Practice Groups opposed the fees and other provisions contained in PacifiCare's offer, and convened a meeting among all of them to discuss strategies for resisting PacifiCare's terms and forcing it to offer a contract that was more lucrative for the physicians. The Respondent Practice Groups retained Mr. Welter to negotiate a different contract on their collective behalf with PacifiCare.

PIWC became a vehicle for the OB/GYNs to use their collective bargaining power to negotiate for higher fees and other, more advantageous terms in contracts with payors than they could have obtained by negotiating unilaterally. The Respondent Practice Groups formed a "Steering Committee" among themselves to determine contract strategy and give instruction and guidance to Mr. Welter in his dealings with payors over contract

Analysis

terms. Mr. Welter and the Respondent Practice Groups also recruited additional OB/GYNs into PIWC - bringing its total membership to more than 80 physicians.

The PIWC physicians authorized Mr. Welter to advise PacifiCare that they rejected its latest contract offer. Mr. Welter told PacifiCare, among other things, that the physicians had joined together to secure higher fees, that they refused to sign a contract without those fees, and that the physicians would negotiate only through him. To be competitively marketable to employers and other purchasers in the Denver metropolitan area, a payor must include in its network of participating physicians a large number of OB/GYNs. Faced with the prospect of having no contracts with the OB/GYNs involved in PIWC, PacifiCare agreed to the terms that Mr. Welter and the PIWC physicians demanded.

Mr. Welter and Respondent Practice Groups, through PIWC, exploited their collective bargaining strength in contract negotiations with several other payors as well. In some cases, at the urging of Mr. Welter, large numbers of PIWC physicians sent contract termination notices to payors that refused to negotiate with Mr. Welter or that resisted the fee increases he demanded on their behalf. Faced with the threat of a boycott and the inability to include this large group of OB/GYNs in their networks of participating physicians, these payors ultimately acceded to Mr. Welter's demands for the PIWC physicians. In these ways, the PIWC physicians received contract terms that were more economically advantageous to them than they could have obtained by negotiating individually rather than collectively. They also received fees that were higher than those that payors were paying to other OB/GYNs in the Denver metropolitan area.

Sometimes a network of competing physicians uses an agent to convey to payors information obtained individually from the physicians about fees or other significant contract terms that they are willing to accept. The agent may also convey to the physicians all payor contract offers, which the physicians then unilaterally decide whether to accept or reject. Such a "messenger

Analysis

model” arrangement, which is described in the 1996 Statements of Antitrust Enforcement Policy in Health Care jointly issued by the Federal Trade Commission and U.S. Department of Justice (*see* <http://www.ftc.gov/reports/hlth3s.htm>.), can facilitate and minimize the costs involved in contracting between physicians and payors, without fostering an agreement among competing physicians on fees or fee-related terms. Such a messenger may not, however, consistent with a competitive model, negotiate fees and other competitively significant terms on behalf of the participating physicians, or facilitate the physicians’ coordinated responses to contract offers by, for example, electing not to convey a payor’s offer to the physicians based on the messenger’s opinion on the appropriateness, or lack thereof, of the offer.

Mr. Welter purported to operate as a messenger, but, in practice, he did not do so. Rather, Mr. Welter used the information he gathered from the PIWC participants, including Respondent Practice Groups, to negotiate fees and other competitively significant terms on the PIWC participants’ collective behalf. Mr. Welter, with the Steering Committee’s concurrence, would not convey a contract offer to the group of PIWC physicians if he believed that the contract’s terms were deficient.

Mr. Welter and the Respondent Practice Groups solicited *de facto* exclusivity to increase PIWC’s collective bargaining power with payors. They persuaded PIWC physicians to terminate affiliations with professional organizations such as independent practice associations and practice management groups to force payors that wanted contracts with the PIWC physicians to deal with Mr. Welter.

Respondents’ joint negotiation of fees and other competitively significant terms has not been reasonably related to any efficiency-enhancing integration. PIWC participants did not accept any form of financial risk-sharing, through arrangements such as capitation or fee withhold, and they have not clinically integrated their practices to create sufficiently substantial potential efficiencies.

Analysis

Respondents' actions have restrained price and other forms of competition among the PIWC participants, caused fees for obstetrical and gynecological services to rise, and harmed consumers, including payors, employers, and individual patients.

The Proposed Consent Order

The proposed order is designed to prevent recurrence of these illegal concerted actions, while allowing Respondents to engage in legitimate conduct that does not impair competition. The proposed order's core prohibitions are contained in Paragraphs II. and III.

Paragraph II. is intended to prevent the Respondents from participating in, or creating, future unlawful physician agreements.

Paragraph II.A. prohibits RTWA, Mr. Welter, and Respondent Practice Groups from entering into or facilitating any agreement between or among any physicians: (1) to negotiate with payors on any physician's behalf; (2) to deal, not to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or to deal with any payor only through an arrangement involving the Respondents.

Paragraph II.B. prohibits these Respondents from facilitating exchanges of information between physicians concerning whether, or on what terms, to contract with a payor. Paragraph II.C. prohibits them from attempting to engage in any action prohibited by Paragraph II.A. or II.B. Paragraph II.D. prohibits them from inducing anyone to engage in any action prohibited by Paragraphs II.A. through II.C.

Paragraph II. also contains two provisos intended to clarify certain types of agreements that Paragraph II. does not prohibit. The first proviso applies to RTWA and Mr. Welter, and the second to the Respondent Practice Groups. Each provides that nothing in Paragraph II. prohibits the applicable Respondent from engaging in conduct that is reasonably necessary to form, participate in, or act in furtherance of, a "qualified risk-sharing

Analysis

joint arrangement" or a "qualified clinically-integrated joint arrangement."

As defined in the proposed order, a "qualified risk-sharing joint arrangement" must satisfy two conditions. First, all physician participants must share substantial financial risk through the arrangement and thereby create incentives for the physician participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. The definition of financial risk-sharing tracks the discussion of that term contained in the Health Care Statements.

As defined in the proposed order, a "qualified clinically-integrated joint arrangement" also must satisfy two conditions. First, all physician participants must participate in active and ongoing programs to evaluate and modify their clinical practice patterns, creating a high degree of interdependence and cooperation among physicians, in order to control costs and ensure the quality of services provided. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. This definition also reflects the analysis contained in the Health Care Statements.

Paragraph II.'s provisos also provide that Paragraph II. does not prohibit the Respondents from facilitating an agreement solely between physicians who are part of the same medical group practice. The proposed order defines such a practice as a bona fide, integrated firm in which physicians practice medicine together as partners, shareholders, owners, members, or employees, or in which only one physician practices medicine.

Paragraph III. prohibits RTWA and Mr. Welter, for a period of three years, from negotiating with any payor on behalf of any PIWC physician, and from advising any PIWC physician to accept

Analysis

or reject any term, condition, or requirement of dealing with any payor.

Mr. Welter is not prohibited from performing legitimate “messenger” services, including with respect to PIWC physicians. As noted above, a properly constituted messenger can efficiently facilitate the establishment of physician-payor contracts and avoid fostering unlawful agreements among the participating physicians. As set forth in the proposed complaint, however, while Mr. Welter purported to operate as a legitimate messenger, in practice he fostered anticompetitive physician agreements by negotiating directly with payors for higher fees on behalf of all PIWC participants, and by advising the PIWC participants collectively to reject various payor offers and to engage in concerted refusals to deal. For this reason, Paragraph III. is a necessary and appropriate supplement to Paragraph II.’s provisions. Under the proposed order, Mr. Welter may serve as a messenger for PIWC physicians, but, pursuant to Paragraph III., may not negotiate for or advise any PIWC physician with respect to payor contracts.

Paragraphs IV.A. and IV.B. require RTWA to distribute the complaint and order to all physicians who participated in PIWC and to the payors that negotiated contracts with RTWA or Mr. Welter on behalf of any Respondent Practice Group. Paragraph VI.A. requires Respondent Practice Groups to terminate, without penalty, at any payor’s request, current contracts, with respect to providing physician services, negotiated by Mr. Welter with payors. This provision is intended to eliminate the effects of Respondents’ anticompetitive concerted actions.

The remaining provisions of Paragraphs IV. through VIII. of the proposed order impose obligations on Respondents with respect to distributing the proposed complaint and order to various persons and reporting information to the Commission. For example, Paragraph IV.C. and V.A. require RTWA and Mr. Welter, respectively, to distribute copies of the complaint and order to the physicians on whose behalf they negotiate payor contracts, and to those payors. Paragraphs IV.E., V.B., and VI.B.

Analysis

require the Respondents to file periodic reports with the Commission detailing how the Respondents have complied with the order. Paragraph VIII. authorizes Commission staff to obtain access to Respondents' records and officers, directors, partners, and employees for the purpose of determining or securing compliance with the order.

The proposed order will expire in 20 years.

Complaint

IN THE MATTER OF

**TIM R. WOFFORD, INDIVIDUALLY AND AS AN
OFFICER OF OKIE CORPORATION**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4061; File No. 0123191
Complaint, October 8, 2002--Decision, October 8, 2002*

This consent order addresses cash rebate offers made by OKie Corporation, and by Respondent Tim R. Wofford, an officer of the corporation – who advertised, labeled, offered for sale, sold, and distributed computer peripheral products to the public, including modems, CD-Rom drive kits, and recordable compact disks – to consumers who purchased their computer peripheral products. The order, among other things, prohibits the respondent from failing to disclose all terms, conditions, or other limitations of a rebate offer on the rebate form. The order also requires the respondent to disclose in any rebate advertising that the rebate offer requires consumers to disclose a fax number and/or email address on their rebate form if such is the case. In addition, the order prohibits the respondent from misrepresenting the time in which any cash rebate, or rebate in the form of credit towards future purchases, will be mailed to consumers; from failing to provide such rebates within the time specified, or if no time is specified, within thirty days; and from violating any provision of the Mail or Telephone Order Rule in connection with rebates in the form of merchandise. The order also prohibits the respondent from failing to provide rebates in the form of services or any other consideration (other than cash, credit towards future purchases, or merchandise) within the time he specifies for delivery, or if no time is specified, within thirty days, unless he offers consumers the option of consenting to a delay or canceling the rebate request and promptly receiving reasonable cash compensation instead of the rebate originally offered.

Participants

For the Commission: *Kerry O'Brien, Linda K. Badger, Erika Wodinsky, and Jeffrey Klurfeld.*

For the Respondent: *John Cullen.*

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that Tim R. Wofford, individually and as an officer of OKie Corporation (“respondent”), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Tim R. Wofford is the president and owner of OKie Corporation (“OKie”). Individually or in concert with others, respondent formulated, directed, or controlled the policies, acts, or practices of OKie, including the acts or practices alleged in this complaint. He resides at 68 Donna Road, Needham, MA 02494-1516.
2. OKie is a Delaware corporation with its principal office or place of business at 283A Centre Street, Holbrook, MA 02343. OKie did business as Prime Peripherals. On November 1, 2001, OKie filed a voluntary petition for relief under Chapter 7 of the Bankruptcy Code, 11 U.S.C. §§ 101 *et seq.*, in the United States Bankruptcy Court for the District of Massachusetts, Case No. 01-18390-JNF.
3. Respondent has advertised, labeled, offered for sale, sold, and distributed computer peripheral products to the public, including Prime Peripheral brand modems, CD-Rom drive kits, and recordable compact disks.
4. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

FALSE SHIPMENT REPRESENTATIONS

5. Respondent has disseminated or has caused to be disseminated advertisements and rebate forms for computer peripheral products, including but not necessarily limited to the attached Exhibits A

Complaint

through E. These advertisements and rebate forms contain the following statements:

A. "MOST PEOPLE JUST SEE OUR
GREAT
PRICES
ENTREPRENEURS SEE THE
LOW PRICES AND OPPORTUNITIES
TO SAVE THEIR DATA...
AND THEIR MONEY!"

FREE!
After Rebate

\$59.99 - \$14.99 - \$45 = \$0
Reg. Price Instant Rebate Mail-in Rebate Final Cost

3 Days Only!
Sunday - Tuesday

PRIME PERIPHERALS
200-Pack CD-R Spindle

.....
Limit 1 Rebate"

(Exhibit A, OfficeMax print advertisement placed as free standing insert in newspapers).

B. "FREE
AFTER
REBATE
Some people only see free after rebate.
Entrepreneurs see an opportunity to make money on their savings.

Complaint

PRIME PERIPHERALS
56K V.90 Modem

....

\$29.⁹⁹ - \$29.⁹⁹ = \$0
Reg. Price Mail-in Rebate Final Cost

PRIME PERIPHERALS
50x CD-ROM Drive Kit

....

\$45 - \$45 = \$0
Reg. \$59.99 Mail-in Rebate Final Cost”

(Exhibit B, OfficeMax print advertisement placed as free standing insert in newspapers).

C. “VALID ONLY 2/18/01-2/20/01

....

Save \$45 at OfficeMax on Prime Peripherals™
200-pack CD-R 80 Minute 16x certified blank media (UPC
6-42184-75200-1)

Complete this coupon and send with a copy of **sales receipt**
& upc label from package by mail to:

Prime Peripherals Offer #45
PO Box 226
Randolph, MA 02368

Mail my check to:

Name _____

Address _____

City _____ State _____ Zip code _____ Fax _____

Telephone (____) _____ Email address _____

I have complied with the requirements of this offer

45 Required Signature _____ Date _____

Complaint

TERMS AND CONDITIONS—Offer good on purchases at OfficeMax from **2-18-01 through 2-20-01**. You must submit this original rebate form with a copy of your sales receipt and the original upc label from package. Photocopies of upc will not be accepted. Your request must be postmarked by MARCH 3, 2001.... Limit ONE rebate per person, household, family or address. This offer cannot be combined with any other offer. Requests from PO Boxes not accepted, and requests with invalid or undeliverable mailing address will be rejected. Offer limited to end-users only. Requests for multiple rebates from groups, clubs, or organizations will not be honored. Your rebate rights cannot be assigned or transferred, and this offer is void where taxed, restricted, or prohibited by law.... Rebate checks will be mailed in approx. 8-10 weeks. If you have not received your check within 12 weeks visit **www.forrebates.com** or call **1-877-783-3546.**"

(Exhibit C, rebate form for Prime Peripherals 200-pack CD-R).

D. "Save \$45
at OfficeMax
on *Prime Peripherals*TM
50X CD-Drive..."

FREE up to \$29 ⁹⁹
at OfficeMax
on *Prime Peripherals*TM
5900 56K modem...
After mail-in Rebate

*Valid only in Continental U.S. Stores 3/11/01-3/17/01;
Alaska and Hawaii 3/18/01-3/24/01; Puerto Rico and St.
Thomas 3/25/01-3/31/01.

Complete this coupon and send with a copy of **sales receipt**
& upc label from package by mail to:

Complaint

RCG Prime Peripherals Offer #50 or 51 PO Box 226
Randolph, MA 02368

Mail my check to:

Name _____

Address _____

City _____ State _____ Zip code _____ Fax _____

Telephone (____) _____ Email address _____

I have complied with the requirements of this offer

Required Signature _____ Date _____

Please check box for appropriate rebate:

Offer #50 Offer #51

TERMS AND CONDITIONS—Offer good on purchases at OfficeMax US, Puerto Rico and St. Thomas stores only. You must submit this original rebate form with a copy of your sales receipt and the original upc label from package. Photocopies of upc will not be accepted. Your request must be postmarked by APRIL 21, 2001.... Limit ONE rebate per person, household, family or address. This offer cannot be combined with any other offer. Requests from PO Boxes not accepted, and requests with invalid or undeliverable mailing address will be rejected. Offer limited to end-users only. Requests for multiple rebates from groups, clubs, or organizations will not be honored. Your rebate rights cannot be assigned or transferred, and this offer is void where taxed, restricted, or prohibited by law.... Rebate checks will be mailed in approx. 8-10 weeks. If you have not received your check within 12 weeks visit **www.forrebates.com** or call **877-783-3546.**"

(Exhibit D, rebate form for Prime Peripherals 50X CD-Drive and 5900 56K modem).

**E. “Save \$20 on Prime Peripherals 50X CD-Rom
at CompUSA (SKU #273808)**

Complaint

Complete this coupon and send with **copy of sales receipt** & upc label from package by mail to: Prime Peripherals Offer #32

PO Box 821
New Rochelle, NY 10802-0821

Mail my check to:

Name _____

Address _____

City _____ State _____ Zip code _____ Fax _____

Telephone (____) _____ Email address _____

I have complied with the requirements of this offer

32 **Required** Signature _____ Date _____

TERMS AND CONDITIONS—Offer good on purchases at CompUSA from 12-16-00 through 2-23-00. You must submit this original rebate form with a copy of your sales receipt and the original upc label from package.

Photocopies of upc will not be accepted. Your request must be postmarked by 1-10-01-01.... Limit ONE rebate per person, receipt, household, family or address. This offer cannot be combined with any other offer. Requests from PO Boxes not accepted, and requests with invalid or undeliverable mailing address will be rejected. Offer limited to end-users only. Requests for multiple rebates from groups, clubs, or organizations will not be honored. Your rebate rights cannot be assigned or transferred, and this offer is void where taxed, restricted, or prohibited by law.... Rebate checks will be mailed in approx. 6-8 weeks. If you have not received your check within 8 weeks visit www.tcarebates.com or call 800-390-2344.”

(Exhibit E, rebate form for Prime Peripherals 50X CD-Rom).

6. Through the means described in Paragraph 5, respondent has represented, expressly or by implication, that:

Complaint

- A. Respondent will mail cash rebates to purchasers of Prime Peripherals computer peripheral products within either six to eight or eight to ten weeks of respondent's receipt of their requests.
- B. Respondent will mail cash rebates to purchasers of Prime Peripherals computer peripheral products within a reasonable period of time.

7. In truth and in fact:

- A. In numerous instances, respondent did not mail cash rebates to purchasers of Prime Peripherals computer peripheral products within either six to eight or eight to ten weeks of respondent's receipt of their requests. In many instances, consumers never received their cash rebates from respondent or experienced delays ranging from one to six months.
- B. In numerous instances, respondent did not mail cash rebates to purchasers of Prime Peripherals computer peripheral products within a reasonable period of time. In many instances, respondent never sent consumers their cash rebates or sent them months after receiving consumers' rebate requests.

Therefore, the representations set forth in Paragraph 6 were, and are, false or misleading.

**UNILATERAL MODIFICATION OF TERMS OR
CONDITIONS OF REBATE OFFER: UNFAIR BUSINESS
PRACTICE**

8. In the advertising and sale of Prime Peripherals computer peripheral products, respondent has offered, expressly or by implication, that consumers would receive cash rebates if they purchased a Prime Peripherals computer peripheral product and submitted a rebate form with proof of purchase. In making this

Complaint

offer, respondent did not require that consumers submit a telephone number, fax number, or email address to be eligible to receive the offered cash rebates. In numerous instances, consumers accepted respondent's rebate offer by purchasing those products and submitting rebate forms with proof of purchase.

9. After receiving rebate requests in conformance with the offer described in Paragraph 8, respondent unilaterally modified the terms or conditions of the rebate offer by requiring that, in addition to submitting a rebate form with proof of purchase, consumers had to submit a telephone number, a fax number, and an email address to receive a rebate. In breach of the original rebate offer, respondent rejected numerous rebate requests from consumers because they did not submit a telephone number, a fax number, and/or an email address.

10. Respondent's practice described above thus has caused substantial and ongoing injury to purchasers of respondent's products that is not outweighed by countervailing benefits to consumers or competition and is not reasonably avoidable by consumers. This practice was, and is, an unfair act or practice.

FAILURE TO DISCLOSE TERMS OR CONDITIONS OF REBATE OFFER

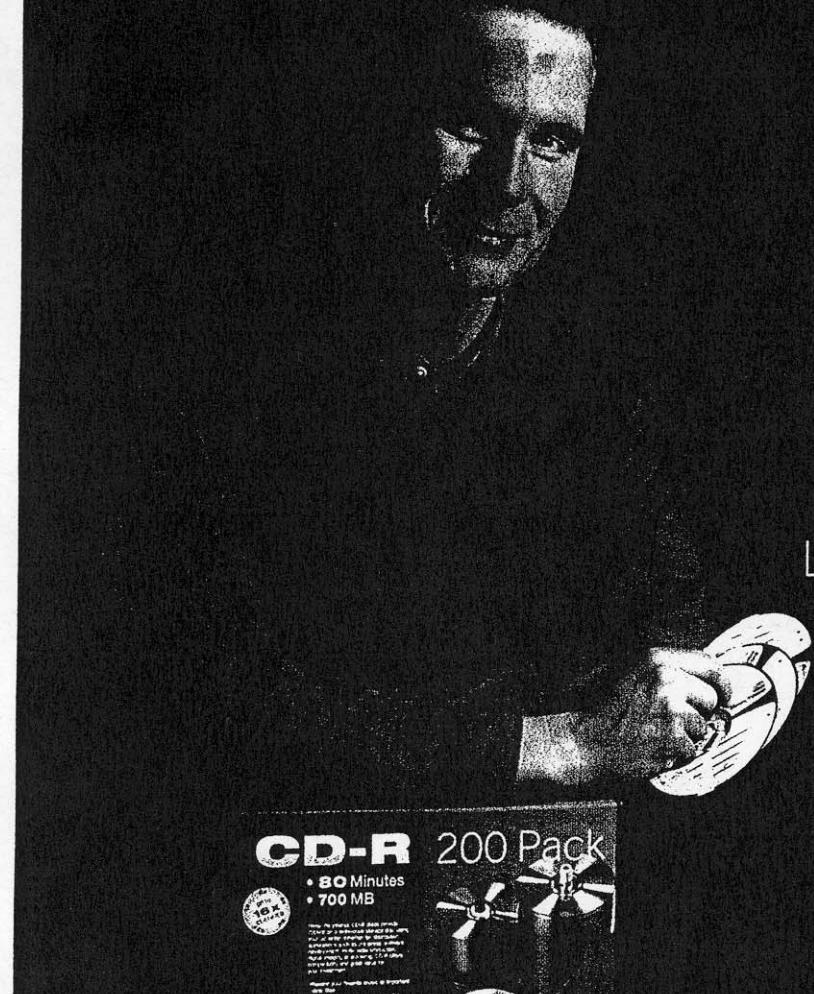
11. In the advertising and sale of Prime Peripherals computer peripheral products, respondent has represented, expressly or by implication, that purchasers of Prime Peripherals computer peripheral products would receive cash rebates if they purchased those products and submitted a rebate form with proper documentation. Respondent has failed to disclose that consumers are required to possess and disclose their telephone number, fax number, and email address on a rebate form to receive those cash rebates. These facts would be material to consumers in their purchase or use of the products. The failure to disclose these facts, in light of the representation made, was, and is, a deceptive practice.

Complaint

12. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices, in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this eighth day of October, 2002, has issued this complaint against respondent.

By the Commission.



MOST PEOPLE JUST SEE OUR

GREAT PRICES

ENTREPRENEURS SEE THE
LOW PRICES AND OPPORTUNITIES
TO SAVE THEIR DATA...
AND THEIR MONEY!

OfficeMax®
officemax.com

YOU SUPPLY THE AMBITION.
WE'LL SUPPLY EVERYTHING ELSE.™



3 Days Only!
Sunday - Tuesday

\$59.99 - \$14.99 - \$45 = \$0
Reg. Price Instant Rebate Mail-In Rebate Final Cost

PRIME PERIPHERALS
200-Pack CD-R Spindle
80-minute audio capacity, 700MB data capacity per disk.
Limit 1 Rebate 2001-5591

GEORGIA-PACIFIC Copier Paper
5-ream carton (2,500 sheets).
8½" x 11." 20 lb., 84 brightness.
Performs well in copiers, fax
machines, inkjet and laser printers.
0611-3859

Buy 1, Get 1
\$15.99
Per Carton
Limit 2 Offers



Exhibit A

Exhibit A

AFTER REBATE

PRIME WOOS



INTERNAL
Modem Card

PRIME PERIPHERALS

56K V.90 Modem

Up to 56K download speed.
Up to 33K upload speed.

\$28.99 - \$29.99 = \$0

PRIME PERIPHERALS

50x CD-ROM Drive Kit

High-speed audio extraction.
Easy installation.

\$45 - \$45 = \$0

Reg. \$99.99

OfficeMax
officemax.com

VALID ONLY 2/18/01-2/20/01

THIS COUPON IS NOT VALID IN ALASKA, HAWAII, PUERTO RICO OR ST. THOMAS.

**Save \$45 at OfficeMax On Prime Peripherals™
200-pack CD-R 80 Minute 16x Certified blank media (UPC 6-42184-75200-1)**
Complete this coupon and send with a copy of sales receipt & upc label from package by mail to:

Prime Peripherals Offer #45
PO Box 226
Randolph, MA 02368

Mail my check to:

Name _____
Address _____
City _____ State _____ Zip code _____ Fax _____
Telephone (____) _____ Email address _____
I have complied with the requirements of this offer
45 Required Signature _____ Date _____

TERMS AND CONDITIONS—Offer good on purchases at OfficeMax from 2-18-01 through 2-20-01. You must submit this original rebate form with a copy of your sales receipt and the original upc label from package. Photocopies of upc will not be accepted. Your request must be postmarked by MARCH 3, 2001. Prime Peripherals is not responsible for lost or misdirected mail. Limit ONE rebate per person, household, family or address. This offer cannot be combined with any other offer. Requests from PO Boxes not accepted, and requests with invalid or undeliverable mailing address will be rejected. Offer limited to end-users only. Requests for multiple rebates from groups, clubs, or organizations will not be honored. Your rebate rights cannot be assigned or transferred, and this offer is void where taxed, restricted, or prohibited by law. Keep copies of all materials submitted; originals become Prime Peripherals property and will not be returned. **WARNING:** Fraudulent submissions could result in federal prosecution under mail fraud status (Title 18, USC Sections 1341 & 1342). Rebate checks will be mailed in approx. 8-10 weeks. If you have not received your check within 12 weeks visit www.forrebates.com or call 1-877-783-3546.

OFFER VALID ON PURCHASES FROM 2-18-01 THROUGH 2-20-01

ONE WEEK ONLY*

Save \$45
at **OfficeMax**
on **Prime Peripherals™**
50X CD-Drive
(UPC 6-42184-00050-8)

FREE up to \$29⁹⁹
at **OfficeMax**
on **Prime Peripherals™**
500 56K modem
#51 (UPC 6-42184-05900-1) After mail-in Rebate

*Valid only in Continental U.S. Stores 3/11/01-3/17/01; Alaska and Hawaii 3/18/01-3/24/01;
Puerto Rico and St. Thomas 3/25/01-3/31/01.

Complete this coupon and send with a copy of **sales receipt** & upc label from package by mail to:
RCG Prime Peripherals Offer #50 or 51 PO Box 226 Randolph, MA 02368

Mail my check to:

Name _____
Address _____

City _____ State _____ Zip code _____ Fax _____

Telephone (_____) _____ Email address _____

I have complied with the requirements of this offer

Required Signature _____ Date _____

Please check box for appropriate rebate:

Offer #50 Offer #51

TERMS AND CONDITIONS—Offer good on purchases made at OfficeMax US, Puerto Rico and St. Thomas stores only. You must submit this original rebate form with a copy of your sales receipt and the original upc label from package. Photocopies of upc will not be accepted. Your request must be postmarked by APRIL 21, 2001. Prime Peripherals is not responsible for lost or misdirected mail. Limit ONE rebate per person, household, family or address. This offer cannot be combined with any other offer. Requests from PO Boxes not accepted, and requests with invalid or undeliverable mailing address will be rejected. Offer limited to end-users only. Requests for multiple rebates from groups, clubs, or organizations will not be honored. Your rebate rights cannot be assigned or transferred, and this offer is void where taxed, restricted, or prohibited by law. Keep copies of all materials submitted: originals become Prime Peripherals property and will not be returned. Rebate checks will be mailed in approx. 8-10 weeks. If you have not received your check within 12 weeks visit www.forrebates.com or call 877-783-3546.

WARNING: Fraudulent submissions could result in federal prosecution under mail fraud status (Title 18, USC Sections 1341 & 1342).
50/51

OFFER #32 -

**Save \$20 on Prime Peripherals 50X CD-Rom
at CompUSA (SKU #273808)**

Complete this coupon and send with copy of sales receipt & upc label from package by mail to:
Prime Peripherals Offer #32

PO Box 821
New Rochelle, NY 10802-0821

Mail my check to:

Name _____

Address _____

City _____ State _____ Zipcode _____ Fax _____

Telephone (____) _____ Email address _____

I have complied with the requirements of this offer

32

Required Signature

Date _____

TERMS AND CONDITIONS - Offer good on purchases at CompUSA from 12-16-00 through 12-23-00. You must submit this original rebate form with a copy of your sales receipt and the original upc label from package. Photocopies of upc will not be accepted. Your request must be postmarked by 1-10-01. Prime Peripherals is not responsible for lost or misdirected mail. Limit ONE rebate per person, receipt, household, family or address. This offer cannot be combined with any other offer. Requests from PO Boxes not accepted, and requests with invalid or undeliverable mailing address will be rejected. Offer limited to end-users only. Requests for multiple rebates from groups, clubs, or organizations will not be honored. Your rebate rights cannot be assigned or transferred, and this offer is void where taxed, restricted or prohibited by law. Keep copies of all materials submitted; originals become Prime Peripherals property and will not be returned. Warning: Fraudulent submission could result in federal prosecution under mail fraud status (Title 18, USC Sections 1341 & 1342). Rebate checks will be mailed in approx. 6-8 weeks. If you have not received your check within 8 weeks visit www.lcarebates.com or call 800-390-2344.

EXHIBIT E

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Western Region proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to § 2.34 of its Rules, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Tim R. Wofford is an officer of OKie Corporation ("OKie"), a Delaware corporation with its principal office or place of business at 283A Centre Street, Holbrook, MA 02343. Individually or in concert with others, he formulates,

Decision and Order

directs, or controls the policies, acts, or practices of OKie. He resides at 68 Donna Road, Needham, MA 02494-1516.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, "respondent" shall mean Tim R. Wofford, individually and as an officer of OKie Corporation, his agents, representatives, and employees.
2. "Rebate" shall mean cash, credit towards future purchases, merchandise, services, or any other consideration offered by respondent to consumers who purchase products or services, and which is provided subsequent to the purchase.
3. "Rebate coupon(s) or form(s)" shall mean any means by which a consumer submits a rebate request.
4. "Mail Order Rule" shall mean the Federal Trade Commission's Trade Regulation Rule Concerning Mail or Telephone Order Merchandise, 16 C.F.R. Part 435, or as the Rule may hereafter be amended.
5. "Clearly and conspicuously" shall mean as follows:
 - A. In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet and online services), the disclosure shall be presented simultaneously in both the audio and visual portions of the advertisement. Provided,

Decision and Order

however, that in any advertisement presented solely through visual or audio means, the disclosure may be made through the same means in which the ad is presented. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The visual disclosure shall be of a size and shade, and shall appear on the screen for a duration, sufficient for an ordinary consumer to read and comprehend it.

- B. In a print advertisement, promotional material (including, but not limited to a rebate coupon or form), or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.
- C. On a product label, the disclosure shall be in a type size and location on the principal display panel sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.

The disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or on any label.

- 6. In the case of advertisements disseminated by means of an interactive electronic medium such as software, the Internet or online services:

- A. “in close proximity” shall mean on the same Web page, online service page, or other electronic page, and proximate to the triggering representation, and shall not include disclosures accessed or displayed through hyperlinks, pop-ups, interstitials or other means;

Decision and Order

B. a disclosure made “through the use of a hyperlink” shall mean a hyperlink that is itself clear and conspicuous, is clearly identified as a hyperlink, is labeled to convey the nature and relevance of the information it leads to, is on the same Web page, online service page, or other electronic page and proximate to the triggering representation, and takes the consumer directly to the disclosure on the click-through electronic page or other display window or panel.

7. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product or service in or affecting commerce, shall not:

- A. make any representation about any rebate offer, unless respondent discloses on the rebate coupon or form, clearly and conspicuously, all terms, conditions, or other limitations of the rebate offer.
- B. require a consumer to disclose a fax number or email address on a rebate coupon or form of any rebate offer, unless respondent discloses, clearly and conspicuously, in any advertisement that mentions the rebate offer that the rebate offer requires consumers to disclose a fax number and/or email address on their rebate coupons or forms.
- C. misrepresent, in any manner, expressly or by implication, the time in which any rebate in the form of cash or credit towards future purchases will be mailed, or otherwise provided to purchasers;

Decision and Order

- D. fail to provide any rebate in the form of cash within the time specified, or, if no time is specified, within thirty (30) days;
- E. fail to provide any rebate in the form of credit towards future purchases within the time specified, or, if no time is specified, within thirty (30) days;
- F. violate any provision of the Mail Order Rule in connection with any rebate in the form of merchandise, including failing to provide the rebate within the time specified, or, if no time is specified, within thirty (30) days, unless respondent offers to the purchaser the option of either:
 - 1. consenting to the delay; or
 - 2. canceling the rebate request and promptly receiving reasonable cash compensation instead of the rebate originally offered; or
- G. fail to provide any rebate in the form of services or any other consideration (other than cash, credit towards future purchases, or merchandise) within the time specified, or, if no time is specified, within thirty (30) days, unless respondent offers to the purchaser the option of either:
 - 1. consenting to the delay; or
 - 2. canceling the rebate request and promptly receiving reasonable cash compensation instead of the rebate originally offered.

II.

IT IS FURTHER ORDERED that respondent Tim R. Wofford shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;

Decision and Order

- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in his possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

III.

IT IS FURTHER ORDERED that respondent Tim R. Wofford, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

IV.

IT IS FURTHER ORDERED that respondent Tim R. Wofford shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which he has complied with this order.

V.

This order will terminate twenty on October 8, 2022, or (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without

Decision and Order

an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from Tim R. Wofford, an officer of OKie Corporation (“OKie”). OKie did business as Prime Peripherals. Mr. Wofford and OKie advertised, labeled, offered for sale, sold, and distributed computer peripheral products to the public, including Prime Peripherals brand modems, CD-Rom drive kits, and recordable compact disks.

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter concerns cash rebate offers that respondent and OKie made to consumers who purchased Prime Peripherals computer peripheral products. The complaint alleges that respondent engaged in false advertising and unfair practices relating to these rebate offers. Specifically, the complaint alleges that respondent falsely represented that he would mail cash rebates to purchasers of Prime Peripherals computer peripheral products within either six to eight or eight to ten weeks, or within a reasonable period of time, of respondent's receipt of their requests. In many instances, consumers never received their cash rebates or experienced delays ranging from one to six months.

The complaint also alleges that, in the advertising and sale of Prime Peripherals computer peripheral products, respondent offered that consumers would receive cash rebates if they purchased a Prime Peripherals computer peripheral product and submitted a rebate form with proof of purchase. In making this offer, he did not require consumers to submit a telephone number, fax number, or email address to be eligible to receive the offered cash rebates. In numerous instances, consumers accepted

Analysis

respondent's rebate offer by purchasing those products and submitting rebate forms with proof of purchase. After receiving rebate requests, respondent unfairly modified the terms or conditions of the rebate offer unilaterally by requiring that, in addition to submitting a rebate form with proof of purchase, consumers submit a telephone number, a fax number, and an email address to receive a rebate. In breach of the original rebate offer, respondent rejected numerous rebate requests from consumers because they did not submit a telephone number, a fax number, and/or an email address.

Finally, the complaint alleges that respondent represented that purchasers of Prime Peripherals computer peripheral products would receive cash rebates if they purchased those products and submitted a rebate form with proper documentation, yet failed to disclose that consumers were required to possess and disclose their telephone number, fax number, and email address on a rebate form to receive those cash rebates. The complaint alleges that his failure to disclose these facts was a deceptive practice.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts and practices in the future. Part I of the proposed order prohibits respondent from failing to disclose all terms, conditions, or other limitations of a rebate offer on the rebate form. It also requires the respondent to disclose in any rebate advertising that the rebate offer requires consumers to disclose a fax number and/or email address on their rebate form if such is the case. Part I of the proposed order also prohibits respondent from misrepresenting the time in which any cash rebate, or rebate in the form of credit towards future purchases, will be mailed to consumers. It also prohibits respondent from failing to provide such rebates within the time specified, or if no time is specified, within thirty days.

Part I of the proposed order also prohibits respondent from violating any provision of the Federal Trade Commission's Trade Regulation Rule Concerning Mail or Telephone Order Merchandise (the "Mail Order Rule") in connection with rebates

Analysis

in the form of merchandise. Among other things, the Mail Order Rule prohibits marketers from failing to provide rebates in the form of merchandise within the time they specify for delivery, or if no time is specified, within thirty days, unless they offer consumers the option of consenting to a delay or canceling the rebate request and promptly receiving reasonable cash compensation instead of the merchandise originally offered. Finally, Part I of the proposed order similarly prohibits respondent from failing to provide rebates in the form of services or any other consideration (other than cash, credit towards future purchases, or merchandise) within the time he specifies for delivery, or if no time is specified, within thirty days, unless he offers consumers the option of consenting to a delay or canceling the rebate request and promptly receiving reasonable cash compensation instead of the rebate originally offered.

Parts II through IV of the proposed order are reporting and compliance provisions. Part V is a provision “sunsetting” the order after twenty years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

**PHILIPS ELECTRONICS NORTH AMERICA
CORPORATION**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4062; File No. 0223095
Complaint, October 8, 2002--Decision, October 8, 2002*

This consent order addresses cash rebate offers made by Respondent Philips Electronics North America Corporation – which manufactures, advertises, labels, offers for sale, sells, and distributes computer peripheral equipment, such as CD-rewritable drives and computer monitors – to consumers who purchased computer peripheral products. The order, among other things, prohibits the respondent – with respect to its marketing of any personal computer or personal computer-related product sold to consumers – from misrepresenting the time in which it will mail any cash rebate or any credit towards future purchases. The order also prohibits the respondent from failing to provide any such rebate within the time specified, or if no time is specified, within thirty days, and from violating the Mail or Telephone Order Rule if it offers rebates in the form of merchandise. In addition, the order prohibits the respondent from misrepresenting any material terms of any rebate program, including the status of or reasons for any delay in providing any rebate. The order also requires the respondent to pay out all valid rebates requests that are due or past due as of the date of service of the order, and to send a rebate to any eligible consumer who contacts the respondent or the FTC for a period of 60 days after service of the order.

Participants

For the Commission: *Linda K. Badger, Matthew D. Gold,
Erika Wodinsky, and Jeffrey Klurfeld.*

For the Respondent: *Thomas M. Hafner, Phillips Electronics
North America.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Philips Electronics North America Corporation, a corporation (“Philips” or “respondent”), has violated the provisions of the

Complaint

Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is a Delaware corporation with its principal office or place of business at 1251 Avenue of the Americas, New York, NY 10020.
2. Respondent has manufactured, advertised, labeled, offered for sale, sold, and distributed consumer electronic equipment and other electronic products to the public. Through its division, Philips Consumer Electronics North America ("PCENA"), respondent has manufactured, advertised, labeled, offered for sale, sold, and distributed computer peripheral equipment, such as CD-rewritable drives and computer monitors.
3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

FALSE SHIPMENT REPRESENTATIONS

4. Respondent has disseminated or has caused to be disseminated advertisements and rebate forms for computer peripheral products, including but not necessarily limited to the attached Exhibits A through C. These advertisements and rebate forms contain the following statements:

A. “\$40 Rebate

Receive a \$40 Rebate with purchase of a CD-Rewritable Drive, model PCRW804.

Offer good May 20 through September 8.”
(Exhibit A, advertisement).

B. “Up to \$100 Rebate*

Up to \$100 mail-in rebate on select Philips Monitors.
Offer good July 1 through September 30, 2001.”
(Exhibit B, advertisement).

Complaint

C. "To receive your rebate:

1. Please fill in the following information:

Name _____
Street Address _____
City _____
State _____ ZIP _____
Phone (area code first) _____
Product Serial Number _____
Email _____

...

Please note:

...

- Please allow 8 weeks for delivery of your rebate check.

...."

(Exhibit C, rebate coupon).

5. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that respondent will deliver cash rebates to purchasers of Philips computer peripheral products within eight weeks of respondent's receipt of their valid requests.

