

# **FEDERAL TRADE COMMISSION DECISIONS**

## **FINDING, OPINIONS, AND ORDERS**

PUBLISHED BY THE COMMISSION

**VOLUME 130**



Compiled by  
The Office of the Secretary  
April J. Tabor and Robert F. Swenson, Editors



**MEMBERS OF THE FEDERAL TRADE COMMISSION  
DURING THE PERIOD  
JULY 1, 2000 TO DECEMBER 31, 2000**

ROBERT PITOFISKY, *Chairman*

Took oath of office April 12, 1995.

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, 1988.

## **TABLE OF CONTENTS**

<b>FEDERAL TRADE COMMISSION DECISIONS .....</b>	<b>i</b>
<b>MEMBERS OF THE FEDERAL TRADE COMMISSION.....</b>	<b>i</b>
<b>Table of Contents .....</b>	<b>ii</b>
<b>Table of Cases.....</b>	<b>iii</b>
<b>FEDERAL TRADE COMMISSION DECISIONS .....</b>	<b>1</b>
<b>INTERLOCUTORY, MODIFYING, VACATING, AND MISCELLANEOUS ORDERS.....</b>	<b>1214</b>

## TABLE OF CASES

Abacus Holding, Inc. ....	<i>See</i> Albertson's, Inc.
ADT Automotive Holdings, Inc. ....	<i>See</i> Manheim Auctions, Inc.
AGRIUM, INC. ....	759
ALBERTSON=S, INC. ....	856
ALLIANT TECHSYSTEMS INC.....	1139
American Stores Company .....	<i>See</i> Albertson's, Inc.
Andrx Corporation .....	<i>See</i> Hoechst Marion Roussel, Inc.
AstraZeneca PLC .....	<i>See</i> Novartis AG
ATLANTIC RICHFIELD COMPANY.....	378
Bayer AG .....	<i>See</i> Novartis AG
BMG MUSIC.....	540
BOEING COMPANY, THE.....	1109
BP AMOCO P.L.C. ....	378
BUY.COM INC. ....	648
CAPITOL RECORDS, INC. ....	584
Carderm Capital L.P. ....	<i>See</i> Hoechst Marion Roussel, Inc.
CONSOLIDATED CIGAR CORPORATION.....	172
Cox Enterprises, Inc.....	<i>See</i> Manheim Auctions, Inc.
Dow AgroSciences.....	<i>See</i> Novartis AG
EMI Group PLC.....	<i>See</i> Capitol Records, Inc.
EMI Music Distribution.....	<i>See</i> Capitol Records, Inc.
FIRSTPLUS FINANCIAL GROUP, INC.....	811
GENERAL CIGAR HOLDINGS, INC. ....	241

General Motors Corporation .....	<i>See</i> Boeing Company, The
HAVATAMPA, INC. ....	309
HOECHST MARION ROUSSEL, INC. ....	1144
Hugh Space and Communications .....	<i>See</i> Boeing Company, The
J & R RESEARCH CORPORATION .....	1
JOHN MIDDLETON, INC.....	343
LANE LIMITED .....	275
MANHEIM AUCTIONS, INC.....	724
McCarthy, Gerald G.....	<i>See</i> J&R Research, Inc.
NOVARTIS AG.....	1051
OFFICE DEPOT, INC. ....	678
Ohnstad, Dennis .....	<i>See</i> Riley Manufactured Homes, Inc.
PFIZER INC. ....	90
RILEY MANUFACTURED HOMES, INC. ....	76
SMARTSCIENCE LABORATORIES, INC.....	698
SONY MUSIC ENTERTAINMENT, INC. ....	495
SWEDISH MATCH NORTH AMERICA, INC. ....	206
SWISHER INTERNATIONAL, INC.....	137
TIME WARNER, INC.....	517
TYCO INTERNATIONAL LTD. ....	827
Tyco International, Ltd. ....	<i>See</i> Manheim Auctions, Inc.
UMG Recordings, Inc. .	<i>See</i> Universal Music & Video Distribution Corp.
Union Oil Company of California .....	<i>See</i> Agrium, Inc.
UNIVERSAL MUSIC & VIDEO DISTRIBUTION CORP. ....	561
Unocal Corporation.....	<i>See</i> Agrium, Inc.
VALUE AMERICA, INC.....	606
WARNER-LAMBERT COMPANY .....	90
WEBTV NETWORKS, INC. ....	948

TABLE OF CASES  
VOLUME 130

v

WEIDER NUTRITION INTERNATIONAL, INC.....	790
Weitz, Gene C.....	<i>See</i> SmartScience Laboratories, Inc.





# **FEDERAL TRADE COMMISSION DECISIONS**

FINDINGS, OPINIONS, AND ORDERS

JANUARY 1, 2000, TO JUNE 30, 2000

**IN THE MATTER OF**

**J & R RESEARCH CORPORATION, ET AL.**

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

*Docket C-3961; File No. 972 3234*  
*Complaint, July 19, 2000--Decision, July 19, 2000*

This consent order addresses J & R Research, Inc.'s, and its principal, Gerald G. McCarthy's claims that pycnogenol, a substance derived from the bark of the maritime pine tree, could mitigate or cure the effects of numerous diseases or disorders. The complaint alleges that the advertising claims made about pycnogenol could not be substantiated. There was no scientific research demonstrating that pycnogenol products can alleviate or cure any of the diseases or disorders mentioned in advertisements and testimonials from consumers appearing in the advertisements for pycnogenol products did not reflect the typical or ordinary experience of members of the public who use pycnogenol products. The consent order requires respondents to possess competent and reliable scientific evidence before making any claim regarding the benefits, performance, or efficacy of any food, drug, or dietary supplement and prevents respondents from misrepresent the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research in an advertisement for any product. Furthermore, when using endorsements or testimonials, respondents must disclose either, what the generally expected results would be for users of the advertised products, or the limited applicability of the endorser's experience to what consumers may generally expect to achieve.

## *Participants*

For the Commission: *Matthew D. Gold* and *Kerry O'Brien*.

For the Respondents: *Gerald McCarthy, J&R Research, Inc., Joseph H. Thibodeau, P.C. and Claude C. Wild III, Patton Boggs, L.L.P.*

## Complaint

**COMPLAINT**

The Federal Trade Commission, having reason to believe that J & R Research Corporation, a corporation, and Gerald G. McCarthy, 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 J & R Research Corporation is an Iowa corporation with its principal office or place of business at 109 Main Street, Massena, Iowa 50853.

2. Respondent Gerald G. McCarthy is an officer of J & R Research Corporation. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of J & R Research Corporation, including the acts or practices alleged in this complaint. His principal office or place of business is the same as that of J & R Research Corporation.

3. Respondents have been general partners in a distributorship that has promoted the products of Kaire International, Inc., a multilevel marketing company. Kaire International's marketing plan allows distributors to earn commissions by recruiting other consumers both to purchase Kaire's products and to become distributors. The amount of commission earned by a distributor is based on the total dollar amount of the products purchased by those consumers and others whom they, in turn, recruit to be distributors.

4. Respondents have profited from the sale of various Kaire International nutritional supplement products containing pycnogenol, a substance derived from the bark of the maritime pine tree. These products have been sold under the names UltraPrime, Maritime Prime, Super Maritime Prime and Maritime Plus (Apycnogenol products@). Respondents= pycnogenol products are Afoods@ and/or Adrugs,@ within the meaning of sections 12 and 15 of the Federal Trade Commission Act.

## Complaint

5. Respondents have sold and disseminated or caused to be disseminated promotional materials to distributors of Kaire International. These promotional materials are intended to be, and are, used by distributors in their efforts to sell Kaire International's pycnogenol products and to recruit other distributors.

6. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as Acommerce@ is defined in Section 4 of the Federal Trade Commission Act.

7. The promotional materials sold and disseminated by respondents, including but not necessarily limited to the attached Exhibits A through F, contain the following statements and depictions:

**A. “THE FACTS ABOUT AN AMAZING, NEW  
HEALTH-BUILDING NUTRIENT FROM FRANCE”**

DR. McCARTHY: Hello, I'm Dr. Gerald McCarthy and, in a few minutes I'll also introduce to you Dr. W. Lamar Rosquist. This tape contains a candid report on a natural occurring nutritional and health promoting new plant compound from France, one that has remarkable healing qualities. Now used by millions in Europe, its relatively new to consumers in the U.S. and Canada. However, there are already tens of thousands of health conscious North Americans who have read the research data or the books that have been published about this compound, who have begun using it, and with excellent health results.

Moreover, many doctors here who practice with holistic or nutritional therapy are finding this to be the single most powerful nutritional healing compound that they've ever used. This patented plant compound . . . has extremely potent health promoting qualities that's been shown to dramatically help

## Complaint

relieve the inflammation, pain and symptoms in many cases of rheumatoid arthritis, osteoarthritis and rheumatism, that fights the effects of diabetes, that helps prevent strokes and the recurrences of strokes. The compound powerfully helps prostate problems and menstrual problems, that dramatically promotes prevention of heart problems, circulatory problems and even tumor formation.

. . . .