6. In truth and in fact, in numerous instances, respondent did not deliver cash rebates to purchasers of Philips computer peripheral products within eight weeks of respondent's receipt of their valid requests. For its promotions offered through PCENA, from January 2001 to January 2002, over fifty thousand consumers experienced delays of up to six months or more. The rebates at issue ranged from \$20 to \$100 in value. Therefore, the representation set forth in Paragraph 5 was, and is, false or misleading.

Complaint

**UNILATERAL MODIFICATION OF TERMS OR
CONDITIONS OF REBATE OFFER: UNFAIR BUSINESS
PRACTICE**

7. In the advertising and sale of computer peripheral products, respondent has offered, expressly or by implication, that consumers would receive cash rebates within eight weeks if they purchased a Philip's computer peripheral product and submitted a rebate form with proof of purchase.
8. After receiving rebate requests in conformance with the offer described in Paragraph 7, respondent extended the time period in which it would deliver the rebates to consumers without consumers agreeing to this extension of time. Respondent failed to deliver the rebates to consumers within the promised time period.
9. Respondent's practice set forth in Paragraphs 7 and 8 was not reasonably avoidable, and caused substantial injury to consumers that was not outweighed by countervailing benefits to consumers or competition. This practice was, and is, an unfair act or practice.
10. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this eighth day of October, 2002, has issued this complaint against respondent.

By the Commission.

\$40 Rebate

REBATE

PHILIPS

Receive a \$40 Rebate with
purchase of a CD-Rewritable
Drive, model PCRW804.

204

8x4x32
CD-Rewritable

Internal
CD-RW

- Plays & records CD
- Prints
- Easy to use, easy to install
- Create your own CDs
- CD-RW media included
- Detailed installation guide

Adaptac

Offer good May 20 through September 8.

Let's make things better.



PHILIPS

EXHIBIT A

Up to \$100 Rebate*

Up to \$100 mail-in rebate
on select Philips Monitors.

Offer good July 1 through September 30, 2001.

Let's make things better.

REBATE



PHILIPS

To receive your rebate:

1. Please fill in the following information:

Name _____
Street Address _____
City _____
State _____ ZIP _____
Phone (area code first) _____
Product Serial Number _____
Email _____

2. Enclose a clear copy of your store sales receipt showing model number, purchase date, and store name.

3. Enclose the original UPC label from product box.

4. Mail this original coupon and the requested information to:

Philips Rebate Offer
Promo. # 01-37104
P.O. Box 9080
Coppell, TX 75019-9080

5. The above requested information must be postmarked by October 6, 2001.

Please note:

- Offer good at participating retailers only.
- Philips Consumer Electronics North America is not responsible for lost, late, mutilated, or misdirected mail.
- Please allow 8 weeks for delivery of your rebate check.
- Omission of any necessary information will result in a return of materials and will require re-submission within the 10/6/01 deadline.
- Offer may not be combined with any other Philips CD Rewritable Drive offers.
- Consumer inquiries, please call 1-866-450-9698 or check rebate status at www.rebateshq.com.
- **TERMS OF THIS OFFER:** Offer runs 5/20/01 through 9/8/01. Offer limited to one per household. Consumer offer only. No requests from groups, clubs or other organizations will be accepted. Void where prohibited, taxed or otherwise restricted by law. Offer good only in USA.

 Philips is a registered trademark of Koninklijke Philips Electronics, N.V.



PHILIPS

EXHIBIT C

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Western Region proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to § 2.34 of its Rules, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent, Philips Electronics North America Corporation, is a Delaware corporation with its principal office or place of business at 1251 Avenue of the Americas, New York, NY 10020.

Decision and Order

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, "respondent" shall mean Philips Electronics North America Corporation, its successors and assigns and its officers, agents, representatives, and employees.
2. "Rebate" shall mean cash, credit towards future purchases, merchandise, services, or any other consideration offered by respondent to consumers who purchase products or services, and which is provided subsequent to the purchase.
3. "Eligible person" shall mean each consumer:
 - a. who has provided to respondent all documentation necessary to qualify that consumer for a rebate under the terms of any rebate offer; and
 - b. whose rebate is due or past due as of the date of service of this order
4. "Mail Order Rule" shall mean the Federal Trade Commission's Trade Regulation Rule Concerning Mail or Telephone Order Merchandise, 16 C.F.R. Part 435, or as the Rule may hereafter be amended.
5. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Decision and Order

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any personal computer or personal computer-related product sold to consumers, including but not limited to, monitors, speakers, sound cards, CD-RW drives, DVD+RW drives, and multimedia projectors, in or affecting commerce, shall not:

- A. misrepresent, in any manner, expressly or by implication, the time in which any rebate in the form of cash or credit towards future purchases will be mailed, or otherwise provided, to purchasers;
- B. fail to provide any rebate in the form of cash within the time specified, or, if no time is specified, within thirty (30) days;
- C. fail to provide any rebate in the form of credit towards future purchases within the time specified, or, if no time is specified, within thirty (30) days;
- D. violate any provision of the Mail Order Rule in connection with any rebate in the form of merchandise, including failing to provide the rebate within the time specified, or, if no time is specified, within thirty (30) days, unless respondent offers to the purchaser the option of either:
 1. consenting to the delay; or
 2. canceling the rebate request and promptly receiving reasonable cash compensation instead of the rebate originally offered;
- E. fail to provide any rebate in the form of services or any other consideration (other than cash, credit towards future purchases, or merchandise) within the time specified, or, if

Decision and Order

no time is specified, within thirty (30) days, unless respondent offers to the purchaser the option of either:

1. consenting to the delay; or
2. canceling the rebate request and promptly receiving reasonable cash compensation instead of the rebate originally offered; or
- F. misrepresent, in any manner, expressly or by implication, any material terms of any rebate program, including the status of or reasons for any delay in providing any rebate.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, shall, in accordance with this Part, provide a rebate to each eligible person.

- A. Within ten (10) business days from the date of service of this order, respondent shall mail a rebate to each eligible person whose name appears on any list or database in respondent's possession.
- B. For a period of sixty (60) days from the date of service of this order, respondent shall provide a rebate to each eligible person who has not been provided a rebate pursuant to Part II.A of this order, and who contacts respondent or the Commission in any manner. Each such rebate shall be mailed within ten (10) business days after respondent receives such person's name and contact information.

III.

IT IS FURTHER ORDERED that respondent Philips, and its successors and assigns shall, for five (5) years after the last date of dissemination of any representation covered by this order,

Decision and Order

maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

IV.

IT IS FURTHER ORDERED that respondent Philips, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

V.

IT IS FURTHER ORDERED that respondent Philips, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed

Decision and Order

filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VI.

IT IS FURTHER ORDERED that respondent Philips, and its successors and assigns, shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

VII.

This order will terminate twenty on October 8, 2022, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Decision and Order

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order with Philips Electronics North America Corporation ("Philips"). Philips manufactures, advertises, labels, offers for sale, sells, and distributes consumer electronic equipment and other electronic products to the public. Through its division, Philips Consumer Electronics North America, Philips manufactures, advertises, labels, offers for sale, sells, and distributes computer peripheral equipment, such as CD-rewritable drives and computer monitors.

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter concerns cash rebate offers that Philips made to consumers who purchased computer peripheral products. The complaint alleges that respondent engaged in deceptive and unfair practices relating to these rebate offers. Specifically, the complaint alleges that respondent falsely represented that it would deliver cash rebates to purchasers of its computer peripheral products within eight weeks. For its promotions offered through its division, Philips Consumer Electronics North America, from January 2001 to January 2002, over fifty thousand consumers experienced delays of up to six months or more. The rebates at issue ranged from \$20 to \$100 in value.

The complaint further alleges that, in the advertising and sale of its computer peripheral products, Philips offered to deliver rebates in eight weeks to consumers who purchased a Philips computer peripheral product and submitted a rebate form with proof of purchase. After receiving rebate requests in conformance with this offer, Philips unilaterally extended the time period in

Analysis

which it would deliver the rebates to consumers without consumers agreeing to this extension of time. According to the complaint, this constituted an unfair business practice.

The proposed consent order contains provisions designed to prevent Philips from engaging in similar acts and practices in the future. Part I applies to Philips' marketing of personal computer or personal computer-related product sold to consumers, including but not limited to, monitors, speakers, sound cards, CD-RW drives, DVD+RW drives, and multimedia projectors. With regard to these products, Part I.A. prohibits the respondent from misrepresenting the time in which it will mail any cash rebate or any credit towards future purchases. Parts I.B. and I.C. prohibit Philips from failing to provide any such rebate within the time specified, or if no time is specified, within thirty days.

Part I.D. prohibits the respondent from violating the Federal Trade Commission's Trade Regulation Rule Concerning Mail or Telephone Order Merchandise (the "Mail Order Rule") if it offers rebates in the form of merchandise. Part I.E. addresses rebates in the form of services or other consideration that the Mail Order Rule does not cover. That provision requires the respondent to provide the rebate in the time specified, or within thirty days if no time is specified, unless the respondent offers the purchaser the option of consenting to the delay or canceling the rebate request and promptly receiving reasonable cash compensation instead of the promised rebate. Part I.F. requires that the company not "misrepresent, in any manner, expressly or by implication, any material terms of any rebate program, including the status of or reasons for any delay in providing any rebate."

Part II of the proposed order is a redress provision which requires the company to pay out all valid rebates requests that are due or past due as of the date of service of the order. This provision also requires the respondent to send a rebate to any eligible consumer who contacts the respondent or the FTC for a period of 60 days after service of the order.

Analysis

Parts III through VI of the proposed order are reporting and compliance provisions. Part VII is a provision “sunsetting” the order after twenty years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

SYSTEM HEALTH PROVIDERS, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4064; File No. 0110196

Complaint, October 24, 2002--Decision, October 24, 2002

This consent order addresses practices used by Respondent Genesis Physicians Group, Inc. (“GPG”) – comprised of approximately 1,250 physicians in the eastern part of the Dallas-Fort Worth metropolitan area (“Dallas area”) – and Respondent System Health Providers, Inc., a management services organization whose voting stock is wholly owned by GPG. The order, among other things, prohibits the respondents from entering into or facilitating agreements among providers: (1) to negotiate on behalf of any provider (including both physicians and non-physician providers of ancillary medical services) with any payor; (2) to deal, refuse to deal, or threaten to refuse to deal with any payor; (3) regarding any term upon which any providers deal, or are willing to deal, with any payor; and (4) not to deal individually with any payor or through any arrangement other than SHP or GPG. The order also prohibits the respondents from exchanging or facilitating the transfer of information among providers concerning any provider’s willingness to deal with a payor, or the terms or conditions, including price terms, on which the provider is willing to deal. In addition, the order prohibits the respondents from attempting to engage in – or encouraging, pressuring, or attempting to induce any person to engage in – any action prohibited by the order. The order also requires Respondent SHP to distribute the complaint and order to its members, payors with which it previously contracted, and specified others, and to terminate, without penalty, payor contracts that it had entered into during the collusive period, at any such payor’s request. In addition, the order contains a proviso to preserve payor contract provisions defining post-termination obligations relating to continuity of care during a previously begun course of treatment.

Participants

For the Commission: *Michael Joel Bloom, Dara J. Diomande, Susan M. Gelles, Robert C. Cancellaro, Barbara Anthony, Joseph Eckhaus, Roberta S. Baruch, D. Bruce Hoffman, and Timothy A. Dayek.*

For the Respondents: *Jerry Beane and Kay Lynn Brumbaugh, Strasburger & Price, LLP.*

Complaint

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Genesis Physicians Group, Inc. (“GPG”) and System Health Providers, Inc. (“SHP”) have violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges in that respect as follows:

RESPONDENTS

PARAGRAPH 1: Respondent SHP is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of Texas, with its office and principal place of business at 12201 Merit Drive, Suite 450, Dallas, TX 75251.

PARAGRAPH 2: Respondent GPG is a non-profit corporation, organized, existing, and doing business under and by virtue of the laws of Texas, with its office and principal place of business at 12201 Merit Drive, Suite 440, Dallas, TX 75251.

JURISDICTION

PARAGRAPH 3: At all times relevant to this Complaint, almost all members of GPG were physicians engaged in the business of providing health care services for a fee. Except to the extent that competition has been restrained as alleged herein, members of GPG have been, and are now, in competition with each other for the provision of physician services.

PARAGRAPH 4: The general business practices of Respondents GPG and SHP, including the acts and practices herein alleged, are in or affecting “commerce” as defined in the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

Complaint

PARAGRAPH 5: Respondents GPG and SHP have been organized in substantial part, and are engaged in substantial activities, for the pecuniary benefit of their members and are therefore corporations within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

OVERVIEW OF MARKET AND PHYSICIAN COMPETITION

PARAGRAPH 6: Respondent GPG has approximately 1,250 members, almost all of whom are physicians licensed to practice medicine in the State of Texas and engaged in the business of providing professional services to patients in the eastern part of the Dallas-Fort Worth metropolitan area (“Dallas area”).

PARAGRAPH 7: Respondent SHP is a management services organization, the voting stock of which is wholly owned by GPG.

PARAGRAPH 8: Physicians often contract with health insurance firms and other third-party payors, such as preferred provider organizations. Such contracts typically establish the terms and conditions, including price terms, under which the physicians will render services to the payors’ subscribers. Physicians entering into such contracts often agree to lower compensation in order to obtain access to additional patients made available by the payors’ relationship with insureds. These contracts may reduce payor costs and enable payors to lower the price of insurance, and thereby result in lower medical care costs for subscribers to the payors’ health insurance plans.

PARAGRAPH 9: Absent agreements among competing physicians on the terms, including price, on which they will provide services to subscribers or enrollees in health care plans offered or provided by third-party payors, competing physicians decide individually whether to enter into contracts with third-party payors to provide services to their subscribers or enrollees, and what prices they will accept pursuant to such contracts.

Complaint

PARAGRAPH 10: Medicare's Resource Based Relative Value System ("RBRVS") is a system used by the United States Centers for Medicare and Medicaid Services to determine the amount to pay physicians for the services they render to Medicare patients. The RBRVS approach provides a method to determine fees for specific services. In general, it is the practice of payors in the Dallas area to make contract offers to individual physicians or groups at a fee level specified in the RBRVS, plus a markup based on some percentage of that fee (*e.g.*, "110% of 2001 RBRVS").

PARAGRAPH 11: In order to be competitively marketable in the Dallas area, a payor's health insurance plan must include in its physician network a large number of primary care physicians and specialists who practice in the Dallas area. Many of the primary care physicians and specialists who practice in the Dallas area are members of GPG.

PARAGRAPH 12: Competing physicians sometimes use a "messenger" to facilitate the establishment of contracts between themselves and payors in ways that do not constitute or facilitate an unlawful agreement on fees and other competitively significant terms. Such a messenger may not, however, consistent with a competitive model, negotiate fees and other competitively significant terms on behalf of the participating physicians, or facilitate the physicians' coordinated responses to contract offers by, for example, electing not to convey a payor's offer to them based on the messenger's opinion on the appropriateness, or lack thereof, of the offer.

RESTRAINT OF TRADE

PARAGRAPH 13: Respondents GPG and SHP, each acting as a combination of competing physicians, have acted to restrain competition by, among other things:

Complaint

- A. facilitating, negotiating, entering into, and implementing agreements among GPG members on price and other competitively significant terms;
- B. refusing to deal with payors except on collectively agreed-upon terms; and
- C. negotiating uniform fees and other competitively significant terms in payor contracts for Respondent GPG's members, and refusing to submit payor offers to members that do not conform to Respondent SHP's standards for contracts.

FORMATION AND OPERATION OF GPG AND SHP

PARAGRAPH 14: In 1995 GPG undertook to educate and assist physicians in contracting with payors for the provision of medical services. GPG, directly or through other organizations which it controlled, entered into contracting activities on behalf of its members, often pursuant to arrangements in which the physicians bore some financial risk (*e.g.*, through agreements to provide required medical services in return for a capitated fee). In or about 1996, GPG formed Genesis Physicians Practice Association ("GPPA") to be the locus of GPG's risk-contracting activities. SHP was formed in 1995 by GPG and Presbyterian Healthcare System, and was envisioned to be a medical management company responsible for managing the contracting, credentialing, utilization management, and quality assurance of GPG (and later GPPA). In 1998 GPG purchased substantially all of Presbyterian's interest in SHP, becoming the sole owner of SHP's voting stock.

PARAGRAPH 15: GPPA's risk contracting resulted in significant losses to GPG physicians, and in 1999 GPPA filed for protection under the bankruptcy laws, discontinued its contracts, and ceased doing business. Prior to and following the demise of GPPA, SHP increasingly undertook, on behalf of GPG and its physicians, to negotiate with payors non-risk contracts that provide for higher fees and other more advantageous terms than

Complaint

its individual physicians could obtain by negotiating unilaterally with payors.

PARAGRAPH 16: Physicians seeking to join GPG apply for membership and, if qualified, are approved for membership by the GPG Membership Committee and Board of Trustees. Each physician then typically has signed a “Participation Agreement” with SHP, authorizing SHP to negotiate non-risk contracts with payors on his or her behalf.

PARAGRAPH 17: SHP personnel have negotiated with payors the fees and other terms pursuant to which SHP members may render medical care to persons covered by the payors. Following acceptance of a contract by vote of SHP’s Board of Directors, SHP has summarized and commented to GPG members on the terms of that contract and offered GPG members an opportunity to opt in or out of the agreement. Unless a physician opted out, he or she was deemed, under the SHP “Participation Agreement,” to have opted in under the SHP-negotiated contract.

PARAGRAPH 18: Rather than acting simply as a “messenger,” as described in Paragraph 12 of this Complaint, SHP actively bargained with payors, often proposing and counter-proposing fee schedules to be applied, among other terms. To maintain its bargaining power, SHP has discouraged GPG members from entering into unilateral agreements with payors. SHP has communicated to GPG members the bargaining advantage gained by negotiating with payors collectively through SHP, in general, and SHP’s determinations that specific fees and other contract terms being offered by payors are “not comparable to market standards” or are otherwise inadequate. Many GPG members have been unwilling to negotiate with payors apart from SHP, and have communicated that fact to payors seeking to resist SHP’s collective demands.

PARAGRAPH 19: SHP had a practice—inconsistent with a messenger model arrangement—of not conveying to GPG members payor offers that SHP deemed deficient, including offers that

Complaint

provide for fees that do not satisfy criteria adopted by SHP's Contracting Committee, which was comprised of 21 GPG members. SHP instead demanded, and often received, more favorable fee and other contract terms—terms that payors would not have offered to GPG's members had those members engaged in unilateral, rather than collective, negotiations with the payors. Only after the payor acceded to fee and other contract terms acceptable to SHP, would SHP convey the payor's proposed contract to GPG members for their consideration.

PARAGRAPH 20: SHP refused to convey payors' proposed fee and other contract terms to GPG members even where the payor has explicitly requested that it do so. SHP's discouraging of physicians' contracting directly with payors and its unwillingness to convey payors' proposed contracts to GPG members unless and until those offers satisfy SHP's criteria have rendered it less likely and more costly for payors to establish competitive physician networks in the Dallas area without first coming to terms with SHP. As a result, payors often have offered or acceded to SHP demands for supracompetitive fees for all GPG members.

LACK OF SIGNIFICANT EFFICIENCIES

PARAGRAPH 21: Since July of 1999, neither GPG and its members nor SHP has sought or been willing to enter into agreements with payors in which GPG, SHP, or GPG's members undertake financial risk-sharing. Further, GPG members have not integrated their practices to create significant potential efficiencies. Respondents' joint negotiation of fees and other competitively significant terms has not been, and is not, reasonably related to any efficiency-enhancing integration.

ANTICOMPETITIVE EFFECTS

PARAGRAPH 22: Respondents' actions described in Paragraphs 13 through 20 of this Complaint have had, or tend to have, the effect of restraining trade unreasonably and hindering

Complaint

competition in the provision of physician services in the Dallas area in the following ways, among others:

- A. prices and other forms of competition among Respondent GPG's members were unreasonably restrained;
- B. prices for physician services were increased; and
- C. competition in the purchase of physician services was restrained to the detriment of health plans, employers, and individual consumers.

PARAGRAPH 23: The combination, conspiracy, acts, and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Such combination, conspiracy, acts, and practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-fourth day of October, 2002, issues its Complaint against Respondents GPG and SHP.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of System Health Providers, Inc. and Genesis Physicians Group, Inc., hereinafter sometimes referred to as “Respondents,” and Respondents having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued, would charge Respondents with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order to Cease and Desist (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments filed thereafter by interested parties pursuant to § 2.34 of the Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and issues the following order:

Decision and Order

1. Respondent System Health Providers, Inc. (“SHP”) is a for-profit corporation organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business located at 12201 Merit Drive, Suite 450, Dallas, TX 75251.
2. Respondent Genesis Physicians Group, Inc. (“GPG”) is a non-profit corporation organized, existing, and doing business under and by virtue of the laws of the State of Texas, with its office and principal place of business located at 12201 Merit Drive, Suite 440, Dallas, TX 75251.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent SHP” means System Health Providers, Inc., its officers, directors, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- B. “Respondent GPG” means Genesis Physicians Group, Inc. its officers, directors, employees, agents, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.

Decision and Order

- C. “Respondents” means Respondent SHP and Respondent GPG.
- D. “Participate” in an entity means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services, to a Payor through such entity. (This definition also applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”)
- E. “Payor” means any Person that pays, or arranges for payment, for all or any part of any Provider services for itself or for any other Person.
- F. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- G. “Preexisting Contract” means a contract that was in effect prior to the receipt, by all Payors that are parties to such contract, of notice sent by Respondent SHP or Respondent GPG pursuant to Paragraph III.B. of this Order, of each such Payor’s right to terminate such contract.
- H. “Principal Address” means either (1) primary business address, if there is a business address, or (2) primary residential address, if there is no business address.
- I. “Provider” means a doctor of allopathic medicine (“M.D.”), a doctor of osteopathic medicine (“D.O.”), or any other Person licensed by the state to provide ancillary health care services.
- J. “Qualified risk-sharing joint arrangement” means an arrangement to provide Provider services in which:

Decision and Order

1. all Providers who participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the Providers who participate to jointly control costs and improve quality by managing the provision of Provider services, such as risk-sharing involving:
 - a. the provision of Provider services to Payors at a capitated rate,
 - b. the provision of Provider services for a predetermined percentage of premium or revenue from Payors,
 - c. the use of significant financial incentives (e.g., substantial withhold) for providers who participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by providers in different specialties offering a complementary mix of services, for a fixed, predetermined payment, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient's condition, the choice, complexity, or length of treatment, or other factors; and
 2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.
- K. “Qualified clinically-integrated joint arrangement” means an arrangement to provide Provider services in which:

Decision and Order

1. all Providers who participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the Providers who participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and
2. any agreement concerning reimbursement or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.

II.

IT IS FURTHER ORDERED that Respondents, directly or indirectly, or through any corporate or other device, in connection with the provision of Provider services in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any Providers:
 1. to negotiate on behalf of any Provider with any Payor,
 2. to deal, refuse to deal, or threaten to refuse to deal with any Payor,
 3. regarding any term, condition, or requirement upon which any Provider deals, or is willing to deal, with any Payor, including, but not limited to, price terms, or
 4. not to deal individually with any Payor, or not to deal with any Payor through any arrangement other than Respondent SHP or other than Respondent GPG.

Decision and Order

- B. Exchanging or facilitating in any manner the exchange or transfer of information among Providers concerning any Provider's willingness to deal with a Payor, or the terms or conditions, including price terms, on which the Provider is willing to deal;
- C. Attempting to engage in any action prohibited by Paragraph II.A. or II.B., above; and
- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any Person to engage in any action that would be prohibited by Paragraphs II.A. through II.C. above.

PROVIDED, HOWEVER, that nothing in this Paragraph II shall prohibit any agreement involving, or conduct by, Respondent SHP or Respondent GPG that is reasonably necessary to form, participate in, or take any other action in furtherance of a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement, so long as the arrangement does not restrict the ability, or facilitate the refusal, of Providers who participate in it to deal with Payors on an individual basis or through any other arrangement.

III.

IT IS FURTHER ORDERED that Respondent SHP shall:

- A. Within thirty (30) days after the date on which this Order becomes final, distribute by first-class mail a copy of this Order and the Complaint to:
 - 1. each Provider who participates, or has participated, in Respondent SHP or Respondent GPG, and
 - 2. each officer, director, manager, and employee of Respondent SHP or Respondent GPG;

Decision and Order

- B. Within thirty (30) days after the date on which this Order becomes final, send copies of this Order, the Complaint, and the notice specified in Appendix A to this Order, by first-class mail return receipt requested, to the chief executive officer of each Payor that is listed in Appendix B or that contracts with Respondent SHP or Respondent GPG for the provision of Provider services;
- C. Terminate, without penalty or charge, any Preexisting Contract with any Payor for the provision of Provider services, upon receipt by Respondent SHP or Respondent GPG of a written request to terminate such contract from any Payor that is a party to the contract or that pays for the Provider services provided through the contract;
PROVIDED, HOWEVER, that nothing contained herein shall affect the operation of any Preexisting Contract provision pertaining to the continuation of patient care for patients undergoing a course of treatment, or payment therefor, following termination of the Preexisting Contract;
- D. For a period of three (3) years after the date this Order becomes final:
 1. Distribute by first-class mail a copy of this Order and the Complaint to:
 - a. each Provider who begins participating in Respondent SHP or Respondent GPG, and who did not previously receive a copy of this Order and the Complaint from Respondent SHP or Respondent GPG, within thirty (30) days of the time that such participation begins,
 - b. each Payor that contracts with Respondent SHP or Respondent GPG for the provision of Provider services, and that did not previously receive a copy of this Order and the Complaint from Respondent SHP

Decision and Order

or Respondent GPG, within thirty (30) days of the time that such Payor enters into such contract, and

- c. each person who becomes an officer, director, manager, and employee of Respondent SHP or Respondent GPG, and who did not previously receive a copy of this Order and the Complaint from Respondent SHP or Respondent GPG, within thirty (30) days of the time that he or she assumes such responsibility with Respondent SHP; and
2. Annually publish in an official annual report or newsletter sent to all Providers who participate in Respondent SHP or Respondent GPG, a copy of this Order and the Complaint with such prominence as is given to regularly featured articles;
- E. Notify the Commission at least thirty (30) days prior to any proposed change in Respondent SHP or Respondent GPG, such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in Respondent SHP or Respondent GPG that may affect compliance obligations arising out of this Order; and
- F. File verified written reports within sixty (60) days after the date this Order becomes final, annually thereafter for three (3) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth:
 1. in detail, the manner and form in which Respondent SHP and Respondent GPG have complied and are complying with this Order, including, but not limited to, (a) information sufficient to describe, for each qualified risk-sharing joint arrangement established or operated by Respondent SHP or Respondent GPG, the manner in which the Providers who participate in such arrangement

Decision and Order

share financial risk, and (b) information sufficient to describe, for each qualified clinically-integrated joint arrangement established or operated by Respondent SHP or Respondent GPG, the manner in which the Providers who participate in such arrangement have integrated their practices, and

2. the name, address, and telephone number of each Payor with which Respondent SHP or Respondent GPG has had any contact during the reporting period.

IV.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission of any change in its Principal Address within twenty (20) days of such change in address.

V.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in their possession, or under their control, relating to any matter contained in this Order;
- B. Upon five (5) days' notice to Respondent SHP, and without restraint or interference from it, to interview officers, directors, or employees of Respondent SHP; and
- C. Upon five (5) days' notice to Respondent GPG, and without restraint or interference from it, to interview officers, directors, or employees of Respondent GPG.

Decision and Order

VI.

IT IS FURTHER ORDERED that this Order shall terminate on October 24, 2022.

By the Commission.

Decision and Order

Appendix A
[letterhead of SHP/GPG]

[name of payor's CEO]
[address]

Dear _____ :

Enclosed is a copy of a complaint and a consent order issued by the Federal Trade Commission against System Health Providers, Inc. (“SHP”) and Genesis Physicians Group, Inc. (“GPG”). I call to your attention Paragraph III.C. of the order, which gives you the right to terminate, without penalty or charge, any contracts with SHP or GPG that were in effect prior to your receipt of this letter.

Sincerely,

Decision and Order

Appendix B

Aetna U.S. Healthcare North Texas, Inc.
Beech Street Corp.
Blue Cross Blue Shield of Texas, A Division of Health Care
Service Corp.
Cigna Healthcare of Texas, Inc.
First Health Group Corp.
HealthSmart Preferred Care, Inc.
Humana Health Plan of Texas, Inc.
IMS Managed Care, Inc.
Pacificare of Texas, Inc.
Private Healthcare Systems, Inc.
ProAmerica Managed Care, Inc.
Regional Healthcare Alliance
United Healthcare of Texas, Inc.

Analysis

**Analysis of Agreement Containing Consent Order to Aid
Public Comment**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order with Genesis Physicians Group, Inc. (“GPG”) and System Health Providers, Inc. (“SHP”) (“Respondents”). The agreement settles charges that Respondents violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by facilitating and implementing agreements among GPG members on price and other competitively significant terms; refusing to deal with payors except on collectively agreed-upon terms; and negotiating uniform fees and other competitively significant terms in payor contracts and refusing to submit to members payor offers that do not conform to Respondent SHP’s standards for contracts. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by any Respondent that said Respondent violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

The Complaint

The allegations in the Commission’s proposed complaint are summarized below.

Respondent GPG has approximately 1,250 members, almost all of whom are physicians licensed to practice medicine in the State

Analysis

of Texas and engaged in the business of providing professional services to patients in the eastern part of the Dallas-Fort Worth metropolitan area (“Dallas area”).

Respondent SHP is a management services organization, the voting stock of which is wholly owned by GPG.

Physicians often contract with health insurance firms and other third-party payors, such as preferred provider organizations. Such contracts typically establish the terms and conditions, including price terms, under which the physicians will render services to the payors’ subscribers. Physicians entering into such contracts often agree to lower compensation in order to obtain access to additional patients made available by the payors’ relationship with insureds. These contracts may reduce payor costs and enable payors to lower the price of insurance, and thereby result in lower medical care costs for subscribers to the payors’ health insurance plans.

Absent agreements among competing physicians on the terms, including price, on which they will provide services to subscribers or enrollees in health care plans offered or provided by third-party payors, competing physicians decide individually whether to enter into contracts with third-party payors to provide services to their subscribers or enrollees, and what prices they will accept pursuant to such contracts.

In order to be competitively marketable in the Dallas area, a payor’s health insurance plan must include in its physician network a large number of primary care physicians (PCPs) and specialists who practice in the Dallas area. Many of the PCPs and specialists who practice in the Dallas area are members of GPG. In particular, GPG members include a large number of PCPs and specialists located near and associated with the two highly-regarded hospitals comprising the Presbyterian Health System. Accordingly, many payors concluded that they could not establish a viable physician network, particularly in areas in which GPG

Analysis

physicians are concentrated, without including a large number of GPG physicians in that network.

Sometimes a network of competing physicians uses an agent to convey to payors information obtained individually from the physicians about fees or other significant contract terms that the physicians are willing to accept. The agent also may convey all payor contract offers to the physicians, which the physicians then unilaterally decide whether to accept or reject. Such a "messenger model" arrangement, which is described in the 1996 Statements of Antitrust Enforcement Policy in Health Care jointly issued by the Federal Trade Commission and U.S. Department of Justice (see <http://www.ftc.gov/reports/hlth3s.htm>), can facilitate contracting between physicians and payors and minimize the costs involved, without fostering an agreement among competing physicians on fees or fee-related terms. Such a messenger may not, however, consistent with a competitive model, negotiate fees and other competitively significant terms on behalf of the participating physicians, or facilitate the physicians' coordinated responses to contract offers by, for example, electing not to convey a payor's offer to the physicians based on the messenger's opinion on the appropriateness, or lack thereof, of the offer.

Rather than acting simply as a "messenger," SHP actively bargained with payors, often proposing and counter-proposing fee schedules to be applied, among other terms. To maintain its bargaining power, SHP discouraged GPG members from entering into unilateral agreements with payors. SHP communicated to GPG members the bargaining advantage gained by negotiating with payors collectively through SHP, in general, and SHP's determinations that specific fees and other contract terms being offered by payors were "not comparable to market standards" or otherwise were inadequate. Many GPG members have been unwilling to negotiate with payors apart from SHP, and communicated that fact to payors seeking to resist SHP's collective demands.

Analysis

SHP had a practice – inconsistent with a messenger model arrangement – of not conveying to GPG members payor offers that SHP deemed deficient, including offers that provide for fees that do not satisfy criteria adopted by SHP’s Contracting Committee, which was comprised of 21 GPG members. SHP instead demanded, and often received, more favorable fee and other contract terms—terms that payors would not have offered to GPG’s members had those members engaged in unilateral, rather than collective, negotiations with the payors. Only after the payor acceded to fee and other contract terms acceptable to SHP, would SHP convey the payor’s proposed contract to GPG members for their consideration.

SHP refused to convey payors’ proposed fee and other contract terms to GPG members even where the payor explicitly has requested that it do so. SHP’s discouraging of physicians’ contracting directly with payors and its unwillingness to convey payors’ proposed contracts to GPG members unless and until those offers satisfy SHP’s criteria have rendered it less likely and more costly for payors to establish competitive physician networks in the Dallas area without first coming to terms with SHP. As a result, payors often have offered or acceded to SHP demands for supracompetitive fees for all GPG members.

Since July of 1999, GPG, its members, and SHP have entered only into fee-for-service agreements with payors, pursuant to which GPG, its members, and SHP did not undertake financial risk-sharing. Further, GPG members have not integrated their practices to create significant potential efficiencies. Respondents’ joint negotiation of fees and other competitively significant terms has not been, and is not, reasonably related to any efficiency-enhancing integration. Instead, the Respondents’ acts and practices have restrained trade unreasonably and hindered competition in the provision of physician services in the Dallas area in the following ways, among others: prices and other forms of competition among Respondent GPG’s members were unreasonably restrained; prices for physician services were increased; and competition in the purchase of physician services

Analysis

was restrained to the detriment of health plans, employers, and individual consumers. Thus, Respondents' conduct has harmed patients and other purchasers of medical services by restricting choice of providers and increasing the price of medical services.

The Proposed Consent Order

The proposed consent order is designed to prevent recurrence of the illegal concerted actions alleged in the complaint while allowing Respondents and member-Providers to engage in legitimate joint conduct.

Paragraph II.A prohibits Respondents from entering into or facilitating agreements among providers: (1) to negotiate on behalf of any provider with any payor; (2) to deal, refuse to deal, or threaten to refuse to deal with any payor; (3) regarding any term upon which any providers deal, or are willing to deal, with any payor; and (4) not to deal individually with any payor or through any arrangement other than SHP or GPG. Use of the term "Provider" in the proposed order, rather than the narrower term "physician," reflects SHP's inclusion of non-physician providers of ancillary medical services in its contracting arrangements.

Paragraph II.B prohibits Respondents from exchanging or facilitating the transfer of information among Providers concerning any Provider's willingness to deal with a payor, or the terms or conditions, including price terms, on which the Provider is willing to deal.

Paragraph II.C prohibits Respondents from attempting to engage in any action prohibited by Paragraph II.A or II.B. Paragraph II.D prohibits Respondents from encouraging, pressuring, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A through II.C.

Paragraph II contains a proviso that allows Respondents to engage in conduct that is reasonably necessary to the formation or operation of a "qualified risk-sharing joint arrangement" or a

Analysis

“qualified clinically-integrated joint arrangement,” so long as the arrangement does not restrict the ability, or facilitate the refusal, of participating providers to deal with payors on an individual basis or through any other arrangement. To be a “qualified risk-sharing joint arrangement,” an arrangement must satisfy two conditions. First, all participating Providers must share substantial financial risk through the arrangement and thereby create incentives for the participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. To be a “qualified clinically-integrated joint arrangement,” an arrangement must satisfy two other conditions. First, all participants must join in active and ongoing programs to evaluate and modify their clinical practice patterns, creating a high degree of interdependence and cooperation among Providers to control costs and ensure the quality of services provided. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement. Both definitions reflect the analyses contained in the 1996 FTC/DOJ Statements of Antitrust Enforcement Policy in Health Care.

Paragraphs III.A and III. B require SHP to distribute the complaint and order to its members, payors with which it previously contracted, and specified others. Paragraph III.C requires SHP to terminate, without penalty, payor contracts that it had entered into during the collusive period, at any such payor’s request. This provision is intended to eliminate the effects of Respondents’ joint price-setting. Paragraph III also contains a proviso to preserve payor contract provisions defining post-termination obligations relating to continuity of care during a previously begun course of treatment. This proviso was implicit in the “termination upon request” provision of the recent Commission Order in *Physicians Integrated Services of Denver*. To avoid any risk of confusion among affected persons and the public-at-large, the proviso is made explicit here.

Analysis

The remaining provisions of the proposed order impose complaint and order distribution, reporting, and other compliance-related provisions. For example, Paragraph III. D requires SHP to distribute copies of the Complaint and Order to incoming SHP Providers, payors that contract with SHP or GPG for the provision of Provider services, and incoming SHP and GPG officers, directors, and employees. Further, Paragraph III.F requires SHP to file periodic reports with the Commission detailing how SHP and GPG have complied with the Order. Paragraph V. authorizes Commission staff to obtain access to Respondents' records and officers, directors, and employees for the purpose of determining or securing compliance with the Order.

The proposed order will expire in 20 years.

Complaint

IN THE MATTER OF

MSC.SOFTWARE CORPORATION

**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT**

Docket 9299; File No. 0010077

Complaint, October 9, 2001--Decision, October 29, 2002

This consent order addresses the acquisitions by Respondent MSC.Software Corporation -- the largest supplier of computer-aided engineering simulation software in the world -- of Universal Analytics, Inc. ("UAI") and Computerized Structural Analysis and Research Corporation ("CSAR"), and possible effects in the market for advanced versions of Nastran, a public domain engineering simulation software program. The order, among other things, requires the respondent to divest -- to one or two acquirers approved by the Commission -- perpetual, worldwide, royalty-free, and non-exclusive licenses to the key intellectual property needed by a new competitor to compete in the sale and licensing of advanced Nastran software, including both the version of MSC.Nastran that was most current as of August 12, 2002, and all the intellectual property rights acquired by MSC in the two challenged acquisitions. The order also requires the respondent, for twelve months, to provide the acquirer or acquirers with ongoing support with respect to MSC.Nastran, in the form of personnel, information, technical assistance, advice and training. In addition, the order requires the respondent, for three years, to grant the acquirer or acquirers the right to use the trademarks or trade names of the licensed software for the purpose of identifying the acquirer as a licensee from MSC. The order also requires the respondent, for ten years, to provide the Commission with prior notice of future acquisitions of any entity engaged in the development or sales of any version of Nastran.

Participants

For the Commission: *P. Abbott McCartney, Peggy D. Bayer, J. Dennis Harcketts, Cecelia M. Waldeck, Rita Leeb, Karen Mills, Kent Cox, Stephanie Langley, Susan Moreno, Melissa Kassier, Michael Cowie, Patrick J. Roach, Richard B. Dagen, Rendell A. Davis, Jr., Daniel P. Ducore, John Yun, Jeffrey H. Fischer, and Daniel P. O'Brien.*

For the Respondent: *Tefft W. Smith and Marimichael Skubel, Kirkland & Ellis.*

Complaint

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission (hereafter "Commission"), having reason to believe that MSC.Software Corporation (hereafter "MSC" or "Respondent") acquired Universal Analytics Inc. (hereafter "UAI") and Computerized Structural Analysis & Research Corporation (hereafter "CSAR") in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

RESPONDENT MSC.SOFTWARE CORPORATION

1. Respondent is a for-profit corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal place of business located at 2 MacArthur Place, Santa Ana, California 92707.
2. Respondent had approximately \$178 million in annual revenue for the fiscal year ending December 31, 2000. Respondent is a developer and supplier of simulation computer software, including advanced simulation software used by the aerospace, automotive and other manufacturing industries. Respondent has long offered an advanced version of a linear structural analysis engineering software product called "Nastran."
3. Respondent is, and at all times relevant herein has been, engaged in commerce as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

Complaint

THE ACQUISITION OF UNIVERSAL ANALYTICS INC.