I know, those are some pretty bold statements. But please bear with me because what you're about to hear on this tape may have far reaching benefits to your health and well being and that of those you love. . . .

. . . [W]hat you're about to hear are health benefits that are scientifically documented within published articles by researchers from around the world and especially within two recently published books authored by Dr. Richard A. Passwater, who is a Ph.D. in biochemistry. Dr. Passwater is one of the nation's most respected biochemists and is often cited as the most recognized scientific researcher and authority on the health-restoring effectiveness of anti-oxidant vitamins and the benefits that other natural anti-oxidant nutritional compounds have on one's health, well being and life span.

. . . .

This report is about one you've probably not heard of yet because its a newly patented compound and is only available from a few sources, but has been hailed as the most powerful anti-oxidant nutrient ever discovered, called pycnogenol. First, it is an anti-oxidant compound just like vitamin C and E are anti-oxidants. But there the similarity ends, because pycnogenol is actually 20 times more powerful an anti-oxidant per milligram than vitamin C, and 50 times more powerful than vitamin E.

## Complaint

Next I'll introduce you to a respected colleague and friend, Dr. W. Lamar Rosquist, N.D., D.C. . . . .

DR. ROSQUIST: This is Dr. Lamar Rosquist speaking. I'm making this tape in an effort to acquaint you with an experience that I've had in using an extraordinary compound called pycnogenol. I'm not going to mention any trade name, I'm just going to talk strictly about a product that has been, I think, one of the greatest discoveries or re-discoveries of the century. . . . Pycnogenol is a flavonoid that is proven to be 20 times more powerful as a flavonoid per milligram than one milligram of vitamin C, and 50 times per milligram more potent than a milligram of vitamin E. So you can see it's quite a powerful flavonoid. This compound, pycnogenol . . . has produced a myriad of results which I've never seen with any other nutritional approaches that I've used in the past.

. . . . In reading the literature that my friend brought me, I saw that this was a compound was tremendous in helping to resolve phlebitis or inflammation of the vein, thrombophlebitis and to help eliminate blood clots in the vein. To help reduce faracoscies (phonetic), to increase circulation, to strengthen the vascular walls. . . . [I] started taking this because of all the things I found that it had possible healthful effects for me. I read that it would help people who had previously suffered CVAs, Cerebral Vascular Accidents, or we commonly call strokes, and it would help strengthen their vascular systems so that it wouldn't be so easy for them to experience a second stroke.

It would also help people who had previous heart attacks. The reason it would help them is because it would strengthen the vascular walls. The vessels would not be so permeable and weak, which allows fluids to flow in and out of the blood vessel walls into the tissue spaces. The linings of the vessels would be stronger, so when a person had too much stress or

## Complaint

too much pressure, their risk of a heart attack or a stroke would be greatly reduced.

Just the mere fact that I could take something that would help protect me so that I would not have to have other problems or episodes with my veins such as I had had, I was willing to take the pycnogenol. I was also willing to take pycnogenol because of my family history. Some of my previous members had weak blood vessels and had strokes and heart attacks. For these reasons I was willing to take pycnogenol as a preventative measure. For sometime I had a prostate problem, and usually men in their 60's get prostate problems. I would have to get up, as many men do, in the middle of the night to eliminate and void the bladder. I read in the literature that this product helps inflammation and inflammatory conditions and I realized that when a person has to void the bladder, there's usually an inflammation of the prostate gland or prostatitis. So, if it will help eliminate inflammatory conditions, it would help the prostate as well as any other type of inflammatory illness that might exist in the body such as phlebitis, which is inflammation of the vein, thrombophlebitis, which is inflammation of the vein with a blood clot, and arthritis which is inflammation of the various articular joints of the body.

So, I started taking 11 of these a day. It was only a matter of a week when I noticed that I didn't have to get up in the middle of the night to void my bladder. I also noticed that the pain in both my thumbs, my fingers and the weakness in my knees while going upstairs have all disappeared.

I had a man from Grand Forks, North Dakota sent to me by his daughter. He had been diagnosed as having terminal lung cancer with tumors in both lungs and they were in areas that were inoperable. Obviously they couldn't operate on the lung and remove the tumors because then he wouldn't have enough lung left to receive oxygen to sustain life. So they told him that he was too far gone for surgery. They thought

### Complaint

chemotherapy and radiation would be too rough on him. They just literally sent him home to die.

He came out to my office, I examined him. Here was a man who was in a very bad condition. His nose was purple, his hands were purple, his face was purple, his lips were purple. He was breathing in short pants, really struggling for oxygen and I didn't know what I could do. But I knew I had been having success with pycnogenol. So I put him on pycnogenol and gave him some other anti-oxidants, vitamin A, vitamin E, vitamin C and zinc and sent him back to his home in Grand Forks, North Dakota.

I didn't know what was going to happen to him. I put him on the saturation dosage like I take. . . . In another 30 days he called me and said I've good news and I've got bad news. And I said, well, give me the bad news first. He said they've discovered that I have a heart problem besides my lung problems and so my doctors here in Grand Forks took all my records, my x-rays, put them in a packet and sent me to Rochester, Minnesota to the Mayo Clinic because my case was too complicated.

When I arrived there, they put me in the hospital, did all kinds of tests and x-rays for a period of seven days. And at the end of seven days they called me into the consultation room and told me that the tumors in my left lung had totally disappeared and they wanted to know what I had done. So, I told them that I had been going to a doctor in Salt Lake and he put me on this special compound that came from France. So they told me whatever you do continue to take it. So I continued to take the product and they told me to come back in 30 days, that now because one lung was better that they could possibly do surgery and if my heart was okay, they were going to do an angiogram on the next visit.

## Complaint

And so I went back there in 30 days, they were going to do the angiogram and they put me in the hospital again. Did the same procedures but this time it was only for three days. And at the end of this time they took me aside and said, now tell us again, what have you been doing? And he said, well, I told you I've been taking these vitamins from this doctor and this compound from France. And, he said, why do you ask? And they said, your tumors are gone in the right lung as well. Because the tumors are gone in the right and the left lung and your breathing is so much better, we don't have to do the angiogram. And he said, well, what do I do now? And they said, go home continue what you're doing and don't stop. Come and see us in three months. I just received a call from him about two weeks ago and he said that he plays golf now very regularly and so this is quite an accomplishment for him to come back from where he was. So when people think according to their condition, how long am I going to take it, well, you figure how long do you want to have the relief from your symptoms? Because many of these symptoms just didn't start building up and coming on all of a sudden. They've been building up and coming on gradually for a long time.

. . . .

Any compound that will make this type of change is remarkable because it means that it's possible to reverse severe medical conditions. It means that you are not just going to take it to stop a situation but you are going to make the condition reversible. We are talking here about the strengthening of the blood vessel walls and the linings of these blood vessels to give us protection against heart attacks and strokes as well as many vascular conditions.

. . . .

It also helps people with Parkinson's disease, and they have mentioned it with Alzheimer's, as well as general senile dementia. A compound that has this many properties is one that nearly everyone needs to take.



## Complaint

. . . .

I thought I might tell you about some case histories. All of these are on a first person basis. These case histories refer to my patients in my practice. Patients that I've put on this product. A doctor called me from Billings, Montana and he asked me if I had anything which would help him with his prostate condition. I asked him to elaborate. He told me that for nine months he had an inflammation of his prostate and he had gone to two urologists, had taken antibiotics and other formulas that they had given him. None had worked. Then I told him that there was a compound that had been helping some of my patients and I was treating other prostate problems with it. He asked me to send him some literature and so I sent him some literature about pycnogenol. The next thing I knew I received a call from him about ten days later and he said, well, I read the literature and decided I'd give this product a try. He said that he had started taking the product the day before and that the pain in his prostate had left and it had not come back. I've followed through with three phone calls since that happened and that was four months ago. When I ask him how his prostate condition is he answers, AI don't have a prostate problem.@

I have a brother-in-law that came to me and also had a prostate problem but he is 83 and you could expect that he would have a prostate problem and he started taking pycnogenol. He used to have to get up three to four times a night. He never gets up at night anymore. He has noticed that his stream is full and he can evacuate his bladder immediately and there is no pain. So, he started thinking well, if this will help my prostate, it will help other things. So he started to put his wife on it and it has helped her arthritis, and now her knees do not give out on her. She has been able to go places this winter more than ever before.

## Complaint

But he has a younger daughter, I guess she is about 35, who has asthma very bad and has had it all her life, and she has it so bad that they have a lung machine that helps her when she gets in severe states of asthmatic attacks. Many times even when the lung machine does not help, they have to take her to an emergency room to get adrenalin to help her over the asthmatic attack. He had read the book written by Dr. Passwater who is a Ph.D. in biochemistry about some of his experience and scientific results that had been accomplished with pycnogenol. Dr. Passwater mentioned that you can take care of asthma and so this brother-in-law had his daughter start taking pycnogenol. This has been six weeks ago and after the first week, she never had to use the lung machine anymore. She is now, as he says, totally free of asthma. And she is now able to walk, take afternoon and evening walks with her friends around the block up to one to two miles with no effects at all, whereas before she had trouble just walking out to her mailbox and back.