4. Prior to its acquisition by Respondent, UAI was a privately-held corporation organized, existing and doing business under and by virtue of the laws of the State of California.
5. Since before the early 1970s, UAI had been a developer and supplier of simulation computer software, including advanced simulation software used by the aerospace, automotive and other manufacturing industries. UAI had long offered an advanced version of Nastran in competition with Respondent.
6. On or about June 24, 1999, Respondent acquired UAI for approximately \$8.4 million.

THE ACQUISITION OF COMPUTERIZED STRUCTURAL ANALYSIS & RESEARCH CORPORATION

7. Prior to its acquisition by Respondent, CSAR was a privately-held corporation organized, existing and doing business under and by virtue of the laws of the State of California.
8. Since before 1986, CSAR had been a developer and supplier of simulation computer software, including advanced simulation software used by the aerospace, automotive and other manufacturing industries. CSAR had long offered an advanced version of Nastran in competition with Respondent.
9. On or about November 4, 1999, Respondent acquired CSAR for approximately \$10 million.

Complaint

TRADE AND COMMERCE

10. Developers of new industrial and consumer products may use computer-aided engineering analysis to simulate and evaluate the robustness of new product designs.
11. Computer simulations in the product development process typically utilize an analytical method called “finite element analysis” (“FEA”). FEA simulates how a structure would perform in response to a defined load. With finite element analysis, computerized models of structures are first divided into small elements, which form a finite element model, and then subjected to computer analysis to simulate the structure’s performance. The software performing this computer analysis is often called a “solver” or “FEA solver.”
12. FEA solvers have been developed to perform many different types of engineering analyses.
13. FEA solvers are differentiated software products with varying features and capabilities. FEA solvers may be differentiated by, among other characteristics, the types of analyses performed, price level, ease of use, speed, size and complexity of problems that can be analyzed, ability to perform system-type analysis, availability of complementary software, type of output and input file format utilized, and computer platform and operating system on which the solver operates. FEA solvers are also differentiated by their record of reliability.
14. “Nastran” is an FEA solver first developed by the U.S. National Aeronautics and Space Administration (“NASA”) over 30 years ago to perform structural analysis for NASA projects. In developing Nastran, NASA wanted a solver to perform a broad range of structural analyses and have the capacity to be further developed and enhanced. After the initial development of Nastran, NASA released the Nastran

Complaint

source code into the public domain to allow broader use and commercial development. NASA registered “Nastran” as a U.S. trademark in 1976.

15. MSC, UAI and CSAR obtained the public domain version of Nastran from NASA and for many years have developed and further enhanced Nastran for licensing to commercial and government users. Each has used the Nastran trademark with permission from NASA. At the time of Respondent’s acquisitions, the features and capabilities of each of these three advanced versions of Nastran were very similar.
16. The aerospace and automotive industries began using the advanced versions of Nastran in the 1970s for advanced linear structural analysis. Nastran has become the standard linear structural solver in these industries. Certain other manufacturing industries also utilize Nastran for advanced linear structural analysis.
17. Prior to Respondent’s acquisitions, users of the advanced versions of Nastran offered by MSC, UAI, or CSAR could readily switch between these versions without substantial loss of functionality because each version offered very similar features and capabilities. Differences in functionality discourage switching from advanced versions of Nastran to other solvers even in response to a significant and nontransitory increase in price.
18. Prior to Respondent’s acquisitions, users of the advanced versions of Nastran offered by MSC, UAI, or CSAR could readily switch between these versions relatively quickly and without spending significant switching costs and time. The advanced versions of Nastran were all derived from the same Nastran public domain code, offered very similar features and capabilities, and used generally the same input and output file formats. Differences in computer code, features and capabilities, and file formats discourage

Complaint

switching from advanced versions of Nastran to other solvers even in response to a significant and nontransitory increase in price.

19. Industry practices or the requirements of multi-party development projects sometimes dictate the use of advanced versions of Nastran, thereby discouraging substitution away from advanced versions of Nastran even in response to a significant and nontransitory increase in price.
20. Prior to Respondent's acquisitions, competition between MSC, UAI, and CSAR to license or sell advanced versions of Nastran was direct and vigorous and helped to hold down prices and to promote product innovation. Prior to Respondent's acquisitions, users had switched and had considered switching between these advanced versions of Nastran in response to relative changes in price and other competitive variables including product features, capabilities, and enhancements.

RELEVANT PRODUCT MARKETS

21. One relevant product market in which to assess the likely effects of Respondent's acquisitions of UAI and CSAR is the licensing or sale of advanced versions of Nastran.
22. Another relevant product market in which to assess the likely effects of Respondent's acquisitions of UAI and CSAR is the broader market consisting of the licensing or sale of FEA solvers for advanced linear structural analysis.
23. Within each of the relevant product markets, separate markets exist for the licensing or sale of the relevant product for specific industries or customer categories, in particular, the aerospace industry and the automotive industry.

Complaint

RELEVANT GEOGRAPHIC MARKETS

24. The relevant geographic markets in which to assess the likely effects of Respondent's acquisitions of UAI and CSAR are
 - a. the United States; and
 - b. the world.

CONCENTRATION

25. Prior to Respondent's acquisitions, MSC, UAI, and CSAR were the only firms competing in the licensing or sale of advanced versions of Nastran. MSC was the dominant competitor with an estimated market share of 90 percent. The remaining share was roughly split between UAI and CSAR. The market for advanced versions of Nastran prior to the acquisitions was highly concentrated with a Herfindahl-Hirschman Index ("HHI") exceeding 8100. (An HHI of 1800 characterizes a highly concentrated market.) Respondent's acquisitions of UAI and CSAR, together and individually, substantially increased that concentration so that the HHI is now 10,000.
26. Prior to Respondent's acquisitions, there were few suppliers competing in the licensing or sale of FEA solvers for advanced linear structural analysis other than MSC, UAI, and CSAR. Prior to Respondent's acquisitions, the market for FEA solvers for advanced linear structural analysis was highly concentrated. Respondent's acquisitions of UAI and CSAR, together and individually, substantially increased that concentration.

Complaint

CONDITIONS OF ENTRY

27. Entry into licensing or sale of advanced versions of Nastran would not be timely, likely, or sufficient to prevent the anticompetitive effects. Entry is difficult because of the substantial cost and time needed to develop an advanced version of Nastran, validate simulation results, and establish a reputation for reliability.
28. Entry into the licensing or sale of FEA solvers for advanced linear structural analysis would not be timely, likely, or sufficient to prevent the anticompetitive effects. Entry is difficult because of the substantial cost and time needed to develop an FEA solver for advanced linear structural analysis, validate simulation results, and establish a reputation for reliability.

COUNT I

THE ACQUISITIONS VIOLATE CLAYTON ACT § 7 AND FTC ACT § 5

29. Respondent's acquisitions of UAI and CSAR, together and individually, have had or will have the effect of substantially lessening competition and tending to create a monopoly in the relevant markets by, among other things:
 - a. eliminating actual, direct, and substantial competition between MSC, UAI, and CSAR, all of which had the ability and incentive to compete, and before the acquisitions did compete, on price and product development and enhancements;
 - b. creating or enhancing MSC's power to raise prices above a competitive level or to withhold or delay product development and enhancements, thereby adversely affecting price and product innovation; and

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- c. preventing other suppliers of engineering software from acquiring UAI and CSAR and increasing competition.
30. Absent the relief described in the attached Notice of Contemplated Relief, Respondent's acquisitions of UAI and CSAR, together and individually, will continue to cause the effects on competition identified above.
31. The effect of Respondent's acquisitions of UAI and CSAR, together and individually, may be substantially to lessen competition or tend to create a monopoly in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

COUNT II**THE ACQUISITIONS CONSTITUTE UNLAWFUL MONOPOLIZATION IN VIOLATION OF FTC ACT § 5**

32. The allegations contained in Paragraphs 1 through 28 are repeated and realleged as though fully set forth here.
33. Respondent has obtained or enhanced monopoly power in the markets for advanced versions of Nastran through the acquisitions.
34. Respondent acted willfully to acquire or enhance monopoly power in the markets for advanced versions of Nastran through the acquisitions.
35. Through the acquisitions, Respondent has engaged in unfair methods of competition in or affecting commerce by monopolizing the markets for advanced versions of Nastran in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

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COUNT III

**THE ACQUISITIONS CONSTITUTE AN
UNLAWFUL ATTEMPT TO MONOPOLIZE IN
VIOLATION OF FTC ACT § 5**

36. The allegations contained in Paragraphs 1 through 28 are repeated and realleged as though fully set forth here.
37. Respondent has engaged in an anticompetitive course of conduct by willfully seeking to obtain or enhance monopoly power in the markets for advanced versions of Nastran through the acquisitions.
38. Respondent acted with a specific intent to monopolize, and to destroy competition in, the markets for advanced versions of Nastran through the acquisitions.
39. At the time Respondent acquired UAI and CSAR, it had a dangerous probability of success in monopolizing the markets for advanced versions of Nastran.
40. Through the acquisitions, Respondent has engaged in unfair methods of competition in or affecting commerce by attempting to monopolize the markets for advanced versions of Nastran in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

NOTICE

Proceedings on the charges asserted against you in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You may file an answer to this complaint. Any such answer must be filed within 20 days after service of the complaint on you.

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If you contest the complaint's allegations of fact, your answer must concisely state the facts constituting each ground of defense, and must specifically admit, deny, explain, or disclaim knowledge of each fact alleged in the complaint. You will be deemed to have admitted any allegations of the complaint that you do not so answer.

If you elect not to contest the allegations of fact set forth in the complaint, your answer shall state that you admit all of the material allegations to be true. Such an answer will constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the ALJ will file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. Such an answer may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice.

If you do not answer within the specified time, you waive your right to appear and contest the allegations of the complaint. The ALJ is then authorized, without further notice to you, to find that the facts are as alleged in the complaint and to enter an initial decision and a cease and desist order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 14 days after the last answer is filed by any party named as a respondent in the complaint. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

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A hearing on the complaint will begin on January 9, 2002, at 10 a.m., in Room 532, or such other date as determined by the ALJ. At the hearing, you will have the right to contest the allegations of the complaint and to show cause why a cease and desist order should not be entered against you.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the acquisitions of UAI and CSAR violate Section 7 of the Clayton Act, as amended, or Section 5 of the Federal Trade Commission Act, as amended, as alleged in the complaint, the Commission may order such relief as is supported by the record and is necessary and appropriate, including but not limited to:

1. An order to create and divest up to two viable on-going businesses each engaged in the licensing or sale of an advanced version of Nastran in competition with MSC Nastran to up to two acquirers acceptable to the Commission, including but not limited to:
 - a. divesting all software, intellectual property, and other assets for the operation of such businesses, including but not limited to the following for MSC Nastran and all MSC Nastran applications, features, enhancements, and library functions for all operating systems and computer platforms: the source code, object libraries, executable programs, test problems, test results, regression test software, development support software, trade secrets, trademarks, patents, know-how, interfaces with complementary software, APIs, manuals, guides, reports, and other documentation;
 - b. facilitating the acquirers' recruitment of Respondent's employees, including but not limited to providing employee lists, personnel files, opportunities to interview and negotiate with the acquirers, eliminating any restrictions on or disincentives to accepting employment with the

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acquirers, and providing incentives for such employees to accept employment with the acquirers;

- c. providing Respondent's customer lists and account information to the acquirers;
- d. allowing Respondent's customers to terminate or rescind contracts or license agreements and to deal with the acquirers, including but not limited to eliminating any restrictions on or disincentives to terminating or rescinding such contracts or license agreements and otherwise refunding or returning consideration paid in advance pursuant to such contracts or license agreements;
- e. furnishing to the acquirers such personnel, information, technical assistance, advice and training as are necessary;
- f. for a defined period of time, maintaining open architecture for MSC Nastran and all input and output file formats so that users of MSC Nastran would not be impeded or penalized if they switched models, files, or complementary software to the divested versions of Nastran;
- g. for a defined period of time, not restricting, precluding, or influencing a supplier of complementary software or services from dealing with the acquirers or the acquirers' products;
- h. for a defined period of time, supporting fully the divested versions of Nastran with Patran and other MSC complementary software products, without charge to the acquirers and on the same basis as MSC Nastran is supported by Patran and other MSC complementary software products; and
- i. such other or additional relief as is necessary to ensure the creation of up to two viable, competitive, and independent

Complaint

entities offering advanced versions of Nastran with the level of features and capabilities offered by MSC.

2. An order to provide prior notice of any acquisitions of firms engaged in the licensing or sale of advanced versions of Nastran or other solvers for advanced linear structural analysis.
3. Such other or additional relief as is necessary to correct or remedy the violations alleged in the complaint.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this ninth day of October, 2001, issues its complaint against said Respondent.

By the Commission.

Decision and Order

Appendix A

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted for public comment an Agreement Containing Consent Order with MSC.Software Corporation (“MSC”) to resolve matters charged in an Administrative Complaint issued by the Commission on October 9, 2001. The Agreement has been placed on the public record for thirty (30) days for receipt of comments from interested members of the public. The Agreement is for settlement purposes only and does not constitute an admission by MSC that the law has been violated as alleged in the Complaint or that the facts alleged in the Complaint, other than jurisdictional facts, are true.

I. The Commission’s Complaint

The Complaint alleged that Respondent MSC.Software Corporation (“MSC”) unlawfully acquired Universal Analytics, Inc. (“UAI”) and Computerized Structural Analysis and Research Corporation (“CSAR”) in 1999 in violation of Section 7 of the Clayton Act and Section 5 of the FTC Act. The Complaint alleged that the acquisitions may substantially lessen competition or lead to a monopoly in the market for advanced versions of Nastran, a public domain engineering simulation software program. Neither acquisition had been reportable under the Hart-Scott-Rodino reporting thresholds, 15 U.S.C. § 18a.

MSC is the largest supplier of computer-aided engineering simulation software in the world. In 2001, its annual worldwide revenue was \$236 million. MSC has an estimated 1350 employees located around the world. MSC has grown substantially through acquisitions, having acquired six other engineering software vendors or resellers since 1998. MSC is a publicly-traded company.

The Complaint alleged that MSC, UAI, and CSAR had long been vigorous competitors, each offering an advanced version of Nastran to customers in the aerospace, automotive and other industries. These competing versions of advanced Nastran all

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derived from a program originally developed by NASA and placed into the public domain. The common origin of these three advanced Nastran versions made switching between them relatively easy. For these reasons, UAI Nastran and CSAR Nastran were close substitutes for MSC.Nastran. Non-Nastran solvers, however, were more distant substitutes. The Complaint alleged that competition among the three advanced Nastran suppliers helped to hold down prices and to promote product innovation.

The Complaint further alleged that MSC was the dominant supplier of advanced versions of Nastran, with an estimated 90 percent of worldwide Nastran revenue. Prior to MSC's acquisitions, UAI and CSAR were the only other firms offering advanced versions of Nastran. They held substantially smaller market shares. Each had about five percent of worldwide advanced Nastran revenues.

The Complaint alleged that the acquisitions were anticompetitive because they increased the level of concentration in already highly concentrated markets. The Complaint further charged that the acquisitions eliminated competition on price and product development and enhancements, created or enhanced MSC's power to raise prices above a competitive level or to withhold or delay product development and enhancements, and prevented the increased competition that MSC expected if other suppliers of engineering software were to acquire UAI and CSAR. Even if other solvers offering advanced analysis capabilities were included in the market, the markets remain highly concentrated and the acquisitions anticompetitive. The Complaint also alleged that MSC's acquisitions were unlawful in separate markets that exist for specific industries or customer categories. According to the Complaint, the appropriate geographic market in which to analyze MSC's acquisitions is the world, although a U.S. market may also exist.

The Complaint also alleged that MSC's acquisitions constitute unlawful monopolization and an attempt to monopolize in

Analysis

violation of Section 5 of the FTC Act. It further alleged that MSC's dominant market share prior to and after the acquisitions satisfied the showing required for monopoly power and dangerous probability of success. Moreover, the Complaint alleged that MSC acted willfully and with the specific intent to obtain and maintain a monopoly in the market for advanced versions of advanced Nastran when it made the acquisitions.

The Complaint further charged that entry is not likely, nor, if it did occur, would it likely be timely or sufficient to prevent the anticompetitive effects of the acquisitions.

II. Terms of the Proposed Consent Order

The proposed Order would provide relief for the alleged anticompetitive effects of the acquisitions principally by means of a divestiture intended to restore competition. In addition, the proposed Order contains further provisions intended to facilitate the restoration of competition.

Divestiture. The principal relief under the proposed Order is to require the Respondent to divest, within 150 days after entry of the Order and to up to two acquirers to be approved by the Commission, perpetual, worldwide, royalty-free, and non-exclusive licenses to the key intellectual property needed by a new competitor to compete in the sale and licensing of advanced Nastran software. ¶ II.A. The licensed intellectual property rights would consist of the version of MSC.Nastran that is most current as of the date that the Consent Agreement is accepted for public comment by the Commission, as well as all the intellectual property rights acquired by MSC in the two challenged acquisitions. ¶ I.L.1.

The licenses would permit the acquirer (or acquirers) to use the licensed rights to sell advanced Nastran software, sublicense others without restriction, and prepare derivative works so as to further develop and enhance the software without further remuneration to MSC once the divestiture is completed. The

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licenses granted would be non-exclusive, meaning that MSC would continue to retain full rights itself to the licensed intellectual property. ¶ II.A. The basic approach reflected in the settlement, therefore, is to replicate in the hands of the acquirer(s) the crucial intellectual property held by MSC in the aftermath of the challenged acquisitions.

The Order language providing for divestiture to “up to two” acquirers tracks the language of the Notice of Contemplated Relief accompanying the Complaint. It reflects MSC’s removal of two independent competitors from the marketplace through the challenged acquisitions. The language is intended to leave open to the Commission the option of requiring that two competitors be re-established.

Purpose. Paragraph II.C. of the proposed Order contains a recitation of the Commission’s purpose in ordering the divestiture. That provision recites that the purpose of the divestiture is to remedy the lessening of competition alleged in the complaint by establishing one or more viable and effective competitors to MSC engaged in the sale, distribution and licensing of advanced Nastran software for use by customers, including customers in the aerospace and automotive industries, and with the ability to engage in further development and enhancement of advanced Nastran software. It states that, in determining whether the licensing of more than one acquirer may be required, or whether to approve the grant of a license to a particular prospective acquirer, the Commission will consider, among other things, the likely future capability of the prospective acquirer or acquirers to provide effective price and innovation competition to MSC. It also recites that the Commission will consider as well, among other things, any provisions for the hiring by the acquirer(s) of personnel knowledgeable concerning the design, development, maintenance, customer support, sales and marketing of the licensed rights.

The Software To Be Licensed. The intellectual property to be licensed includes all rights relating to the version of MSC.Nastran

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that is most current as of the date the consent agreement is accepted by the Commission for public comment. ¶ I.L.1.a. Divestiture of rights to MSC's current version of MSC Nastran is a necessary remedial measure to facilitate the re-establishment of the competition that MSC allegedly eliminated with its two acquisitions. Such divestiture addresses the switching of former UAI and CSAR customers to MSC's own version of advanced Nastran, including former UAI and CSAR customers who may have adapted their prior procedures and customer-written software routines to the MSC version. In addition, such divestiture addresses the fact that MSC has incorporated new features in its releases of MSC.Nastran, including features taken from the CSAR and UAI versions acquired in 1999, and has not carried on any further development of the UAI and CSAR versions of Nastran following the acquisitions. Divestiture of the acquired assets alone would not restore the competitive conditions that existed before the acquisitions (the *status quo ante*), because the 3-year old UAI and CSAR codes are no longer as commercially viable as they were when MSC acquired them. Licensing of the current version of MSC.Nastran is required to give the acquirer or acquirers what UAI and CSAR formerly had: an up-to-date product upon which to base sales and future development efforts.

In addition to the current version of MSC.Nastran, MSC is also required to license to the acquirer(s) all of the intellectual property acquired in the UAI and CSAR acquisitions. ¶ I.L.1.b. and -.c. This relief is integral to the fundamental approach reflected in the settlement, which is to replicate in the hands of the acquirer(s) the intellectual property held by MSC in the aftermath of the challenged acquisitions. Licensing all the UAI and CSAR computer codes (in addition to MSC.Nastran) is justified to permit an acquirer(s) to offer all the computer codes formerly available from UAI and CSAR, including the ability to select aspects of the UAI Nastran and CSAR Nastran codes for possible inclusion in its future advanced Nastran product that have not been incorporated into MSC.Nastran since the acquisitions.

Analysis

The Order details a broad range of intellectual property rights to be licensed to the acquirer(s). See ¶ I.L.2. In addition to the licensed intellectual property and physical or electronic copies embodying the intellectual property, MSC is also required to divest copies of other materials useful to an acquirer in establishing itself as a competitor to MSC. These include all of the customer files acquired by MSC as a result of the challenged acquisitions, as well as all marketing information, sales training materials, and current (as of the divestiture date) customer lists, customer contact information, and customer support log database contents relating to customers who use MSC.Nastran in the United States. ¶ I.E.2. The latter information should be of particular use by an acquirer that may wish to differentiate itself from MSC by its responsiveness to customer needs. In the past, both UAI and CSAR used such tactics to compete against MSC.

Post-Divestiture Rights. In addition to the licensed rights described above, the Order provides for further rights by the acquirer(s) in the post-divestiture period:

For twelve months after the divestiture date, the acquirer has the right to obtain from MSC ongoing support with respect to MSC.Nastran, in the form of personnel, information, technical assistance, advice and training. This includes reasonable consultation with knowledgeable employees of MSC to ensure that the acquirer's personnel can maintain, develop and support the Licensed Rights in a manner comparable to MSC. This continuing support does not extend to the licensed UAI and CSAR intellectual property, and will be provided at MSC's direct cost. ¶ I.K.4. This continuing support obligation complements the hiring opportunities afforded to the acquirer under other provisions of the Order discussed below.

For not less than three years after the divestiture date, the acquirer has the right to use the trademarks or trade names of the licensed software for the purpose of identifying the acquirer as a licensee from MSC. The acquirer does not otherwise obtain any

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rights of any kind to the name “MSC” or “MSC.Nastran” or related logos and trademarks of MSC. ¶ I.K.4.

Hiring of MSC Personnel. In order to ensure the ability of the acquirer to provide effective competition, the Order contains procedures to facilitate the acquirer’s hiring of valuable MSC personnel. ¶ V. In the aftermath of the acquisitions, MSC was essentially the only employer of computer programmers with thorough knowledge of the proprietary versions of advanced Nastran. The future success of the acquirer in providing ongoing innovation competition in developing advanced Nastran may depend to a significant degree on its hiring of personnel (particularly programmers and customer support engineers) with knowledge of this large and complex body of computer code.

Customer Contracts. Prior to the acquisitions, most of MSC’s advanced Nastran customers purchased the software on an annual lease basis – that is, for one-year terms with annual payments and in quantities determined according to annual needs. In the aftermath of the acquisitions, and especially in the 2001-2002 period, many customers converted annual leases for advanced Nastran to “paid-up” licenses – that is, licenses to use the software for an extended term, generally 25 years, for a larger advance payment and continuing maintenance fees during the contract term. This conversion may disadvantage future advanced Nastran competitors who may no longer have access to these customers at competitive prices.

To address the effect of these conversions on the acquirer’s ability to attract a customer base, the proposed Order provides that, for a period of one year after the divestiture date, any customer who was converted from an annual lease to a paid-up license for MSC.Nastran in the period since the acquisitions has the right to terminate or rescind its license in whole or in part in order to deal with the acquirer. If a customer chooses to do so, MSC is required to refund or return a pro rata portion of the consideration paid in advance for its paid-up MSC.Nastran license. ¶ VII.A. The Order also provides that MSC is to provide

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affected customers with written notice of such rights within fourteen days following the divestiture date. ¶ VII.B.

The formula for such refunds bases the pro-rata allocation on the lesser of four years or the contract term. ¶ VII.A. This refund formula should provide substantial incentive for affected customers to consider switching to the acquirer in whole or in part. Under this formula, customers who converted to a paid-up license since mid-year 2001 and who determine to switch to the acquirer at mid-year 2003 will be entitled to a refund of one-half or more of their advance payment for the paid-up MSC.Nastran license.

Although these provisions authorize refund payments by MSC to some customers, they are neither a penalty nor disgorgement. Their purpose is not to punish MSC or deprive it of ill-gotten gains. Rather, the provisions are in furtherance of the principal divestiture relief provided under the Order. They are intended to remove any penalty or disincentive on customers who had no alternative to MSC's terms after 1999, but who might now consider doing business with the acquirer of the divested assets. Indeed, no payment will be due from MSC to a customer unless and until the customer chooses to do business with the acquirer.

Post-Divestiture Conduct. The Order includes provisions intended to prevent MSC from disadvantaging the acquirer in its post-divestiture dealings with customers or suppliers.

Advanced Nastran software is used in conjunction with other complementary software. Complementary software includes programs known as "pre- and post-processors" or "meshers" that are used to process input to or output from advanced Nastran and make it useful with other computer data, such as designs produced by CAD software. Complementary software of this sort is produced by various suppliers and by MSC itself. The Order requires MSC, for three years after the divestiture date, to maintain the interoperability of the current and any future versions of MSC's complementary software (including but not limited to

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its product MSC.Patran) with the licensed software (¶ VIII.A.); and prohibits MSC from influencing a supplier of complementary software or services to refuse to deal with the acquirer or stop supporting interoperability with any of the licensed software (¶ VIII.B.).

During the same three-year period, MSC is required to maintain all current input and output file formats for MSC.Nastran. This is to ensure that users of MSC.Nastran would not be impeded or penalized in their use of models, files, or complementary software if they switched to the version of advanced Nastran offered by the acquirer. ¶ VIII.C. The Order also requires that MSC not refuse to deal with any customer or prospective customer for the reason, in whole or in part, that such customer or prospective customer deals with the acquirer. ¶ VIII.D. The latter provision is intended to prevent MSC from inhibiting the pre-acquisition practice of many customers to maintain simultaneous licenses for more than one source of advanced Nastran software.

Prior Notice of Future Acquisitions. For a period of ten years, the Order requires MSC to provide prior notice of future acquisitions of any entity engaged in the development or sales of any version of Nastran. ¶ IX. This provision is warranted under existing Commission policy because of the risk that MSC may in the future carry out anticompetitive acquisitions that otherwise would not come to the attention of the Commission because the transactions are likely to fall below the Hart-Scott-Rodino reporting thresholds. See Statement of FTC Policy Concerning Prior Approval and Prior Notice Provisions (June 21, 1995).

Monitor, Trustee and Reporting. The proposed Order contains standard monitor and trustee provisions. The Monitor provisions, set out in Paragraph III, authorize appointment of a person to oversee MSC's compliance with the terms of the Order. Such a monitor is warranted in light of the technical nature of the products at issue and the potential complexity of some compliance issues, including employee hiring and customer refunds. The

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trustee provisions, set out in Paragraph IV, contemplate appointment of a trustee to complete the required divestiture if MSC does not do so within the 150 days specified in the Order. Under these provisions, the Commission will appoint a trustee who will undertake to accomplish the required divestiture at no minimum price. The trustee will have one year to complete the divestiture. Finally, the proposed Order contains provisions for MSC to file regular reports concerning its compliance with the Order terms. ¶ X.

III. Opportunity for Public Comment

The Proposed Order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Agreement and comments received, and will decide whether it should withdraw from the Agreement or make final the Order contained in the Agreement.

By accepting the Proposed Order subject to final approval, the Commission anticipates that the competitive issues described in the Complaint will be resolved. The purpose of this analysis is to invite and facilitate public comment concerning the Proposed Order. It is not intended to constitute an official interpretation of the Agreement and Proposed Order or to modify their terms in any way.

Statement

Statement of Commissioner Mozelle W. Thompson

The Commission has made final a consent agreement to resolve the Commission's administrative complaint against MSC.Software. I voted to accept the agreement; however, I am concerned that industry and the private bar do not mistakenly make too much of the fact that the Commission did not require an up-front buyer for this licensing divestiture.

As a general rule, the Commission is more likely to require that parties present up-front buyers for assets when divesting less than an ongoing business. In this unique case, however, the Commission decided to resolve its concerns about MSC.Software's two consummated acquisitions by accepting an order requiring a prompt divestiture to restore lost competition, instead of potentially delaying relief further by first forcing MSC.Software to negotiate an asset sale to a potential buyer. The Commission makes such remedial assessments on a case-by-case basis, and such assessments would likely vary between relief proscribed for consummated mergers and relief for mergers prior to their consummation under Hart-Scott-Rodino reviews – the vast majority of Commission merger work. I am comfortable with the remedial action in this particular instance because the Commission has fully vetted the divestiture package's market acceptability with industry incumbents. Thus, I am fully confident that the asset package will function successfully in the marketplace and facilitate viable competition.

Complaint

IN THE MATTER OF

**AMERICAN INSTITUTE FOR CONSERVATION OF
HISTORIC AND ARTISTIC WORKS**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4065; File No. 0110244

Complaint, October 30, 2002--Decision, October 30, 2002

This consent order addresses practices used by Respondent American Institute for Conservation of Historic and Artistic Works (“AIC”), an association of professional conservators – who manage, care for, preserve, or treat cultural objects, including artistic, historical, archeological, scientific, and religious objects – with approximately 3,100 members, many of whom provide professional services for a fee or who are employed by organizations that provide such services for a fee. The order, among other things, prohibits the respondent from maintaining or enforcing any policy, ethical rule, interpretation, commentary or guideline that impedes or restricts price competition among conservation professionals, including the provision of free or discounted services. The order also requires the respondent to remove the provisions that are inconsistent with the order from the *AIC Code of Ethics*, from the *Guidelines for Practice of the AIC*, from the *Commentaries to the Guidelines*; and from the respondent’s Web site, and to publish the revisions of these documents in those places. In addition, the order requires the respondent to publish a copy of the order and complaint in the *AIC News* and on its Web site.

Participants

For the Commission: *L. Barry Costilo, Richard B. Dagen, Joseph Eckhaus, Roberta S. Baruch, Russell Porter, Louis Silvia, and Mary T. Coleman.*

For the Respondent: *Barbara Ryland, Crowell & Moring.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that the American Institute for

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Conservation of Historic and Artistic Works (“Respondent” or “AIC”), a corporation, has violated and is violating the provisions of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges as follows:

PARAGRAPH ONE: Respondent American Institute for the Conservation of Historic and Artistic Works, is a corporation organized and existing under the laws of the District of Columbia with its principal office and place of business at 1717 K Street, N.W., Suite 200, Washington, DC 20006.

PARAGRAPH TWO: Respondent is a professional association organized for the purpose, among others, of serving the interests of its conservation professional members. AIC has approximately 3,100 members. A conservation professional manages, cares for, preserves, or treats cultural objects, including artistic, historical, archeological, scientific, and religious objects. The conservation professional may determine the condition, the need for treatment or restoration, and the appropriate method for preservation of such objects, and perform the required work to minimize deterioration or to restore such objects to their original state.

PARAGRAPH THREE: The general business practices of Respondent and its members, including the acts and practices herein alleged, are in or affecting “commerce” as defined in the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

PARAGRAPH FOUR: Respondent engages in substantial activities for the economic benefit of its members. At all times relevant to this Complaint, Respondent is and has been organized in substantial part for the profit of its members, and is therefore a corporation within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

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PARAGRAPH FIVE: Many of Respondent's members provide conservation professional services for a fee or are employed by conservation related organizations that provide conservation professional services for a fee. Except to the extent that competition has been restrained as herein alleged, many of AIC's members have been and are now in competition among themselves and with other conservation professionals.

PARAGRAPH SIX: Respondent acting as a combination of its members, and in agreement with at least some of its members, has acted to restrain price competition among conservation professionals by restricting its members from offering conservation professional services at discounted fees or for free.

PARAGRAPH SEVEN: In furtherance of the combination and agreement alleged in Paragraph Six, Respondent has adopted and maintained provisions in its *Commentaries to the Guidelines for Practice of the AIC* that state "the consistent undercutting of local or regional market rates should be understood to be an unprofessional practice" and further state "when damage to the cultural property is imminent, and funding is limited, a conservation professional may work at reduced fees or pro bono."

PARAGRAPH EIGHT: The purpose, effects, tendency, or capacity of the combination, agreement, and acts or practices described in Paragraphs Six and Seven, have been and are to restrain competition unreasonably and to injure consumers by:

- A. discouraging and restricting price competition among conservation professionals; and
- B. depriving consumers and other users of conservation services of the benefit of free and open competition among conservation professionals.

Complaint

PARAGRAPH NINE: The combination, agreement, and acts or practices described above constitute unfair methods of competition and unfair acts and practices in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such combination, agreement, and acts or practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirtieth day of October, 2002, issues its Complaint against AIC.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of the American Institute for Conservation of Historic and Artistic Works (“AIC”), hereinafter sometimes referred to as “Respondent,” and Respondent having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of the Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to § 2.34 of its Rules, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

Decision and Order

1. Respondent American Institute for the Conservation of Historic and Artistic Works, is a corporation organized and existing under the laws of the District of Columbia with its principal office and place of business at 1717 K Street, N.W., Suite 200, Washington, DC 20006.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED, that for the purposes of this Order, the following definitions shall apply:

- A. "Respondent" or "AIC" means the American Institute for Conservation of Historic and Artistic Works, its officers, executive board, specialty groups, committees, task forces, representatives, agents, employees, successors and assigns;
- B. "Conservation Professional" means one who manages, cares for, preserves, or treats cultural objects, including artistic, historical, archeological, scientific, and religious objects. The conservation professional may determine the condition, the need for treatment or restoration, and the appropriate method for preservation of such objects, and perform the required work to minimize deterioration or to restore such objects to their original state; and
- C. "Regulating" means (1) adopting, maintaining or enforcing any rule, regulation, interpretation, ethical ruling, policy, commentary, or guideline; (2) taking or threatening to take formal or informal disciplinary action; or (3) conducting formal or informal investigations or inquiries.

Decision and Order

II.

IT IS FURTHER ORDERED that Respondent, directly or indirectly, or through any corporate or other device, in or in connection with Respondent's activities as a professional association in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, do forthwith cease and desist from: Regulating, restricting, impeding, declaring unethical or unprofessional, interfering with or advising against price competition among Conservation Professionals, including, but not limited to, the provision of free or discounted services.

III.

IT IS FURTHER ORDERED that Respondent shall:

- A. Within ninety (90) days after the date on which this Order becomes final, remove from *AIC's Code of Ethics, Guidelines for Practice of the AIC, and Commentaries to the Guidelines for Practice of the AIC*, and from the AIC constitution and bylaws and any other existing AIC policy statement, commentary or guideline, including, but not limited to, those appearing on the AIC website, any provision, interpretation, policy statement, commentary or guideline which is inconsistent with Paragraph II of this Order and publish in the *AIC News* or in any successor publications, and on AIC's website, the revised versions of such documents. Following entry of the final Order, AIC shall also publish the revised version of such documents as early as feasible in the *AIC Directory*, but in no event later than twelve (12) months after the Order becomes final.
- B. Within one hundred twenty (120) days after the date on which this Order becomes final, publish a copy of this Order and the Complaint in the *AIC News* with such prominence as feature articles that are regularly published in the *AIC News*.

Decision and Order

- C. Within sixty (60) days after the date on which this Order becomes final, publish and retain for at least one (1) year a copy of this Order and Complaint on the AIC website. The Order and Complaint, and the revised versions of the documents described in Paragraph III (A) of this Order, should be accessible with a link placed in a prominent position on the website's homepage, which should read "AIC changes its *Commentaries to the AIC Code of Ethics and Guidelines for Practice*."

IV.

IT IS FURTHER ORDERED that Respondent shall file written reports within sixty (60) days after the date on which this Order became final, every sixty (60) days thereafter until the requirements set forth in this Order have been met, and annually thereafter for four (4) years on the anniversary of the date on which this Order became final, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which it has complied and is complying with the Order. Such reports should include in detail, but not be limited to, any action taken in connection with the activities covered by Paragraph II.

V.

IT IS FURTHER ORDERED that for a period of five (5) years after the date this Order is entered, Respondent shall maintain and make available to the Commission staff for inspection and copying upon reasonable notice, records adequate to describe in detail any action taken in connection with the activities covered by Paragraph II of this Order.

VI.

IT IS FURTHER ORDERED that, Respondent shall notify the Commission at least thirty (30) days prior to any proposed

Decision and Order

change in the Respondent, such as dissolution, assignment, sale resulting in the emergence of a successor corporation or association, the creation or dissolution of subsidiaries, or any other change in Respondent that may affect compliance obligations arising out of this Order.

VII.

IT IS FURTHER ORDERED that this Order shall terminate on October 30, 2022.

By the Commission.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from the American Institute for Conservation of Historic and Artistic Works (“AIC”). AIC has its principal place of business in Washington, DC .

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and decide whether it should withdraw from the agreement or make final the agreement's proposed order.

AIC is an association of professional conservators. The complaint alleges that AIC engages in substantial activities for the economic benefit of its members. The complaint alleges that AIC has approximately 3,100 members, many of whom provide professional services for a fee or who are employed by organizations that provide such services for a fee.

A conservation professional is a person who manages, cares for, preserves, or treats cultural objects, including artistic, historical, archeological, scientific, and religious objects. The conservation professional may determine the condition, the need for treatment or restoration, and the appropriate method for preservation of such objects, and perform the required work to minimize deterioration or to restore such objects to their original state.

The complaint charges that AIC has violated Section 5 of the Federal Trade Commission Act by acting as a combination of its members and in agreement with some of its members to restrain price competition among conservation professionals. The complaint alleges that in furtherance of the combination and agreement AIC has adopted and maintained *Commentaries to the Guidelines for Practice of the AIC* that state that “the consistent

Analysis

undercutting of local or regional market rates should be understood to be unprofessional behavior." They further state that "when damage to the cultural property is imminent, and funding is limited, a conservation professional may work at reduced fees or pro bono." Read together, these provisions mean that only in these limited circumstances can a conservator work for free or at reduced fees without being considered to be engaging in "unprofessional behavior."

The complaint alleges that the above acts and practices constitute unfair methods of competition which have restrained competition unreasonably. It further alleges that the effects of the acts and practices are to discourage and restrict price competition among conservation professionals and to deprive consumers and users of conservation services of the benefit of free and open competition.

AIC has signed a consent agreement containing the proposed consent order. The proposed consent order would prohibit AIC from maintaining or enforcing any policy, ethical rule, interpretation, commentary or guideline that impedes or restricts price competition among conservation professionals, including provision of free or discounted services.

To ensure and monitor compliance, the consent order provides, among other things, that within 90 days after the order becomes final AIC shall remove the provisions that are inconsistent with the order from *AIC's Code of Ethics, Guidelines for Practice of the AIC, Commentaries to the Guidelines* and AIC's website, and publish the revisions of these documents in such places. In addition, the order requires AIC to publish a copy of the order and complaint in the *AIC News*. It further provides that the order and complaint shall be published on the AIC web site, with a link placed in a prominent position on the web site's home page. The proposed consent order also contains other provisions to monitor compliance.

Analysis

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreements and proposed orders or to modify in any way their terms.

Complaint

IN THE MATTER OF

SHELL OIL COMPANY, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT

*Docket C-4059; File No. 0210123
Complaint, September 27, 2002--Decision, November 18, 2002*

This consent order addresses the acquisition by the Royal Dutch/Shell Group of Companies, through Respondent Shell Oil Company – engaged in almost all aspects of the energy business, including exploration, production, refining, transportation, distribution, and marketing – of Respondent Pennzoil-Quaker State Company, which manufactures and markets products such as lubricants, branded and unbranded motor oils, base oil, and other automotive and specialty industrial products. The order, among other things, requires the respondents to divest Pennzoil’s 50 percent interest in Excel Paralubes – a joint venture with Conoco Inc. that produces paraffinic base oil, the principal component of finished lubricants used for passenger car motor oil, heavy duty engine oil, automatic transmission fluid, and other lubricant products – to an acquirer approved by the Commission. The order also prohibits the respondents from divesting the Pennzoil Excel Paralubes interest to Conoco. In addition, the order requires the respondents to freeze at approximately current levels Pennzoil’s right to obtain certain base oil supply under a contract with ExxonMobil, and – at the option of the acquirer of the Excel Paralubes interest, and as approved by the Commission – to purchase Group II base oil from the acquirer for up to one year. An accompanying Order to Hold Separate requires the respondents to hold separate and maintain the assets to be divested, pending their divestiture.