. . . .

In our church area, we had a young man, 35 years of age, that was a juvenile diabetic and was losing his eyesight. He was suffering from a diabetic complication called peripheral retinopathy. This means the blood vessels in the back of the iris are so fragile as a result of years of taking insulin that his vessels had become very weak and they could not withstand pressure. The slightest little pressure would cause these blood vessels to break. Blood started filling into the vitreous humor of the eye. The blood in front of the optic disk made it impossible to see through it, therefore he was going blind. The young man came to my office and we started him on pycnogenol for seven months. Three months ago his eyesight started coming back. The blood vessels in the back of the eye were becoming stronger and because of this the bleeding slowed down to the point that now the blood that was in the eye was being resolved and absorbed by the body. The ophthalmologist was now able to go into his eye and by using lasers, zap some of these vessels that were weak and which

### Complaint

allowed blood to build up in the vitreous humor. He has noticed that his level of blood insulin has dropped and that's also an interesting thing.

The other day a woman called at my office and told me about her young child who had juvenile diabetes and that he was up to seven units a day. They were so depressed about it and I told her about the story of this young gentleman who was losing his eyesight. She started giving her son some pycnogenol and in less than two weeks his number of units of insulin had dropped from seven down to three. Many people who have diabetes have other problems especially circulatory problems, heart problems and have responded tremendously to taking pycnogenol.

. . . .

I have MS patients taking pycnogenol now. I have one MS patient in Phoenix, Arizona that is excited because she has been taking pycnogenol now for about four months. Her daughter is getting married in a couple of months. She has been in a wheelchair for about five years and she's excited because she's getting to the point where she's starting to stand and to walk a little. She's very excited about walking down the aisle and standing next to her daughter when she gets married. This didn't happen all at once. Many people take their product and figure well, I'll take it for 30 days and in 30 days its either going to work or I'll stop taking it. How long do you think free radicals have been working on your body to tear it down and destroy it and limit its use? It has been happening all your life. So don't think that in 30 days you're going to change something that's been taking so long to develop. Fortunately, the exciting result about this product is that so many people get overnight, instantaneous results. But given time, it will also work on some of those slower developing conditions such as arthritis.

## Complaint

. . . . We were on a cruise ship and had 1500 people on it.  
. . . . We were sitting at our dining room table on the first night out. The pharmacist and I were talking shop. Naturally he's talking about the new kinds of drugs and other things that are on the market and I'm talking about my office patients. I told him the story about this gentleman from North Dakota and the results I had with him taking this pycnogenol and he had never heard of this compound before. After we finished talking, the woman who was sitting to my left with her husband, tugged on my coat and she said, we've been listening to your conversation and I wanted to tell you that the very thing you've been talking about, the lung cancer the man in North Dakota has, has been a problem with me. My husband and I are on this cruise because I have lung cancer with an inoperable tumor that's wrapped itself around my esophagus. I've gone through radiation and I've gone through chemotherapy and this hair that I have is a wig. Then she introduced me to her husband, and her husband was one of the top medical surgeons in the United States. So, her husband immediately asked where they could get some pycnogenol. Well on this cruise I=d brought extra bottles with me. Now I've stayed in touch with his woman and her husband and she's gone back for three subsequent tests, back to the Western Division of the Mayo Clinic in Scottsdale, Arizona. She's gone back there three times and the tumor has not grown. It started to get smaller. This morning she called me from Arizona to tell me that she had just come out of Mayo Clinic and they could not find any trace of the tumors in her lungs or around her esophagus. She's feeling better and her husband, who is as I told you a surgeon, is eternally grateful.

. . . .

I have another case that I want to talk about and this is a woman that called me one day and said, Adoctor, is there anything you can do to help me with my leg.@ I said, Awhat's wrong?@ She said, Ayou know I have diabetes and I have developed a condition called osteomyelitis. With this

## Complaint

osteomyelitis I developed an infection in my right leg and it went into the bone marrow,@ and in osteomyelitis the infection is usually from a staphylococcus organism, which is one of the most resistant organisms to antibiotics there is. She said the antibiotics didn't kill the organisms and she started getting decay of her bone and her legs started swelling up and she had horrible pains. So they amputated her leg below the knee. She said it was now starting to happen in the left leg and that they now wanted to amputate her left leg. She said that she had become used to the prosthesis on her right leg and that she could get around but that she didn't want to live if she had to wear two prosthesis. She asked me if I knew of anything that might help her. I told her AI'll send you some literature on the pine bark extract called pycnogenol. I think this might help you.@ She started taking pycnogenol. . . . . In two weeks she called me, and all the pain was gone from her good leg, and all the swelling was gone. The infection and the inflammation in the bone marrow, which the antibiotics hadn't touched, was gone. The doctor did not have to amputate her leg.

. . . .

I'm finding that people have results with pycnogenol. I have a patient who lives in Malad, Idaho who had a severe cerebral vascular accident, a stroke, which left his whole left side of his body paralyzed. He could hardly walk. He came to me for other treatments and I told him about pycnogenol and he started taking it. Now he's walking almost normally, his balance and equilibrium are perfect. His biggest fear and the biggest fear of anyone that has had a stroke, is a second stroke. And he doesn't want that to happen.

I've heard of all types of cases and this is interesting because here in the United States, every other week in the newspaper, there is always something new about products like

## Complaint

the u-tree which is a type of pine tree that also has a bark similar to the maritime pine which pycnogenol comes from. Medical science is now using the extract from the bark of the u-tree to treat ovary, breast and uterine cancers. The same type of compound that's found in the u-tree is found in the bark of the maritime pine. I have three cases that I'm monitoring right now that have the same condition that killed the actor, Michael Landon. Cancer of the pancreas. They're desperate. That everyone of these cases have now lived three times longer than they were supposed to. They were given months to live, now they have lived much longer. They had jaundice, they are free of the jaundice. Their eyes aren't yellow, their skin is not yellow. They have no idea how long they're going to live. I have no idea how long they are going to live, but they're taking pycnogenol and they're taking the other anti-oxidants A, C, E and zinc faithfully.

. . . .

What are the other conditions that they're using pycnogenol for? I'm using it for arthritis, for bursitis, for diabetics, for people that have had strokes and heart attacks or people who have had predispositions to strokes or heart attacks. I'm using it for skin problems, for Parkinson's cases. .

..

I've found that this is a great product for people that have liver conditions from let's say alcoholism. Let me make one statement here and you can take this for what it's worth. Is it better, let's say if you're an alcoholic and you drink, or you're a smoker and you smoke, and say that because you have this problem you're not going to take pycnogenol and let your body deteriorate and wear down or is it better to add pycnogenol and try to fight some of those free radicals that you're bringing into your body? It's my estimation that everyone ought to be taking pycnogenol if they have one of these problems. They should be taking pycnogenol just to stop the further deterioration of their condition. Remember

## Complaint

what I have talked about. Quality of life and quantity of life can be expanded by the use of pycnogenol. . . .

Because I do not have case histories right now in front of me, I can not tell you all the other results that I have had happen. And we're talking about gastrointestinal problems straightening up, diarrhea straightening up, livers becoming decongested.

. . . .

I had someone take pycnogenol and all of a sudden they were able to sleep. And are able to get better rest at night than they have achieved for many years. So, you're going to find that this has a tranquilizing affect on the nervous system because it can cross the blood brain barriers as I mentioned earlier.

It also works really well with people who have edema. They're able to reduce the swelling that takes place in their legs. We have found that it will help the asthmatics, the edemas, the vascular conditions and, another thing I've found that it helps, is jet lag. So this would be an ideal product for people that are in the aircraft industry. Pilots, stewardess and people that do a lot of traveling will find that they do not have jet lag.

You will also find that pycnogenol helps nearly any kind of problem. . . . There are going to be many doctors in this company that will have results similar to or even greater than mine.

DR. McCARTHY: This is Dr. McCarthy again, and I hope that you were inspired by hearing Dr. Rosquist's in practice results that confirm the information that I shared with you at the beginning of this tape. So let me summarize some of the main points about pycnogenol as scientifically

## Complaint

documented within Dr. Passwater's two books on pycnogenol, that will help confirm why Dr. Rosquist, who you've just heard was able to report the various results that he has been seeing in his patients.

Pycnogenol literally helps to slow down the body's aging process. . . . Dr. Passwater and other researchers have found pycnogenol to be protective against hardening of the arteries. It helps to prevent the biochemical mechanisms that cause the plaque build up that often occurs within arteries, no matter what a person's age may be. Because of that, it greatly helps to reduce the risk of heart problems, and very important, it's used to help prevent recurrences of sudden acute heart problems. In fact, many people use pycnogenol to protect and improve the health and elasticity of the heart's coronary arteries and other blood vessels within the body. One famous British medical scholar has referred to pycnogenol as the arterial sclerosis antidote. Because pycnogenol greatly strengthens your body's blood vessels, the capillaries, arteries and veins, edema, -- or swelling of the legs is greatly reduced. And because of the increased vessel walls strength, it dramatically helps to prevent strokes and other circulatory problems within the body are also helped, as are the symptoms of PMS, menstrual problems such as excessive menstrual bleeding, water retention and so forth.

Pycnogenol is now used to greatly help prevent or actually reverse the circulatory and nervous system complications of diabetes, such as easy bruising, fragile capillaries and poor circulation. Pycnogenol is widely known to actually help repair and rebuild capillary function when it's deficient. Scientific studies and gratifying healing results reported by doctors show that pycnogenol can greatly help arthritis and rheumatism and severe prostate problems. It's used to heal and reduce varicose veins, phlebitis and hemorrhoids. It's dramatically effective against psoriasis and many other skin problems. It has a calming affect on the nervous system and helps provide better and deeper sleep, plus more pep and



### Complaint

energy upon awakening. Pycnogenol is remarkably effective against asthma, hay fever and other allergies. . . .

As regards arthritis, the types where inflammation is involved, pycnogenol thus helps to reduce the swelling, irritation and pain in the body's joints. In osteoarthritis where wear and tear on joint cartilages is primary, understand that your joint cartilages are mostly composed of collagen, and pycnogenol literally binds with, protects and helps rebuild collagen wherever it occurs within the body. So, this anti-inflammatory and joint rebuilding quality of pycnogenol can help all of the joints of the body including those in the low back and neck, shoulders, elbows, hands, hips, knees and so forth. The same anti-inflammatory affect and tissue collagen rebuilding affect of pycnogenol greatly helps tendinitis, bursitis, muscle soreness and injuries. In fact, it greatly speeds up the healing time of injured, damaged body tissues after accidents or surgery such as skin damage, or trauma, bed sores, muscles that have been strained, joints that have been sprained and so forth. Because of that, athletes of all types around the world are now using pycnogenol on a daily basis to give them a definite competitive edge and to rapidly heal athletic injuries to get back into competition in a fraction of the time that would be required without using pycnogenol.

. . . . In fact, Dr. Passwater shows that it has such a powerful, but natural, anti-viral affect, that it's been shown to inhibit herpes and even polio viruses. Pycnogenol helps to boost a person's muscular stamina and agility of body movement at any age, it sharpens memory and other mental processes. As I mentioned earlier, ponder again on the magnitude of this fact, the compound reduces the risks of, and has been shown to help, fully 60 of our most troublesome, chronic, degenerate of health conditions, naturally.

To mention just a few more of those, it's used to help people who have Alzheimer's, Parkinson's and senility.

## Complaint

Because pycnogenol protects brain cells and nerve cells from chemical damage by free radicals, it's used to heal chronic gum problems. It's used in cases of cataracts, chronic fatigue and to repair liver damage. It helps to repair degeneration of the eye's retina and in fact has been noted to improve the sharpness of vision within normal eyes. It greatly helps chronically dry skin. Pycnogenol is used to improve blood circulation over the entire body. When poor blood circulation in the pelvis is part of the cause, it even helps reverse male sexual inadequacy. Also, because pycnogenol helps to normalize capillary strength and resistance, it can be a powerful natural aid in reducing high blood pressure and the health risks that can cause.

Note that you can and should refer to Dr. Passwater's two books to back up everything on this tape about pycnogenol. One of the most intriguing things that Dr. Passwater documents is that pycnogenol has a strong, anti-cariogenic and anti-neoplastic affect - that is the ability to help prevent and inhibit tumor cell production of the body. . . .

Now, before closing this tape, just one last word. Don't be surprised if your doctor hasn't yet gotten the facts on pycnogenol. And the point is this, if what you've heard on this tape makes sense to you and it should, do not accept the opinion of any doctor regarding pycnogenol who you can not verify as to having studied the latest research papers or books on the compound that contains the facts. So, do your doctor a favor and loan him or her Dr. Passwater's two books on pycnogenol. Believe me, that doctor will eventually thank you with sincere gratitude for having done so because of the stunning healing affects that they'll quickly see in scores of their patients who they will have recommended pycnogenol to.

And very important, the information that we just shared with you about pycnogenol is meant to be strictly educational. And though pycnogenol has helped countless people with various conditions, that help is the result of the powerful

## Complaint

nutritional effect that pycnogenol can render. But where it comes to identifying what your physical problems may be, that is the job of your physician. So, Dr. Rosquist and I suggest that in all cases where you have various signs and symptoms of a physical problem, be sure to first consult with your doctor, weigh his or her advice, then consider adding the magic of super nutrition to your daily schedule. Do not attempt on your own to try to treat unidentified signs and symptoms that have not yet been identified by your doctor with pycnogenol or anything for that matter. That is the job of your doctor. . . . @

(Exhibit A, J & R Research Corporation cassette tape).

**B. "13 DOCTORS CONFIRM A HEALTH-BUILDING  
BREAKTHROUGH"**

Dr. McCarthy: Hello. I=am Dr. Gerald McCarthy. I=am a D.C. and am president and CEO of J & R Research Corporation, and I urge you to listen very carefully to this brief tape because it=s message may very well give you or someone you love a new lease on life from improved health and vitality, more energy and feeling of well-being. Plus a new way to relieve the cause of many types of acute and chronic pain.

In a moment, I=ll introduce you to thirteen medical professionals -- doctors who will reveal their exciting in-practice results from a new and patented breakthrough in nutritional science. Already used by countless doctors in Europe, it=s relatively new to the U.S. and Canada, but these thirteen doctors and thousands of others are now proving it to be the single most powerful nutritional health promoting compound they=ve ever used.

. . . .

## Complaint

Dr. McCarthy: [T]he name of the compound is pycnogenol. . . . And, it=s a totally safe to use extract from the bark of the french maritime pine tree. Now, before these doctors share their experiences with you, there are several things I need to point out. First, their enthusiasm about pycnogenol is unique. Never before has a nutritional compound so captured the attention of mainstream medical doctors. . . . Next, their excitement is about a very specific and exclusive formulation of pycnogenol. One that=s specially produced by a company in **Longmont, Colorado**. [Emphasis added].

. . . .

Dr. Shields: I am Dr. Russell B. Shields. I am a medical doctor and since 1963 I=ve been practicing medicine as a board certified family physician. . . . That is before my immune system started to malfunction. When that happened, I became more and more disabled with rheumatoid arthritis, and during the next nine years, my condition continued to deteriorate. I became extremely handicapped. The periarticular swelling and pain in my joints was severe. I rarely slept more than two hours at a time. Also, it looked like a hip replacement was needed. [M]y brother, who is also a medical doctor, had suggested many times that I try something new. . . . It was a compound from pine tree bark called pycnogenol. . . . And now here=s what happened. As a scientist, I=ve got to admit, the results that followed were far beyond any ever witnessed in my practice. In fact, I was virtually overwhelmed by the relief that occurred over a period of time. Today I=ve regained 100% normal function of all joints, and am free of pain. The range of motion of my joints is back to normal. My gratitude for this compound and what its done, is beyond anything that words can convey. But I=ll try to express it by saying this, anyone with degenerative health conditions who fails to give this compound a try is passing up the single greatest opportunity to help correct their immune system malfunction.

## Complaint

Also, realize that there are many anti-oxidant products on the market, and many of them are good basic products but there=s only one that I endorse 100%, and those are the pycnogenol formulations produced in Colorado. No other anti-oxidant compound provides even remotely the same degree of result. . . . [I] could reveal many case histories wherein I=ve successfully used pycnogenol and the Colorado company=s other compounds. . . . Their use, especially for patients with hard to treat degenerative conditions, will I=m sure soon reach the attention of the mass media.

. . . .

Dr. Buerger: My name is Clark L. Buerger, Jr., B.S., M.D. I . . . practiced for over 40 years in the specialty of OB/GYN. I am 77 years old but still keep my license active. I am one of the founding fellows of the American College of OB/GYN. . . . While shopping . . . , the salesman noticed how crippled I was and brought me a chair to sit in while he demonstrated his products. He asked me if I would like to try a nutrient that is the strongest anti-oxidant currently available. I was very skeptical and doubted that this man could offer me anything that could improve my condition. However, I told him that I would be glad to give it a try. I later became extremely excited over this which I call the wonder pill of the century! I was loaded with degenerative disease such as diabetic neuropathy, degenerative arthritis, high blood pressure, prostate problem, hemorrhoids, arterial sclerosis with cardio vascular changes, and Crohnes Disease. I had a total right knee performed, the removal of all the bone in the joint and replaced with stainless steel. My left knee was equally as bad and the doctor suggested that I have both done at the same time, but I refused and only had the right knee operated on. I was happy over this decision because my left knee is now back to normal without surgery. After starting on pycnogenol

## Complaint

from Colorado, I was in for a great surprise. In time, I had a complete turnaround of all my symptoms. My prostate cleared, my neuropathy cleared, my blood pressure came down, my hemorrhoids improved, my left knee, as I told you, was completely back to normal and my Crohns Disease had markedly improved. Then I ran out of pycnogenol. All of my symptoms returned. I immediately went out and searched for pycnogenol and found a look alike in a local health food store. To my dismay, my conditions remained unchanged. Finally, my pycnogenol arrived from Colorado and in time I again improved. . . . . I have patients with lupus, Parkinson=s Disease, arthritis, prostate problems, and fibromyalgia. All of these conditions are showing marked improvement. . . . .