Participants

For the Commission: *Dennis F. Johnson, Marc W. Schneider, Barbara K. Shapiro, Patricia V. Galvan, Geary Gessler, Mohsin Syed, Phillip L. Broyles, Eric D. Rohlck, Elizabeth A. Piotrowski, Daniel P. Ducore, Jeffrey Fischer and Mary T. Coleman.*

For the Respondents: *Steve Newborn and Laura Wilkinson, Clifford Chance Rogers & Wells, and Rufus Oliver, Baker Botts.*

Complaint

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission (“FTC” or “Commission”), having reason to believe that Respondent Shell Oil Company (“Shell”) and Respondent Pennzoil-Quaker State Company (“Pennzoil”) have entered into an agreement and plan of merger whereby Shell proposes to acquire all of the outstanding common stock of Pennzoil and to merge with Pennzoil, that such agreement and plan of merger violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

I. RESPONDENTS

Shell Oil Company

1. Respondent Shell is a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at One Shell Plaza, Houston, Texas 77002.
2. Respondent Shell is, and at all times relevant herein has been, a diversified energy company engaged, either directly or through affiliates, in the business of manufacturing, refining, distributing, transporting, and marketing petroleum products, including gasoline, diesel fuel, jet fuel, base oil, motor oil, lubricants, petrochemicals, and other petroleum products. Shell’s affiliates include Equilon Enterprises LLC, which is 100 percent owned by Shell, and Motiva Enterprises LLC, which is 50 percent owned by Shell and 50 percent owned by Saudi Refining Inc.

Complaint

3. Respondent Shell is, and at all times relevant herein has been, engaged in commerce as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affecting commerce as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

Pennzoil-Quaker State Company

4. Respondent Pennzoil is a corporation organized, existing and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at Pennzoil Place, Houston, Texas 77252.
5. Respondent Pennzoil is, and at all times relevant herein has been, engaged, either directly or through affiliates, in the business of manufacturing, refining, distributing and marketing branded and unbranded motor oil, transmission fluid, lubricants, greases, base oil, automotive polishes, automotive chemical products, car care products, and specialty industrial products. Pennzoil’s affiliates include Excel Paralubes, a joint venture that is 50 percent owned by Pennzoil and 50 percent owned by Conoco Inc.
6. Respondent Pennzoil is, and at all times relevant herein has been, engaged in commerce as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affecting commerce as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED MERGER

7. Pursuant to an agreement and plan of merger dated March 25, 2002, Shell intends to acquire all of the outstanding voting securities of Pennzoil and to merge Pennzoil with a wholly-owned subsidiary of Shell.

Complaint

III. TRADE AND COMMERCE

A. Relevant Product Market

8. Paraffinic base oil is a refined petroleum product that is the principal component, or “basestock,” of finished lubricant products used for a variety of applications, including passenger car motor oil, heavy duty engine oil, automatic transmission fluid, and other lubricants.
9. Paraffinic base oil is divided by the American Petroleum Institute into three groups (Groups I, II and III) based on differences in sulfur content, saturates level, and viscosity index. Group II paraffinic base oil has less than 0.03% sulfur by weight, more than 90% saturates by weight, and a viscosity index ranging from 80 to 120. Motor oil blenders need Group II paraffinic base oil in order to meet the performance standards necessary for many of today's lubricants. Group II paraffinic base oil will also be necessary for the production of other lubricants as new performance standards are adopted. If the price of Group II paraffinic base oil were to increase by 5-10%, blenders of motor oil and other lubricants would not substitute to other products in sufficient volume to make the price increase unprofitable.
10. A relevant line of commerce (*i.e.*, product market) in which to analyze the effects of the proposed merger is the refining and marketing of Group II paraffinic base oil.

B. Relevant Geographic Market

11. A relevant section of the country (*i.e.*, geographic market) in which to analyze the proposed merger is the United States and Canada, where the merger would reduce competition in the refining and marketing of Group II paraffinic base oil. If the price of Group II paraffinic base oil in the United States and Canada were to increase by 5-10%, blenders of motor oil and other lubricants would not switch to sources of

Complaint

supply outside that area in sufficient volume to make the price increase unprofitable.

C. Market Structure

12. Through its ownership interests in Motiva Enterprises LLC and Equilon Enterprises LLC, Shell is engaged in the refining and marketing of Group II paraffinic base oil. Through its ownership interest in Excel Paralubes, Pennzoil also is engaged in the refining and marketing of Group II paraffinic base oil. Pennzoil also has a long-term contract with Exxon Mobil Corporation that gives Pennzoil control over additional supplies of Group II base oil that could potentially increase in volume if Exxon Mobil increases Group II production at its Gulf Coast refineries.
13. The refining and marketing of Group II paraffinic base oil in the United States and Canada would be highly concentrated as a result of the proposed merger. Following the merger, Shell would control more than 39% of Group II refining capacity in the United States and Canada. Market concentration, as measured by the Herfindahl-Hirschmann Index, would increase by more than 700 points to a level in excess of 2,300.

D. Entry Conditions

14. Entry into the relevant market in the relevant section of the country is difficult and would not be timely, likely or sufficient to prevent the anticompetitive effects that are likely to result from the proposed merger. Constructing a new refinery or converting an existing Group I refinery to produce Group II base oil is capital intensive, is subject to significant regulatory constraints, and would require several years to accomplish. As a result, new entry would not be able to prevent a 5-10% increase in the price of Group II paraffinic base oil.

Complaint

IV. VIOLATIONS CHARGED

15. Shell and Pennzoil are actual and potential competitors in the refining and marketing of Group II paraffinic base oil in the United States and Canada.
16. The effect of the proposed merger, if consummated, may be substantially to lessen competition in the refining and marketing of Group II paraffinic base oil in the United States and Canada in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, in the following ways, among others:
 - a. by eliminating direct competition between Shell and Pennzoil in the refining and marketing of Group II paraffinic base oil;
 - b. by increasing the likelihood that the combined Shell/Pennzoil will unilaterally exercise market power; and
 - c. by increasing the likelihood of, or facilitating, collusion or coordinated interaction between the combined Shell/Pennzoil and other competitors in the refining and marketing of Group II paraffinic base oil;

each of which increases the likelihood that the price of Group II paraffinic base oil will increase in the United States and Canada.

V. STATUTES VIOLATED

17. The proposed merger between Shell and Pennzoil violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and would, if consummated, violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

Complaint

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-seventh day of September, 2002, issues its complaint against said Respondents.

By the Commission.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed merger involving Respondent Shell Oil Company and Respondent Pennzoil-Quaker State Company, hereinafter referred to as “Respondents,” and Respondents having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts as set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that the Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Hold Separate and Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the

Decision and Order

Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Shell Oil Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at One Shell Plaza, Houston, Texas 77002.
2. Respondent Pennzoil-Quaker State Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at Pennzoil Place, Houston, Texas 77252.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

I.

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Atlas” means Atlas Processing Company, its officers, directors, employees, agents and representatives, successors, and assigns; its joint ventures, including, but not limited to, the Pennzoil Excel Paralubes Interest, subsidiaries, divisions, groups and affiliates controlled by Atlas; and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- B. “Pennzoil” means Pennzoil-Quaker State Company, its officers, directors, employees, agents and representatives, successors, and assigns; its joint ventures, subsidiaries (including, but not limited to, Atlas), divisions, groups and affiliates controlled by Pennzoil; and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.

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- C. “Royal Dutch Petroleum” means the Royal Dutch Petroleum Company, its officers, directors, employees, agents and representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Royal Dutch Petroleum; and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- D. “Shell” means Shell Oil Company, its officers, directors, employees, agents and representatives, successors, and assigns; its parents (including, but not limited to, Royal Dutch Petroleum), joint ventures, subsidiaries, divisions, groups and affiliates controlled by Shell (including, but not limited to, Shell ND Company); and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- E. “Respondents” means Shell and Pennzoil, individually and collectively, and the Person resulting from the Merger.
- F. “Acquirer” means the Person who acquires pursuant to Paragraph II or IV of this Order.
- G. “Base Oil” means paraffinic-based lubricant stock of all types, grades, viscosities, and qualities suitable for blending into finished oils (*e.g.*, passenger car motor oil, heavy duty engine oil, automatic transmission fluid, hydraulic fluids, or gear oils).
- H. “Commission” means the Federal Trade Commission.
- I. “Conoco” means Conoco Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 600 North Dairy Ashford, Houston, TX 77079, its officers, directors, employees, agents and representatives, successors, and assigns; its parents, joint

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ventures, subsidiaries, divisions, groups and affiliates controlled by Conoco, and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.

- J. “Effective Date of Divestiture” means the date on which the applicable divestiture is consummated.
- K. “Excel Paralubes” means the joint venture formed by agreement dated August 2, 1994, between Atlas and Conoco, which produces Base Oil at a facility in Westlake, LA, and which is operated by Conoco.
- L. “Existing Customer Supply Agreements” means all agreements in effect as of the date Respondents execute the Consent Agreement, between Pennzoil and/or Atlas and any Person other than Pennzoil or Atlas for Base Oil produced by Excel Paralubes.
- M. “ExxonMobil/Pennzoil Base Oil Agreement” means the base oil supply agreement dated as of May 4, 2000, between Pennzoil and Exxon Mobil Corporation, and any amendments or successors to such agreement.
- N. “Group II Base Oil” means Base Oil that meets the necessary sulfur, saturates and viscosity index standards for Group II Base Oil established by the American Petroleum Institute, specifically (1) less than 0.03% sulfur by weight, (2) greater than 90% saturates by weight, and (3) viscosity index 80 - 120.
- O. “Merger” means the acquisition of Pennzoil by Shell through the proposed merger of Shell ND Company and Pennzoil as described in the Agreement and Plan of Merger dated as of March 25, 2002, by and among Shell Oil Company, Shell ND Company, and Pennzoil-Quaker State Company.

Decision and Order

- P. “Pennzoil Excel Paralubes Interest” means all of Pennzoil’s and Atlas’s interests in Excel Paralubes, including their partnership interest and all assets, rights, and agreements related thereto, including, but not limited to:
1. All of Pennzoil’s and Atlas’s rights under all contracts and agreements between Pennzoil or Atlas and Excel Paralubes, including, but not limited to, the May 12, 1995, “Lubricating Base Oil Sale and Purchase Agreement between Excel Paralubes and Atlas Processing Company,” and amendments thereto;
 2. All of Pennzoil’s and Atlas’s rights under all contracts and agreements between Pennzoil or Atlas and Conoco relating to Excel Paralubes; and
 3. All Existing Customer Supply Agreements.
- Q. “Person” means any individual, partnership, firm, trust, association, corporation, joint venture, unincorporated organization, or other business or governmental entity.

II.

IT IS FURTHER ORDERED that:

- A. Respondents shall divest, within twelve (12) months after the date Respondents execute the Agreement Containing Consent Orders, the Pennzoil Excel Paralubes Interest to an Acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission, absolutely and in good faith and at no minimum price.
- B. Respondents shall negotiate in good faith with the Acquirer, at Acquirer’s option, an agreement not exceeding one (1) year in length, with no renewal or evergreen rights, for Respondents to purchase from the Acquirer Group II Base

Decision and Order

Oil. Such agreement shall be subject to the prior approval of the Commission.

- C. Respondents shall not, prior to the Effective Date of Divestiture, enter into any agreement or understanding with the Acquirer for Respondents to purchase Group II Base Oil, other than an agreement as provided in Paragraph II.B. of this Order. *Provided, however,* Respondents shall give the Commission ten (10) days prior notice of the implementation of any subsequent agreement between the Acquirer and Respondents for the Respondents to purchase from the Acquirer Group II Base Oil.
- D. Respondents shall not divest the Pennzoil Excel Paralubes Interest to Conoco, and shall take all actions necessary to enforce the Letter Agreement dated August 30, 2002 between Shell and Conoco relating to Excel Paralubes.
- E. The purpose of this Paragraph is to ensure that the Acquirer is a viable independent competitor in the refining, supplying, marketing, and selling of Group II Base Oil produced by Excel Paralubes, without interruption, in the same way in which Pennzoil was engaged at the time of the announcement of the Merger, to ensure that the Acquirer has the option to enter into an agreement to supply Respondents with Group II Base Oil on competitive terms, and to remedy the lessening of competition in Group II Base Oil resulting from the proposed Merger as alleged in the Commission's Complaint.

III.**IT IS FURTHER ORDERED** that:

- A. Respondents shall not submit any proposed annual volume forecast under paragraph 2(c) of the ExxonMobil/Pennzoil Base Oil Agreement that proposes or forecasts a request or

Decision and Order

lifting schedule for Group II Base Oil that exceeds 1,500 barrels per day; and

- B. Respondents shall not acquire, exercise any option to acquire, or attempt to acquire, directly or indirectly, Group II Base Oil in excess of 1,500 barrels per day pursuant to the ExxonMobil/Pennzoil Base Oil Agreement.
- C. The purpose of this Paragraph is to ensure that Respondents do not increase their share of the market for Group II Base Oil through additional supply of more than 1,500 barrels per day under the ExxonMobil/Pennzoil Base Oil Agreement, and to remedy the lessening of competition in Group II Base Oil resulting from the proposed Merger as alleged in the Commission's Complaint.

IV.

IT IS FURTHER ORDERED that:

- A. If Respondents have not, within the time period required by Paragraph II.A. of this Order, fully complied with the obligations specified in Paragraph II of this Order, the Commission may appoint a Trustee to effectuate the divestiture of the Pennzoil Excel Paralubes Interest consistent with the purpose stated in Paragraph II.E.
- B. In the event that the Commission or the United States Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Trustee in such action. Neither the appointment of a Trustee nor a decision not to appoint a Trustee under this Paragraph shall preclude the Commission or the United States Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute

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enforced by the Commission, for any failure by Respondents to comply with this Order.

- C. If a Trustee is appointed by the Commission or a court pursuant to Paragraph IV.A. or IV.B. of this Order, Respondents shall consent to the following terms and conditions regarding the Trustee's powers, duties, authority, and responsibilities:
 1. The Commission shall select that Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Trustee, Respondents shall be deemed to have consented to the selection of the proposed Trustee.
 2. Subject to the prior approval of the Commission, the Trustee shall have the exclusive power and authority to divest Pennzoil Excel Paralubes Interest as required by this Order.
 3. Within ten (10) days after appointment of the trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed Trustee, of the court, transfers to the Trustee all rights and powers necessary to permit the Trustee to effect the divestiture required by this Order.
 4. The Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in Paragraph IV.C.3. to accomplish the divestiture, which shall be subject to prior approval of the Commission. If, however, at the end of the twelve-month period, the

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Trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed Trustee, by the court; *provided, however,* the Commission may extend the divestiture period only two (2) times.

5. Subject to any demonstrated legally recognized privilege, the Trustee shall have full and complete access to the personnel, books, records and facilities related to Atlas and Excel Paralubes (except Conoco's confidential information that would not have been available to Respondents) or to any other relevant information as the Trustee may request. Respondents shall develop such financial or other information as the Trustee may request and shall cooperate with the trustee. Respondents shall take no action to interfere with or impede the Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Trustee, by the court.
6. The Trustee shall use his or her best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however,* if the Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission, *provided, further, however,* that Respondents shall select such entity within five (5)

Decision and Order

business days of receiving notification of the Commission's approval.

7. The Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as necessary to carry out the Trustee's duties and responsibilities. The Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Trustee, by the court, of the account of the Trustee, including fees for his or her services, all remaining monies shall be paid at the direction of the Respondents, and the Trustee's power shall be terminated. The Trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the Trustee's divesting the assets to be divested.
8. Respondents shall indemnify the Trustee and hold the Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Trustee.
9. If the Trustee ceases to act or fails to act diligently, a substitute Trustee shall be appointed in the same manner as provided in Paragraph IV.C. of this Order.

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10. The Commission or, in the case of a court-appointed Trustee, the court may on its own initiative or at the request of the Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.
11. The Trustee shall have no obligation or authority to operate or maintain the assets required to be divested by this Order.
12. The Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Trustee's efforts to accomplish the divestiture.
13. Respondents may require the Trustee to sign a customary confidentiality agreement; *provided, however,* such agreement shall not restrict the trustee from providing any information to the Commission.

V.

IT IS FURTHER ORDERED that:

- A. Within thirty (30) days after the date this Order becomes final, and every thirty (30) days thereafter until Respondents have fully complied with Paragraphs II and IV of this Order, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they have complied, are complying, and will comply with this Order. Respondents shall include in their compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with the Order, including a description of all substantive contacts or negotiations for the divestiture and the identity of all parties contacted. Respondents shall include in their compliance reports copies of all written communications

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to and from such parties, all internal memoranda, and all reports and recommendations concerning divestiture.

- B. One (1) year from the date this Order becomes final, annually for the next nine (9) years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which they have complied and are complying with Paragraphs II, III, IV, and VI of this Order.

VI.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in either corporate Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of the Order.

VII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities, and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents relating to any matters contained in this Order; and

Decision and Order

- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding any such matters.

VIII.

IT IS FURTHER ORDERED that this Order shall terminate on November 18, 2012.

By the Commission.

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ORDER TO HOLD SEPARATE AND MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed merger involving Respondent Shell Oil Company and Respondent Pennzoil-Quaker State Company, hereinafter referred to as “Respondents,” and Respondents having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts as set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that the Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues this Order to Hold Separate and Maintain Assets (“Hold Separate Order”).

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1. Respondent Shell Oil Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at One Shell Plaza, Houston, Texas 77002.
2. Respondent Pennzoil-Quaker State Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at Pennzoil Place, Houston, Texas 77252.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

I.

IT IS ORDERED that, as used in this Hold Separate Order, the following definitions shall apply:

- A. “Atlas” means Atlas Processing Company, its officers, directors, employees, agents and representatives, predecessors, successors, and assigns; its joint ventures, (including, but not limited to, the Pennzoil Excel Paralubes Interest), subsidiaries, divisions, groups and affiliates controlled by Atlas; and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- B. “Pennzoil” means Pennzoil-Quaker State Company, its officers, directors, employees, agents and representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries (including, but not limited to, Atlas), divisions, groups and affiliates controlled by Pennzoil; and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.

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- C. “Royal Dutch Petroleum” means the Royal Dutch Petroleum Company, its officers, directors, employees, agents and representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Royal Dutch Petroleum; and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- D. “Shell” means Shell Oil Company, its officers, directors, employees, agents and representatives, predecessors, successors, and assigns; its parents (including, but not limited to, Royal Dutch Petroleum Company), joint ventures, subsidiaries, divisions, groups and affiliates controlled by Shell (including, but not limited to, Shell ND Company); and the respective officers, directors, employees, agents, representatives, successors, and assigns of each.
- E. “Respondents” means Shell and Pennzoil, individually and collectively, and the Person resulting from the Merger.
- F. “Base Oil” means paraffinic-based lubricant stock of all types, grades, viscosities, and qualities suitable for blending into finished oils (*e.g.* passenger car motor oil, heavy duty engine oil, automatic transmission fluid, hydraulic fluids, or gear oils).
- G. “Commission” means the Federal Trade Commission.
- H. “Conoco” means Conoco Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 600 North Dairy Ashford, Houston, TX 77079, its officers, directors, employees, agents and representatives, successors, and assigns; its parents, joint ventures, subsidiaries, divisions, groups and affiliates controlled by Conoco, and the respective officers,

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directors, employees, agents, representatives, successors, and assigns of each.

- I. “Effective Date of Divestiture” means the date on which the applicable divestiture is consummated.
- J. “Excel Paralubes” means the joint venture formed by agreement dated August 2, 1994, between Atlas and Conoco, which produces Base Oil at a facility located in Westlake, LA, and which is operated by Conoco.
- K. “Existing Customer Supply Agreements” means all agreements in effect as of the date Respondents execute the Consent Agreement, between Pennzoil and/or Atlas and any Person other than Pennzoil or Atlas for Base Oil produced by Excel Paralubes.
- L. “Held Separate Joint Venture Interest” means the Pennzoil Excel Paralubes Interest and the Joint Venture Interest Employees.
- M. “Hold Separate Period” means the time period during which the Hold Separate Order is in effect, which shall begin no later than ten (10) days after the date the Hold Separate Order becomes final and terminate pursuant to Paragraph V. hereof.
- N. “Joint Venture Interest Employees” means all personnel of Respondents whose primary responsibilities relate to the Held Separate Joint Venture Interest, including but not limited to those Persons listed in Confidential Appendix B, and all Persons who may be hired for the Held Separate Joint Venture Interest.
- O. “Material Confidential Information” means competitively sensitive or proprietary information not independently known to a Person from sources other than the Person to which the information pertains, and includes, but is not

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limited to, all customer lists, price lists, marketing methods, patents, technologies, processes, or other trade secrets. The Held Separate Joint Venture Interest shall be considered a Person separate from Respondents (as defined in this Hold Separate Order and the Decision and Order) for this purpose.

- P. “Merger” means the acquisition of Pennzoil by Shell through the proposed merger of Shell ND Company and Pennzoil as described in the Agreement and Plan of Merger dated as of March 25, 2002, by and among Shell Oil Company, Shell ND Company, and Pennzoil-Quaker State Company
- Q. “Pennzoil Excel Paralubes Interest” means all of Pennzoil’s and Atlas’s interests in Excel Paralubes, including their partnership interest and all assets, rights, and agreements related thereto, including, but not limited to:
1. All of Pennzoil’s and Atlas’s rights under all contracts and agreements between Pennzoil or Atlas and Excel Paralubes, including, but not limited to the May 12, 1995, “Lubricating Base Oil Sale and Purchase Agreement between Excel Paralubes and Atlas Processing Company,” and amendments thereto;
 2. All of Pennzoil’s and Atlas’s rights under all contracts and agreements between Pennzoil or Atlas and Conoco relating to Excel Paralubes; and
 3. All Existing Customer Supply Agreements.
- R. “Person” means any individual, partnership, firm, trust, association, corporation, joint venture, unincorporated organization, or other business or governmental entity.

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II.

IT IS FURTHER ORDERED that:

- A. During the Hold Separate Period, Respondents shall hold the Held Separate Joint Venture Interest separate, apart, and independent as required by this Hold Separate Order and shall vest the Held Separate Joint Venture Interest with all rights, powers, and authority necessary to conduct its business; Respondents shall not exercise direction or control over, or influence directly or indirectly, the Held Separate Joint Venture Interest or any of its operations, or the Hold Separate Trustee, except to the extent that Respondents must exercise direction and control over the Held Separate Joint Venture Interest as is necessary to assure compliance with this Hold Separate Order, the Consent Agreement, and with all applicable laws, including, in consultation with the Hold Separate Trustee, continued oversight of the Held Separate Joint Venture Interest's compliance with policies and standards concerning the safety, health, and environmental aspects of its operations and the integrity of its financial controls; and Respondents shall have the right to defend any legal claims, investigations or enforcement actions threatened or brought against any Held Separate Joint Venture Interest.
- B. Until the Effective Date of Divestiture, Respondents shall take such actions as are necessary to maintain the viability and marketability of the Held Separate Joint Venture Interest to prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets, except for ordinary wear and tear.
- C. The purpose of this Hold Separate Order is to: (1) preserve the Held Separate Joint Venture Interest as a viable, competitive, and ongoing business independent of Respondents until the divestitures required by the Decision and Order are achieved; (2) assure that no Material

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Confidential Information is exchanged between Respondents and the Held Separate Joint Venture Interest, except in accordance with the provisions of this Hold Separate Order; (3) prevent interim harm to competition pending the relevant divestitures and other relief; and (4) help remedy any anticompetitive effects of the proposed Merger.

- D. Respondent shall hold the Held Separate Joint Venture Interest separate, apart, and independent on the following terms and conditions:
 1. Thomas H. Reilly shall serve as Hold Separate Trustee, pursuant to the agreement executed by the Hold Separate Trustee and Respondents and attached as Confidential Appendix A (“Trustee Agreement”).
 - a. The Trustee Agreement shall require that, no later than five (5) days after this Hold Separate Order becomes final, Respondents transfer to the Hold Separate Trustee all rights, powers, and authorities necessary to permit the Hold Separate Trustee to perform his/her duties and responsibilities, pursuant to this Hold Separate Order and consistent with the purposes of the Decision and Order.
 - b. No later than five (5) days after this Hold Separate Order becomes final, Respondents shall, pursuant to the Trustee Agreement, transfer to the Hold Separate Trustee all rights, powers, and authorities necessary to permit the Hold Separate Trustee to perform his/her duties and responsibilities, pursuant to this Hold Separate Order and consistent with the purposes of the Decision and Order.
 - c. The Hold Separate Trustee shall have the responsibility, consistent with the terms of this Hold Separate Order and the Decision and Order, for

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monitoring the organization of the Held Separate Joint Venture Interest; for serving on the Excel Paralubes management committee as Respondents' voting member; for managing the Held Separate Joint Venture Interest through the Manager; for maintaining the independence of the Held Separate Joint Venture Interest; and for monitoring Respondents' compliance with their obligations pursuant to this Hold Separate Order and the Decision and Order.

- d. The Hold Separate Trustee shall have full and complete access to all personnel, books, records, documents and facilities of the Held Separate Joint Venture Interest or to any other relevant information as the Hold Separate Trustee may reasonably request including, but not limited to, all documents and records kept by Respondents in the ordinary course of business that relate to the Held Separate Joint Venture Interest. Respondents shall develop such financial or other information as the Hold Separate Trustee may request and shall cooperate with the Hold Separate Trustee. Respondents shall take no action to interfere with or impede the Hold Separate Trustee's ability to monitor Respondents' compliance with this Hold Separate Order and the Consent Agreement or otherwise to perform his/her duties and responsibilities consistent with the terms of this Hold Separate Order.
- e. The Hold Separate Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Hold Separate Trustee's duties and responsibilities.
- f. The Commission may require the Hold Separate Trustee to sign an appropriate confidentiality

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agreement relating to Commission materials and information received in connection with performance of the Hold Separate Trustee's duties.

- g. Respondents may require the Hold Separate Trustee to sign a confidentiality agreement prohibiting the disclosure of any Material Confidential Information gained as a result of his or her role as Hold Separate Trustee to anyone other than the Commission.
- h. Thirty (30) days after the Hold Separate Order becomes final, and every thirty (30) days thereafter until the Hold Separate Order terminates, the Hold Separate Trustee shall report in writing to the Commission concerning the efforts to accomplish the purposes of this Hold Separate Order. Included within that report shall be the Hold Separate Trustee's assessment of the extent to which the businesses comprising the Held Separate Joint Venture Interest are meeting (or exceeding) their projected goals as are reflected in operating plans, budgets, projections or any other regularly prepared financial statements.
- i. If the Hold Separate Trustee ceases to act or fails to act diligently and consistent with the purposes of this Hold Separate Order, the Commission may appoint a substitute Hold Separate Trustee consistent with the terms of this paragraph, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of the substitute Hold Separate Trustee within five (5) days after notice by the staff of the Commission to Respondents of the identity of any substitute Hold Separate Trustee, Respondents shall be deemed to have consented to the selection of the proposed substitute trustee. Respondents and the substitute Hold Separate Trustee shall execute a

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Trustee Agreement, subject to the approval of the Commission, consistent with this paragraph.

2. No later than five (5) days after this Hold Separate Order becomes final, Respondents shall enter into a management agreement with, and transfer all rights, powers, and authorities necessary to manage and maintain the Held Separate Joint Venture Interest, to Daniel J. Bradley (“Manager”).
 - a. In the event that Daniel J. Bradley ceases to act as Manager, then Respondents shall select a substitute Manager, subject to the approval of the Commission, and transfer to the substitute Manager all rights, powers and authorities necessary to permit the substitute Manager to perform his/her duties and responsibilities, pursuant to this Hold Separate Order.
 - b. The Manager shall report directly and exclusively to the Hold Separate Trustee and shall manage the Held Separate Joint Venture Interest independently of the management of Respondents. The Manager shall not be involved, in any way, in the operations of the other businesses of Respondents during the term of this Hold Separate Order.
 - c. The Manager shall have no financial interests affected by Respondents’ revenues, profits or profit margins, except that the Manager’s compensation for managing the Held Separate Joint Venture Interest may include economic incentives dependent on the financial performance of the Held Separate Joint Venture Interest if there are also sufficient incentives for the Manager to operate the Held Separate Joint Venture Interest at no less than current rates of operation (including, but not limited to, current rates of production and sales) and to achieve the objectives of this Hold Separate Order.

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- d. The Manager shall make no material changes in the present operation of the Held Separate Joint Venture Interest except with the approval of the Hold Separate Trustee, in consultation with the Commission staff.
 - e. The Manager shall have the authority, with the approval of the Hold Separate Trustee, to remove Joint Venture Interest Employees and replace them with others of similar experience or skills. If any person ceases to act or fails to act diligently and consistent with the purposes of this Hold Separate Order, the Manager, in consultation with the Hold Separate Trustee, may request Respondents to, and Respondents shall, appoint a substitute person, which person the Manager shall have the right to approve.
 - f. In addition to those Joint Venture Interest Employees within the Held Separate Joint Venture Interest, the Manager may employ such Persons as are reasonably necessary to assist the Manager in managing the Held Separate Joint Venture Interest.
 - g. The Hold Separate Trustee shall be permitted, in consultation with the Commission staff, to remove the Manager for cause. Within fifteen (15) days after such removal of the Manager, Respondents shall appoint a replacement Manager, subject to the approval of the Commission, on the same terms and conditions as provided in Paragraph II.D.2 of this Hold Separate Order.
3. The Held Separate Joint Venture Interest shall be staffed with sufficient employees to maintain the viability and competitiveness of the Held Separate Joint Venture Interest. To the extent that any Joint Venture Interest Employees leave or have left the Held Separate Joint Venture Interest prior to the Effective Date of

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Divestiture, the Manager, with the approval of the Hold Separate Trustee, may replace departing or departed employees with persons who have similar experience and expertise or determine not to replace such departing or departed employees.

4. In connection with support services or products not included within the Held Separate Joint Venture Interest, Respondents shall continue to provide, or offer to provide, the same support services to the Held Separate Joint Venture Interest as are being provided to such business interest by Respondents as of the date the Consent Agreement is signed by Respondents. For services that Pennzoil previously provided to the Held Separate Joint Venture Interest, Respondents may charge the same fees, if any, charged by Respondents for such support services as of the date this Consent Agreement is signed by Respondents. For any other services or products that Respondents may provide to the Held Separate Joint Venture Interest, Respondents may charge no more than the same price they charge others for the same services or products. Respondents' personnel providing such services or products must retain and maintain all Material Confidential Information of the Held Separate Joint Venture Interest on a confidential basis, and, except as is permitted by this Hold Separate Order, such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any person whose employment involves any of Respondents' businesses, other than the Held Separate Joint Venture Interest. Such personnel shall also execute confidentiality agreements prohibiting the disclosure of any Material Confidential Information of the Held Separate Joint Venture Interest.
 - a. Respondents shall offer to the Held Separate Joint Venture Interest any services and products that

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Respondents provide to their other businesses directly or through third party contracts, or that they have provided directly or through third party contracts to the businesses constituting the Held Separate Joint Venture Interest at any time since January 1, 2002. The Held Separate Joint Venture Interest may, at the option of the Manager with the approval of the Hold Separate Trustee, obtain such services and products from Respondents. The services and products that Respondents shall offer the Held Separate Joint Venture Interest shall include, but shall not be limited to, the following:

- (1) Human resources administrative services, including but not limited to labor relations support, pension administration, and health benefits;
- (2) Environmental health and safety services, which develops corporate policies and insures compliance with federal and state regulations and corporate policies;
- (3) Preparation of tax returns;
- (4) Audit services;
- (5) Information systems, which constructs, maintains, and supports all computer systems;
- (6) Processing of accounts payable;
- (7) Technical support;
- (8) Finance and financial accounting services;
- (9) Procurement of supplies;

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- (10) Procurement of goods and services utilized in the ordinary course of business by the Held Separate Joint Venture Interest; and
- (11) Legal services;
- b. the Held Separate Joint Venture Interest shall have, at the option of the Manager with the approval of the Hold Separate Trustee, the ability to acquire services and products from third parties unaffiliated with Respondents.
5. Respondents shall cause the Hold Separate Trustee, the Manager, and each Joint Venture Interest Employee having access to Material Confidential Information to submit to the Commission a signed statement that the individual will maintain the confidentiality required by the terms and conditions of this Hold Separate Order. These individuals must retain and maintain all Material Confidential Information relating to the Held Separate Joint Venture Interest on a confidential basis and, except as is permitted by this Hold Separate Order, such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any other person whose employment involves any of Respondents' businesses other than the Held Separate Joint Venture Interest. These persons shall not be involved in any way in the management, production, distribution, sale, marketing, or financial operations of the competing products of Respondents.
6. No later than ten (10) days after the date this Hold Separate Order becomes final, Respondents shall establish written procedures, subject to the approval of the Hold Separate Trustee, covering the management, maintenance, and independence of the Held Separate

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Joint Venture Interest consistent with the provisions of this Hold Separate Order.

7. No later than ten (10) days after the date this Hold Separate Order becomes final, Respondents shall circulate to employees of the Held Separate Joint Venture Interest and to Respondents' employees who are responsible for the refining and sale of Base Oil in the United States, a notice of this Hold Separate Order and the Consent Agreement.
8. The Hold Separate Trustee and the Manager shall serve, without bond or other security, at the cost and expense of Respondents, on reasonable and customary terms commensurate with the person's experience and responsibilities.
9. Respondents shall indemnify the Hold Separate Trustee and Manager and hold each harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Hold Separate Trustee's or the Manager's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Hold Separate Trustee or the Manager.
10. Respondents shall provide the Held Separate Joint Venture Interest with sufficient financial resources:
 - a. as are appropriate in the judgment of the Hold Separate Trustee to operate the Held Separate Joint Venture Interest as it is currently operated;

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- b. to perform all maintenance to, and replacements of, the assets of the Held Separate Joint Venture Interest;
- c. to carry on existing and planned capital projects and business plans; and
- d. to maintain the viability, competitive vigor, and marketability of the Held Separate Joint Venture Interest.

Such financial resources to be provided to the Held Separate Joint Venture Interest shall include, but shall not be limited to, (i) general funds, (ii) capital, (iii) working capital, and (iv) reimbursement for any operating losses, capital losses, or other losses; provided, however, that, consistent with the purposes of the Decision and Order, the Manager may reduce in scale or pace any capital or research and development project, or substitute any capital or research and development project for another of the same cost.

11. Respondents shall not, during the Hold Separate Period, offer Joint Venture Interest Employees positions with Respondents. The acquirer approved by the Commission pursuant to the Decision and Order shall have the option of offering employment to any Joint Venture Interest Employees. Respondents shall not interfere with the employment, by the Commission-approved acquirer, of such employees; shall not offer any incentive to such employees to decline employment with the Commission-approved acquirer or to accept other employment with the Respondents; and shall remove any impediments that may deter such employees from accepting employment with the Commission-approved acquirer including, but not limited to, any non-compete or confidentiality provisions of employment or other contracts that would affect the ability of such

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employees to be employed by the Commission-approved acquirer, and the payment, or the transfer for the account of the employee, of all current and accrued bonuses, pensions and other current and accrued benefits to which such employees would otherwise have been entitled had they remained in the employment of the Respondents.

12. For a period of one (1) year commencing on the Effective Date of Divestiture, Respondents shall not employ or make offers of employment to Joint Venture Interest Employees who have accepted offers of employment with the Commission-approved acquirer unless the individual has been terminated by the acquirer.
13. Notwithstanding the requirements of Paragraph II.D.11, Respondents shall offer a bonus or severance to Joint Venture Interest Employees that continue their employment with the Held Separate Joint Venture Interest until termination of the Hold Separate Period (in addition to any other bonus or severance to which the employees would otherwise be entitled).
14. Except for the Manager, Joint Venture Interest Employees, and support services employees involved in providing services to the Held Separate Joint Venture Interest pursuant to Paragraph II.D.4., and except to the extent provided in Paragraph II.A., Respondents shall not permit any other of its employees, officers, or directors to be involved in the operations of the Held Separate Joint Venture Interest.
15. Respondents shall assure that Joint Venture Interest Employees receive, during the Hold Separate Period, their salaries, all current and accrued bonuses, pensions and other current and accrued benefits to

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which those employees would otherwise have been entitled.

16. Respondents' employees (excluding support services employees involved in providing support to the Held Separate Joint Venture Interest pursuant to Paragraph II.D.4.) shall not receive, or have access to, or use or continue to use any Material Confidential Information of the Held Separate Joint Venture Interest not in the public domain except:
 - a. as required by law;
 - b. to the extent that necessary information is exchanged in the course of consummating the Merger;
 - c. in negotiating agreements to divest assets pursuant to the Consent Agreement and engaging in related due diligence;
 - d. in complying with this Hold Separate Order or the Consent Agreement;
 - e. in overseeing compliance with policies and standards concerning the safety, health and environmental aspects of the operations of the Held Separate Joint Venture Interest and the integrity of the Held Separate Joint Venture Interest's financial controls;
 - f. in defending legal claims, investigations or enforcement actions threatened or brought against or related to the Held Separate Joint Venture Interest; or
 - g. in obtaining legal advice.

Nor shall the Manager or Joint Venture Interest Employees receive or have access to, or use or continue to use, any Material Confidential Information not in the public

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domain about Respondents and relating to Respondents' businesses, except such information as is necessary to maintain and operate the Held Separate Joint Venture Interest. Respondents may receive aggregate financial and operational information relating to the Held Separate Joint Venture Interest only to the extent necessary to allow Respondents to prepare United States consolidated financial reports, tax returns, reports required by securities laws, and personnel reports. Any such information that is obtained pursuant to this subparagraph shall be used only for the purposes set forth in this subparagraph.

17. Respondents and the Held Separate Joint Venture Interest shall jointly implement, and at all times during the Hold Separate Period maintain in operation, a system, as approved by the Hold Separate Trustee, of access and data controls to prevent unauthorized access to or dissemination of Material Confidential Information of the Held Separate Joint Venture Interest, including, but not limited to, the opportunity by the Hold Separate Trustee, on terms and conditions agreed to with Respondents, to audit Respondents' networks and systems to verify compliance with this Hold Separate Order.

III.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in either corporate Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries or any other change in the corporation that may affect compliance obligations arising out of the Hold Separate Order.

Order

IV.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Hold Separate Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities, and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents relating to any matters contained in this Hold Separate Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding any such matters.

V.

IT IS FURTHER ORDERED that this Hold Separate Order shall terminate at the earlier of:

- A. three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. the day after the divestiture required by the Consent Agreement is completed.

By the Commission.

Order

CONFIDENTIAL APPENDIX A

HOLD SEPARATE TRUSTEE AGREEMENT

[Redacted From Public Record Version]

CONFIDENTIAL APPENDIX B

JOINT VENTURE INTEREST EMPLOYEES

[Redacted From Public Record Version]

Attachments

to

Order to Hold Separate and Maintain Assets

[Public Record Version]

ATTACHMENT A

NOTICE OF DIVESTITURE AND REQUIREMENT FOR CONFIDENTIALITY

COLORADO ASSETS

Conoco Inc. (“Conoco”) and Phillips Petroleum Company (“Phillips”), hereinafter referred to as “Respondents,” have entered into an Agreement Containing Consent Orders (“Consent Agreement”) with the Federal Trade Commission relating to the divestiture of certain assets, including the “Colorado Assets.”

The term “Colorado Assets” as defined in the Federal Trade Commission’s Decision and Order (“Decision and Order”), means the (1) Conoco Denver Refinery Assets and (2) Phillips Colorado Retail Assets. The term “Conoco Denver Refinery Assets” as defined in the Decision and Order, means, Conoco’s refinery located at Commerce City, Colorado and other related assets specified in the Decision and Order. The term “Phillips Colorado Retail Assets” as defined in the Decision and Order, means all of Phillips’ Retail Assets in Colorado as of the date Conoco and Phillips executed the Consent Agreement.

Under the terms of the Consent Agreement, if the Respondents fail to divest the Colorado Assets within twelve (12) months from the date upon which Conoco and Phillips execute the Consent Agreement, a trustee will be appointed to divest the Colorado Assets.

The Colorado Assets must be managed and maintained as a separate, ongoing business, independent of all other businesses of the Respondents or ConocoPhillips, until the Colorado Assets are divested. All competitive information relating to the Colorado Assets must be retained and maintained by the persons involved in the operation of the Colorado Assets on a confidential basis, and such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any other person whose employment involves any other business of the Respondents or ConocoPhillips, except as is necessary to fulfill the purposes of the Decision and Order. Persons involved in similar activities at Conoco, Phillips or ConocoPhillips shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any similar information to or with any other person whose employment involves the Colorado Assets. Any violation of the Consent Agreement may subject Respondents or ConocoPhillips to civil penalties and other relief as provided by law.

ATTACHMENT B

NOTICE OF DIVESTITURE AND REQUIREMENT FOR CONFIDENTIALITY

PHILLIPS WOODS CROSS ASSETS

Conoco Inc. (“Conoco”) and Phillips Petroleum Company (“Phillips”), hereinafter referred to as “Respondents,” have entered into an Agreement Containing Consent Orders (“Consent Agreement”) with the Federal Trade Commission relating to the divestiture of certain assets, including the “Phillips Woods Cross Assets.”

The term “Phillips Woods Cross Assets” as defined in the Federal Trade Commission’s Decision and Order (“Decision and Order”), means the (1) Phillips Woods Cross Refinery Assets and (2) Phillips Woods Cross Retail Assets. The term “Phillips Woods Cross Refinery Assets” as defined in the Decision and Order, means, Phillips’ refinery located at Woods Cross, Utah and other related assets specified in the Decision and Order. The term “Phillips Woods Cross Retail Assets” as defined in the Decision and Order, means all of Phillips’ Retail Assets in Wyoming, Utah, Idaho, and Montana as of the date Conoco and Phillips executed the Consent Agreement.

Under the terms of the Consent Agreement, if the Respondents fail to divest the Phillips Woods Cross Assets within twelve (12) months from the date upon which Conoco and Phillips execute the Consent Agreement, a trustee will be appointed to divest the Phillips Woods Cross Assets.

The Phillips Woods Cross Assets must be managed and maintained as a separate, ongoing business, independent of all other businesses of the Respondents or ConocoPhillips, until the Phillips Woods Cross Assets are divested. All competitive information relating to the Phillips Woods Cross Assets must be retained and maintained by the persons involved in the operation of the Phillips Woods Cross Assets on a confidential basis, and such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any other person whose employment involves any other business of the Respondents or ConocoPhillips, except as is necessary to fulfill the purposes of the Decision and Order. Persons involved in similar activities at Conoco, Phillips or ConocoPhillips shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any similar information to or with any other person whose employment involves the Phillips Woods Cross Assets. Any violation of the Consent Agreement may subject Respondents or ConocoPhillips to civil penalties and other relief as provided by law.

CONFIDENTIAL ATTACHMENT C

TRUSTEE AGREEMENT

[Redacted From Public Record Version]

CONFIDENTIAL ATTACHMENT D

EMPLOYEES

[Redacted From Public Record Version]

Analysis

Analysis of Proposed Consent Order to Aid Public Comment**I. Introduction**

The Federal Trade Commission (“Commission” or “FTC”) has issued a complaint (“Complaint”) alleging that the proposed merger of Shell Oil Company (“Shell”) and Pennzoil-Quaker State Company (“Pennzoil”) (collectively “Respondents”) would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and has entered into an agreement containing consent orders (“Agreement Containing Consent Orders”) pursuant to which Respondents agree to be bound by a proposed consent order that requires divestiture of certain assets (“Proposed Consent Order”) and a hold separate order that requires Respondents to hold separate and maintain certain assets pending divestiture (“Hold Separate Order”). The Proposed Consent Order remedies the likely anticompetitive effects arising from Respondents’ proposed merger, as alleged in the Complaint, and the Hold Separate Order preserves competition pending divestiture.

II. Description of the Parties and the Transaction

Shell Oil Company, headquartered in Houston, Texas, is the United States operating entity for the Royal Dutch/Shell Group of Companies (collectively referred to as “Shell”). Shell is engaged in virtually all aspects of the energy business, including exploration, production, refining, transportation, distribution, and marketing. As part of the relief ordered by the Commission in *Chevron/Texaco*, Docket C-4023 (Jan. 2, 2002), Texaco divested its interest in Equilon Enterprises LLC to Shell and its interest in Motiva Enterprises LLC to Shell and Saudi Refining Company. Equilon and Motiva are engaged in the production, distribution and marketing of refined products, including base oil, gasoline, diesel fuel, and other products. During fiscal year 2001, Shell had worldwide revenues of approximately \$135.2 billion and net income of approximately \$10.9 billion.

Analysis

Pennzoil, headquartered in Houston, Texas, is engaged in the business of manufacturing and marketing lubricants, car care products, base oils, branded and unbranded motor oils, transmission fluids, gear lubricants, greases, automotive polishes, automotive chemicals, other automotive products, and specialty industrial products. Pennzoil manufactures and markets conventional and synthetic motor oils primarily under the Pennzoil and Quaker State brands. Pennzoil is also engaged in the franchising, ownership and operation of quick lube oil change centers under the Jiffy Lube name. During fiscal year 2001, Pennzoil had worldwide revenues of approximately \$2.3 billion.

Pennzoil has a 50/50 joint venture with Conoco Inc. called Excel Paralubes that operates a base oil refinery located in Westlake, Louisiana, adjacent to Conoco's petroleum products refinery at Lake Charles, Louisiana. Pennzoil obtains a substantial portion of its base oil requirements from its interest in Excel Paralubes. Pennzoil also has a 10-year base oil supply agreement with Exxon Mobil Corporation, which became effective August 1, 2000, as a result of the Commission's order in *Exxon/Mobil*, Docket C-3907 (Jan. 26, 2001). Pursuant to that agreement, Pennzoil is entitled to obtain up to 6,500 barrels per day of base oil from ExxonMobil, in grades and quantities that are proportionate to ExxonMobil's Gulf Coast base oil production. Part of this volume consists of Group II paraffinic base oil, which is the relevant market alleged in the Complaint.

Pursuant to an agreement and plan of merger dated March 25, 2002, Shell intends to acquire all of the outstanding voting securities of Pennzoil. The transaction is structured such that Shell ND, a wholly-owned subsidiary of Shell, will acquire the Pennzoil shares and then be merged into Pennzoil, with Pennzoil surviving as a wholly-owned subsidiary of Shell. Each outstanding common share of Pennzoil will be converted into the right to receive \$22 in cash.

Analysis

III. The Complaint

The Complaint alleges that the merger of Shell and Pennzoil would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in the refining and marketing of Group II paraffinic base oil in the United States and Canada. To remedy the alleged anticompetitive effects of the merger, the Proposed Order requires Respondents to divest Pennzoil's 50% interest in Excel Paralubes, which represents Pennzoil's only base oil ownership position. Respondents also have agreed to freeze at approximately current levels Pennzoil's right to obtain Group II base oil supply under the contract with ExxonMobil that was obtained as part of the relief in the *Exxon/Mobil* merger proceeding.

Shell and Pennzoil are competitors in the refining and marketing of Group II paraffinic base oil in a geographic market that consists of the United States and Canada. The refining and marketing of Group II paraffinic base oil in this market would be highly concentrated as a result of the merger. Following the proposed merger, Shell would control at least 39% of Group II refining capacity in the United States and Canada. Overall market concentration, as measured by the Herfindahl-Hirschmann Index (HHI), would increase by more than 700 points to a level in excess of 2,300.

The refining and marketing of Group II paraffinic base oil is a relevant line of commerce (*i.e.*, product market). Paraffinic base oil is a refined petroleum product that is the principal component, or "basestock," of finished lubricants used for a variety of applications, including passenger car motor oil, heavy duty engine oil, automatic transmission fluid, and other lubricant products. In the *Exxon/Mobil* investigation, the Commission concluded that paraffinic base oil constitutes a relevant market.

Developments in the industry since the *Exxon/Mobil* merger indicate that a market consisting of Group II paraffinic base oils

Analysis

has evolved. The American Petroleum Institute divides paraffinic base oil into three groups (Groups I, II and III) based on differences in sulfur content, saturates level, and viscosity index. Group II paraffinic base oil has less than 0.03% sulfur by weight, more than 90% saturates by weight, and a viscosity index ranging from 80 to 120. Group II base oil is needed in order to meet current performance standards for lighter-viscosity motor oil formulations (such as 5W-20 and 5W-30), as well as requirements for other lubricants. As new performance standards are adopted, there will be even greater demand for Group II base oil for the production of motor oil and other lubricants. If the price of Group II base oil were to increase by 5-10%, blenders of motor oil and other lubricants would not substitute to other basestocks in sufficient quantities to prevent the increase.

The Complaint alleges that the proposed transaction would lessen competition in a geographic market consisting of the United States and Canada. There is little Group II production outside of the United States and Canada. Further, imports of Group II base oil would be subject to significant freight penalties and would not be competitive with production in the United States and Canada. If the price of Group II base oil in the United States and Canada were to increase by 5-10%, blenders of motor oil and other lubricants would not switch to sources of supply outside the United States and Canada in sufficient quantities to prevent the increase.

There are few significant producers of Group II base oil in the United States and Canada. The proposed merger would eliminate Pennzoil as a major competitor, and would combine Shell, the market leader, into a close partnership with Conoco, another leading producer. As a result of the proposed merger, Shell would control at least 39% of Group II refining capacity in the United States and Canada, and concentration in the relevant market as measured by the Herfindahl-Hirschmann Index would increase by more than 700 points to a level in excess of 2,300.

Analysis

Entry into the relevant market is difficult and would not be timely, likely or sufficient to prevent the anticompetitive effects that are likely to result from the proposed merger. Constructing a new refinery or converting an existing Group I refinery to make Group II base oil would require substantial investment, would be subject to significant regulatory obstacles, and would take several years to accomplish. As a result, new entry would not be able to prevent a 5-10% increase in Group II base oil prices.

The Complaint charges that the proposed merger, absent relief, is likely to substantially lessen competition and lead to higher prices of Group II paraffinic base oil, by eliminating direct competition between Shell and Pennzoil, by increasing the likelihood that the combined Shell/Pennzoil will unilaterally exercise market power, and by increasing the likelihood of collusion or coordinated interaction among competitors in the refining and marketing of Group II paraffinic base oil.

To remedy the likely competitive harm, the Proposed Order requires Respondents to divest Pennzoil's interest in Excel Paralubes and to freeze Pennzoil's ability to obtain additional Group II supply under the agreement with ExxonMobil. This relief will effectively remedy any anticompetitive effects that could be expected to arise from this transaction.

IV. Resolution of the Competitive Concerns

The Commission has provisionally entered into an Agreement Containing Consent Orders with Shell and Pennzoil in settlement of the Complaint. The Agreement Containing Consent Orders contemplates that the Commission would issue the Complaint and enter the Proposed Order and the Hold Separate Order for the divestiture of certain assets described below.

In order to remedy the anticompetitive effects that have been identified, Respondents have agreed to divest Pennzoil's 50% interest in Excel Paralubes, and to freeze Pennzoil's right to obtain additional Group II supply under the contract with

Analysis

ExxonMobil at approximately current levels. If the required divestiture has not been accomplished within the required time, then Respondents are required to transfer Pennzoil's interest in Excel Paralubes to a trustee, who will have the responsibility of accomplishing the required divestiture.

Paragraph II.A. of the Proposed Order requires Respondents to divest Pennzoil's interest in Excel Paralubes, at no minimum price, within twelve months after executing the Order, to an acquirer that receives the prior approval of the Commission.

Paragraph II.B. requires Respondents to negotiate with the acquirer, at the acquirer's option, a supply agreement for Respondents to purchase Group II base oil. Such agreement may not exceed one year, may not contain renewal or evergreen rights, and is subject to prior approval by the Commission. Paragraph II.C. provides that, prior to the effective date of divestiture, Respondents may not enter into any agreement to purchase Group II base oil from the acquirer other than one made pursuant to Paragraph II.B.

Paragraph II.D. of the Proposed Order explicitly provides that Respondents may not divest the Pennzoil Excel Paralubes Interest to Conoco, and must enforce a letter agreement with Conoco relating to Excel Paralubes. Conoco already has a significant share of the Group II market, and the addition of Pennzoil's share of Excel Paralubes would result in a significant increase in concentration. In addition, under the Joint Venture Agreement forming the Excel Paralubes partnership, Conoco may, under certain circumstances, have a right of first refusal or a first option to purchase Pennzoil's interest in Excel Paralubes. Conoco has entered into an agreement with Respondents dealing with its waiver of such rights, and consenting to the assignment of a supply agreement pursuant to which Pennzoil purchases base oil from Excel Paralubes.

Paragraph III limits Respondents' use of their rights to purchase Group II base oil from ExxonMobil under the

Analysis

ExxonMobil/Pennzoil Base Oil Agreement. That agreement allows Pennzoil to obtain base oil from ExxonMobil in the proportionate types and amounts corresponding to production at designated ExxonMobil refineries. Pennzoil currently is taking approximately 1,500 barrels per day of Group II under this contract. Any significant increase in that amount could unduly increase concentration. Accordingly, Paragraph III prevents Respondents from increasing their share of the market for Group II Base Oil through additional supply under this agreement.

If Respondents have not accomplished the divestiture within the required time period, Paragraph IV provides that the Commission may appoint a trustee to divest the Pennzoil Excel Paralubes Interest, at no minimum price, to a buyer approved by the Commission. The trustee will have the exclusive power and authority to accomplish the divestiture within twelve months, subject to any necessary extensions by the Commission. Paragraph IV.C.5 requires that the trustee will have access to information related to Atlas and Excel Paralubes as necessary to fulfill his or her obligations. (Atlas is the wholly-owned subsidiary of Pennzoil that holds Pennzoil's interest in the Excel Paralubes partnership.) The trustee shall use his or her best efforts to negotiate the most favorable price and terms for the divestiture, subject to the Respondents' absolute and unconditional obligation to divest expeditiously at no minimum price. If the trustee receives more than one bona fide offer from entities approved by the Commission, the trustee will divest to the party selected by the Respondents.

Other provisions of Paragraph IV.C. generally provide that Respondents are responsible for management expenses incurred by the trustee, that the trustee has authority to employ other persons necessary to carry out his or her duties and responsibilities, and that Respondents indemnify and hold the trustee harmless against any liabilities or expenses arising out of, or in connection with, performance of the trustee's duties. Respondents may require the trustee to sign a customary confidentiality agreement, provided that such agreement may not

Analysis

restrict the trustee from providing any information to the Commission.

Paragraphs V - VIII of the Proposed Order contain certain general provisions. Pursuant to Paragraph V, Respondents are required to provide the Commission with a report of compliance with the Proposed Order every thirty days until the divestiture is completed and annually for nine years after the first year the Order becomes final. Paragraph VI provides for notification to the Commission in the event of any corporate changes in the Respondents. Paragraph VII requires that Respondents provide the Commission with access to their facilities and employees for the purposes of determining or securing compliance with the Proposed Order. Finally, Paragraph VIII terminates the Order ten years from the date it becomes final.

V. Opportunity for Public Comment

The Proposed Order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. The Commission, pursuant to a change in its Rules of Practice, has also issued its Complaint in this matter, as well as the Hold Separate Order. Comments received during this thirty day comment period will become part of the public record. After thirty (30) days, the Commission will again review the Proposed Order and the comments received and will decide whether it should withdraw from the Proposed Order or make final the agreement's Proposed Order.

By accepting the Proposed Order subject to final approval, the Commission anticipates that the competitive problems alleged in the Complaint will be resolved. The purpose of this analysis is to invite public comment on the Proposed Order, including the proposed divestiture, and to aid the Commission in its determination of whether it should make final the Proposed Order contained in the agreement. This analysis is not intended to constitute an official interpretation of the Proposed Order, nor is it intended to modify the terms of the Proposed Order in any way.

Complaint

IN THE MATTER OF

ROBERT M. CURRIER

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4067; File No. 0023211

Complaint, December 13, 2002--Decision, December 13, 2002

This consent order addresses representations in infomercials for "Snorenz" – a dietary supplement consisting of oils and vitamins that is sprayed on the back of the throat of persons who snore – made by Respondent Dr. Robert M. Currier. The order, among other things, requires the respondent to possess competent and reliable scientific evidence to substantiate representations that Snorenz – or any other food, drug, or dietary supplement – reduces or eliminates snoring or the sound of snoring, or eliminates, reduces or mitigates the symptoms of sleep apnea. The order also requires the respondent – when acting as an expert endorser – actually to exercise his represented expertise in the form of an examination or testing at least as extensive as an expert in the field would normally conduct. In addition, the order requires the respondent – whenever he advertises that certain products are effective in reducing or eliminating snoring or the sounds of snoring – to affirmatively disclose a warning statement about sleep apnea and the need for physician consultation. The order also requires the respondent to possess and rely upon adequate substantiation to support any representation about the benefits, performance, efficacy, or safety of Snorenz or any other product, service or program, and – if the respondent makes such representations as an expert endorser – he must possess substantiation in the form of an examination or testing at least as extensive as an expert in the field would normally conduct. In addition, the order prohibits the respondent from making false claims about scientific support for any product, service, or program, and requires him to disclose any material connection between himself and any product, program or service he endorses.

Participants

For the Commission: *Lemuel W. Dowdy, Walter C. Gross, III, Laureen Kapin, James Reilly Dolan, Elaine D. Kolish, and Randi M. Boorstein.*

For the Respondent: *Denise Burke.*

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that Robert M. Currier ("respondent"), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Robert M. Currier is a resident of Michigan. He is a doctor of osteopathic medicine who specializes in eye surgery and diseases of the eye. His principal office and place of business is located at 127 Park Place, Alpena, Michigan 49707.
2. Respondent has appeared in television infomercials promoting SNORenz. These infomercials were aired on various broadcast and cable channels. SNORenz is a topical spray that purports to reduce or eliminate snoring or the sounds associated with snoring by lubricating the vibrating tissues in the throat with a combination of oils, vitamins, and trace ingredients. SNORenz is a "food," and/or "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.
3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.
4. Respondent has made statements as an expert endorser in advertisements for SNORenz, including but not necessarily limited to television infomercials that were aired on various broadcast and cable channels. These advertisements contained the following statements:

INFOMERCIAL: VP SNORenz 2- JD [Exhibit A]

ON SCREEN: Dr. Bob Currier, Physician and Surgeon

- A. DR. BOB CURRIER: Well what snoring really is, Jon, is simply a relaxation of the tissues in the back of the throat. It's when we fall asleep, much of our muscles in our body as

Complaint

well as our throat relax. That's the time we sleep. We're supposed to get our rest. What happens with that, though, unfortunately is as the tissues relax, they occlude or actually narrow, and they cause a funnel effect for the air as it goes through, flapping the tissue. This is in the back of the throat, hence creating the noise. It's very positional, it's very – also very dependent on habits, and then also it affects really how much we sleep and how much we rest we actually get throughout the night.

B. DR. BOB CURRIER: Well, to take this just a little bit further, a dentist has studied this and has actually sprayed this in models, and he actually used a dye at the time so he could see where it was applied. In the soft tissues, in the back of the throat, the ones that we see that flap and flutter and that need the lubrication, what -- it is applied there, but where the technology goes even further and better through this liposome technology is to apply it evenly, and the very neat thing about this is it stays. It stays there all night. That's where others have failed. And that's also where a lot of the appliances, that's where also a lot of the applications of surgeries, pills, other things that have been attempted and tried have failed. This product here stays there. It's easy application.

INFOMERCIAL: VP SNORENZ 4 - JD [Exhibit B]

C. DR. BOB CURRIER. Well, it is a problem, but the real problem is awareness. A lot of people are not aware, as you were, that you didn't snore, you don't snore, and people don't want to offend someone else that they may sleep with or someone in their family by telling them that they snore. And they've put up with it for years. The problem with that is all the things that go with it. Even on a personal level. Me personally, I snore and have snored, and I've used the product as well and it's worked great for me. Why do I know this? Because my energy level, I feel better. I get better sleep. The problems happen I think people go to

Complaint

sleep, they assume they're automatically going to wake up rested. They don't and then they wake up with a headache, less energy, they hurt, they're sore, they're irritable. The health problems are really insidious, but let's not even go that deep. Let's just talk about things that happen to us on an everyday basis. The energy level we have. We're not rested. That's the problem.

- D. DR. BOB CURRIER: Interestingly enough, it's not only the results of the studies we got, but the comments we received. Many people, again, they're aware of snoring, but they aren't aware of the problems that come with it. And actually it's like until it's resolved, the snoring itself, oh, my word, what a problem it was. And you can see the changes it's made. That was probably the most interesting part of doing that whole study was the comments that we got back, the little stories that people had through the week you know, of using the product. And that was the beauty of this. I loved doing the study, it was highly effective.
 - E. DR. BOB CURRIER: With the effectiveness of its staying there, it's a winner. And that's how it works.
5. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that:
- A. SNORenz significantly reduces or eliminates snoring or the sound of snoring in users of the product.
 - B. A single application of SNORenz significantly reduces or eliminates snoring or the sound of snoring for six to eight hours.
 - C. SNORenz can eliminate, reduce or mitigate the symptoms of sleep apnea including daytime tiredness and frequent interruptions of deep restorative sleep.

Complaint

6. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that he possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 5, at the time the representations were made.
7. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 5, at the time the representations were made. Among other reasons, the single study that respondent relied upon that purported to use a double blind, controlled design contained basic flaws in design (such as failure to apply an appropriate measurement to assess sound reduction, failure to include a statistical analysis of the results, insufficient duration of the testing period, and failure to develop a baseline against which any improvement could be measured). Therefore, the representation set forth in Paragraph 6 was, and is, false or misleading.
8. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that clinical research proves that SNORenz significantly reduces or eliminates snoring or the sound of snoring.
9. In truth and in fact, clinical research does not prove that SNORenz significantly reduces or eliminates snoring or the sound of snoring. Among other things, critical components of the research were not done by an independent entity qualified to conduct studies or by Dr. Currier. Rather, officials from Med Gen, Inc., the manufacturer of SNORenz, composed the questionnaire used in the study and compiled the results from completed questionnaires submitted by study participants. Therefore, the representation set forth in Paragraph 8 was, and is, false or misleading.
10. In the advertising and sale of SNORenz, respondent has represented, expressly or by implication, that the product reduces or eliminates snoring or the sound of snoring. Respondent has failed to disclose or to disclose adequately that SNORenz is not

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intended to treat sleep apnea for which snoring is a primary symptom, that sleep apnea is a potential life-threatening condition, and that persons who have symptoms of sleep apnea should consult a physician. These facts would be material to consumers in their purchase or use of the product. The failure to disclose adequately these facts, in light of the representation made, was, and is, a deceptive practice.

11. Through the use of the statements contained in the infomercials referred to in Paragraph 4, respondent has represented, directly or by implication, that, at the time he made the representations set forth in Paragraph 5, he possessed and relied upon a reasonable basis for such representations, consisting of an actual exercise of his represented expertise in the causes and treatments for snoring at least as extensive as an expert in that field would normally conduct in order to support the conclusions presented in the endorsement.

12. In truth and in fact, at the time he made the representations set forth in Paragraph 5, respondent did not possess and rely upon a reasonable basis for such representations. Therefore, respondent's representations set forth in paragraph 11 were false and misleading.

13. Through the statements contained in the infomercials referred to in Paragraph 4, respondent has represented, expressly or by implication, that he endorses SNORenz. Respondent has failed to disclose or failed to disclose adequately that he has a material connection with Med Gen, Inc., the manufacturer of SNORenz, in that he is an investor in the company and may have a financial interest in promoting the sale of SNORenz. This fact would be material to consumers in their purchase decision regarding SNORenz. The failure to disclose this fact, in light of the representations made, was and is a deceptive practice.

14. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in

Complaint

violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission on this thirteenth day of December, 2002, has issued this complaint against respondent.

By the Commission.

[1] FEDERAL TRADE COMMISSION
[2] INDEX
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[5] VIDEOTAPE: Page
[6] VP Snorenz 2- JD (3 mos. Free)
[7] VPS2 Soft 3
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PROCEEDINGS

[1]
[2]
[3] **ON SCREEN:** Client: Trudeau Marketing/TVI
[4] Project: VP Snorenz 2 (JD)
[5] Price Point: Soft Offer
[6] Edit Date: 10-6-98
[7] Editor: SR
[8] Audio: Mixed
[9] Notes: 800-392-4006
[10] MALE ANNOUNCER: The following is a paid
[11] commercial brought to you by Kevin Trudeau's Tru
[12] Vantage International.
[13] **ON SCREEN:** The following is a paid commercial
[14] for Snorenz brought to you by Kevin Trudeau's
[15] Tru-Vantage International, America's premier direct
[16] response marketing company.
[17] **JON DENNY:** For millions of Americans, this is
[18] the most annoying and unwelcome signed imaginable.
[19] That's right, more than 90 million Americans have a
[20] snoring problem, and it can cause sleeplessness,
[21] headaches, a lack of energy throughout the day, and
[22] that goes for the snorer as well as the person trying
[23] to sleep nearby.
[24] Join us and find out how to instantly solve
[25] your snoring problem in this special edition of Vantage

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Page 4

[1] FEDERAL TRADE COMMISSION
[2]
[3] In the Matter of:
[4] Med Gen, Inc.) Matter No. 0023211
[5]
[6]
[7] October 13, 1999
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[13] The following transcript was produced from a
[14] live tape provided to For The Record, Inc. On May 8,
[15] 2000.

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[1] Point.
[2] **ON SCREEN:** Vantage Point with Kevin Trudeau
[3] Jon Denny
[4] **JON DENNY:** I'm Jon Denny, and this is a
[5] special edition of Vantage Point. We're going to talk
[6] about snoring today, and if you're a snorer or just
[7] happen to sleep next to one, then you know snoring is
[8] no laughing matter. Snoring can and does seriously
[9] diminish the quality of your sleep, your life and it
[10] could drive two people apart, meaning the snorer and
[11] the person next to the snorer.
[12] My guests today are Dr. Bob Courier, physician,
[13] surgeon and associate clinical professor at Michigan
[14] State University, and John Ziglar, who represents a
[15] company that manufactures a product called Snorenz,
[16] which is designed to end your snoring problem.
[17] Gentlemen, thank you for joining me.
[18] Guys, got to ask you this first question,
[19] because for some people it's a light matter, and for
[20] others it seriously impacts their life, certainly
[21] impacts their sleep. What causes snoring? What is the
[22] reason behind that all-too-familiar rumbling sound that
[23] keeps half of America, it seems, up every night?
[24] **ON SCREEN:** DR. BOB COURIER, Physician Surgeon
[25] DR. BOB COURIER: Well, what snoring really is,

Page 5

[1] Jon, is simply a relaxation of the tissues in the back
[2] of your throat. It's when we fall asleep, much of our
[3] muscles in our body as well as our throat relax.
[4] That's the time we sleep. We're supposed to get our
[5] rest.

[6] What happens with that, though, unfortunately
[7] is as the tissues relax, they occlude or actually
[8] narrow, and they cause a funnel effect for the air as
[9] it goes through, flapping the tissue. This is in the
[10] back of the throat, hence creating the noise. It's
[11] very positional, it's very — also very dependent on
[12] habits that we have, such as smoking, our dietary
[13] habits, and then also it affects really how much we
[14] sleep and how much rest we actually get throughout a
[15] night.

[16] JON DENNY: Now, you were both snorers
[17] presumably.

[18] DR. BOB COURIER: Absolutely.

[19] JOHN ZIGLAR: Sure.

[20] JON DENNY: Tell me, how did you get involved
[21] in Snorenz? How did this all come about?

[22] JOHN ZIGLAR: This all came about, Jon, I met a
[23] friend down in Fort Lauderdale, Florida named Paul
[24] Cravitz. Paul Cravitz was in the banking industry, and
[25] he had a Korean man that came into his office with a

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[1] came home after talking with Paul, and I told my wife
[2] about this new product that we were looking at, and she
[3] said — and she says, Well, when are you going to bring
[4] it home? And I said, Well, honey, I said really, you
[5] know, you don't snore that bad. And she said it really
[6] wasn't for her. And up until that point, I really
[7] didn't realize that I snored.

[8] JON DENNY: Um-hum.

[9] JOHN ZIGLAR: But I did turn over in the bed an
[10] awful lot at night, and I knew that, and so I used the
[11] product, and John, what I found is for me personally, I
[12] quit turning over so many times at night, and I began
[13] to get a more peaceful, restful sleep. So, that's what
[14] personally happened in my life.

[15] JON DENNY: Well, that raises an interesting
[16] point, because for some people snoring — in a litany
[17] of problems that we face on an everyday basis, snoring
[18] is not at the top of the list. But in fact, if you
[19] speak to people who sleep next to a snorer, as well as
[20] the snorer themselves, there are some real health
[21] issues, there are some real serious concerns that a
[22] snorer has or should have. How does and why does a
[23] snorer — why should a snorer worry about this? Why is
[24] it a problem?

[25] DR. BOB COURIER: Well, it is a problem, but

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[1] product in a little bottle and it didn't have any
[2] labels on it or anything, but he says, This will make
[3] you quit snoring. And Paul looked at it, and he put it
[4] over on the side of his desk and didn't think too much
[5] about it, but he did make the mistake of telling his
[6] wife that somebody had come in with this product, and
[7] she asked him would he go ahead and bring it home and
[8] try it.

[9] ON SCREEN: John Ziglar, Master Strategies
[10] Researcher

[11] JOHN ZIGLAR: The bottom line is, he did use
[12] the product, it did make him quit snoring, but it
[13] tasted terrible, and so Paul says, Whoa, you know, what
[14] a price to pay. So, he took that product, he developed
[15] it, he took it to the laboratories, and they did some
[16] liposome technology with the product, and they put a
[17] flavor to the product to make it so that it tasted
[18] good, and we now call the product Snorenz, and it's
[19] just phenomenal.

[20] JON DENNY: And in your first exposure to it,
[21] you were a rumbler. We heard Harley Davidson sounds
[22] coming from you at night is the word on the street.
[23] Tell me your first experience with the product.

[24] JOHN ZIGLAR: My first experience really, when
[25] I — I had been married for 25 years, my wife, Linda, I

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[1] the real problem is an awareness. A lot of people
[2] aren't aware, as you were, that you didn't snore. You
[3] don't snore. It's — and people don't want to offend
[4] someone else that they may sleep with or someone in
[5] their family by telling them they snore, and they have
[6] put up with it for years.

[7] The problem with that is all the things that go
[8] with it, even on a personal level. Me personally, I
[9] snore and have snored, and I've used the product, as
[10] well, and it's worked great for me. Why do I know
[11] this? Because of my energy level, I feel better, I get
[12] better sleep. The problems that happen, I think people
[13] go to sleep, they assume they're automatically going to
[14] wake up rested. They don't. And then they wake up
[15] with a headache, less energy, they hurt, they're sore,
[16] they're irritable.

[17] The health problems are really insidious. We
[18] can go into hypertension, problems with your heart,
[19] your cardiovascular system that can go into this, but
[20] let's not even go that deep. Let's just talk about the
[21] things that happen to us on an everyday basis, the
[22] energy level that we have. We're not rested. That's
[23] the problem.

[24] JON DENNY: So, you're saying snorers get less
[25] rest — get a less restful sleep?

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[1] DR. BOB COURIER: Absolutely, they do not [2] sleep.
[3] JOHN ZIGLAR: See, what happened to me — what [4] was going on in my night is I would literally turn over [5] 20 or 30 times a night, and the reason I would is [6] because I would go to sleep, my tissues would relax, I [7] would snore — I would literally wake myself up, and [8] then I would turn over, and I would turn — I didn't [9] wake up and get up out of the bed to turn over.
[10] I would just wake up and turn over, and what [11] that does is it keeps me, John, from getting the deep, [12] restful sleep.
[13] We get letters, we've got a letter from a lady [14] out in Phoenix, also, who told us that for the first [15] time in her life she started taking this product, and [16] she can remember her dreams. Well, you see, dreaming [17] is an important thing, and we all dream if we get [18] peaceful, restful sleep.
[19] JON DENNY: But isn't — isn't dreaming or the [20] dream state indicative of a deep, restful, REM sleep I [21] think they call it?
[22] JOHN ZIGLAR: Yes, it is.
[23] JON DENNY: So, if you're a snorer, you won't [24] dream as much, meaning you're not getting as deep a [25] sleep. Is that the point?

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[1] DR. BOB COURIER: That is correct. You almost, [2] because of the snoring, and sometimes we're not aware [3] of it, we keep waking ourselves up. We snore, then we [4] wake up, then we try to reposition ourselves. We're [5] just not comfortable. We can't get our air, we can't [6] get the oxygen we need, hence the headache, the [7] irritability when we wake up. We're not rested, that's [8] the problem.
[9] ON SCREEN: Dr. Bob Courier, Physician Surgeon
[10] DR. BOB COURIER: Another side effect, a cute [11] story, my brother's also a snorer, I think this is just [12] something that runs in families, as well. Anyway, he [13] has since tried the product, as I have, and I use it, [14] and I think it's fantastic, because it does stop the [15] snoring. My brother has also — he doesn't have the [16] aches and pains he used to wake up with.

[17] You were also talking about the tossing and [18] turning. We're also forgetting his wife used to jab [19] him in the middle of the night. So, he does not wake [20] up bruised. So, this also helps, a little sidelight [21] there.

[22] JON DENNY: How does Snorenz work? Is there [23] have been other products available over the course of [24] the last, you know, 10 to 20 years that have been in [25] pill form, surgeries, people have gone through painful,

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[1] expensive surgeries. In fact, we're going to — I [2] think we're going to talk to a caller later who has a [3] story to share with us about this product and the [4] journey she went through with her husband to [5] essentially reduce this problem or eliminate this [6] problem. How does this product work?
[7] JOHN ZIGLAR: John, what we've done is we have [8] taken all natural oils, and we have taken and put them [9] together in a liposome formulation, and we have taken [10] it so that you can actually spray this product into the [11] back of your throat, and the process is really quite [12] simple. Have you ever seen a car go down the road that [13] didn't have enough oil in it, and you hear the clatter [14] and the clanking?
[15] ON SCREEN: John Ziglar, Master Strategies [16] Researcher
[17] JOHN ZIGLAR: Well, what happens is we took [18] that same philosophy, that same technology, and we [19] said, Hey, if we can oil the parts and we can take and [20] make a topical solution that will stay in a place for [21] an extended period of time, we can eliminate the noise [22] of snoring. You're still going to have the same amount [23] of air that's going to pass through the passage, but [24] all we're going to do is we're going to lubricate the [25] parts so that there is no noise associated so that you

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[1] don't then wake up or wake up your neighbor.
[2] JON DENNY: So, it's essentially lubricating [3] what part of the throat and which part of the throat is [4] causing that sound?
[5] DR. BOB COURIER: Well, to take this just a [6] little bit further, a dentist has studied this and has [7] actually sprayed this in models, and he actually used a [8] dye at the time so he could see where it was applied.
[9] In the soft tissues, in the back of the throat, the [10] ones that we see that flap and flutter and that need [11] the lubrication, what — it is applied there, but where [12] the technology goes even further and better through [13] this liposome technology is to apply it evenly, and the [14] very neat thing about this is it stays. It stays there [15] all night. That's where others have failed. And [16] that's also where a lot of the appliances, that's where [17] also a lot of the applications of surgeries, pills, [18] other things that have been attempted and tried have [19] failed. This product here stays there. It's easy [20] application.

[21] As a physician, one of the problems that I have [22] with patients is compliance, trying to get them to use [23] and continually use something. If we're going to get [24] restful sleep, we need it on an every-night basis.
[25] This is accrued, we have a clock and a bank and it's

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[1] for sleeping purposes.
[2] So, this isn't something just one night good
[3] sleep will help. This is something that's accrued over
[4] time. When you get good sleep, that helps a lot. We
[5] need compliance. With the ease of application, what he
[6] is talking about, where the effectiveness of it staying
[7] there, it's a winner, and that's how it works.

[8] **JON DENNY:** So, it's basically, correct me if
[9] I'm wrong, it's two or three sprays in the back of your
[10] mouth. I have a friend who underwent a session with a
[11] dentist who fitted him with a clamp of some sort, which
[12] pushed his jaw out and tried to create more breathing
[13] space essentially, and that lasted for about three or
[14] four months. This works, and it stays working for
[15] people?

[16] **DR. BOB COURIER:** Yes, and what you're trying
[17] to do with the appliance is just simply trying to open
[18] up the airway more so you don't get the fluttering of
[19] the tissues, and that's what we do when we snore. When
[20] we snore, we essentially wake ourselves up in a snore
[21] and then reposition ourselves, trying to, again, open
[22] up our airway to get more air so we get more oxygen.

[23] What happens with this product, this
[24] lubricates, stays there, again through the technology,
[25] and then you don't have the snore; hence, you don't

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[1] wake up; hence, you get a more restful sleep.
[2] **JOHN ZIGLAR:** And the problem, John, with the
[3] appliance is it's very uncomfortable, and there have
[4] been a lot of people — and dentists will tell you that
[5] they have got patients who have paid for the procedure,
[6] paid to get the appliance, could not sleep with it
[7] hooked up, and so it did not work for them, because
[8] they were so uncomfortable.

[9] **JON DENNY:** Right.

[10] **JOHN ZIGLAR:** Okay? So, when I saw this first
[11] — this product the first time, I looked at this thing
[12] and I thought, Oh, my goodness, you know, I'm going to
[13] spray oil in the back of my throat, I'm thinking WD-40
[14] or something like that and an oil slick, and I'm going,
[15] Oh, but it's the consistency of water, and the nice
[16] thing about it is that it doesn't — there's no feeling
[17] associated with the spray in the back of your throat.
[18] All you get is a nice, clean, peppermint taste, which
[19] made it wonderful, so compliance — people will do it.

[20] **JON DENNY:** Well, the after taste —

[21] **JOHN ZIGLAR:** Yes.

[22] **JON DENNY:** — in the morning when you wake up
[23] is much better.

[24] **JOHN ZIGLAR:** Exactly.

[25] **JON DENNY:** You don't feel like you have an oil

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[1] sludge at all. It's a minty taste.
[2] **ON SCREEN:** 800-392-4006
[3] **MR. DENNY:** If you have a snoring problem, if
[4] you have problems sleeping next to a snorer, then
[5] Snorenz may be the answer you've been waiting for.
[6] Remember, snoring is a medical condition. Studies have
[7] shown that snoring can seriously reduce your energy
[8] levels, your concentration and can seriously affect
[9] your work habits, as well, and you can be sure your
[10] snoring is seriously bothering someone other than you.

[11] Snorenz is the first all-natural spray that has
[12] been proven to give you a healthy, natural, good
[13] night's sleep. It has no side effects. It's as easy
[14] as a few sprays before bed, and it lasts all night, and
[15] if you want more information on Snorenz, if you want to
[16] stop the snoring, if it's a snorer next to you or if
[17] you be the snorer, you may want to call the 800 number
[18] on your screen.

[19] We have I believe a caller on the line from
[20] Arizona, and I believe it's Tina Hines (phonetic).
[21] Tina, are you on the air with us?

[22] **TINA HINES:** I'm here.

[23] **JON DENNY:** Great. How are you feeling today?

[24] **TINA HINES:** I've got a sore throat, but other
[25] than that, good. I'm listening to your show, and I

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[1] have to tell you that snoring, you know, is a lot more
[2] dangerous than people think. My husband was a chronic
[3] snorer, he's a firefighter/paramedic, so I wasn't the
[4] only one affected by this. I mean, we didn't sleep
[5] together for years.

[6] **JON DENNY:** Now, you've been married for how
[7] long, Tina?

[8] **TINA HINES:** Sixteen years.

[9] **JON DENNY:** Sixteen years, and this was a
[10] problem that occurred right from the start of your
[11] marriage?

[12] **TINA HINES:** Oh, yeah.

[13] **JON DENNY:** You found you were married to a
[14] snorer?

[15] **TINA HINES:** Oh, absolutely, and the poor guy,
[16] it would be all night, John, turn over, turn over. It
[17] did not matter, he could be sleeping on his head, and
[18] he would still snore.