. . . .

Dr. Phillips: . . . . I=m a doctor of podiatric medicine and surgery. . . . .

[C]onditions that I have seen personally in my office practice improve were conditions such as arthritis, diabetic ulcers, decubatus ulcers, neurotrophic ulcers, and edema, along with cases of diabetic neuropathy. Personally, I=ve experienced resolvment of a chronic skin condition I=ve had for 25 years. Through family and associates, I=ve seen improvement in rotator cuff problem and associated pain, and also lupus, Crohns Disease, hypertension, irritable bowel syndrome, bronchitis, asthma and the list goes on. In regards to ADD with a five year old male, this little boy had been on Ritalin at 20 milligrams per day. He did terrible. He didn=t eat. He didn=t sleep. He argued all the time with the parents and he was crabby. They put this child on pycnogenol and also within a certain period of time, he slept better, he ate better, he had a better personality. He had an increased focus and was more attentive. One statement that really got my attention was that the mother called my up one evening and she said: AThank you very much for giving my son back to me.@ And, this really hit home.

## Complaint

....

Dr. Cunningham: . . . . I=ve been an optometrist for the past eight years. I specialize in behavioral and functional vision with great emphasis on visual perception. . . . I had heard much about pycnogenol so I began purchasing just basic pycnogenol at the local store for a period of time and nothing happened. So my first impression was that pycnogenol was a hoax. Then a friend contacted me and encouraged my to try pycnogenol from a company in Colorado. . . . [W]hat struck me the most was that my vision was noticeably improved. The depth, contrast, color and also my peripheral awareness had all improved. . . . It just stands to reason that pycnogenol, an anti-oxidant 50 times more powerful than Vitamin E and 20 times more powerful than Vitamin C, will have an amazing effect on the retinal tissue. I can foresee the widespread use of Pycnogenol with other anti-oxidants to treat the various conditions of the retina.

Dr. Shore: . . . . I am an osteopathic physician and surgeon. . . . I have some patients that I would like to tell you about and some of the results of these patients have gotten them from using the Pycnogenol that we get from this company in Colorado. FR is a patient who has rheumatoid arthritis. Prior to starting pycnogenol, she was taking cortisone, as well as tetracycline and also needed to use a walker, and it took her approximately five to eight minutes to get from the living room to answer the door bell. She was able to get off the Prednisone; she was able to get off the tetracycline and she no longer needed the walker. I have had several patients with ADD and ADHD, attention deficit disorder and attention deficit hyperactive disorder, who have gotten excellent results with pycnogenol. Some of the patients have been able to get off their prescribed medications entirely and other of the patients have been able to decrease their dosage by as much as 50%.

## Complaint

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Now, all of us may not get results quickly, but everybody will get results with Pycnogenol if they stay on the product long enough and at a high enough dose.

....

Dr. Fischbach: . . . . I=am a medical doctor specializing in family practice and ophthalmology. I was introduced to pycnogenol by a friend approximately three years ago. . . . Now I=ve had some experience with multiple disorders and illnesses, among which are multiple sclerosis, rheumatoid arthritis, fibromyalgia, attention deficit disorder and attention hyperactive disorder, diabetes, osteoarthritis, lupus and the list goes on and on. My experience is quite extensive. I=d like to give you a few examples of some very dramatic cases that I=ve had over the years. One that comes to mind immediately is of a woman in her 60's with multiple sclerosis who came to me after having been tried on virtually all conventional medications without any success whatsoever. She came hobbling in with a cane and looked very distraught and very much in pain. . . . [I] placed her both on the pycnogenol and aloe vera and the next time I saw her she came in and said that she thought this was starting to help her. . . . And the next visit I had with her, she definitely noticed a tremendous difference. . . . And the following visit we had, she came in, she did not even have her cane with her -- she left it in the waiting room. She didn=t even realize she did this. She says she feels wonderful. She hasn=t felt his good in many, many years. . . . I had never been able to achieve these types of results with any other conventional medication. . . .

I saw a boy . . . who had attention deficit disorder and his mother told me that try as hard as he could in school, he just could not concentrate. This caused tremendous problems with his grades; as a result, his self esteem was very low. She was



### Complaint

familiar with the drug Ritalin used in Attention Deficit Disorder but was very concerned about all she had read and the side effect profile. . . . [W]e placed him on pycnogenol and she notified me a while later that the results were amazing. He now was able to concentrate. He could perform his studies and his grades improved dramatically; his self confidence was now back, and she was just amazed and so was he at how dramatic a turn around this compound did for him. It was just incredible!

Another friend of mine has severe osteoarthritis of both knees, to the extent where there is no longer any cartilage between the two main bones and he basically is in a situation of bone rubbing against bone whenever he=s walking. This naturally has led to a tremendous amount of pain on a regular basis. I placed him on pycnogenol and again, a short while later, he told me that he started to notice an improvement and we spoke again a while later and he said his symptoms were almost gone. He could now wake up without any pain. His mobility was much improved and he just could not believe the difference. . . .

Now these are some examples, just a few, of what I have seen pycnogenol do over the last three years and it=s interesting because prior to the introduction of Pycnogenol in this country, conventional anti-oxidants that have been available, which are Vitamin C and Vitamin E, just couldn=t even come close to doing things like what I=ve just related to you. Vitamin C, we found to be 20 times less potent than pycnogenol; Vitamin E, 50 times less potent. . . .

[I] have researched this quite thoroughly and found that the only pycnogenol that is of superior quality comes from a company in Colorado. And, all the other pycnogenols I=ve seen are far, far less potent.

## Complaint

. . . .

While in fact these products have been extensively studied in Europe and their safety and effectiveness proven without question, the relatively recent introduction to this country has not yet generated a body of evidence to support what we who have used them already know. . . . .

(Exhibit B, J & R Research Corporation, cassette tape).

C.

NATURE=S MIRACLES  
AN M.D.=s EXPERIENCE

By  
Dr. Gary Fischbach M.D.

## INTRODUCTION

. . . .

The air we breathe, the water we drink, the foods we eat, and the way we choose to live our lives will be our epitaph. The culprit - trillions of tiny molecules called Afree radicals.@ These unstable oxygen molecules unleashed by pollutants, chemicals, stress, and even physical exertion and sunlight are felt to be largely responsible for the degenerative process known as aging, and even more important, the largest contributor to disease. From the common cold to widespread cancer, we have become victims of this deadly chain of events, initiated by Afree radicals,@ that ultimately wears down our immune system and its ability to defend the body.

. . . .

The conventional weapons in this fight, Aanti-oxidants@ as they are known, have been Vitamin C, E and Beta Carotene. This is the classic David versus Goliath - like trying to put out a forest fire with a water pistol - hopeless.

. . . .

## Complaint

God help us if we do not wake up soon. Our legacies left to our children might make it difficult to survive.

While needless to say, all the preceding declarations of doom are quite depressing, all is not lost. The picture is no longer as hopeless as it once was. In the pages that follow, you will learn of a compound unlike any other previously discovered. A substance that has been widely used in Europe by doctors and other health care providers for over forty years. A compound that is able for the first time to be winning the battle against free radical destruction.

. . . .

So why, you might ask, aren't these substances well known and readily available to everyone? Why don't doctors know about them? Why haven't they been popularized in the media? Why hasn't the FDA, the Government's Food and Drug Administration, examined the studies abroad, seen the potential benefits, and pushed these compounds through? Well sadly, the fact is that it costs over 200 million dollars and 10 years of research to gain the FDA's ringing endorsement these days - a practice that has deprived us Americans of the many benefits afforded people in other countries whose laws are not nearly as stringent. As a matter of fact, these very substances we have been discussing are not only in widespread use in Europe and Scandinavia, but for many conditions, they are the number one recommended treatment by doctors. . . . .

But make no mistake - the information that follows is not intended as a promise or cure; we make no medical claims. Rather, it is based on the experiences of people with a large variety of medical problems and conditions. We refer to this as anecdotal evidence, as opposed to that which is derived

## Complaint

from scientific studies. While, in fact, these substances have been extensively studied in Europe for over 40 years, and their safety and effectiveness proven without question, their relatively recent introduction to this country has not yet generated a body of evidence to support what we, who have used them, already know. Without question these studies will follow, and create such significant and overwhelming proof, that the medical establishment will be unable to deny the facts.

. . . .  
. . . . Studies have shown it to be 20 times more potent than Vit. C and 50 times more powerful than Vit. E as an antioxidant. The compound=s name - MARITIME PINE.

. . . .  
As previously stated, this compound has been carefully studied for decades, and has been in widespread use throughout Europe and Scandinavia against a multitude of medical conditions. Over the years, professors, physicians, researchers, and even a 1986 Nobel Prize nominee have sung the praises of this ASuper Antioxidant.@ Finally, it is now available in the United States.

. . . .

## REFERENCE TABLES

. . . .