[19] Well, it got so bad that even at the fire
[20] department, he was being hassled at the fire
[21] department, because these guys sleep at different
[22] shifts, they don't all sleep at the same time, and when
[23] John was sleeping, he would be waking everybody else
[24] up, so they would be pounding on the walls and he'd
[25] come home all aggravated, he'd come home and want to

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[1] sleep.
[2] They even built a partition around my husband's
[3] bunk bed to try to keep out the noise. Well, it got so
[4] bad he finally went to the doctor, and in order for the
[5] insurance company to pay for this surgery, they put him
[6] in the hospital, in the sleep center, and found out
[7] that he also had sleep apnea, which is very dangerous,
[8] because when you're snoring, you stop breathing, then
[9] you forget to sleep.

[10] So, they did the surgery, and needless to say,
[11] it lasted for a while, and then after that he started
[12] up again, and he would not even believe when I would
[13] tell him, John, you're snoring again. You don't want
[14] to go through surgery and find out that you're snoring
[15] again.

[16] JON DENNY: So, this was after a surgery, he
[17] had — the problem re-emerged.

[18] TINA HINES: Right, they did surgery on all his
[19] sinuses, they went through his nose and removed all his
[20] polyps, thinking that was the problem. So, now he's in
[21] for the second surgery, and they decided they are going
[22] to remove part of his uvula, and the roof of his mouth,
[23] his tonsils and his adenoids, and this way it will give
[24] his tongue more room, I guess is what they said, so he
[25] wouldn't snore.

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[1] Well, he went through this, and it was a
[2] horrible surgery. I really felt very, very bad for
[3] him. He was out of work for six weeks, and he had high
[4] hopes that this was going to work and our life was
[5] going to change, we could sleep in the same room
[6] together, go on vacation, the guys wouldn't be hassling
[7] him.

[8] Well, that did work for quite a while, and then
[9] it started up again, and I'll tell you what, I was even
[10] afraid to tell him, because I couldn't believe it
[11] myself. It's aggravating, it's annoying, I don't get a
[12] good night's sleep, he doesn't get a good night's
[13] sleep. I hated to say it, but I was happier when he
[14] was at the fire department because I got a good night's
[15] sleep.

[16] JON DENNY: Tina, I want to interrupt you for a
[17] second, because this is a — you know, a real relatable
[18] story to some. Perhaps not all have gone through
[19] surgeries and so forth, but for the millions of people
[20] who sleep next to a snorer, their lives are affected,
[21] as well. How did you find your life or your sleep
[22] quality affected by sleeping next to a snorer?

[23] TINA HINES: Well, I didn't, I chased him out.
[24] Actually, I had insomnia and I don't get a good — I
[25] mean, I could hear the dog turn over. So, he would

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[1] have to go out in the other room, but I could still
[2] hear him through the vents, but I'd get up in the
[3] morning, and I would be a grouch at work, because I was
[4] — I was tired.

[5] JON DENNY: Yes.

[6] TINA HINES: And I was aggravated. You're
[7] talking two surgeries, what's it going to take? He
[8] tried those stupid nose strip things, they didn't work.
[9] So, one day I'm sitting here watching TV and I
[10] see a commercial out here in Phoenix and a couple is
[11] talking about the same thing, and I'm thinking, Well,
[12] what have I got to lose?

[13] Well, my husband tells me I'm nuts, because if
[14] two surgeries didn't work, the spray was not going to
[15] work. I figure, Well, I'm going to try it. So, I sent
[16] for it, put it on the nightstand, the first night he
[17] was home, I woke him up, I said, John, spray your
[18] throat. He said, Yeah, yeah, yeah, yeah. I said,
[19] John, please, spray your throat. So, we sprayed his
[20] throat, and I'm like waiting — I'm laying there, I'm
[21] laying there, I'm like, Oh, wow, he was sleeping, there
[22] was no noise coming out of him. And I was — I was
[23] pretty well hooked. And he still was not a believer.
[24] He said it was just a fluke. So, it took a few times
[25] of using the Snorenz.

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[1] Now, I'll tell you what, he's taken it up to
[2] the fire department. I have the wives calling from the
[3] fire department asking me the 800 number. I've given
[4] away more bottles, I can't tell you, because I belong
[5] to the Snorenz Bottle of the Month Club, and I just
[6] gave one to my daughter last week, she came over, and
[7] she was like, Mom, I'm going crazy, Kenny's snoring. I
[8] said, Here, take my last bottle, take it home.

[9] JON DENNY: And how long now has your family or
[10] your husband in particular been using Snorenz?

[11] TINA HINES: Oh, for — oh, months.

[12] JON DENNY: For months.

[13] TINA HINES: Months, absolutely.

[14] JON DENNY: And it works for him pretty much
[15] every night.

[16] TINA HINES: Well, he takes it in his little
[17] duffle bag when he goes to the fire department, because
[18] being a medic, also, he might be called to another
[19] station, he doesn't want to go to another station with,
[20] you know, guys he doesn't know and start snoring. So,
[21] he carries it in his little bag, and everyplace he
[22] goes, the Snorenz goes with him.

[23] JON DENNY: Right. Well, Tina, thank you for
[24] calling from Arizona.

[25] TINA HINES: Hey, thanks for the Snorenz, I'll

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[1] tell you.
[2] JON DENNY: Well, we appreciate you calling and
[3] continue to get a full silent night's sleep.
[4] TINA HINES: Absolutely.
[5] JON DENNY: Okay, Tina, thank you.
[6] TINA HINES: Thank you.
[7] JON DENNY: Bob, tell us about some of your
[8] patients who have been turned on to Snorenz.
[9] DR. BOB COURIER: Well, I'll give you a good
[10] example. I have Mike. Now, we always think of a
[11] snorer as someone that's older, okay, that's a little
[12] bit more passed middle age, always a male, and it's
[13] always grandpa, the chainsaw, somebody like that.
[14] Interestingly enough, I had a 25-year-old patient of
[15] mine named Mike who is an optician. Now, Mike was
[16] trying to qualify, okay, for the certifying exam to
[17] become a certified optician. He was losing energy.
[18] He just couldn't — he couldn't understand it.
[19] He couldn't understand why he didn't have the get-up
[20] and go to do his job, plus go home to study. He's
[21] single. He lives by himself.
[22] So, he's wondering why. I said, Well, you
[23] know, maybe you're not sleeping well. And he said,
[24] Well, you know, I just can't sleep. So, what happens
[25] to him is I give him some Snorenz. I said, Well just

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[1] try this, it's just an outside shot, I said you have
[2] got to try this, let me know how it works.
[3] He comes back, now, I don't see him in a week
[4] or two on another appointment basis, he comes back, and
[5] my word, he just — he's just aglow. He passed the
[6] certifying exam, he feels like he is more awake, more
[7] energetic, he feels like he can do anything, he can
[8] conquer the world. He's 25 years old.
[9] What has happened is he relayed this story:
[10] What happened to him is he would fall asleep, he
[11] couldn't get to sleep at night, okay, so he'd sit up
[12] and watch late night TV and he becomes an insomniac.
[13] What he would do is fall asleep, but he would
[14] awake with a snore. This way, with using Snorenz, he
[15] could get his clock back in order, he could go to
[16] sleep, and he could go to sleep snoring free, wake up
[17] refreshed in the morning. He figured it all out real
[18] simply, and it took us years to figure all this out,
[19] and he did it in a very short time.
[20] Now, he doesn't have a bed partner, and so what
[21] happens is he did this for himself, for his own energy
[22] level, and so, you know, it has worked successfully for
[23] him. It isn't always a bedmate telling someone that
[24] they have it. He did it for himself.

[25] JON DENNY: You think of snorers as older

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[1] people, your grandfather, your father. I remember
[2] growing up my father — listening to my father across
[3] the hallway snoring, it sounded like the start of the
[4] Indianapolis 500 every night. But, in fact, younger
[5] people snore, too, do they not? In fact, there's a
[6] study out about students who were snorers who were
[7] proven to have lower test scores. Tell me about that.

[8] JOHN ZIGLAR: I was reading the newspaper here
[9] in Chicago one day and the Sun Times has an article,
[10] and the top of the article says, "Test scores affected
[11] by snoring." So, I'm looking at it, I'm thinking, Wow,
[12] you know, there's actually been a study done, and what
[13] had happened is a research program was done over in
[14] West Germany with medical students, and what they did
[15] is they tracked an entire medical school class from the
[16] day they started until the day they finished, and they
[17] put them in two categories.

[18] One category was the snorers and over here was
[19] the category of the nonsnorers, and after everything
[20] was said and done, are from start to finish, the
[21] nonsnorers scored six percent higher on their test than
[22] the snorers did, all other things being equal.

[23] JON DENNY: And you just happened to run across
[24] this. So, it's now becoming an awareness. People are
[25] becoming aware now, and it's — see, it's all too

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[1] obvious now when you read something like this why that
[2] would happen, because we're all aware, and my patients
[3] are aware of this.

[4] Interestingly enough, I store this on the —
[5] well, on shelves and such in the office. When we do
[6] our inventory at the end of the day, I find that some
[7] has been taken. I don't want to say stolen, because
[8] these are my patients, and we have created a
[9] relationship, but actually, it's missing.

[10] ON SCREEN: This is a paid commercial for
[11] Snorenz

[12] DR. BOB COURIER: So, what happens is it just
[13] plain gets taken. People want this. People are now
[14] aware, and I think this is what's happening here, and
[15] we know why people don't score well. They don't sleep
[16] well. They snore.

[17] ON SCREEN: 800-392-4006

[18] JON DENNY: Ninety million Americans snore.

[19] That doesn't include the countless millions who sleep
[20] next to a snorer, and if you want more information
[21] about this revolutionary, breakthrough product, which
[22] has been proven effective in 97 percent of cases to
[23] eliminate or reduce the sound of snoring, call the
[24] toll-free 800 number on your screen, get more
[25] information about Snorenz, do it for him, do it for

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[1] yourself, do it for your family. It is worth the phone
[2] call, and it is pennies per day to end the snoring
[3] problem forever.

[4] This is a product, as I mentioned, that has
[5] been proven effective in double-blind studies, and you
[6] actually conducted the studies out of your auspices in
[7] Michigan. Tell us about a double-blind study, what it
[8] is and how Snorenz worked.

[9] DR. BOB COURIER: Really, just to define what a
[10] double-blind study is in general is nobody knows what
[11] product anybody is getting. The doctor isn't aware of
[12] it, okay, and nor are the patients. For example, we're
[13] giving a block or a bunch of bottles, for example, in
[14] this case, Snorenz, and we are to distribute this out
[15] to our patients in a test pattern, they are going to
[16] use it for a week, but I am blind to the fact of what
[17] product am I giving them, the placebo or dummy product
[18] versus the actual product itself. I'm not aware, so I
[19] cannot influence the study results.

[20] I accumulate the study results, I gather the
[21] patients and have them get compliant with it for use
[22] over a week's time, but I don't — I can't affect it.
[23] The patients can't affect it. So, I am blind to it,
[24] and so are the patients.

[25] Interestingly enough, it's not only the results

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[1] of the studies we got but the comments we received.
[2] Many people, again, they're aware of snoring, but they
[3] aren't aware of the problems that come with it, and
[4] actually it's like — until it's resolved, the snoring
[5] itself, oh, my word, what a problem it was, and you can
[6] see the changes it's made. That was probably the most
[7] interesting part of doing that whole study, was the
[8] comments that we got back, the little stories that
[9] people have through the week, you know, of using this
[10] product, and that was the beauty of this.

[11] I loved doing this study. It was highly
[12] effective.

[13] JON DENNY: And John, this is an all-natural
[14] product?

[15] JOHN ZIGLAR: It's all-natural oils, and we
[16] also have some vitamins that we have also put into the
[17] product.

[18] JON DENNY: Tell us about snorer's breath. I'm
[19] going to test this here. I hope I don't get it in my
[20] eye. It would eliminate my — some problem in my eye,
[21] perhaps, but I — it's minty, actually it tastes a lot
[22] like mouthwash, I mean, it's — in a good way. Three
[23] sprays of this before bed, and how long will this last,
[24] through the night?

[25] JOHN ZIGLAR: It will last through the night.

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[1] It will last from six to eight hours.
[2] JON DENNY: And in what cases doesn't this
[3] work?
[4] JOHN ZIGLAR: You know, when I first got this
[5] product, we did test — and I have given it to
[6] everybody that I know that snores so that I could find
[7] out, you know, because I always wanted to know exactly
[8] how did it work on everybody else. So, we had one
[9] friend we gave it to, and quite honestly, they had been
[10] married for three years, they're already sleeping in
[11] different bedrooms because he snores so loudly, and he
[12] would go to bed — they would go to bed together, wake
[13] up in different rooms.
[14] And so Kevin was taking the product, and the
[15] first night it worked perfectly, the second night it
[16] worked perfectly, third night it worked perfectly,
[17] fourth night, didn't work, fifth night, didn't work.
[18] He called me up and he says, Look, you know, it works
[19] temporarily, but after that, it doesn't — it doesn't
[20] work. And I said, Wait a minute, you know, there's got
[21] to be a reason. There's something wrong here, the only
[22] guy it doesn't work on in the world.
[23] And he says, Well — so, I started to ask him
[24] some questions, and here's the point. What I found out
[25] was the night that it did not work, he had a beer just

Page 28

[1] before he went to bed, and what we had here was a
[2] situation where the alcohol in the beer literally cut
[3] through the oils in our product, and it went down his
[4] throat, so it was not there. Since it was not there,
[5] it could not work, and it proved that he still was a
[6] snorer, he just needed the product to stay where it was
[7] so that he would live without the noise.

[8] JON DENNY: So, you suggested that he sort of
[9] cut down his drinking right before going to bed.

[10] JOHN ZIGLAR: Exactly, don't eat or drink
[11] anything 30 minutes before you go to bed, or if you do,
[12] then take a couple of swallows of water just to clear
[13] your pallet so that your throat is clean so that when
[14] you put the product in on the back of your tongue, then
[15] it will stay there.

[16] JON DENNY: Right. Your wives are happy,
[17] gentlemen, that you —

[18] DR. BOB COURIER: Happier, happier.

[19] JON DENNY: We won't get into that, but they're
[20] happy that your snoring problems have been reduced or
[21] eliminated.

[22] DR. BOB COURIER: Yes, very much so.

[23] JOHN ZIGLAR: And now, you know, I roll over
[24] and Linda gives me a kiss before we go to bed, and I
[25] think that's just real sweet. She's checking to see if

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- [1] I've taken the Snorenz, okay?
[2] **JON DENNY:** If you want more information about
[3] this revolutionary, all-natural, vitamin-based spray,
[4] no pills, no surgery, no clamps, no strips across your
[5] nose, Snorenz will end your snoring problem and do it
[6] naturally. It is pennies in comparison to the value
[7] and the almost priceless value of a full, restful,
[8] silent night's sleep for all, and that goes for the
[9] snorer as well as the person sleeping next to the
[10] snorerailroad.
[11] For more information, call the 800 number on
[12] the screen.
[13] Dr. Bob Courier, thank you for joining us on
[14] Vantage Point.
[15] **DR. BOB COURIER:** Thank you for having me.
[16] **JON DENNY:** And, John Ziglar, thank you.
[17] **JOHN ZIGLAR:** Enjoyed it.
[18] **JON DENNY:** I may knock off a few sprays
[19] tonight and try to get my snoring down. This is Jon
[20] Denny saying good-bye from Vantage Point, and we will
[21] see you next time.
[22] **ON SCREEN:** For more information on Snorenz
[23] call: 800-392-4006
[24] Tru-Vantage International
[25] 7300 Lehigh Ave.

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- [1] Niles, IL 60714
[2] (847)647-0300
[3] **ON SCREEN:** The preceding has been a paid
[4] commercial for SNORENZ brought to you by Kevin
[5] Trudeau's Tru-Vantage International, America's premier
[6] direct response marketing company.
[7] (The videotape was concluded.)
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- [1] **CERTIFICATION OF TRANSCRIBER**
[2]
[3] DOCKET/FILE NUMBER: 0023211
[4] CASE TITLE: MED GEN, INC.
[5] RECORDING DATE: OCTOBER 13, 1999
[6] TRANSCRIPTION DATE: MAY 15, 2000
[7] I HEREBY CERTIFY that the transcript contained
[8] herein is a full and accurate transcript of the
[9] videotapes transcribed by me on the above cause before
[10] the FEDERAL TRADE COMMISSION to the best of my
[11] knowledge and belief.

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SUSANNE Q. TATE

CERTIFICATION OF PROOFREADER

- [1] I HEREBY CERTIFY that I proofread the
[2] transcript for accuracy in spelling, hyphenation,
[3] punctuation and format.

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[2] OFFICIAL TRANSCRIPT PROCEEDING
[3]
[4] FEDERAL TRADE COMMISSION
[5]
[6] MATTER NO. 0023211
[7]
[8] TITLE MED GEN INC.
[9]
[10] DATE RECORDED: OCTOBER 13, 1999
[11] TRANSCRIBED: MAY 10, 2000
[12]
[13] PAGES 1 THROUGH 35
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[16] VP SNORENZE 4 - JD W/ DISCLAIMER SNR4
[17] VIDEOTAPE
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[1] FEDERAL TRADE COMMISSION
[2]
[3] In the Matter of:)
[4] Med Gen, Inc.,) Matter No. 0023211
[5]
[6] October 13, 1999
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[12] The following transcript was produced from a
[13] videotape provided to For The Record, Inc. on May 8,
[14] 2000.
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[2] INDEX
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[4] VIDEOTAPE PRESENTATION: PAGE:
[5] VP SNORENZE 4-JD W/ DISCLAIMER SNR4 3
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PROCEEDINGS
ON SCREEN:
[4] Tru-Vantage & Mercury Media
[5] Present
[6] VP SNORENZ 4
[7] JD WITH DISCLAIMERS // SNR4
[8] 28:30 MINUTES
[9] 1-800-835-8941
[10] TUESDAY, NOVEMBER 17, 1998
[11] NCMG MASTER #293 Randy Pfeiffer
[12] CUSTOMIZATION BY NORTH COUNTRY MEDIA GROUP
[13] www.ncmg.com
ON SCREEN:
[16] The following is a paid commercial for SNORENZ
[17] brought to you by Kevin Trudeau's Tru-Vantage
[18] International, America's premier direct response
[19] marketing company.
[21] ANNOUNCER: The following is a paid commercial
[22] brought to you by Kevin Trudeau's Tru Vantage
[23] International.
[24] (Music playing.)
[25] UNIDENTIFIED MALE: For millions of Americans,

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[1] this is the most annoying and unwelcome sound in the
[2] world.
[3] **ON SCREEN:** News clippings.
[4] **ANNOUNCER:** That's right, more than 90 million
[5] Americans have a snoring problem and it can cause
[6] sleeplessness, headaches and a lack of energy, and that
[7] goes for the snorer, as well as the person trying to
[8] sleep next to the snorer.
[9] What can be done about it? On Vantage Point
[10] today, hear about a new discovery that could eliminate
[11] the sound of snoring.
[12] **ON SCREEN:** VANTAGE POINT with Kevin Trudeau.
[13] **ON SCREEN:** John Denny.
[14] **JOHN DENNY:** Hi, I'm John Denny, and this is a
[15] special edition of Vantage Point. We're going to talk
[16] about snoring today, and if you're a snorer, or just
[17] happen to sleep next to one, then you know snoring is no
[18] laughing matter. Snoring can and does seriously diminish
[19] the quality of your sleep, your life, and it could drive
[20] two people apart, meaning the snorer and the person next
[21] to the snorer.
[22] My guests today are Dr. Bob Currier, physician,
[23] surgeon and associate clinical professor at Michigan
[24] State University, and John Ziglar, who represents a
[25] company that manufactures a product called Snorenz, which

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[1] is designed to end your snoring problem.
[2] Gentlemen, thank you for joining me. Guys, got
[3] to ask you this first question, because for some people
[4] it's a light matter and for others it seriously impacts
[5] their life, certainly impacts their sleep. What causes
[6] snoring? What is the reason behind that all too familiar
[7] rumbling sound that keeps half of America, it seems, up
[8] every night?
[9] **ON SCREEN:** Dr. Bob Currier, Physician/Surgeon.
[10] **DR. BOB CURRIER:** Well, what snoring really is,
[11] John, is just simply a relaxation of the tissues in the
[12] back of your throat. It's when we fall asleep, much of
[13] our muscles in our body, as well as our throat relax.
[14] That's the time we sleep. We're supposed to get our
[15] rest.
[16] **JOHN DENNY:** Um-hmm.
[17] **DR. BOB CURRIER:** What happens with that,
[18] though, unfortunately, is as the tissues relax, they
[19] occlude or actually narrow, and they cause a funnel
[20] effect for the air as it goes through, flapping the
[21] tissue.
[22] **JOHN DENNY:** Um-hmm.
[23] **DR. BOB CURRIER:** This is in the back of the
[24] throat, hence creating the noise. It's very positional.
[25] It's very — also very dependant on habits that we have,

Page 6

[1] such as smoking or dietary habits. And then also it
[2] affects really how much we sleep and how much rest we
[3] actually get throughout a night.
[4] **JOHN DENNY:** Now, you were both snorers,
[5] presumably?
[6] **DR. BOB CURRIER:** Um-hmm.
[7] **JOHN ZIGLAR:** Sure.
[8] **DR. BOB CURRIER:** Absolutely.
[9] **JOHN DENNY:** Tell me, how did you get involved
[10] in Snorenz? How did this all come about?
[11] **ON SCREEN:** John Ziglar, SNORENZ.
[12] **JOHN ZIGLAR:** This all came about, John, I met
[13] a friend down in Fort Lauderdale, Florida, named Paul
[14] Kravitz.
[15] **JOHN DENNY:** Um-hmm.
[16] **JOHN ZIGLAR:** Paul Kravitz was in the banking
[17] industry. And he had a Korean man that came into his
[18] office with a product. He had a little bottle of it, it
[19] didn't have any labels on it or anything, but he says
[20] this will make you quit snoring. And Paul looked at it
[21] and he put it over on the side of his desk, he didn't
[22] think too much about it. But he did make the mistake of
[23] telling his wife that somebody had come in with this
[24] product. And she asked him would he go ahead and bring
[25] it home and try it. Bottom line is he did use the

Page 7

[1] product, it did make him quit snoring, but it tasted
[2] terrible.
[3] And, so, Paul says Whoa, you know, what a price
[4] to pay, so he took that product, he developed it, he took
[5] it to the laboratories and they did some liposome
[6] technology with the product and they put a flavor to the
[7] product to make it so that it tasted good and we now call
[8] the product Snorenz, and it's just phenomenal.
[9] **JOHN DENNY:** And in your first exposure to it -
[10]
[11] **JOHN ZIGLAR:** Correct.
[12] **JOHN DENNY:** — you were a rumbler. You — we
[13] heard Harley-Davidson sounds coming from you at night —
[14] **JOHN ZIGLAR:** (Laughter).
[15] **JOHN DENNY:** — is the word on the street.
[16] **JOHN ZIGLAR:** (Laughter).
[17] **JOHN DENNY:** Tell me your first experience with
[18] the product.
[19] **JOHN ZIGLAR:** My first experience really, when
[20] I — I had been married for 25 years, my wife, Linda. I
[21] came home after talking with Paul and I told my wife
[22] about this new product that we were looking at. And she
[23] said — and she says well, when are you going to bring it
[24] home. And I said Well, honey, I said, really, you know,
[25] you don't snore that bad. And she said it really wasn't

[1] for her.
[2] JOHN DENNY: (Laughter).
[3] DR. BOB CURRIER: (Laughter).
[4] JOHN ZIGLAR: And up until that point I really
[5] didn't realize that I snored.
[6] JOHN DENNY: Um-hmm.
[7] JOHN ZIGLAR: But I did turn over in the bed an
[8] awful lot at night, and I knew that. And, so, I used the
[9] product and, John, what I found is for me personally, I
[10] quit turning over so many times at night. And I began to
[11] get a more peaceful, restful sleep.
[12] JOHN DENNY: Um-hmm.
[13] JOHN ZIGLAR: So, that's what personally
[14] happened in my life.
[15] JOHN DENNY: Well, that raises an interesting
[16] point, because for some people snoring in a litany of
[17] problems, you know, that we face on an everyday basis,
[18] snoring is not at the top of the list. But, in fact, if
[19] you speak to people who sleep next to a snorer, as well
[20] as the snorer themselves, there are some real health
[21] issues, there are some real serious concerns that a
[22] snorer has, or should have. How does, and why does, a
[23] snorer — why should a snorer worry about this? Why is
[24] it a problem?
[25] DR. BOB CURRIER: Well, it is a problem, but

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[1] the things that happen to us on an everyday basis: the
[2] energy level that we have. We're not rested.
[3] JOHN DENNY: So, you're saying snorers —
[4] DR. BOB CURRIER: That's the battle.
[5] JOHN DENNY: — snorers get less rest, get a
[6] less restful —
[7] DR. BOB CURRIER: Absolutely. They do not
[8] sleep.
[9] JOHN ZIGLAR: See, what happened to me, what
[10] was going on in my night, is I would literally turn over
[11] 20 or 30 times a night. And the reason I would is
[12] because I would go to sleep, my tissues would relax, I
[13] would snore — I would literally wake myself up, and then
[14] I would turn over. And I would turn. Well, now, I
[15] didn't wake up and get up out of the bed to turn over.
[16] JOHN DENNY: Um-hmm.
[17] JOHN ZIGLAR: I would just wake up and turn
[18] over. And what that does is it keeps me, John, from
[19] getting the deep, restful sleep.
[20] JOHN DENNY: Hmm.
[21] JOHN ZIGLAR: We get letters. We got a letter
[22] from a lady out in Phoenix also who told us that for the
[23] first time in her life she started taking this product
[24] and she can remember her dreams. Well, you see, dreaming
[25] is an important thing, and we all dream, if we get

Page 10

[1] the real problem is an awareness. A lot of people aren't
[2] aware, as you were, that you didn't snore, you don't
[3] snore. It's — and people don't want to offend someone
[4] else that they may sleep with or someone in their family
[5] by telling them they snore.
[6] JOHN DENNY: Um-hmm.
[7] DR. BOB CURRIER: And they've put up with it
[8] for years.
[9] JOHN DENNY: Um-hmm.
[10] DR. BOB CURRIER: The problem with that is all
[11] the things that go with it, even on a personal level. Me
[12] personally, I snore and have snored, and I've used the
[13] product, as well, and it's worked great for me.
[14] ON SCREEN: These statements have not been
[15] evaluated by the Food and Drug Administration. This
[16] product is not intended to diagnose, treat, cure or
[17] prevent any disease.
[18] DR. BOB CURRIER: Why do I know this? Because
[19] of my energy level, I feel better, I get better sleep.
[20] The problems that happen, I think people go to
[21] sleep, they assume they're automatically going to wake up
[22] rested. They don't. And then they wake up with a
[23] headache, less energy, they hurt, they're sore, they're
[24] irritable. The health problems are really insidious.
[25] But let's not even go that deep. Let's just talk about

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[1] peaceful, restful sleep.
[2] JOHN DENNY: But isn't dreaming or the dream
[3] state indicative of a deep, restful, REM sleep, I think
[4] they call it?
[5] DR. BOB CURRIER: Yes. Yes, it is.
[6] JOHN DENNY: So if you're a snorer, you won't
[7] dream as much, meaning you're not getting as deep a
[8] sleep. Is that what —
[9] DR. BOB CURRIER: That is correct. You almost,
[10] because of the snoring, and sometimes we're not aware of
[11] it, keep waking ourselves up. We snore, and we huh
[12] (indicating), and then we wake up, then we try to
[13] reposition ourselves. We're just not comfortable. We
[14] can't get our air; we can't get the oxygen we need, hence
[15] the headache, the irritability when we wake up. We're
[16] not rested. That's the problem.
[17] ON SCREEN:
[18] Dr. Bob Currier
[19] Physician/Surgeon.
[20] DR. BOB CURRIER: Another side effect, a cute
[21] story, my brother is also a snorer. I think this is just
[22] something that runs in families, as well. Anyway, he has
[23] since tried the product, as I have, and I use it and I
[24] think it's fantastic because it does stop the snoring.
[25] My brother has also — he doesn't have the aches and

Page 11

Page 12

[1] pains he used to wake up with.
[2] You were also talking about the tossing and
[3] turning, we're also forgetting his wife used to jab him
[4] in the middle of the night, so he does not wake up
[5] bruised, so this also helps, a little sidelight there.
[6] DR. BOB CURRIER: Yes.
[7] JOHN DENNY: How does Snorenz work? There have
[8] been other products available, over the course of the
[9] last, you know, 10 and 20 years that are — have been in
[10] pill form, surgeries. People have gone through painful,
[11] expensive surgeries.
[12] In fact, we're going to — I think we're going
[13] to talk to a caller later who has a story to share with
[14] us about this product and the journey she went through
[15] with her husband to essentially reduce this problem or
[16] eliminate this problem. How does this product work?
[17] JOHN ZIGLAR: John, what we've done is we have
[18] taken all-natural oils, and we have taken and put them
[19] together in a liposome formulation. And we have taken it
[20] and so that you can actually spray this product into the
[21] back of your throat. And the process is really quite
[22] simple. Have you ever seen a car go down the road that
[23] didn't have enough oil in it?
[24] JOHN DENNY: Um-hmm.
[25] JOHN ZIGLAR: And you hear the clatter and the

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[1] that we say that flap and flutter and then need the
[2] lubrication —
[3] JOHN DENNY: Yeah.
[4] DR. BOB CURRIER: — when it is applied there,
[5] but when the technology goes even further and better
[6] through this liposome technology, is to apply it evenly.
[7] And the very neat thing about this is it stays. It stays
[8] there all night.
[9] JOHN DENNY: Hmm.
[10] DR. BOB CURRIER: That's where others have
[11] failed, and that's also where a lot of the appliances,
[12] that's where also a lot of the applications of surgeries,
[13] pills, other things that have been attempted and tried
[14] have failed.
[15] JOHN DENNY: Um-hmm.
[16] DR. BOB CURRIER: This product here stays
[17] there. It's easy application. As a physician, one of
[18] the problems that I have with patients is compliance,
[19] trying to get them to use and continually use something.
[20] JOHN DENNY: Um-hmm.
[21] DR. BOB CURRIER: If we're going to get a
[22] restful sleep, we need it on an every-night basis. This
[23] is accrued, we have a clock and we have a bank and it's
[24] for sleeping purposes. So, it isn't something that just
[25] one night good sleep will help. This is something that's

Page 13

[1] clanking.
[2] ON SCREEN:
[3] JOHN ZIGLAR
[4] SNORENZ
[5] JOHN DENNY: Yes.
[6] JOHN ZIGLAR: Well, what happens is we took
[7] that same philosophy, that same technology, and we said
[8] hey, if we can oil the parts and we can take and make a
[9] topical solution that will stay in a place for an
[10] extended period of time, we can eliminate the noise —
[11] JOHN DENNY: Um-hmm.
[12] JOHN ZIGLAR: — of snoring. You're still
[13] going to have the same amount of air that's going to pass
[14] through the passage, but all we're going to do is we're
[15] going to lubricate the parts so that there is no noise
[16] associated so that you don't then wake up or wake up your
[17] neighbor.
[18] JOHN DENNY: So, it's essentially lubricating
[19] what part of the throat, and which part of the throat is
[20] causing that sound?
[21] DR. BOB CURRIER: Well, to take this just a
[22] little bit further, a dentist has studied this and has
[23] actually sprayed this in models, and he actually used a
[24] dye at the time so he could see where it was applied. In
[25] the soft tissues, in the back of the throat, the ones

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[1] accrued over time. When you get good sleep, that helps a
[2] lot. We need compliance. With the ease of application,
[3] as what he is talking about, okay?
[4] JOHN DENNY: Um-hmm.
[5] DR. BOB CURRIER: With the effectiveness of its
[6] staying there, it's a winner. And that's how it works.
[7] JOHN DENNY: So, it's basically — correct me
[8] if I'm wrong — it's two or three sprays in the back of
[9] your mouth. I have a friend who underwent a session with
[10] a dentist who fitted him with a clamp of some sort, which
[11] pushed his jaw out and tried to create more breathing
[12] space essentially, and that lasted for about three to
[13] four months. This works, and it stays working for
[14] people?
[15] DR. BOB CURRIER: Yes, what you're trying to do
[16] with the appliance is just simply try to open up the
[17] airway more so you don't get the fluttering of the
[18] tissues.
[19] JOHN DENNY: Um-hmm.
[20] DR. BOB CURRIER: What — and that's what we do
[21] when we snore. When we snore, we essentially wake
[22] ourselves up in a snore, and then reposition ourselves,
[23] trying to again open up our airway to get more air so we
[24] get more oxygen. What happens with this product, this
[25] lubricates, stays there, again through the technology.

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[1] and then you don't have the snore; hence, you don't wake
[2] up; hence, you get a more restful sleep.
[3] JOHN ZIGLAR: And the problem, John, with the
[4] appliance is it's very uncomfortable.
[5] JOHN DENNY: Um-hmm.
[6] JOHN ZIGLAR: And there have been a lot of
[7] people, and dentists will tell you that they have got
[8] patients who have paid for the procedure, paid to get the
[9] appliance, could not sleep with it hooked up.
[10] JOHN DENNY: Um-hmm.
[11] JOHN ZIGLAR: And, so, it did not work for them
[12] because they were so uncomfortable.
[13] JOHN DENNY: Um-hmm.
[14] JOHN ZIGLAR: Okay? And, so, when I saw this
[15] first — this product the first time, I looked at this
[16] thing and I thought oh, my goodness, you know, I'm going
[17] to spray oil in the back of my throat. I'm thinking WD-
[18] 40 or something like that, you know —
[19] JOHN DENNY: Right.
[20] JOHN ZIGLAR: — and an oil slick, and I'm
[21] going oh, but it's the consistency of water. And the
[22] nice thing about it is is that it does — there's no
[23] feeling associated with the spray in the back of your
[24] throat. All you get is a nice, clean, peppermint taste -
[25]

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[1] snoring, if it's a snorer next to you or if you be the
[2] snorer, you may want to call the 800 number on your
[3] screen.
[4] We have, I believe, a caller on the line from
[5] Arizona, and I believe it's Tina Heinz. Tina, are you on
[6] the air with us?
[7] TINA HEINZ: I'm here.
[8] JOHN DENNY: Great. How you feeling today?
[9] TINA HEINZ: Good. I'm listening to your show,
[10] and I have to tell you that snoring, you know, is a lot
[11] more dangerous than people think.
[12] JOHN DENNY: Hmm.
[13] TINA HEINZ: My husband was a chronic snorer.
[14] He's a firefighter/paramedic, so I wasn't the only one
[15] affected by this.
[16] JOHN DENNY: Hmm. Um-hmm.
[17] TINA HEINZ: I mean, we didn't sleep together
[18] for years.
[19] JOHN DENNY: Now, you've been married for how
[20] long, Tina?
[21] TINA HEINZ: Sixteen years.
[22] JOHN DENNY: Sixteen years. And this was a
[23] problem that occurred right from the start of your
[24] marriage?
[25] TINA HEINZ: Oh, yeah.

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[1] JOHN DENNY: Hmm.
[2] JOHN ZIGLAR: — which made it wonderful, so
[3] compliant, people will do it.
[4] ON SCREEN: This is a paid commercial for
[5] Snorenz.
[6] DR. BOB CURRIER: Well, the aftertaste.
[7] JOHN ZIGLAR: Yes.
[8] DR. BOB CURRIER: In the morning, when you wake
[9] up, it's better.
[10] JOHN ZIGLAR: Exactly.
[11] DR. BOB CURRIER: You don't feel like you have
[12] an oil sludge at all. It's a minty taste.
[13] ON SCREEN: 1-800-835-8941
[14] JOHN DENNY: If you have a snoring problem, if
[15] you have problems sleeping next to a snorer, then Snorenz
[16] may be the answer you've been waiting for. Snoring can
[17] seriously reduce your energy levels, your concentration,
[18] and can seriously affect your work habits, as well. And
[19] you can be sure your snoring is seriously bothering
[20] someone other than you.
[21] Snorenz is the first all-natural spray that has
[22] been proven to give you a healthy, natural, good night's
[23] sleep. It has no side effects, it's as easy as a few
[24] sprays before bed, and it lasts all night. If you want
[25] more information on Snorenz, if you want to stop the

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[1] JOHN DENNY: I mean, you found you were married
[2] to a snorer?
[3] TINA HEINZ: Oh, absolutely. And the poor guy,
[4] it would be all night, John, turn over, turn over. It
[5] did not matter, he could be sleeping on his head and he
[6] would still snore. Well, it got so bad that even at the
[7] fire department he was being, you know, hassled at the
[8] fire department because these guys sleep at different
[9] shifts, they don't all sleep at the same time.
[10] JOHN DENNY: Um-hmm.
[11] TINA HEINZ: And when John was sleeping, he
[12] would be waking everybody else up, and they'd be pounding
[13] on the walls, and he'd come home all aggravated, he'd
[14] come home and want to sleep. They built a partition
[15] around my husband's bunk bed to try to keep out the
[16] noise.
[17] (Laughter).
[18] TINA HEINZ: Well, it got so bad he finally
[19] went to the doctor and, in order for the insurance
[20] company to pay for this surgery, they put him in the
[21] hospital in the sleep center and found out that he also
[22] had sleep apnea, which is very dangerous because when
[23] you're snoring you stop breathing and you forget to
[24] sleep.
[25] JOHN ZIGLAR: Um-hmm.

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[1] TINA HEINZ: So, they did this surgery, and
[2] needless to say, it lasted for a while and after that he
[3] started up again, and he would not even believe when I
[4] would tell him John, you're snoring again.

[5] JOHN DENNY: Hmm.

[6] TINA HEINZ: You don't want to go through
[7] surgery and find out that you're snoring again.

[8] JOHN DENNY: So, this was after a surgery, he
[9] had — the problem re-emerged?

[10] TINA HEINZ: Right, they did surgery on all his
[11] sinuses. They went through his nose, and they removed
[12] all his polyps, thinking that was the problem. So, now,
[13] he's in for a second surgery, and they decided that
[14] they're going to remove part of his uvula and the roof of
[15] his mouth, his tonsils and his adenoids.

[16] JOHN DENNY: Hmm.

[17] TINA HEINZ: And this will give his tongue more
[18] room, I guess is what they said, so he wouldn't snore.

[19] DR. BOB CURRIER: Um-hmm.

[20] TINA HEINZ: Well, he went through this and it
[21] was a horrible surgery. I really felt very, very bad for
[22] him. He was out of work for six weeks, and he had high
[23] hopes that this was going to work and our life was going
[24] to change, we could sleep in the same room together, go
[25] on vacation, the guys wouldn't be hassling him. Well,

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[1] that did work for quite a while and then it started up
[2] again.

ON SCREEN:

[3] Caller from Phoenix, AZ

[4] Tina Heinz

[5] TINA HEINZ: And I tell you, I was even afraid
[6] to tell him, because I couldn't believe it myself. It's
[7] aggravating; it's annoying. I don't get a good night's
[8] sleep; he doesn't get a good night's sleep. I hated to
[9] say, but I was happy when he was at the fire department
[10] because I got a good night's sleep.

[11] (Laughter).

[12] JOHN DENNY: Tina, I want to interrupt you for
[13] a second, because this is, you know, a real relatable
[14] story to some, perhaps not all have gone through
[15] surgeries and so forth, but for the millions of people
[16] who sleep next to a snorer, their lives are affected as
[17] well. How did you find your life or your sleep quality
[18] affected by sleeping next to a snorer?

[19] TINA HEINZ: Well, I didn't, I chased him out.

[20] JOHN DENNY: Right.

[21] TINA HEINZ: Actually, I have insomnia, and I
[22] don't get — I mean, I could hear the dog turn over, so
[23] he'd have to go into the other room, and I would still
[24] hear him through the vents, but I would get up in the

Page 22

[1] morning and I would be a grouch at work because I was —

[2] I was tired.

[3] JOHN DENNY: Yes.

[4] JOHN ZIGLAR: Um-hmm.

[5] TINA HEINZ: And I was aggravated. You're

[6] talking two surgeries, what is it going to take? He

[7] tried those stupid nose-strip things, they didn't work.

[8] JOHN DENNY: Hmm.

[9] TINA HEINZ: So, one day I'm sitting here

[10] watching TV and I see a commercial out here in Phoenix,

[11] and a couple's talking about the same things. And I'm

[12] thinking, well, what have I got to lose. My husband

[13] tells me I'm nuts because his two surgeries didn't work,

[14] a spray was not going to work.

[15] I figure well, I'm going to try it. So, I sent

[16] for it; put it on the nightstand. First night he was

[17] home, I woke him up, I said John, spray your throat; he's

[18] like yeah, yeah, yeah, yeah. I said John, please, spray

[19] your throat. So, we sprayed his throat, and I'm like

[20] wait, I'm laying there, I'm laying there, I'm like oh,

[21] wow, he was sleeping, there was no noise coming out of

[22] him.

[23] And I was — I was pretty well hooked. And he

[24] still was not a believer; he said it was just a fluke.

[25] So, it took a few times of using the Snorenz. Now, I

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[1] tell you what, he's taking it up to the fire department.

[2] I had the wives calling up from the fire department

[3] asking me the 800 number. I've given away more bottles,

[4] I can't tell you —

[5] JOHN DENNY: (Laughter).

[6] TINA HEINZ: — because I bought the Snorenz

[7] bottle-of-the month club.

[8] JOHN DENNY: Um-hmm.

[9] TINA HEINZ: And I just gave one to my daughter

[10] last week. She came over and she was like Mom, I'm going

[11] crazy, Timmy's snoring. I said here, take my last

[12] bottle, take it home.

[13] JOHN DENNY: And how long now has your family

[14] or your husband in particular been using Snorenz?

[15] TINA HEINZ: Oh, for months.

[16] JOHN DENNY: For months?

[17] TINA HEINZ: Months, absolutely.

[18] JOHN DENNY: And it works for him pretty much

[19] every night?

[20] TINA HEINZ: Well, he takes it in his little

[21] duffle bag when he goes to the fire department, because

[22] being a medic also he might be called to another station.

[23] He doesn't want to go to another station with, you know,

[24] guys he doesn't know and start snoring.

[25] JOHN DENNY: Hmm.

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[1] TINA HEINZ: So, he carries it in his little
[2] bag and every place he goes the Snorenz goes with him.
[3] JOHN DENNY: Right. Well, Tina, thank you for
[4] calling from Arizona.
[5] TINA HEINZ: Hey, thanks for the Snorenz, I'll
[6] tell you.
[7] JOHN DENNY: Well, we appreciate your calling
[8] and continue to get a full, silent night's sleep.
[9] TINA HEINZ: Absolutely.
[10] JOHN DENNY: Okay, Tina, thank you.
[11] TINA HEINZ: Thank you.
[12] JOHN DENNY: Bob, tell us about some of your
[13] patients who have been turned on to Snorenz.
[14] DR. BOB CURRIER: Well, I'll give you a good
[15] example. I have Mike. Now, we always think of a snorer
[16] as someone that's older, okay, and that's a little bit
[17] more past middle age, always a male, and it's always
[18] Grandpa, the chain saw —
[19] JOHN DENNY: Um-hmm.
[20] DR. BOB CURRIER: — somebody like that.
[21] Interestingly enough, I had a 25-year-old patient of mine
[22] named Mike who is an optician. Now, Mike was trying to
[23] qualify, okay, for the certifying exam to become a
[24] certified optician. He was losing energy. He just
[25] couldn't — he couldn't understand it, he couldn't

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[1] understand why he didn't have the get-up-and-go to do his
[2] job plus go home to study.
[3] He's single. He lives by himself. So, he's
[4] wondering why. I said, well, you know, maybe you're not
[5] sleeping well. And he said well, you know, I just — I
[6] just can't sleep. And so what happens to him is I give
[7] him some Snorenz. I said well, just try this, it's just
[8] an outside shot, and I said you've got to try this, let
[9] me know how it works.
[10] He comes back, now I don't see him in a week or
[11] two, on another appointment basis. He comes back and my
[12] word, he says — he's just aglow. He passed the
[13] certifying exam; he feels like he is more awake, more
[14] energetic. He feels like he can do anything. He can
[15] conquer the world, he's 25 years old.
[16] ON SCREEN: These statements have not been
[17] evaluated by the Food and Drug Administration. This
[18] product is not intended to diagnose, treat, cure or
[19] prevent any disease.
[20] DR. BOB CURRIER: And what has happened is he
[21] relayed the story. What happened to him is he would fall
[22] asleep; he couldn't get to sleep at night, okay, so he'd
[23] sit up and watch late-night TV, he becomes an insomniac.
[24] What he would do is fall asleep, but he'd wake with a
[25] snore.

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[1] This way, with using Snorenz, he could get his
[2] clock back in order, he could go to sleep, and he could
[3] go to sleep snoring free, wake up refreshed in the
[4] morning. He figured it all out real simple, and it took
[5] us years to figure all this out and he did it in a very
[6] short time.
[7] JOHN DENNY: Um-hmm.
[8] DR. BOB CURRIER: Now, he doesn't have a bed
[9] partner, and so what happens is he did this for himself,
[10] for his own energy level.
[11] JOHN DENNY: Um-hmm.
[12] DR. BOB CURRIER: And, so, you know, there it
[13] has worked successfully for him. It isn't always a bed
[14] mate telling someone that they have it.
[15] JOHN DENNY: Um-hmm.
[16] JOHN ZIGLAR: That's right.
[17] DR. BOB CURRIER: He did it for himself.
[18] JOHN ZIGLAR: Right.
[19] JOHN DENNY: You think of snorers as older
[20] people, your grandfather, your father. I remember
[21] growing up, my father — listening to my father across
[22] the hallway snoring. It sounded like the start of the
[23] Indianapolis 500 every night. But, in fact, younger
[24] people snore, too, do they not? In fact, there's a study
[25] out about students who were snorers who were proven to

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[1] have lower test scores. Tell me about that.
[2] JOHN ZIGLAR: I was reading the newspaper here
[3] in Chicago one day, and the Sun-Times has an article and
[4] the top of the article says Test Scores Affected by
[5] Snoring. And, so, I'm looking at it and I'm thinking
[6] wow, you know, there's actually been a study done. And
[7] what had happened is a research program was done over in
[8] West Germany with medical students.
[9] JOHN DENNY: Um-hmm.
[10] JOHN ZIGLAR: And what they did is they tracked
[11] an entire medical school class from the day they started
[12] to the day they finished, and they put them in two
[13] categories. One category was the snorers, and over here
[14] was the category of the non-snorers. And after
[15] everything was said and done from start to finished, the
[16] non-snorers scored 6 percent higher on their tests —
[17] JOHN DENNY: Hmm.
[18] JOHN ZIGLAR: — than the snorers did, all
[19] other things being equal.
[20] DR. BOB CURRIER: Hmm. And you just happened
[21] to run across this, so it's now becoming an awareness.
[22] JOHN ZIGLAR: Exactly.
[23] DR. BOB CURRIER: Right. People are becoming
[24] aware now. And it's — see, it's all too obvious now
[25] when you read something like this why that would happen,

[1] because we're all aware, and my patients are aware.
[2] Interestingly enough, I store this on — well on shelves
[3] and such in the office. When we do our inventory at the
[4] end of the day, I find that some has been taken. I don't
[5] want to say stolen, because these are my patients and
[6] we've created a relationship, but actually it's missing.

[7] JOHN DENNY: Right.

[8] DR. BOB CURRIER: So, what happens is it just
[9] plain gets taken, people want this.

[10] JOHN DENNY: Hmm.

[11] DR. BOB CURRIER: People are now aware. And I
[12] think this is what's happening here, and we know why
[13] people don't score well, they don't sleep well, they
[14] snore.

[15] ON SCREEN: This is a paid commercial for
[16] Snorenz.

[17] JOHN DENNY: Ninety million Americans snore.
[18] That doesn't include the countless millions who sleep
[19] next to a snorer.

[20] ON SCREEN: 1-800-835-8941.

[21] JOHN DENNY: And if you wanted more information
[22] about this revolutionary, breakthrough product which has
[23] been proven effective in 97 percent of cases to eliminate
[24] or reduce the sound of snoring, call the toll-free 800
[25] number on your screen, get more information about

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[1] JOHN DENNY: And, John, this is an all-natural
[2] product?
[3] JOHN ZIGLAR: It's all-natural oils. And we
[4] also have some vitamins —
[5] JOHN DENNY: Um-hmm.
[6] JOHN ZIGLAR: — that we have also put into the
[7] product.
[8] JOHN DENNY: And tell us about snorer's breath.
[9] I'm going to test this here.
[10] JOHN ZIGLAR: Yes.
[11] JOHN DENNY: I hope I don't get it in my eye.
[12] (Laughter).
[13] JOHN DENNY: In my — in my — some problem in
[14] my eye perhaps, but it's minty.
[15] JOHN ZIGLAR: Yes.
[16] JOHN DENNY: Actually, it tastes a lot like
[17] mouthwash, I mean, in a good way. Three sprays of this
[18] before bed.
[19] JOHN ZIGLAR: Right.
[20] JOHN DENNY: And how long will this last,
[21] through the night?
[22] JOHN ZIGLAR: It'll last through the night.
[23] It'll last from six to eight hours.
[24] JOHN DENNY: Um-hmm. In what cases doesn't
[25] this work?

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[1] Snorenz.
[2] Do it for him, do it for yourself, do it for
[3] your family. It is worth the phone call, and it is
[4] pennies per day to end the snoring problem. This is a
[5] product, as I mentioned, that has been proven effective
[6] in studies. And you actually conducted the studies out
[7] of your auspices in Michigan. Tell us about how Snorenz
[8] worked.

[9] DR. BOB CURRIER: Interestingly enough, it's
[10] not only the results of the studies we got, but the
[11] comments we received. Many people, again, they're aware
[12] of snoring, but they aren't aware of the problems that
[13] come with it. And actually it's like until it's
[14] resolved, the snoring itself, oh, my word, what a problem
[15] it was. And you can see the changes it's made. That was
[16] probably the most interesting part of doing that whole
[17] study —

[18] JOHN DENNY: Um-hmm.

[19] DR. BOB CURRIER: — was the comments that we
[20] got back, the little stories that people had through the
[21] week —

[22] JOHN DENNY: Yes.

[23] DR. BOB CURRIER: — you know, of using this
[24] product. And that was the beauty of this. I loved doing
[25] the study, it was highly effective.

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[1] JOHN ZIGLAR: You know, when I first got this
[2] product, we did test, and I've given it to everybody that
[3] I know that snores —
[4] JOHN DENNY: Um-hmm.
[5] JOHN ZIGLAR: — so that I could find out, you
[6] know, because I always wanted to know exactly how did it
[7] work on everybody else. And, so, we had one friend we
[8] gave it to and, quite honestly, they've been married for
[9] three years, they're already sleeping in different
[10] bedrooms because he snores so loudly —
[11] JOHN DENNY: Hmm.
[12] JOHN ZIGLAR: — and he would go to bed, they
[13] would go to bed together, wake up in different rooms.
[14] And, so, Kevin was taking the product and the first night
[15] it worked perfectly; second night it worked perfectly;
[16] third night it worked perfectly; fourth night, didn't
[17] work; fifth night, didn't work.
[18] He called me up and he says look, you know, it
[19] works temporarily but after that it doesn't work. And I
[20] said wait a minute, you know, there's got to be a reason,
[21] there's something wrong here that only guy it doesn't
[22] work for all in the world. (Laughter). And he says well
[23] — and so I started to ask him some questions, and here's
[24] the point, what I found out was the night that it did not
[25] work, he had a beer just before he went to bed.

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[1] JOHN ZIGLAR: You know, when I first got this
[2] product, we did test, and I've given it to everybody that
[3] I know that snores —
[4] JOHN DENNY: Um-hmm.
[5] JOHN ZIGLAR: — so that I could find out, you
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[21] there's something wrong here that only guy it doesn't
[22] work for all in the world. (Laughter). And he says well
[23] — and so I started to ask him some questions, and here's
[24] the point, what I found out was the night that it did not
[25] work, he had a beer just before he went to bed.

[1] JOHN DENNY: Hmm.
[2] JOHN ZIGLAR: And what we have here was a
[3] situation where the alcohol in the beer literally cut
[4] through the oils in our product and it went down his
[5] throat, so it was not there.
[6] JOHN DENNY: Um-hmm.
[7] JOHN ZIGLAR: Since it was not there, it could
[8] not work, and it proved that he still was a snorer, he
[9] just needed the product to stay where it was —
[10] JOHN DENNY: Um-hmm.
[11] JOHN ZIGLAR: — so that he would live without
[12] the noise.
[13] JOHN DENNY: So, you suggested that he sort of
[14] cut down his drinking right before going to bed?
[15] JOHN ZIGLAR: Exactly. Don't eat or drink
[16] anything 30 minutes before you go to bed —
[17] JOHN DENNY: Um-hmm.
[18] JOHN ZIGLAR: — or if you do, then take a
[19] couple of swallows of water just to clear your palate so
[20] that your throat is clean —
[21] JOHN DENNY: Um-hmm.
[22] JOHN ZIGLAR: — so that when you put the
[23] product in, on the back of your tongue, that it'll stay
[24] there.
[25] JOHN DENNY: Your wives are happy, gentlemen,

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[1] that you are —
[2] DR. BOB CURRIER: Happier.
[3] JOHN DENNY: Happier. We won't get into that,
[4] but they're happy that your snoring problems have been
[5] reduced or eliminated?
[6] DR. BOB CURRIER: Yes, very much so.
[7] JOHN ZIGLAR: And now, you know, I roll over
[8] and Linda gives me a kiss before we go to bed, and I
[9] think that's just real sweet. She's checking to see if
[10] I've taken the Snorenz, okay?
[11] (Laughter).
[12] JOHN DENNY: If you want more information about
[13] this revolutionary, all-natural, vitamin-based spray, no
[14] pills, no surgery, no clamps, no strips across your nose,
[15] Snorenz will end your snoring problem and do it
[16] naturally. It is pennies in comparison to the value and
[17] the almost priceless value of a full, restful, silent
[18] night's sleep for all, and that goes for the snorer as
[19] well as the person sleeping next to the snorer.
[20] For more information, call the 800 number on
[21] the screen. Dr. Bob Currier, thank you for joining us on
[22] Vantage Point.
[23] DR. BOB CURRIER: Thank you for having me.
[24] JOHN DENNY: And, John Ziglar, thank you.
[25] JOHN ZIGLAR: You're welcome.

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[1] JOHN DENNY: I may knock off a few sprays
[2] tonight and try to get my snoring down. This is John
[3] Denny saying goodbye from Vantage Point, and we will see
[4] you next time.
[5] (Music playing.)
[6] **ON SCREEN:**
[7] For more information or to order Snorenz call:
[8] 1-800-835-8941
[9] If snoring is accompanied by any signs of Sleep
[10] Apnea, you should consult a physician before using any
[11] product.
[12]
[13] **ON SCREEN:**
[14] Tru-Vantage International
[15] 7300 N. Lehigh Ave. Niles, IL 60714 (847)647-
[16] 0300
[17] ANNOUNCER: The preceding has been a paid
[18] commercial brought to you by Kevin Trudeau's Tru-Vantage
[19] International.
[20] **ON SCREEN:**
[21] The preceding has been a paid commercial for
[22] SNORENZ brought to you by Kevin Trudeau's Tru-Vantage
[23] International, America's premier direct response
[24] marketing company.
[25] (End of videotape.)

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[1] **CERTIFICATION OF TYPIST**
[2]
[3] **MATTER NUMBER:** 0023211
[4] **CASE TITLE:** MED GEN INC.
[5] **TAPING DATE:** OCTOBER 13, 1999
[6] **TRANSCRIPTION DATE:** MAY 13, 2000
[7]
[8] I HEREBY CERTIFY that the transcript contained
[9] herein is a full and accurate transcript of the tapes
[10] transcribed by me on the above cause before the FEDERAL
[11] TRADE COMMISSION to the best of my knowledge and belief.
[12]
[13] **DATED:** MAY 15, 2000
[14]
[15]
[16]
[17] **SARA J. VANCE**
[18] **CERTIFICATION OF PROOFREADER**
[19]
[20] I HEREBY CERTIFY that I proofread the transcript for
[21] accuracy in spelling, hyphenation, punctuation and
[22] format.
[23]
[24]
[25] **ELIZABETH M. FARRELL**

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Lawyer's Notes

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, his attorney, and counsel for Federal Trade Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Proposed respondent Robert M. Currier, D. O. is a doctor of osteopathic medicine licensed to practice in the state of Michigan, with a specialty in eye surgery and diseases of the eye. His principal office and place of business is located at 127 Park Place, Alpena, Michigan 49707.

Decision and Order

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
2. "Clearly and prominently" shall mean as follows:
 - A. In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet and online services), the disclosure shall be presented simultaneously in both the audio and video portions of the advertisement. Provided, however, that in any advertisement presented solely through video or audio means, the disclosure may be made through the same means in which the ad is presented. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The video disclosure shall be of a size and shade, and shall appear on the screen for a duration sufficient for an ordinary consumer to read and comprehend it. In addition to the foregoing, in interactive media, the disclosure shall also be unavoidable and shall be presented prior to the consumer incurring any financial obligation.

Decision and Order

- B. In a print advertisement, promotional material, or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears. In multipage documents, the disclosure shall appear on the cover or first page.
- C. On a product label, the disclosure shall be in a type size and location on the principal display panel sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.

The disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or on any label.

- 3. Unless otherwise specified, "respondent" shall mean Robert M. Currier and his agents, representatives, and employees.
- 4. "Drug" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
- 5. "Food" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
- 6. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of SNORenz or any other food, drug, or dietary supplement, in or affecting commerce, shall not make

Decision and Order

any representation, in any manner, expressly or by implication that:

- A. Such product reduces or eliminates snoring or the sound of snoring in users of the product;
- B. A single application of such product reduces or eliminates snoring or the sound of snoring for any specified period of time; or
- C. Such product can eliminate, reduce or mitigate the symptoms of sleep apnea including daytime tiredness and frequent interruptions of deep restorative sleep

unless at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation. Provided that, for any representation made by respondent as an expert endorser, respondent must possess and rely upon competent and reliable scientific evidence, and an actual exercise of respondent's represented expertise, in the form of an examination or testing of the foods, drugs, or dietary supplements at least as extensive as an expert in the field would normally conduct in order to support the conclusions presented in the representation.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product that has not been shown by competent and reliable scientific evidence to be effective in the treatment of sleep apnea, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that the product is effective in reducing or eliminating snoring or the sounds of snoring, unless he discloses, clearly and prominently, and in close proximity to the representation, that such product is not intended to treat sleep

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apnea, that the symptoms of sleep apnea include loud snoring, frequent episodes of totally obstructed breathing during sleep, and excessive daytime sleepiness, that sleep apnea is a potentially life-threatening condition, and that persons who have symptoms of sleep apnea should consult their physician or a specialist in sleep medicine. Provided, however, that for any television commercial or other video advertisement fifteen (15) minutes in length or longer or intended to fill a broadcasting or cablecasting time slot fifteen (15) minutes in length or longer, the disclosure shall be made within the first thirty (30) seconds of the advertisement and immediately before each presentation of ordering instructions for the product. Provided further, that, for the purposes of this provision, the presentation of a telephone number, e-mail address, or mailing address for listeners to contact for further information or to place an order for the product shall be deemed a presentation of ordering instructions so as to require the announcement of the disclosure provided herein.

III.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the endorsing, manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of SNORenz or any other product, service, or program in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the benefits, performance, efficacy, or safety of any such product, service, or program, unless, at the time the representation is made, respondent possesses and relies upon competent and reliable evidence, which, when appropriate, must be competent and reliable scientific evidence, that substantiates the representation. Provided that, for any representation made by respondent as an expert endorser, respondent must possess and rely upon competent and reliable scientific evidence, and an actual exercise of respondent's represented expertise, in the form of an examination or testing of the products, services, or programs at least as extensive as an

Decision and Order

expert in the field would normally conduct in order to support the conclusions presented in the representation.

IV.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the endorsing, manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, service, or program in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

V.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the endorsing of any product, service, or program in or affecting commerce, shall disclose, clearly and prominently a material connection, where one exists, between respondent and any individual or entity manufacturing, labeling, advertising, promoting, offering for sale, selling, or distributing such product, service or program. For purposes of this order, "material connection" shall mean any relationship that might materially affect the weight or credibility of the endorsement and would not be reasonably expected by consumers.

VI.

Nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

Decision and Order

VII.

Nothing in this order shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VIII.

IT IS FURTHER ORDERED that respondent shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

IX.

IT IS FURTHER ORDERED that respondent, for a period of five (5) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to

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the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

X.

IT IS FURTHER ORDERED that respondent shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which he has complied with this order.

XI.

This order will terminate on December 13, 2022, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the

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later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from Dr. Robert M. Currier (the "proposed respondent"). This matter concerns claims Dr. Currier made infomercials for a purported anti-snoring product called SNORenz.

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

SNORenz is a dietary supplement consisting of oils and vitamins that is sprayed on the back of the throat of persons who snore. The Commission's complaint charges that Dr. Currier failed to have a reasonable basis for claims, which he made in infomercials for SNORenz, about the product's efficacy in (1) reducing or eliminating snoring or the sounds of snoring, (2) reducing or eliminating snoring or the sounds of snoring for six to eight hours, and (3) treating the symptoms of sleep apnea. Dr. Currier is also charged with making false claims that clinical proof establishes the efficacy of SNORenz. Further, the complaint alleges that the proposed respondent failed to disclose that the product is not intended to treat sleep apnea; that sleep apnea is a potentially life-threatening disorder characterized by loud snoring, frequent interruptions of sleep, and daytime tiredness; and that persons experiencing those symptoms should seek medical attention. In addition, the complaint alleges that, when Dr. Currier made claims about SNORenz' efficacy, he failed to have a reasonable basis for such claims consisting of an actual exercise of his represented expertise in the causes and treatment for snoring. Finally, the complaint alleges that the proposed respondent failed to disclose adequately that a material connection

Analysis

existed between himself and the product's manufacturer and marketer, Med Gen, Inc.

Part I of the consent order requires that Dr. Currier possess competent and reliable scientific evidence to substantiate representations that SNORenz or any other food, drug, or dietary supplement reduces or eliminates snoring or the sound of snoring; reduces or eliminates snoring or the sound of snoring for any specified period of time through a single application; or eliminates, reduces or mitigates the symptoms of sleep apnea. It also requires that Dr. Currier, when acting as an expert endorser, actually exercise his represented expertise in the form of an examination or testing at least as extensive as an expert in the field would normally conduct. Part II of the order requires that, for any product Dr. Currier advertises that has not been shown to be effective in the treatment of sleep apnea, he must affirmatively disclose, whenever the advertisement represents that the product is effective in reducing or eliminating snoring or the sounds of snoring, a warning statement about sleep apnea and the need for physician consultation.

Part III of the order requires proposed respondent to substantiate any representation about the benefits, performance, efficacy, or safety of SNORenz or any other product, service or program. If Dr. Currier makes such representations as an expert endorser, he must possess substantiation in the form of an examination or testing at least as extensive as an expert in the field would normally conduct. Part IV prohibits false claims about scientific support for any product, service, or program. Part V requires that Dr. Currier disclose any material connection between himself and any product, program or service he endorses. Parts VI and VII of the proposed order permit proposed respondent to make certain claims for drugs or dietary supplements, respectively, that are permitted in labeling under laws and/or regulations administered by the U.S. Food and Drug Administration.

Analysis

The remainder of the proposed order contains standard requirements that respondent maintain advertising and any materials relied upon as substantiation for any representation covered by substantiation requirements under the order, notify the Commission of any change in his employment, and file one or more reports detailing its compliance with the order. Part XI of the proposed order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

The purpose of this analysis is to facilitate public comment on the proposed order, and is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

This proposed order, if issued in final form, will resolve the claims alleged in the complaint against the named respondent. It is not the Commission's intent that acceptance of this consent agreement and issuance of a final decision and order will release any claims against any unnamed persons or entities associated with the conduct described in the complaint.

Complaint

IN THE MATTER OF

MICROSOFT CORPORATION

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4069; File No. 0123240

Complaint, December 20, 2002--Decision, December 20, 2002

This consent order addresses representations made – for Passport Single Sign-In service, an online authentication service, and for two add-on services that respectively provide online purchasing and parental consent services – by Respondent Microsoft Corporation. The order, among other things, prohibits the respondent from misrepresenting (1) what personal information is collected from or about consumers; (2) the extent to which the respondent's product or service will maintain, protect or enhance the privacy, confidentiality, or security of any personally identifiable information collected from or about consumers; (3) the steps the respondent will take with respect to personal information it has collected in the event that it changes the terms of the privacy policy in effect at the time the information was collected; (4) the extent to which the service allows parents to control what the information their children can provide to participating sites or the use of that information by such sites; and (5) any other matter regarding the collection, use, or disclosure of personally identifiable information. The order also requires the respondent to establish and maintain a comprehensive information security program in writing that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers. In addition, the order requires the respondent to obtain within one year, and on a biannual basis thereafter, for twenty years, an assessment and report from a qualified, objective, independent third-party professional certifying that the respondent has in place a security program (1) that provides protections that meet or exceed the protections required by the order; and (2) is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of consumers' personal information has been protected.

Participants

For the Commission: *Ellen Finn, Eric Imperial, Mamie Kresses, Jessica L. Rich, Louis Silversin, Gerard R. Butters and Paul A. Pautler.*

For the Respondent: *Charles E. Buffon, Covington & Burling, and Linda Norman, Microsoft.*

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that Microsoft, a corporation (“respondent”) has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Microsoft is a Washington corporation with its principal office or place of business at One Microsoft Way, Redmond, Washington 98052. Respondent, a software and technology company, has advertised and promoted its sign-on and online wallet services, Passport and Passport Express Purchase (aka Passport Wallet), through the company’s Web site at www.passport.com and elsewhere on the Internet.
2. The acts and practices of respondent as alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

Passport Security

3. Following the launch of Passport in October 1999, respondent disseminated or caused to be disseminated various versions of a “Microsoft .NET Passport Q&A” on Passport.com, including but not necessarily limited to that attached as Exhibit A, containing the following statements:

Security and Privacy

How secure is .NET Passport?

.NET Passport achieves a high level of Web Security by using technologies and systems designed to prevent unauthorized access to your personal information.

Complaint

Exhibit A, Microsoft .NET Passport Q&A,
<http://www.passport.com/Consumer/ConsumerQA.asp?lc>.

4. Respondent also disseminated or caused to be disseminated on the home page of its Web site at Passport.com various advertisements, including but not necessarily limited to that shown in Exhibit B, containing the following statements:

Security

Use .NET Passport from any computer on the Internet. Your .NET Passport is protected by powerful online security technology and a strict privacy policy.

Exhibit B, Passport Home Page,
<http://www.passport.com/Consumer/Default.asp?lc=1033>.

5. Respondent also disseminated or caused to be disseminated various privacy policies on Passport.com, including but not limited to the attached Exhibit C, containing the following statements:

SECURITY OF YOUR PERSONAL INFORMATION

Your .NET Passport information is stored on secure .NET Passport servers that are protected in controlled facilities.

Exhibit C, Microsoft .NET Passport Privacy Policy,
<http://www.passport.com/Consumer/PrivacyPolicy.asp?lc=1033>.

6. Through the means described in Paragraphs 3-5, respondent represented, expressly or by implication, that it maintained a high level of online security by employing sufficient measures reasonable and appropriate under the circumstances to maintain and protect the privacy and confidentiality of personal information obtained from or about consumers in connection with the Passport and Passport Wallet services.

Complaint

7. In truth and in fact, respondent did not maintain a high level of online security by employing sufficient measures reasonable and appropriate under the circumstances to maintain and protect the privacy and confidentiality of personal information obtained from or about consumers in connection with the Passport and Passport Wallet services. In particular, respondent failed to implement and document procedures that were reasonable and appropriate to: (1) prevent possible unauthorized access to the Passport system; (2) detect possible unauthorized access to the Passport system; (3) monitor the Passport system for potential vulnerabilities; and (4) record and retain system information sufficient to perform security audits and investigations. In light of these deficiencies, taken together, the representation set forth in Paragraph 6 was false or misleading.

Passport Wallet Security

8. Respondent has promoted its Passport Express Purchase service, also referred to as Passport Wallet, as an online service that facilitates consumers' online purchases by transmitting credit card numbers, billing information, and shipping information stored in their Passport wallet to participating Express Purchase sites.

9. Following the launch of Passport Wallet in October 1999, respondent disseminated or caused to be disseminated on the home page of its Web site at Passport.com various advertisements, including but not necessarily limited to that shown in Exhibit B, containing the following statements:

Store information in .NET Passport wallet that will help you make faster safer online purchases at any .NET Passport express purchase site.

Exhibit B, Passport Home Page,
<http://www.passport.com/Consumer/Default.asp?lc=1033>.

Complaint

10. Respondent also disseminated or caused to be disseminated various versions of a “Microsoft .NET Passport Q&A” on Passport.com, including but not necessarily limited to that attached as Exhibit A, containing the following statements:

What is Microsoft .NET Passport and what can I do with it?

* * *

With a .NET Passport, you can:

* * *

Make faster, more secure online purchases with .NET Passport express purchase.

Exhibit A, Microsoft .NET Passport Q&A,
<http://www.passport.com/Consumer/ConsumerQA.asp?lc>.

11. Through the means described in paragraphs 9 and 10, respondent represented, expressly or by implication, that purchases made at a Passport Express Purchase site with Passport Wallet are safer or more secure than purchases made at the same Passport Express Purchase site without using the Passport Wallet.

12. In truth and in fact, purchases made at a Passport Express Purchase site with Passport Wallet are not, for most consumers, safer or more secure than purchases made at the same Passport Express Purchase site without using the Passport Wallet. Most consumers making credit card purchases at a Passport Express Purchase site receive identical security whether they use Passport Wallet to complete a transaction or purchase directly from the Passport Express Purchase site without using a Passport Wallet. Therefore, the representations set forth in paragraph 11 were false or misleading.

Complaint

Passport Privacy - Data Collection

13. Respondent has disseminated or caused to be disseminated various privacy policies on Passport.com, including but not limited to the attached Exhibit C, which contains the following statements:

This Privacy Statement discloses the privacy practices for the .NET Passport Web Site and .NET Passport Services in accordance with the requirements of the TRUSTe Privacy Program. When you visit a web site displaying the TRUSTe trademark, you can expect to be notified of [w]hat personally identifiable information of yours is collected. . . .

Exhibit C, Microsoft .NET Passport Privacy Policy,
<http://www.passport.com/Consumer/PrivacyPolicy.asp?lc=1033>.

14. This privacy statement also described in detail the information collected from or about consumers in connection with their use of the Passport, including, but not limited to: what information is collected by Passport when a consumer registers at the Passport.com site; what information is collected by Passport and by a participating site when a consumer registers for Passport through that participating site; what information is collected by participating sites when a consumer signs in with a Passport; “operational” information generated in connection with a Passport account; the association of a unique identification number with every Passport account; and the collection of sign-in and other information in temporary cookies that are deleted when the consumer signs out of Passport.

15. Through the means described in paragraphs 13-14, respondent represented, expressly or by implication, that Passport did not collect any personally identifiable information other than that described in its privacy policy.

Complaint

16. In truth and in fact, Passport did collect personally identifiable information other than that described in its privacy policy. In particular, Passport collected, and maintained for a limited period of time, a personally identifiable record of the sites to which a Passport user signed in, along with the dates and times of sign in, which customer service representatives linked to a user's name in order to respond to a user's request for service. Therefore, the representation set forth in paragraph 15 was false or misleading.

Kids Passport

17. Respondent has promoted its Kids Passport service as an online service that assists parents in protecting their children's online privacy.

18. Since the introduction of Kids Passport in April 2000, respondent has disseminated or caused to be disseminated various Kids Passport web pages and privacy policies, including but not necessarily limited to the attached Exhibits D and E, which contain the following statements:

A. **Welcome to Kids Passport**
Helping parents protect their children's privacy
online

...

Learn about the Children's Online Privacy
Protection Act

Discover how Passport Kids is helping parents to keep their children's identity safe online.

...

Microsoft Kids Passport is a free service that helps you conveniently protect and control your children's online privacy. . . With Kids Passport, you can grant or deny consent to participation (*sic*) web sites (including the Microsoft family of web

Complaint

sites) to collect personal information from your children. In addition, you can make specific choices for each child and for each site, all in one convenient, centralized location.

Exhibit D, Kids Passport web pages,
<http://kids.passport.com>.

B. Microsoft Kids Passport Privacy Statement

Microsoft is especially concerned about the safety and protection of children's personal information collected and used online. Microsoft Kids Passport ("Kids Passport") allows parents to consent to the collection, use and sharing of their children's information with Passport participating sites and services that have agreed to use Kids Passport as their parental consent process.

...

USE OF CHILDREN'S PERSONAL INFORMATION BY PASSPORT

...

Passport does not share this information contained in your child's Passport profile with third parties, except for Passport participating sites where you have consented to such sharing, or as otherwise disclosed in this statement.

...

CONTROL OF CHILDREN'S PERSONAL INFORMATION

Kids Passport allow you to limit the amount of information shared with the sites and services participating in the Kids Passport program. You can choose to allow Passport to share all of the information in your child's Passport profile with a

Complaint

participating site or service, or you can limit the information shared to just a unique identifier or age range.

...

Exhibit E, Microsoft Kids Passport Privacy Statement,
[http://www.passport.com/
consumer/privacy/policy.asp?PPIcid=1033](http://www.passport.com/consumer/privacy/policy.asp?PPIcid=1033).

19. Through the means described in Paragraph 18, respondent represented, expressly or by implication, that the Kids Passport service provided parents with control over the information their children could provide to participating Passport sites and the use of that information by such sites.

20. In truth and in fact, the Kids Passport service did not provide parents with control over the information their children could provide to participating Passport sites and the use of that information by such sites. For instance, once a parent set up a child's Passport account and provided consent for the collection and/or disclosure of the types of personal information listed in respondent's privacy policy, respondent permitted the child to edit or change certain fields of personal information and change account settings set by the parent. Respondent also failed to clearly inform parents that in some instances information would be disclosed to Passport Web sites that do not participate in the Kids Passport service. Therefore, the representations set forth in paragraph 19 were false or misleading.

21. The acts and practices of respondent as alleged in this complaint constituted unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this twentieth day of December, 2002, has issued this complaint against respondent.



Microsoft® .NET Passport Q&A

Click a topic below for answers to common questions about the Microsoft .NET Passport service.

.NET Passport Single Sign-in Service

[What is Microsoft .NET Passport and what can I do with it?](#)

[How does .NET Passport work?](#)

[Where can I use .NET Passport?](#)

[Does .NET Passport share my profile information with participating sites?](#)

[How do I sign in to .NET Passport participating sites?](#)

[Where can I register for a .NET Passport?](#)

.NET Passport Express Purchase and .NET Passport Wallet

[What is .NET Passport express purchase?](#)

[How do I use .NET Passport express purchase?](#)

[What is the .NET Passport wallet?](#)

[What personal information is stored in my .NET Passport wallet?](#)

Kids Passport

[What is Kids Passport?](#)

[How does a Kids Passport account work?](#)

Security and Privacy

[How secure is .NET Passport?](#)

[What about the privacy of my information?](#)

[What is the .NET Passport privacy statement?](#)

[Why should I trust Microsoft with my information?](#)

Microsoft .NET Passport Single Sign-in Service

What is Microsoft .NET Passport and what can I do with it?

.NET Passport is an online service that makes it possible for you to use your e-mail address and a single password to sign in—securely—to any .NET Passport participating Web site or service.

With a .NET Passport, you can:

- Sign in to .NET Passport participating sites **using your e-mail address and a single password** so you don't have to remember a different sign-in name and password at every Web site.
- **Make faster, more secure online purchases** with .NET Passport express purchase.

- **Protect and control online privacy for children with Kids Passport.**

How does .NET Passport work?

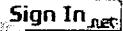
With .NET Passport, you don't need to register a member name and password at each new site you visit—simply use the e-mail address and password that you registered as your .NET Passport to sign in to any participating site or service.

The information you register with .NET Passport is stored online, securely, in the .NET Passport database as your ".NET Passport profile." When you sign in to a .NET Passport participating site by typing your e-mail address and password in the .NET Passport sign-in box, .NET Passport confirms that:

- The e-mail address you typed is registered with .NET Passport.
- The password you typed is correct.

.NET Passport then notifies the site that you are who you say you are (that you have provided valid "sign-in credentials"), and you are given access to the participating site.

Once you sign in to one .NET Passport participating site during an Internet session, you can sign in to others simply by clicking the .NET Passport sign-in button on each site.

The .NET Passport sign-in button is generally found in the upper-right corner of the page and looks like this: 

Where can I use .NET Passport?

You can use your .NET Passport at any of these .NET Passport participating sites. The list of participating sites is updated frequently, so you may want to check it often.

Does .NET Passport share my profile information with participating sites?

.NET Passport lets you choose how much—if any—of your .NET Passport profile information you want to share with participating sites when you sign in.

You can use the check boxes near the bottom of the 'Registration' page to choose which information to share. You can also change your profile-sharing options at any time after registration on the .NET Passport Member Services page.

For more information about sharing your profile information, please read the Microsoft .NET Passport privacy statement.

How do I sign in to .NET Passport participating sites?

To sign in to a .NET Passport participating site:

- Click the .NET Passport sign-in button and type your e-mail address and the password you created when you registered for a .NET Passport.
—Or—
- At some participating sites, you can sign in by typing your e-mail address and password in the .NET Passport sign-in box on the site's home page.

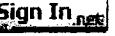
After you've signed in using your .NET Passport once, you can sign in to other .NET Passport participating sites simply by clicking the .NET Passport sign-in button on that

site.

The .NET Passport sign-in button is usually found in the upper-right corner of the Web page, and looks like this: 

Where can I register for a .NET Passport?

You can register for a .NET Passport at www.passport.com or at any .NET Passport participating site.

You may already have a .NET Passport. If you have an MSN® Hotmail® or MSN.com account, you already have a .NET Passport. You can use your e-mail address and password from either of those services to sign in wherever you see the .NET Passport sign-in button. 

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.NET Passport Express Purchase

What is .NET Passport express purchase?

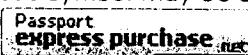
.NET Passport express purchase is a service that you can use to make purchases online by accessing the purchasing information held securely in your .NET Passport wallet.

A .NET Passport express purchase can be made only at participating sites, and you must have a .NET Passport wallet to make a .NET Passport express purchase.

How do I use .NET Passport express purchase?

When you are ready to make a purchase at a participating site, click the .NET Passport express purchase button to access the payment, shipping, and billing information held in your .NET Passport wallet. That information is sent to the merchant securely, making it possible for you to complete the transaction without typing your payment information.

The .NET Passport express purchase symbol may be displayed as a button or a link.



Express purchase using .NET Passport

What is the .NET Passport wallet?

The .NET Passport wallet makes it possible for you to store credit card information and your shipping and billing addresses in a secure, online location. Only you have access to the information in your .NET Passport wallet.

When you're ready to make an online purchase at a participating .NET Passport express purchase site, you can access this information and send it to the merchant instantly and securely—without retying your payment information.

You must register for a .NET Passport before you can create your .NET Passport wallet. If you already have a .NET Passport and want to create your .NET Passport wallet, go to .NET Passport Member Services and click the Create or edit my .NET Passport wallet

link.

What personal information is stored in my .NET Passport wallet?

The information stored in your .NET Passport wallet includes your credit card information and your shipping and billing addresses. This information is never sent to a participating site without your explicit consent.

You can store multiple cards and addresses in your wallet, and choose which ones to use for each purchase. Because this information is stored online, you don't have to retype it each time you buy something at a participating site.

Your .NET Passport wallet can store major credit cards, and debit cards that do not require a personal identification number (PIN).

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Microsoft Kids Passport

What is Kids Passport?

Kids Passport makes it possible for children to have their own .NET Passports while giving parents or guardians control over what .NET Passport profile information their children can share with participating Kids Passport sites.

Sites that offer the Kids Passport service may have areas that collect, use, or disclose children's personal information. With Kids Passport, parents can choose—on a site-by-site basis—what information a child can share with participating sites and services, and what the site can do with the information it does collect.

Kids Passport is not a Web filter that parents can use to keep their children from accessing specific sites.

How does a Kids Passport account work?

When a child tries to sign in to a participating site or service that requires personally identifiable information, the child must obtain consent from a parent or guardian before sharing that information.