I am not stating that these compounds will cure, improve, or even alter these conditions whatsoever. I am merely offering up a significant body of Aanecdotal@ evidence derived from personal experience with these substances in my practice. These encounters happen to support the massive amount of foreign literature accumulated over the last few decades illustrating the health benefits of these substances. . . .

.  
(copy of reference tables attached as Exhibit C).

Complaint

D. A. . . .

Dear Friend,

You had asked for this information on Attention Deficit Disorder. Remember . . . We had visited on the phone?

Dr. McCarthy=s enclosed brief tape reveals a new, safe to use, non-drug, nutritional breakthrough method for relief of ADD. . .

If you had thought that powerful stimulant drugs were the only means of relief for ADD, the good news is this:

Every week from coast to coast, many thousands of grateful parents, adult ADD sufferers and ADD support group members. . . are discovering dramatic relief with this new, nutritional method.

. . . .

As you listen to Dr. McCarthy=s brief tape you will hear the experiences of three doctors who reveal typical case histories of patients they had taken off of Ritalin-- and other drugs-- then, placing them on Pycnogenol, how those patients experienced wonderful relief.

Also, you will hear the experiences of a typical, grateful parent, and an adult ADD sufferer who gained relief with Pycnogenol.. . . @  
(Exhibit D, J & R Research Corporation promotional letter).

## Complaint

E. ADR. McCARTHY: Hello, this is Dr. McCarthy again, and this report is a vital update on the astonishing new nutritional compound previously reported to you on my audio Tapes 1-A and 2-A. On Tape 1-A, you heard Dr. W. Lamar Rosquist refer to it as the "nutritional miracle" of the <90s. Well, in line with that statement, this tape will reveal the remarkable effectiveness of that safe to use compound for another very pressing national health problem, Attention Deficit Disorder, also Attention Deficit Hyperactivity Disorder. You'll get the facts on this new approach to ADD or ADHD and in detail. Not only from me, but from several physicians, two medical practitioners, a pharmacist, a doctor of chiropractic and grateful parents of ADD suffering children, plus an adult with ADD. . . .

ADD, or ADHD, is a baffling and frustrating disorder, not only for those who suffer from it, but also for their loved ones and our nation's physicians who have done their best to treat it. The frustration among physicians is because science has not yet found the cause or causes of ADD. . . . One thing that is a fact, millions have been prescribed powerful stimulant drugs in the attempt to help ADD. But there are two problems with drug treatment. One, in many cases drugs such as Ritalin, Dexedrine and Cylert, often do not work very well. And second, they cause very dangerous side effects. But the good news is this: Every week from coast to coast, many thousands of parents, adult ADD sufferers plus countless ADD support group members are discovering wonderful natural relief with pycnogenol . . . .

First, I'll introduced you to Dr. Gary T. Fischbach, M.D. Dr. Fischbach practices internal medical as a family medical practitioner and also practices ophthalmology. . . . [H]e is one of the few medical doctors in the U.S. who has over three years in-depth clinical experience with the virtually astounding health results pycnogenol provides. Listen especially to his experiences with ADD patients.

## Complaint

DR. FISCHBACH: I was introduced to pycnogenol by some associates here in the town that I live in and became very intrigued by some of the claims that were being made, experiences that were had by physicians in Europe, specifically, with quite a number of disorders, and became intrigued enough to investigate the literature and did some of my own testing as well. And, to my amazement, I found that pycnogenol was very effective against quite a number of disease processes, and I could finally achieve results with this natural compound that before I could not achieve with conventional pharmaceuticals.

Let me give you some examples. I've been able to effectively improve conditions such as multiple sclerosis, rheumatoid arthritis, osteoarthritis, fibromyalgia, lupus, as well as attention deficit disorder and attention deficit hyperactive disorder. The latter two I have found over the years to be an extremely difficult disorder to treat, both for the patient and for the family . . . . And it's just been amazing the response that I've gotten from parents of children who I've placed on the compound pycnogenol. They see results usually very rapidly and they comment that the child's behavior is able to be maintained over the course of a whole day, something which we often not see with Ritalin.

Let me tell you that I've seen a couple cases that I must say are remarkable and extremely dramatic. I had one mother, after her son began pycnogenol tell me that the child was able to sit quietly, carry on a conversation, play with his cousin uninterrupted and what even happened is that the child noticed this, and we're talking about a six year old child. He could feel the difference and he would actually run to take pycnogenol, whereas before the mother had to actually force him to take the Ritalin. She understandably was beside herself with joy at these results and just praised the coming of pycnogenol, so to speak.

## Complaint

And I've had numerous other cases equally dramatic. The feedback from parents has been astounding. They notice rapid results and they all comment that the behavior pattern has been smoothed out completely without any peaks and valleys and their school work has improved dramatically. I must also say that I've had some experience where they would run out of the brand that I was exposing them to and would be forced to seek other means of obtaining the compound. They would find some at their local health food store. They would come to me showing me a bottle of pycnogenol and would ask me "Doctor, isn't this actually the same compound?" I would tell them politely, "No, this really isn't anywhere near the quality of the pycnogenol that I have gotten for you. And you can experiment yourself and try what you find at the health food store and compare it to the compound that you had gotten from me." And, lo and behold, each time this occurred they would then come back to me and tell me that they could not feel any benefit whatsoever from the compound they had purchased themselves and ask me what was the difference. Well, then I would proceed to tell them that this company located in Colorado manufactures the highest quality pycnogenol available anywhere and this company has an exclusive patent for their process. . . .

I must say that I have never seen such a change in individuals with so many varied problems as I have with the use of Pycnogenol and that includes all my experiences with all types of pharmaceutical drugs. . . .

. . . .

DR. McCARTHY: . . . . [I]n a minute you'll hear the experiences of two typical consumers who are benefitting from pycnogenol. One whose son is taking it . . . .

RAY: . . . . [It] can be very frustrating and very stressful when your child has ADHD because they don't follow instructions, they don't make eye contact, they don't listen to you, it seems like they're ignoring you. They're always in trouble, they're



## Complaint

impulsively hitting. It's just you really feel out of control and discipline just doesn't work. . . . David was on Ritalin. He went through the child study team and psychological evaluation, he went to a neurologist and they said it's ADHD. He did focus a little better in school. Not right away. We changed the dose of the Ritalin, the doctor told us to, he got a little better. But the immediate side effect, he would come home with the Ritalin rebound it was called. He would literally bounce off the wall when this Ritalin would wear off. It was horrible. You'd come home from school, your kid's all glassy-eyed, running from one wall to the next, bouncing off, and you're calling his name and he doesn't even know you're there. He wasn't sleeping, he's up until one o'clock in the morning because he couldn't sleep. His lips were real dry, he had tummy aches. He was on it for I guess about two months or so. Thanksgiving we decided to give Pycnogenol. . . . Well, he started following multiple instructions, making eye contact, tracking what you're saying. You could see him looking at you, tracking what you're saying. . . . He focuses for an hour and a half in the morning and an hour and a half in the afternoon. I got to tell you, it's a different kid. It really, really is . . . @

(Exhibit E, J & R Research Corporation cassette tape).

**F. AFAIRBORNE PYCNOGENOL MONOGRAPH #2**

## Relative to Attention Deficit Disorder &amp; ADHD

The data within this monograph was created for our Fairborne Association=s member -- physicians who practice in the field. This information is to further disclose facts obtained regarding the compound Pycnogenol, and particularly its efficacy for alleviation of the signs and symptoms of Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder or ADHD.

. . . .

## Complaint

The commercial source for the compound we continue to utilize, is the same formulator in Colorado referred to in our first monograph. The only reason we continue to use that source is because their proprietary, blended *formulations* of Pycnogenol have significantly greater bioavailability than *basic* Pycnogenol sold over the counter in pharmacies and other sources. . . . .

. . . .

Interesting to note is the fact that even though, over the years, many so called Anutritional@ approaches to ADD have been attempted, no nutritional methods had heretofore produced *significant* alleviation of symptoms.

However, not only is Pycnogenol proving to be exceedingly efficacious for ADD, from the anecdotal results reported from the field it is becoming a very attractive *first-line* method of choice by many physicians, in preference to conventional drug administration. Also, in most cases, traditional *drug* therapy can usually be discontinued - or significantly reduced - provided the patient continues to consume Pycnogenol.

. . . .

**TYPICAL RESULTS WITH ADD/ADHD PATIENTS:**

- (a) A generalized calming effect.
- (b) Significantly increased mental alertness and increased ability to remain focused upon a given task or problem.
- (c) Activities and plans much more organized.
- (d) Far less impulsiveness of behavior.
- (e) Decreased aggressiveness.
- (f) A subjective feeling of being Aat ease.@
- (g) More in control of one=s thoughts.
- (h) Particularly exhibited in young children and teenage ADD patients,

## Complaint

as well as the above:

1. Improved grades in school.
2. Improved recognition of and cooperation with requests from teachers and parents.
3. Less noisiness and disruptive behavior in class, at home, among siblings and peers.
4. Marked improvement in the ability to remain still. (Decreased Restlessness).

. . . .

### **PHASE 3: DRUG REDUCTION AND/OR ELIMINATION**

For ADD patients currently being treated with drugs such as Ritalin, Cylert and Dexedrine, as you know, those drugs are often withdrawn gradually, to avoid drug-dependent withdrawal symptoms. (Refer to your PDR). It is entirely up to the physician as to *when* to begin gradually decreasing daily dosages of Ritalin, etc. during Pycnogenol administration. However, keep this in mind:

. . . .

Reports from physicians in the field indicate that as Ritalin, etc., is gradually decreased over a number of days, for most patients it can be *entirely* eliminated. However, a smaller percentage of patients may still require some drug intervention as well. And, then, in most cases, only at peak stress periods such as afternoon school sessions and so forth. Moreover, the drug *dosage* required at those peak stress periods is significantly lower than formerly required before initiating Pycnogenol dosage. . . .@

(Exhibit F, Respondent J & R Research Corporation promotional material).

8. Through the means described in Paragraph 7, respondents

## Complaint

have represented, expressly or by implication, that Kaire International=s pycnogenol products:

- A. dramatically treat or improve rheumatoid arthritis, osteoarthritis and rheumatism, including the elimination or reduction of inflammation and pain associated with these disorders;
- B. reduce the amount of insulin needed to treat diabetes;
- C. treat and/or improve health disorders associated with diabetes, including neuropathy, retinopathy, osteomyelitis, circulatory problems and heart problems;
- D. help treat lupus, Parkinson=s Disease, multiple sclerosis and fibromyalgia;
- E. treat or improve digestive disorders, including Crohnes Disease and irritable bowel syndrome;
- F. help prevent strokes and the reoccurrence of strokes;
- G. dramatically improve physical disabilities caused by stroke;
- H. dramatically help prevent heart disease, including arterial sclerosis;
- I. reduce blood pressure;
- J. dramatically improve and help prevent circulatory problems, including phlebitis, thrombophlebitis, blood clots, and varicose veins;
- K. dramatically promote the shrinkage of tumors and help prevent tumor formation;

## Complaint

- L. treat cancer and/or prolong the life of cancer victims;
- M. reduce or eliminate inflammation of the prostate;
- N. eliminate or reduce the incidence of asthma attacks and symptoms caused by allergies;
- O. improve eyesight and treat disorders of the retina;
- P. help rebuild joints and soft tissue;
- Q. greatly accelerate the healing time of injuries;
- R. improve or cure skin conditions such as psoriasis and acne;
- S. treat Attention Deficit Disorder and Attention Deficit Hyperactive Disorder;
- T. reduce or eliminate the need for medication in individuals with Attention Deficit Disorder and Attention Deficit Hyperactive Disorder; and
- U. are twenty times more protective as an antioxidant than Vitamin C, and fifty times more protective than Vitamin E.

9. Through the means described in Paragraph 7, respondents have represented, expressly or by implication, that testimonials from consumers appearing in the advertisements for Kaire International=s pycnogenol products reflect the typical or ordinary experience of members of the public who use pycnogenol products.

10. Through the means described in Paragraph 7, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the

## Complaint

representations set forth in Paragraphs 8 and 9, at the time the representations were made.

11. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraphs 8 and 9, at the time the representations were made. Therefore, the representation set forth in Paragraph 10 was, and is, false or misleading.

12. Through the means described in Paragraph 7, respondents have represented, expressly or by implication, that scientific research demonstrates that Kaire International=s pycnogenol products:

- A. dramatically treat or improve rheumatoid arthritis, osteoarthritis and rheumatism, including the elimination or reduction of inflammation and pain associated with these disorders;
- B. reduce the amount of insulin needed to treat diabetes;
- C. dramatically treat and/or improve health disorders associated with diabetes, including retinopathy, osteomyelitis, circulatory problems and heart problems;
- D. help treat Parkinson=s Disease and multiple sclerosis;
- E. help prevent strokes and the reoccurrence of strokes;
- F. dramatically improve physical disabilities caused by stroke;
- G. dramatically help prevent heart disease, including arterial sclerosis;
- H. dramatically improve and help prevent circulatory problems, including phlebitis, thrombophlebitis, blood clots and varicose veins;

## Complaint

- I. dramatically promote the shrinkage of tumors and help prevent tumor formation;
  - J. treat cancer and/or prolong the life of cancer victims;
  - K. reduce or eliminate inflammation of the prostate;
  - L. eliminate or reduce the incidence of asthma attacks and symptoms caused by allergies;
  - M. improve eyesight and treat disorders of the retina;
  - N. help rebuild joints and soft tissue;
  - O. greatly accelerate the healing time of injuries;
  - P. improve or cure skin conditions such as psoriasis; and
  - Q. are twenty times more protective as an antioxidant than Vitamin C, and fifty times more protective than Vitamin E.
13. In truth and in fact, scientific research does not demonstrate that Kaire International=s pycnogenol products:
- A. dramatically treat or improve rheumatoid arthritis, osteoarthritis and rheumatism, including the elimination or reduction of inflammation and pain associated with these disorders;
  - B. reduce the amount of insulin needed to treat diabetes;
  - C. dramatically treat and/or improve health disorders associated with diabetes, including retinopathy, osteomyelitis, circulatory problems and heart problems;

## Complaint

- D. help treat Parkinson=s Disease and multiple sclerosis;
- E. help prevent strokes and the reoccurrence of strokes;
- F. dramatically improve physical disabilities caused by stroke;
- G. dramatically help prevent heart disease, including arterial sclerosis;
- H. dramatically improve and help prevent circulatory problems, including phlebitis, thrombophlebitis, blood clots and varicose veins;
- I. dramatically promote the shrinkage of tumors and help prevent tumor formation;
- J. treat cancer and/or prolong the life of cancer victims;
- K. reduce or eliminate inflammation of the prostate;
- L. eliminate or reduce the incidence of asthma attacks and symptoms caused by allergies;
- M. improve eyesight and treat disorders of the retina;
- N. help rebuild joints and soft tissue;
- O. greatly accelerate the healing time of injuries;
- P. improve or cure skin conditions such as psoriasis; and
- Q. are twenty times more protective as an antioxidant than Vitamin C, and fifty times more protective than Vitamin E.

Therefore, the representations set forth in Paragraph 12, were, and are false or misleading.



Complaint

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 nineteenth day of July, 2000, has issued this complaint against respondents.

By the Commission.

**Complaint Exhibits**

**EXHIBIT A**

**AUDIO CASSETTE TAPE**

## EXHIBIT B

### 'AUDIOCASSETTE TAPE

Complaint

# NATURE'S MIRACLES

AN M.D.'s EXPERIENCE



By  
*Dr. Gary Fischbach M.D.*

EXHIBIT C

FEDERAL TRADE COMMISSION DECISIONS  
VOLUME 130

## Complaint

TABLES REFERENCE CHART		SEE TABLE(S)	MARITIME PINE @ 20 MG/TAB	MARITIME PINE PLUS OTHER NUTRIENTS	ALOE VERA JUICE CONCENTRATE	ALOE VERA GEL	EMU OIL PAIN CREAM	COLLOIDAL SILVER
ABRASIONS	a					✓		
ACHES, MINOR	1+ 9	✓					✓	
ACNE	7				✓			✓
ACQUIRED IMMUNE AIDS DEFICIENCY SYNDROME	5	✓	✓	✓				✓
AGING	1	✓						
ALLERGIES	2	✓		✓				
ALZHEIMER'S	4	✓	✓					
ARTHRITIS	2 9	✓		✓			✓	
ASTHMA	2	✓		✓				
ATHEROSCLEROSIS	1	✓						
ATHLETE'S FOOT	8					✓		
ATTENTION DEFICIT DISORDER	4	✓	✓					
ATTENTION DEFICIT HYPERACTIVE DISORDER	4	✓	✓					
AUTISM	4	✓	✓					
BACKACHE	1+ 9	✓					✓	
BLOOD CLOTS	1	✓						
BLOOD PRESSURE, HIGH	1	✓						
BOILS	8					✓		
171		CONTINUED						

## Complaint

TABLES REFERENCE CHART		SEE TABLE(S)	MARITIME PINE @ 20 MG/TAB	MARITIME PINE PLUS OTHER NUTRIENTS	ALOE VERA JUICE CONCENTRATE	ALOE VERA GEL	EMU OIL PAIN CREAM	COLLOIDAL SILVER
CONJUNCTIVITIS (PINK EYE)	10							✓
CONSTIPATION	6							
CONTUSION	9+	✓		✓			✓	
COUGH	3	✓		✓				✓
CRADLE CAP	8					✓		✓
CRAMPS	2	✓		✓				
CREST SYNDROME	3	✓		✓				✓
CROHN'S DISEASE	2	✓		✓				
CUTS	8					✓		✓
DANDRUFF	2	✓		✓				
DEMENTIA	4	✓	✓					
DENTURE SORES	7			✓				✓
DEPRESSION	4	✓	✓					
DERMATITIS	1	✓						
DIABETES	2	✓		✓				
DIABETIC RETINOPATHY	2	✓		✓				
DIAPER RASH	8					✓		✓
DIARRHEA	2	✓		✓				
[3]		CONTINUED						