The child can make this request directly through Kids Passport. The parent or guardian reviews the request and can either grant a specific level of consent, or deny consent altogether. In some cases, denying consent for a site to gather personally identifiable information will prevent a child from using the Web site.

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Security and Privacy

How secure is .NET Passport?

.NET Passport achieves a high level of Web security by using technologies and systems that are designed to prevent unauthorized access to your personal information. Here are the primary ways that .NET Passport protects your information:

- You must type your .NET Passport password to sign in to participating sites or to access your .NET Passport profile information. However, .NET Passport never

reveals your password to participating sites.

- .NET Passport uses industry-standard security technologies to encrypt your password, e-mail address, and .NET Passport wallet information whenever it's transmitted over the Internet.
- When making a .NET Passport express purchase, you can only access your .NET Passport wallet for a few minutes before you're required to retype your password.
- After several unsuccessful attempts to sign in, .NET Passport temporarily blocks further attempts. This makes it much more difficult for someone to guess your password using a password-cracking program.
- .NET Passport stores "cookies" (small text files) on your computer to enable you to sign in to participating sites. All .NET Passport cookies are encrypted. When you sign out of .NET Passport, all .NET Passport cookies are deleted from your computer.

What about the privacy of my information?

Microsoft is committed to protecting the privacy of people who use .NET Passport.

- Microsoft does not share the personal information in your .NET Passport profile with other companies without your consent.
- You may choose to have Microsoft share your .NET Passport profile information with other companies when you sign in to their .NET Passport-enabled sites. Sharing this information can make registration faster and lets sites offer you personalized services. You can indicate on the .NET Passport registration form, or in your .NET Passport profile following registration, which information to share.
- Sites that offer the .NET Passport service must display their own privacy statements and are bound by rules that require them to disclose how they use your .NET Passport information.
- If you have a .NET Passport wallet, your wallet information is never shared with participating sites at sign-in. Your .NET Passport wallet information is only shared when you choose which pieces to send to the merchant during a .NET Passport express purchase.

What is the .NET Passport privacy statement?

Your privacy is important to us. The .NET Passport privacy statement is based on the following fair information practices and enforcement principles that are widely endorsed by consumer privacy advocates, such as TRUSTe and BBBOnLine:

- **Notice** of how information will be used
- **Choice** about what information you want to share
- **Consent** to collection and distribution of personal information
- **Access** to personal information 24 hours a day, 7 days a week

For more information, please read the [Microsoft .NET Passport privacy statement](#).

Why should I trust Microsoft with my information?

In recent years, Microsoft has consistently been ranked as one of the most respected corporations in North America by the general public.

In addition, Microsoft has been a champion of Internet privacy standards and privacy organizations for many years.

More recently, Microsoft became a member of the Board of Directors for BBB*OnLine* and helped spearhead the global Online Privacy Alliance, a coalition of more than 80 global corporations and organizations working to promote consumer privacy online. Microsoft continues to work closely with government and consumer privacy groups worldwide.

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[**For Consumers**](#) | [**For Business**](#) | [**For Press**](#) | [**International**](#)

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[TRUSTe Approved Privacy Statement](#) | [Terms of Use](#)

One password.

One easy way to Sign in and Shop online.

- ▶ Look for the new .NET Passport button [Sign In.net](#)
- Sign in at any participating .NET Passport, and then **sign in to other participating sites with a single click**. Read more about our new name.
- ▶ **Use ONE sign-in name and password** at all .NET Passport sites.
- ▶ **Store information in .NET Passport wallet** that will help you make faster, safer online purchases at any .NET Passport express purchase site.

Sign up for your FREE .NET Passport today!

Members

- ▶ [Edit the information in your .NET Passport](#)
- ▶ [Reset your password](#)
- ▶ [Use your .NET Passport at these sites](#)

Businesses

- ▶ [Use .NET Passport on your Web site](#)

And it's free!



Security

Use .NET Passport from any computer on the Internet. Your .NET Passport is protected by powerful online security technology, and a [strict privacy policy](#). You control which sites access it.

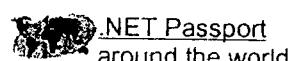
[Get your FREE .NET Passport today!](#)

[.NET Passport Q&A](#)

Other great .NET Passport services:

▶ [Kids Passport](#)

Your kids can have their own .NET Passports and you control what information they share with participating sites.



[.NET Passport around the world](#)



Microsoft .NET Passport is Committed to Safeguarding Your Privacy

Microsoft® .NET Passport ("NET Passport") recognizes that your privacy and the protection of your personal information is important to you. This statement discloses how we ensure that your personal information is protected while using the .NET Passport Web Site (www.passport.com), and while using the .NET Passport Services at participating web sites.

The .NET Passport Services include the following: .NET Passport sign-in, .NET Passport wallet and .NET Passport express purchase, and Kids Passport. By using the .NET Passport Web Site and the .NET Passport Services, you consent to the data practices described in this statement.

This statement includes an additional section that specifically describes our commitment to privacy for the Kids Passport service. You can read the [Kids Passport Privacy Statement](#) section below.

You should also familiarize yourself with the .NET Passport Terms of Use at <http://www.passport.com/Consumer/TermsOfUse.asp> before choosing to use the .NET Passport Services. For more information about how the .NET Passport Services work, visit <http://www.passport.com/Consumer/HowPassportWorks.asp>.

TRUSTe CERTIFICATION

Microsoft is a member of TRUSTe, an independent, non-profit initiative that exists to help people feel confident about using the Internet for communicating, shopping, researching, and living. TRUSTe aims to build this confidence by promoting the principles of disclosure and fair information practices among the web sites that participate in the program.

This Privacy Statement discloses the privacy practices for the .NET Passport Web Site and .NET Passport Services in accordance with the requirements of the TRUSTe Privacy Program. When you visit a web site displaying the TRUSTe trademark, you can expect to be notified of:



- What personally identifiable information of yours is collected.
- What organization is collecting the information.
- How the information is used.
- With whom the information may be shared.
- What choices are available to you regarding the collection, use, and distribution of the information.
- What kind of security procedures are in place to protect the loss, misuse, or alteration of information under the company's control.
- How you can correct any inaccuracies in the information.

Questions regarding this Privacy Statement should be directed to passpriv@microsoft.com. If any TRUSTe-certified web site, including this one, has not responded to your inquiry or your inquiry has not been satisfactorily addressed, please [contact TRUSTe](#).

COLLECTION AND STORAGE OF YOUR PERSONAL INFORMATION

During Registration

When you register for a .NET Passport account or a Kids Passport account, .NET Passport collects two kinds of information from you:

- **Personally identifiable information**, which is information that either personally identifies you or allows others to contact you. The personally identifiable information collected by .NET Passport includes your e-mail address, because your .NET Passport is based on your e-mail address. .NET Passport may also collect your name and/or phone number depending on which .NET Passport Services you register for.
- **Non-personally identifiable or "demographic" information**, which by itself does not identify you or allow others to contact you. The non-personally identifiable information that .NET Passport collects may include your country, state/region, ZIP/Postal Code, time zone, gender, birthday, and occupation.

If you choose to create a .NET Passport wallet, .NET Passport collects additional personally identifiable information, including your name, telephone number, credit card information, and billing and shipping addresses.

.NET Passport may also collect a secret question and secret answer that you provide. You use your secret question and answer to help verify your identity to .NET Passport if you need to reset your password.

You can register for a .NET Passport at a .NET Passport participating site or service, or at the .NET Passport Web Site (www.passport.com). The services you register for, and the amount and kind of information collected during registration, can vary depending on where you register.

If you register for a .NET Passport at a .NET Passport participating site or service, you will be opening two different accounts simultaneously:

- One with the participating site or service.
—And—
- One with .NET Passport.

You can then use your .NET Passport to sign in to that participating site and to all other .NET Passport participating sites and services.

Note Some .NET Passport participating sites may require you to open an MSN.com or Hotmail.com e-mail account when you register. These e-mail addresses are automatically registered as .NET Passports, so in this case you would be registering for:

- A .NET Passport.
- An account at the .NET Passport participating site or service.
—And—
- Free e-mail services through MSN.com or Hotmail.com.

Not all of the information you provide during registration at a participating site will be stored by .NET Passport. Some information (for example, clothing sizes or music preferences) may be specific to—and stored by—the participating site or service. If a .NET Passport participating site uses a single registration form to collect both .NET Passport information and site-specific information, the information stored by .NET Passport will be identified on the form by a .NET Passport icon next to each field.

If you register at the .NET Passport Web Site, you will simply be registering for a .NET Passport. All of the information you provide when you register at the .NET Passport Web Site will be stored by .NET Passport.

The information collected by .NET Passport—which may include your e-mail address, name, country, state/region, ZIP/Postal Code, time zone, gender, birthday, and occupation—comprise your .NET Passport "profile." You can access and edit your .NET Passport profile at any time after

registration by going to .NET Passport Member Services at <http://memberservices.passport.com> and clicking the Edit my .NET Passport profile link.

When Signing In

When you use your .NET Passport to sign in to other .NET Passport participating sites, some of those sites may collect additional information from you so you can register with them as well.

You should review the privacy statement for each .NET Passport participating site you register with to determine how each site or service will use the information it collects.

The .NET Passport Wallet

If you also create a .NET Passport wallet, your .NET Passport wallet information is stored separately from your .NET Passport profile. You can access and edit your .NET Passport wallet information by going to .NET Passport Member Services at <http://memberservices.passport.com> and clicking the Create or edit my .NET Passport wallet link.

General

Personally identifiable information that you provide to .NET Passport may be stored and processed in the United States or any other country in which Microsoft or its affiliates, subsidiaries, or agents maintain facilities. By using the .NET Passport Services, you consent to any such transfer of information outside of your country.

USE OF YOUR PERSONAL INFORMATION

.NET Passport will not share, sell, or use your personal information in a manner that differs from what is described in this Privacy Statement, unless we have your consent.

.NET Passport uses the information for the operation and maintenance of your .NET Passport account and the .NET Passport Services.

.NET Passport sends you a welcome e-mail message when you first register, informing you about the service and telling you how to manage your .NET Passport account. .NET Passport may also send you periodic updates or surveys related to the .NET Passport Services. These e-mails are considered essential to the provision of the service you have requested. You are not able to choose to unsubscribe to these mailings, but you may choose not to participate in the surveys.

.NET Passport also occasionally hires other companies to provide limited services on our behalf, such as answering customer support inquiries or performing statistical analyses of our services. .NET Passport will only provide those companies the information they need to deliver the services, and they are prohibited from using that information for any other purpose.

From time to time, .NET Passport may report average age, gender, and other aggregate membership statistics to our participating sites. These reports will not include personal information that identifies you or allows others to contact you.

.NET Passport will disclose personal information if required to do so by law or in the good-faith belief that such action is necessary to:

- a. Conform to legal requirements or comply with legal process served on Microsoft.
- b. Protect and defend the rights or property of Microsoft, .NET Passport, or .NET Passport participating sites.
- c. Enforce the Terms of Use.
—Or—
- d. Act under exigent circumstances to protect the personal safety of users of Microsoft, the .NET Passport Web Site, or the public.

.NET Passport participating sites and services with whom you choose to share the information can use it for a variety of purposes. These can include personalizing your experience at their sites and reducing registration time by using information in your .NET Passport account to pre-fill their registration forms. **We recommend that you review the privacy statement at each .NET Passport participating site before you share your personal information with them.**

CONTROL OF YOUR PERSONAL INFORMATION

You control which .NET Passport participating sites and services receive the information in your .NET Passport profile and .NET Passport wallet. The information stored by .NET Passport is not shared with a .NET Passport participating site or service unless you explicitly choose to provide it by clicking the .NET Passport sign-in link or the .NET Passport express purchase button on that site. It is important for you to read the privacy statement and terms of use for each .NET Passport participating site or service you visit before you sign in or make a .NET Passport express purchase, so that you understand how the site may use your .NET Passport information.

Some of your .NET Passport information is never shared with any .NET Passport participating site. This includes your password, your .NET Passport security key (which you can only get by visiting a site that uses this service), and your secret question and secret answer.

Your .NET Passport Profile

You can decide which pieces of information in your .NET Passport profile to share with the .NET Passport participating sites that you sign in to. You can use the check boxes on the 'Registration' page and the 'Edit Your .NET Passport Profile' page to choose whether to share your e-mail address, your name, and other profile information.

There are two specific cases, however, in which a .NET Passport participating site will receive your profile information (except your password and secret question and secret answer) regardless of your check-box settings:

- The participating site where you registered for your .NET Passport will receive the profile information you provided during registration.
- If you registered an @msn.com, @hotmail.com, @webtv.net, or @compaq.net .NET Passport, then those e-mail domains will always receive your profile information when you visit their sites.

In general, the e-mail address associated with your .NET Passport account is not shared with .NET Passport participating sites or services. However, a few sites currently require your e-mail address in order to provide you their services. (For example, Hotmail requires your e-mail address to provide your requested e-mail services.) In those cases, .NET Passport will provide your e-mail address to those sites when you sign in to them.

The .NET Passport Wallet

You control which pieces of information in your .NET Passport wallet are shared with .NET Passport express purchase participating sites and services on a per-transaction basis. After clicking the .NET Passport express purchase button at a participating site, you will be able to choose which credit card and billing and shipping address information to send to the participating site for that purchase.

Other Information

Some sites need additional .NET Passport information to operate your account properly. This "operational" information is shared automatically with the participating site or service when you sign in using your .NET Passport.

Operational information does not include the personal information that you provide as part of your .NET Passport profile, and it is shared with the site regardless of whether you choose to share your profile information with the site when you sign in.

The operational information shared at sign-in includes:

- The version number .NET Passport assigns to your profile. (A new number is assigned each time you change your .NET Passport profile to tell participating sites that the information has been updated. Your personal .NET Passport profile information is not shared without your permission.)
 - Also, whether—
 - Your e-mail address has been verified.
 - Your account has been deactivated.
 - Your account is a Kids Passport account.
 - Your account has an associated .NET Passport wallet.
 - You have consented to be listed in the Hotmail member directory or other public directories.

ACCESS TO YOUR PERSONAL INFORMATION

You can always add, update, or make other changes to the information in your .NET Passport profile or .NET Passport wallet by visiting .NET Passport Member Services at <http://memberservices.passport.com>.

SECURITY OF YOUR PERSONAL INFORMATION

Your .NET Passport information is stored on secure .NET Passport servers that are protected in controlled facilities. You must type the correct password to access your .NET Passport information, and your password is never shared with .NET Passport participating sites.

When you request to have your .NET Passport information sent to a .NET Passport participating site, .NET Passport uses industry-standard security technologies to encrypt it for secure transmission over the Internet.

MANAGED .NET PASSPORTS

If you received your .NET Passport from someone else, without registering for it yourself, your .NET Passport may belong to a "managed domain." In a managed domain, the administrator of a company with whom you have a business relationship (for example, your employer) can create your .NET Passport for you, including your .NET Passport e-mail address and password. You can use the .NET Passport much like any other .NET Passport. The company administrator, however, has control over the .NET Passport and can edit your .NET Passport profile, reset your password, and manage the .NET Passport account without your permission.

USE OF A UNIQUE ID

.NET Passport associates a .NET Passport unique identifier with every .NET Passport account at registration. The unique identifier is a unique 64-bit number that .NET Passport sends (encrypted) to each .NET Passport participating site that you choose to sign in to. This unique identifier makes it possible for the site to determine whether you are the same person from one sign-in session to the next. It can also allow you to personalize your experience at a site, even if you choose to sign in anonymously (that is, to not share your e-mail address, name, or any of your other .NET Passport profile data).

USE OF COOKIES

A cookie is a very small text file that a web site saves to your computer's hard disk to store information that you provide about yourself or to store your preferences. .NET Passport uses cookies whenever you sign in to a .NET Passport participating site. .NET Passport stores your unique identifier, the time you signed in, and whatever .NET Passport profile information you have chosen to share with participating sites, in a secure, encrypted cookie on your hard disk. The cookie allows you to move from page to page at the participating site without having to sign in again on each page.

- You have the ability to accept or decline cookies using the settings on your browser. If you choose to decline cookies, you will not be able to sign in using your .NET Passport.

When you sign out of .NET Passport, all .NET Passport-related cookies from all .NET Passport participating sites are deleted from your computer. However, the sites you visited may store their own cookies on your computer, and these may persist after you sign out of .NET Passport. .NET Passport recommends that you read each participating site's privacy statement to understand their policies and practices.

.NET PASSPORT PARTICIPATING SITES' USE OF YOUR PERSONAL INFORMATION

To become a .NET Passport participating site, web sites must agree to protect your personal information. All participating sites are required to have a posted privacy statement and to use commercially reasonable efforts to comply with industry-standard privacy guidelines and practices. And all U.S.-based sites are encouraged (but not required) to be registered with an independent, industry-recognized, privacy assurance organization such as TRUSTe or BBBOnLine.

Nevertheless, the privacy practices of .NET Passport participating sites will vary. **Therefore you should carefully review the privacy statement for each .NET Passport participating site you sign in to, in order to determine how each site or service will use the information it collects.**

If .NET Passport becomes aware of ongoing, site-specific issues with a .NET Passport participating site, we will work to address those issues with the site. If at any time you believe that a .NET Passport participating site has not adhered to these principles, please notify .NET Passport by e-mail at passpriv@microsoft.com.

CHANGES TO THIS PRIVACY STATEMENT

.NET Passport will occasionally update this Privacy Statement. When we do, we will also revise the "last updated" date at the bottom of the Privacy Statement. For material changes to this Privacy Statement, .NET Passport will notify you by placing a prominent notice on the .NET Passport Web Site. .NET Passport encourages you to periodically review this Privacy Statement to stay informed about how we are protecting your information. Your continued use of the .NET Passport Services constitutes your agreement to this Privacy Statement.

ENFORCEMENT OF THIS PRIVACY STATEMENT

As a licensee of TRUSTe, and upholding our commitment to protecting the privacy of your personal information, .NET Passport has agreed to disclose its information practices and to have its privacy practices reviewed for compliance by TRUSTe. If you have questions regarding this statement, you should first contact .NET Passport by sending an e-mail message to:

passpriv@microsoft.com

If you do not receive acknowledgment of your inquiry or your inquiry has not been addressed to your satisfaction, you should then contact TRUSTe at:

www.truste.org/users/users_watchdog.html

TRUSTe will serve as a liaison with .NET Passport to resolve your concerns.

CONTACT INFORMATION

If you have questions regarding .NET Passport or this Privacy Statement, or if you have a problem with a .NET Passport participating site, please send an e-mail message to:

passpriv@microsoft.com

You can also contact .NET Passport by postal mail at:

Microsoft .NET Passport Privacy
Microsoft Corporation
One Microsoft Way
Redmond, Washington 98052

.NET Passport will use all commercially reasonable efforts to promptly determine and correct the problem.

Microsoft Kids Passport Privacy Statement

Microsoft is especially concerned about the safety and protection of children's personal information collected and used online. Microsoft Kids Passport ("Kids Passport") allows parents to consent to the collection, use, and sharing of their children's information with .NET Passport participating sites and services that have agreed to use Kids Passport as their parental consent process.

Note Kids Passport is currently available only in the United States, but we plan to make it available in other countries in the future.

CHILDREN'S ACCESS TO SITES WITHOUT PARENTAL CONSENT

.NET Passport participating sites and services that utilize Kids Passport may have areas that are accessible to all users, including children, as well as areas that require parental consent because they collect, use, or disclose the personal information of children. If your child tries to access an area of these sites or services that does not collect any personal information (and therefore does not require parental consent), the site may permit your child to access these areas.

If your child tries to access an area that does collect, use, or disclose personal information, the site may either display a new page that directs your child to an area of the site that does not require parental consent, or display an error page that tells your child that they need a parent's permission to use this area of the web site. This page will also direct them to the Kids Passport site, where there are instructions on how to obtain parental consent.

COLLECTION OF CHILDREN'S PERSONAL INFORMATION

When you register your child for a Kids Passport, you will be asked to provide your child's birth date, sign-in name, password, password reset question and answer, e-mail address, country, and state or region. You will also be given the opportunity to control the sharing of e-mail address, name, and other registration information.

If your child registers for a .NET Passport on his or her own, .NET Passport will collect the information normally collected from individuals who register for a .NET Passport with the participating site. If any participating site asks .NET Passport to collect your child's age, and the age your child enters qualifies him or her as a child, then your child will be blocked from using his or her .NET Passport until you provide your consent. Unless you provide your consent, the participating site will receive none of the information your child entered during registration.

USE OF CHILDREN'S PERSONAL INFORMATION BY .NET PASSPORT

When you create a Kids Passport, the information you provide is stored in your child's .NET Passport profile. .NET Passport uses this information to operate its services, as described above, in the [.NET Passport Privacy Statement](#). By creating a Kids Passport you are consenting to the collection, use, and disclosure of the information in your child's .NET Passport profile as described in this statement.

.NET Passport does not share the information contained in your child's .NET Passport Profile with third parties, except for .NET Passport participating sites where you have consented to such sharing, or as otherwise disclosed in this statement.

USE OF CHILDREN'S PERSONAL INFORMATION BY .NET PASSPORT PARTICIPATING SITES AND SERVICES

Kids Passport shares your child's information with participating sites and services in accordance with the consent you have given for your child's Kids Passport account.

These .NET Passport participating sites provide a variety of products and services to online users. All of these sites agree to have a posted privacy statement describing how they use personal information collected by their web site.

For more information, you can view the current list of [Kids Passport participating sites and services](#). These .NET Passport participating sites will not collect, use, or disclose your child's information except in accordance with your consent decisions.

CONTROL OF CHILDREN'S PERSONAL INFORMATION

Kids Passport allows you to limit the amount of information shared with the sites and services participating in the Kids Passport program. You can choose to allow .NET Passport to share all information in your child's .NET Passport profile with a participating site or service, or you can limit the information shared to just a unique identifier and an age range.

Kids Passport also allows you to choose, on site-by-site basis, up to three types of consent for how Kids Passport participating sites and services will collect, use, and disclose your child's personal information.

- You can choose "deny," which instructs the site to deny access to areas of the site or service that require the collection or permit the disclosure of personal information.
- You can give "limited consent," which means that you consent to the information being used for the operation of the site or service, including personalization, but not sharing it with any other third parties, except as necessary to operate the site or service.
- You can give "full consent," which means that you consent to the information being used for the operation of the site, for personalization and for sharing the information with other third parties.

Not all participating sites and services offer all three levels of consent. For example, some sites and services (such as e-mail or chat services) inherently involve the potential sharing of personal information with third parties, so the "limited consent" option would, in effect, deny access to the service. In such cases, the site may offer only the "full" and "deny" consent options.

For more information, you can view the current list of [Kids Passport participating sites and services](#). It is important that you read the privacy statement and terms of use for each web site you are granting consent to.

VERIFICATION OF PARENTAL CONSENT

A valid credit card number helps .NET Passport verify that you are an adult. Kids Passport obtains and verifies parental consent through the use of a credit card validation process. There is no charge to your credit card. This process checks that the credit card number is valid and validates address information.

SECURITY OF CHILDREN'S PERSONAL INFORMATION

Your child's Kids Passport information is stored on secure Microsoft servers that are protected in controlled facilities. When your child requests to have their Kids Passport information sent to a .NET Passport participating site or service—in accordance with the level of consent you have granted—the information is encrypted and securely sent to that web site using advanced encryption technology.

ACCESSING AND UPDATING YOUR CHILD'S PERSONAL INFORMATION

You can change, edit, update, or delete the information in your child's Kids Passport account at any time. To update your child's account information (including updating your child's preferences and changing your consent level for individual web sites), visit Kids Passport at <http://kids.passport.com> and click Parent's Point. You can also make changes to the list of web sites you have previously granted consent to.

CONTACT INFORMATION

If you have questions regarding Kids Passport or this Privacy Statement, please send an e-mail message to:

passpriv@microsoft.com

You can also contact .NET Passport by postal mail at:

KIDS Passport
Microsoft Corporation
One Microsoft Way
Redmond, Washington 98052

Last Updated: October 8, 2001

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[Passport Home](#) | [Kids Passport](#) | [Member Services](#) [Site Directory](#) | [Privacy Policy](#) | [Help](#) [Passport sign in](#)

Parents' Point

Kids' Corner

Kids Passport Help

Kids Privacy Policy

Welcome to Kids Passport

----- Helping parents protect their children's privacy online.

Parents' Point

Set up and edit accounts, or review and complete requests for consent.

Kids' Corner

Request permission to use sites, and view your pending requests.

Kids Site Directory

See the participating sites.



Kids Passport Help

Find the answer to your question.

Learn about the Children's Online Privacy Protection Act

Discover how Kids Passport is helping parents to keep their child's identity safe online.

[Help](#) | [What is Kids Passport](#) | [Where can I use Passport?](#) | [International](#)

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Get a Passport for your child

Please read this important information, and then fill out the registration form below.

Microsoft® Kids Passport is a free service that helps you conveniently protect and control your children's online privacy. Today, many Web sites routinely collect personal information. With Kids Passport, you can grant or deny consent to participation Web sites (including the Microsoft family of Web sites) to collect personal information from your children. In addition, you can make specific choices for each child and for each site, all in one convenient, centralized location.

Follow these simple steps to set up a Kids Passport account for your child:

1. Fill out the registration form below to provide us with the following personal information: your child's sign-in name and password, an e-mail address for you or your child; and your child's date of birth. We are also asking you for some additional information to make it easier to reset the password if your child forgets it. Your child's Kids Passport does not include the wallet service.
2. Provide consent to Passport to collect, use, and/or disclose this information to participating sites your child signs in to.
3. Verify you are an adult by creating a Passport wallet and providing a valid credit card number. (The credit card is for verification purposes only, you will not be charged.)

To learn more about the Kids Passport information practices, read the [Kids Privacy Policy](#). To learn more about the new federal law that protects children's personal information online, see the Children's Online Privacy Protection Act.

Step 1 of 3: Get a Passport for your child

Parents: Fill out the registration form below with information about your child.

Fields marked with will be stored in your Passport.

[Help](#)

Child's Sign-in Name

@passport.com

Child's Password

Six-character minimum; no spaces

Retype Child's Password

Child's Birth Date

Month Day (e.g., 1999)

Passport requires your birth date to comply with current law.



Tired of registration forms? You can speed registration and get personalized services at participating Microsoft Passport sites by sharing your Passport information with them when you sign in. Check the boxes below to choose how much of your Passport information Microsoft can share with other companies' Passport sites at sign-in:

- Share my e-mail address
 Share my other registration information

[More about Passport, privacy, and security](#)



[Member Services](#) [Terms of Use](#) [Privacy Statement](#)

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Microsoft Kids Passport Privacy Statement

Microsoft is especially concerned about the safety and protection of children's personal information collected and used online. Microsoft Kids Passport ("Kids Passport") allows parents to consent to the collection, use, and sharing of their children's information with Passport participating sites and services that have agreed to use Kids Passport as their parental consent process.

Note Kids Passport is currently available only in the United States, but we plan to make it available in other countries in the future.

CHILDREN'S ACCESS TO SITES WITHOUT PARENTAL CONSENT

Passport participating sites and services that utilize Kids Passport may have areas that are accessible to all users, including children, as well as areas that require parental consent because they collect, use, or disclose the personal information of children. If your child tries to access an area of these sites or services that does not collect any personal information (and therefore does not require parental consent), the site may permit your child to access these areas.

If your child tries to access an area that does collect, use, or disclose personal information, the site may either display a new page that directs your child to an area of the site that does not require parental consent, or display an error page that tells your child that they need a parent's permission to use this area of the web site. This page will also direct them to the Kids Passport site, where there are instructions on how to obtain parental consent.

COLLECTION OF CHILDREN'S PERSONAL INFORMATION

When you register your child for a Kids Passport, you will be asked to provide your child's birth date, sign-in name, password, password reset question and answer, e-mail address, country, and state or region. You will also be given the opportunity to control the sharing of e-mail address, name, and other registration information.

If your child registers for a Passport on his or her own, Passport will collect the information normally collected from individuals who register for a Passport with the participating site. If any participating site asks Passport to collect your child's age, and the age your child enters qualifies him or her as a child, then your child will be blocked from using his or her Passport until you provide your consent. Unless you provide your consent, the participating site will receive none of the information your child entered during registration.

USE OF CHILDREN'S PERSONAL INFORMATION BY PASSPORT

When you create a Kids Passport, the information you provide is stored in your child's Passport profile. Passport uses this information to operate its services, as described above, in the Passport Privacy Statement. By creating a Kids Passport you are consenting to the collection, use, and disclosure of the information in your child's Passport profile as described in this statement.

Passport does not share the information contained in your child's Passport Profile with third parties, except for Passport participating sites where you have consented to such sharing, or as otherwise disclosed in this statement.

USE OF CHILDREN'S PERSONAL INFORMATION BY PASSPORT PARTICIPATING SITES AND SERVICES

Kids Passport shares your child's information with participating sites and services in accordance with the consent you have given for your child's Kids Passport account.

These Passport participating sites provide a variety of products and services to online users. All of

these sites agree to have a posted privacy statement describing how they use personal information collected by their web site.

For more information, you can view the current list of Kids Passport participating sites and services. **These Passport participating sites will not collect, use, or disclose your child's information except in accordance with your consent decisions.**

CONTROL OF CHILDREN'S PERSONAL INFORMATION

Kids Passport allows you to limit the amount of information shared with the sites and services participating in the Kids Passport program. You can choose to allow Passport to share all information in your child's Passport profile with a participating site or service, or you can limit the information shared to just a unique identifier and an age range.

Kids Passport also allows you to choose, on site-by-site basis, up to three types of consent for how Kids Passport participating sites and services will collect, use, and disclose your child's personal information.

- You can choose "deny," which instructs the site to deny access to areas of the site or service that require the collection or permit the disclosure of personal information.
- You can give "limited consent," which means that you consent to the information being used for the operation of the site or service, including personalization, but not sharing it with any other third parties, except as necessary to operate the site or service.
- You can give "full consent," which means that you consent to the information being used for the operation of the site, for personalization and for sharing the information with other third parties.

Not all participating sites and services offer all three levels of consent. For example, some sites and services (such as e-mail or chat services) inherently involve the potential sharing of personal information with third parties, so the "limited consent" option would, in effect, deny access to the service. In such cases, the site may offer only the "full" and "deny" consent options.

For more information, you can view the current list of Kids Passport participating sites and services. It is important that you read the privacy statement and terms of use for each web site you are granting consent to.

VERIFICATION OF PARENTAL CONSENT

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CONTACT INFORMATION

If you have questions regarding Kids Passport or this Privacy Statement, please send an e-mail message to:

passpriv@microsoft.com

You can also contact Passport by postal mail at:

KIDS Passport
Microsoft Corporation
One Microsoft Way
Redmond, Washington 98052

Last Updated: August 15, 2001

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Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act, 15 U.S.C. § 45 *et seq.*; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules.

The Commission having thereafter considered the matter and having determined that it has reason to believe that the respondent has violated the said Acts and Regulations, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, and having duly considered the comments received, now in further conformity with the procedure described in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Microsoft is a Washington corporation with its principal office or place of business at One Microsoft Way, Redmond, Washington 98052.

Decision and Order

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. “Personally identifiable information” or “personal information” shall mean individually identifiable information from or about an individual including, but not limited to: (a) a first and last name; (b) a home or other physical address, including street name and name of city or town; (c) an email address or other online contact information, such as an instant messaging user identifier or a screen name that reveals an individual’s email address; (d) a telephone number; (e) a Social Security Number; (f) a persistent identifier, such as a customer number held in a “cookie” or processor serial number, that is combined with other available data that identifies an individual; or (g) any information that is combined with any of (a) through (f) above.
2. “Covered online service” shall mean Passport, Kids Passport, Passport Wallet, any substantially similar product or service, or any multisite online authentication service.
3. Unless otherwise specified, “respondent” shall mean Microsoft Corporation, its successors and assigns and its officers, agents, representatives, and employees acting within the scope of their authority on behalf of, or in active concert or participation with Microsoft Corporation.
4. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

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I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, marketing, promotion, offering for sale, or sale of a covered online service, in or affecting commerce, shall not misrepresent in any manner, expressly or by implication, its information practices, including:

- A. what personal information is collected from or about consumers;
- B. the extent to which respondent's product or service will maintain, protect or enhance the privacy, confidentiality, or security of any personally identifiable information collected from or about consumers;
- C. the steps respondent will take with respect to personal information it has collected in the event that it changes the terms of the privacy policy in effect at the time the information was collected;
- D. the extent to which the service allows parents to control what information their children can provide to participating sites or the use of that information by such sites; and
- E. any other matter regarding the collection, use, or disclosure of personally identifiable information.

II.

IT IS FURTHER ORDERED that respondent, and its successors and assigns, in connection with the advertising, marketing, promotion, offering for sale, or sale of a covered online service, in or affecting commerce, shall establish and maintain a comprehensive information security program in writing that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about

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consumers. Such program shall contain administrative, technical, and physical safeguards appropriate to respondent's size and complexity, the nature and scope of respondent's activities, and the sensitivity of the personal information collected from or about consumers, including:

- A. The designation of an employee or employees to coordinate and be accountable for the information security program.
- B. The identification of material internal and external risks to the security, confidentiality, and integrity of customer information that could result in the unauthorized disclosure, misuse, alteration, destruction, or other compromise of such information, and assessment of the sufficiency of any safeguards in place to control these risks. At a minimum, this risk assessment should include consideration of risks in each area of relevant operation, including: (1) employee training and management; (2) information systems, including network and software design, information processing, storage, transmission and disposal; and (3) prevention, detection, and response to attacks, intrusions, or other systems failures.
- C. Design and implementation of reasonable safeguards to control the risks identified through risk assessment, and regular testing or monitoring of the effectiveness of the safeguards' key controls, systems, and procedures.
- D. Evaluation and adjustment of respondent's information security program in light of the results of the testing and monitoring required by paragraph C, any material changes to respondent's operations or business arrangements, or any other circumstances that respondent knows or has reason to know may have a material impact on its information security program.

Decision and Order

III.

IT IS FURTHER ORDERED that respondent obtain within one (1) year, and on a biannual basis thereafter, an assessment and report from a qualified, objective, independent third-party professional, using procedures and standards generally accepted in the profession, that certifies:

- A. that respondent has in place a security program that provides protections that meet or exceed the protections required by Part II of this order; and
- B. that respondent's security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of consumer's personal information has been protected.

The report required by this paragraph shall be prepared by a Certified Information System Security Professional (CISSP) or by a person or organization approved by the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission.

IV.

IT IS FURTHER ORDERED that respondent, and its successors and assigns, shall for a period of five (5) years after the date of service of this order maintain and upon request make available to the Federal Trade Commission for inspection and copying a print or electronic copy of the following documents relating to compliance with this order:

- A. a sample copy of each different print, broadcast, cable, or Internet advertisement, promotion, information collection form, Web page, screen, email message, or other document containing any representation to consumers regarding respondent's collection, use, and security of personal information from or about consumers. Each Web page copy

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shall be dated and contain the full URL of the Web page where the material was posted online. Electronic copies shall include all text and graphics files, audio scripts, and other computer files used in presenting the information on the Web. Provided, however, that after creation of any Web page or screen in compliance with this order, respondent shall not be required to retain a print or electronic copy of any amended Web page or screen to the extent that the amendment does not affect respondent's compliance obligations under this order;

- B. all plans, reports, studies, reviews, audits, audit trails, policies, and training materials, whether prepared by or on behalf of respondent, relating to respondent's compliance with this order; and
- C. any documents, whether prepared by or on behalf of respondent, that contradict, qualify, or call into question respondent's compliance with this order.

V.

IT IS FURTHER ORDERED that respondent, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having managerial responsibilities relating to the subject matter of this order. Respondent shall deliver this order to such current personnel within thirty (30) days after the date of service of this order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities.

VI.

IT IS FURTHER ORDERED that respondent Microsoft Corporation, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the

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corporation that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that respondent Microsoft Corporation, and its successors and assigns, shall within sixty (60) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

VIII.

This order will terminate on December 20, 2022, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;

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- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Microsoft Corporation (“Microsoft”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

Microsoft develops, manufactures, licenses, and supports a myriad of software products, sells hardware devices, provides consulting services, trains and certifies system developers, and offers a variety of online services. This matter concerns allegedly false or misleading representations made in connection with three related Microsoft services: the Passport Single Sign-In service (“Passport”); Passport Express Purchase (generally referred to as “Passport Wallet”); and Kids Passport (referred to collectively as the “Passport services”). Passport is an online authentication service that allows consumers to sign in at multiple Web sites with a single username and password. Passport Wallet and Kids Passport are add-on services that provide online purchasing and parental consent services.

The Commission’s proposed complaint alleges that Microsoft misrepresented:

- (1) that it maintained a high level of online security by employing sufficient measures reasonable and appropriate under the circumstances to maintain and protect the privacy and confidentiality of personal information obtained from or about consumers in connection with the Passport and Passport Wallet services;

Analysis

- (2) that purchases made at a Passport Express Purchase site with Passport Wallet are safer or more secure than purchases made at the same Passport Express Purchase site without using the Passport Wallet;
- (3) that Passport did not collect any personally identifiable information other than that described in its privacy policy, when, in fact, Passport collected, and maintained for a limited period of time, a personally identifiable record of the sites to which a Passport user signed in, along with the dates and times of sign in, which customer service representatives linked to a user's name in order to respond to a user's request for service; and
- (4) that the Kids Passport service provided parents with control over the information their children could provide to participating Passport sites and the use of that information by such sites.

The proposed consent order applies to the collection and storage of personal information from or about consumers in connection with the advertising, marketing, promotion, offering for sale, or sale of Passport, Kids Passport, Passport Wallet, any substantially similar product or service, or any multisite online authentication service. It contains provisions designed to prevent Microsoft from engaging in practices similar to those alleged in the complaint in the future.

Specifically, Part I of the proposed order prohibits misrepresentations regarding Microsoft's information practices, including:

- what personal information is collected from or about consumers;
- the extent to which respondent's product or service will maintain, protect or enhance the privacy, confidentiality, or

Analysis

security of any personally identifiable information collected from or about consumers;

- the steps respondent will take with respect to personal information it has collected in the event that it changes the terms of the privacy policy in effect at the time the information was collected;
- the extent to which the service allows parents to control what the information their children can provide to participating sites or the use of that information by such sites; and
- any other matter regarding the collection, use, or disclosure of personally identifiable information.

Part II of the proposed order requires Microsoft to establish and maintain a comprehensive information security program in writing that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers. The security program must contain administrative, technical, and physical safeguards appropriate to Microsoft's size and complexity, the nature and scope of its activities, and the sensitivity of the personal information collected from or about consumers. Specifically, the order requires Microsoft to:

- designate an employee or employees to coordinate and be accountable for the information security program;
- identify material internal and external risks to the security, confidentiality, and integrity of customer information that could result in the unauthorized disclosure, misuse, alteration, destruction, or other compromise of such information, and assess the sufficiency of any safeguards in place to control these risks. At a minimum, this risk assessment will include consideration of risks in each area of relevant operation, including: (1) employee training and management; (2) information systems, including network

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and software design, information processing, storage, transmission and disposal; and (3) prevention, detection, and response to attacks, intrusions, or other systems failures.

- design and implement reasonable safeguards to control the risks identified through risk assessment, and regularly test or monitor the effectiveness of the safeguards' key controls, systems, and procedures.
- evaluate and adjust its information security program in light of the results of testing and monitoring, any material changes to its operations or business arrangements, or any other circumstances that Microsoft knows or has reason to know may have a material impact on its information security program.

Part III of the proposed order requires that Microsoft obtain within one year, and on a biannual basis thereafter, an assessment and report from a qualified, objective, independent third-party professional, using procedures and standards generally accepted in the profession, certifying that: (1) Microsoft has in place a security program that provides protections that meet or exceed the protections required by Part II of this order; and (2) Microsoft's security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of consumer's personal information has been protected.

Parts IV through VII of the proposed order are reporting and compliance provisions. Part IV requires Microsoft's retention of materials relating to its privacy and security representations and to its compliance with the order's information security program. Part V requires dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part VI ensures notification to the FTC of changes in corporate status. Part VII mandates compliance reports within sixty (60) days after service of the order and at such other times as the Federal Trade Commission may require. Part VII is a

Analysis

provision "sunsetting" the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify their terms in any way.