FEDERAL TRADE COMMISSION DECISIONS  
VOLUME 130

## Complaint

TABLES REFERENCE CHART		SEE TABLE(S)	MARITIME PINE @ 20 MG/TAB	MARITIME PINE PLUS OTHER NUTRIENTS	ALOE VERA JUICE CONCENTRATE	ALOE VERA GEL	EMU OIL PAIN CREAM	COLLOIDAL SILVER
BRONCHITIS	3	✓		✓				✓
BRUISES	9						✓	
BURNS	8					✓		✓
BURSITIS	2	✓		✓				
CANCER, INTERNAL	5	✓	✓	✓				✓
CANCER, SKIN	5+ 8	✓	✓	✓	✓			✓
CANDIDA	7			✓				✓
CANKER SORE	8					✓		✓
CARBUNCLES	8					✓		✓
CARPAL TUNNEL SYNDROME	2+ 9	✓		✓			✓	
CATARACTS	1	✓						
CELLULITIS	10							✓
CHICKEN POX	10							✓
CHOLESTEROL, HIGH	2	✓		✓				
CHRONIC FATIGUE SYNDROME	3	✓		✓				✓
CIRCULATION, POOR	1	✓						
COLDS	3	✓		✓				✓
COLIC	6			✓				
		CONTINUED						

28

## Complaint

TABLES REFERENCE CHART		SEE TABLE(S)	MARITIME PINE @ 20 MG/TAB	MARITIME PINE PLUS OTHER NUTRIENTS	ALOE VERA JUICE CONCENTRATE	ALOE VERA GEL	HEMU OIL PAIN CREAM	COLLOIDAL SILVER
DIVERTICULITIS	2	✓		✓				
DUODENITIS	6			✓				
EAR INFECTION, CANAL	10							✓
ECZEMA	2	✓		✓				
	2	✓		✓				
	4	✓	✓					
ENERGY, LOW	2	✓		✓				
EPILEPSY	1	✓						
EPSTEIN-BARR VIRUS	3	✓		✓				✓
ESOPHAGITIS	6			✓				
FIBROMYALGIA	2	✓		✓				
FLU	3	✓		✓				✓
FOLLICULITIS	10							✓
FROSTBITE	8				✓			
FUNGAL INFECTION	10							✓
GASTRITIS	6			✓				
GENITAL HERPES	3	✓		✓				✓
GINGIVITIS	3	✓		✓				✓
CONTINUED								30

FEDERAL TRADE COMMISSION DECISIONS  
VOLUME 130

## Complaint

TABLES REFERENCE CHART		SEE TABLE(S)	MARITIME PINE @ 20 MG/TAB	MARITIME PINE PLUS OTHER NUTRIENTS	ALOE VERA JUICE CONCENTRATE	ALOE VERA GEL	EMU OIL PAIN CREAM	COLLOIDAL SILVER
GOUT	2	✓		✓				
HAY FEVER	1	✓						
HEADACHE	1+ 9	✓					✓	
HEART ATTACK	2	✓		✓				
HEART DISEASE	2	✓		✓				
HEMORRHOIDS	2+ 8	✓		✓	✓			
HEPATITIS	3	✓		✓				✓
HERPES ZOSTER (SHINGLES)	1+ 8	✓				✓		✓
HIDRADENITIS	10							✓
HODGKIN'S DISEASE	3	✓		✓				✓
HYPERTENSION	1	✓						
HYPERTENSIVE RETINOPATHY	1	✓						
HYPOGLYCEMIA	2	✓		✓				
IMPOTENCE	1	✓						
INDIGESTION	6			✓				
INFECTIONS	6+ 8			✓	✓			✓
INFLAMMATION	2+ 9	✓		✓		✓		
INFLUENZA	3	✓		✓				✓
311		CONTINUED						



## Complaint

TABLES REFERENCE CHART	SEE TABLE(S)	MARITIME PINE @ 20 MG/TAB					EMU OIL PAIN CREAM	COLLOIDAL SILVER
		MARITIME PINE PLUS OTHER NUTRIENTS	ALOE VERA JUICE CONCENTRATE	ALOE VERA GEL				
INSECT BITES & STINGS	8			✓				✓
INSOMNIA	2	✓		✓				
JET LAG	1	✓						
JOINT PAIN	2+ 9	✓		✓		✓		
LEG CRAMPS	1+ 9	✓				✓		
LEUKEMIA	5	✓	✓	✓				✓
LUPUS	3	✓		✓				✓
LYME DISEASE	3	✓		✓				✓
MACULAR DEGENERATION	2	✓		✓				
MANIC DEPRESSIVE	4	✓	✓					
MEASLES	6+ 8			✓	✓			✓
MEMORY, SLUGGISH	4	✓	✓					
MENSTRAL CRAMPS	2	✓		✓				
MIGRAINE	1	✓						
MULTIPLE SCLEROSIS (MS)	2	✓		✓				
MUSCLE PAIN	1+ 9	✓				✓		
NAUSEA	2	✓		✓				
NERVOUS DISORDERS	1	✓						
CONTINUED								32

FEDERAL TRADE COMMISSION DECISIONS  
VOLUME 130

## Complaint

TABLES REFERENCE CHART		SEE TABLE(S)	MARITIME PINE @ 20 MG/TAB	MARITIME PINE PLUS OTHER NUTRIENTS	ALOE VERA JUICE CONCENTRATE	ALOE VERA GEL	EMU OIL PAIN CREAM	COLLOIDAL SILVER
OSTEOARTHRITIS	2+ 9	✓			✓		✓	
PAIN	2+ 9	✓			✓		✓	
PARKINSON'S DISEASE	1	✓						
PHLEBITIS	2	✓			✓			
PREMENSTRUAL SYNDROME (PMS)	2	✓			✓			
PROSTATITIS	3	✓			✓			✓
PSORIASIS	2	✓			✓			
RASHES	2+ 8	✓	✓		✓			✓
RESTLESS LEG SYNDROME	1	✓						
RHEUMATOID ARTHRITIS	3	✓			✓			✓
SCLERODERMA	3	✓			✓			✓
SCURVY	1	✓						
SEBORRHEA	2	✓			✓			
SENILITY	4	✓	✓					
SINUS CONGESTION	10							✓
SINUSITIS (INFECTION)	10							✓
SJOGREN'S SYNDROME	2	✓			✓			
STRESS	1	✓						

33

CONTINUED

[33]

CONTINUED

## Complaint

[illegible]

## Complaint

**DIRECTIONS:**

**TABLE 1 MARITIME PINE**

1. Start at DETOXIFICATION dosage. See Table DETOX 1. Take several days to build up to SATURATION, according to your weight.
2. Maintain SATURATION for 30 days. If your progress is satisfactory, stay on SATURATION until attaining your desired health. If your progress is not satisfactory, increase your dose to DOUBLE SATURATION as noted below. Take Maritime Pine total daily dose 1/2 morning, 1/2 late afternoon. Drink plenty of pure water.
3. Once you have attained satisfactory health, slowly decrease your dose until you reach a MAINTENANCE dose; Do not decrease so low that your symptoms of poor health come back.

WEIGHT	MARITIME PINE @20mg/tab SATURATION	MARITIME PINE @20mg/tab DOUBLE SATURATION	
20#	1 tab	2 tabs	Aches, Minor**
40#	2 tabs	4 tabs	Aging
60#	3 tabs	6 tabs	Atherosclerosis
80#	4 tabs	8 tabs	Backaches**
100#	5 tabs	10 tabs	Blood Clots
120#	6 tabs	12 tabs	Blood Pressure, High
140#	7 tabs	14 tabs	Cataracts
160#	8 tabs	16 tabs	Circulation, Poor
180#	9 tabs	18 tabs	Dermatitis
200#	10 tabs	20 tabs	Epilepsy
220#	11 tabs	22 tabs	Hay Fever
240#	12 tabs	24 tabs	Headache**
			Herpes Zoster (Shingles)*
			Hypertension
			Hypertensive Retinopathy
			Impotence
			Jet Lag
			Leg Cramps**
			Migraine
			Muscle Pain**
			Nervous Disorders
			Parkinson's Disease
			Restless Leg Syndrome
			Scurvy
			Stress
			Stroke
			Vascular Eye Disease

\* SEE TABLE 8 ALOE VERA GEL AND COLLOIDAL SILER

\*\* SEE TABLE 9 EMU OIL PAIN CREAM

## Complaint

TABLE 2 MARITIME PINE & ALOE VERA JUICE CONCENTRATE	
Allergies	Hemorrhoids *
Arthritis **	Hypoglycemia
Asthma	Inflammation **
Bursitis	Insomnia
Carpal Tunnel Syndrome **	Joint Pain **
Cholesterol, High	Macular Degeneration
Contusions **	Menstrual Cramps
Cramps	Multiple Sclerosis
Crohn's Disease	Nausea
Dandruff	Osteoarthritis **
Diabetes	Pain **
Diabetic Retinopathy	Phlebitis
Diarrhea	Premenstrual Syndrome
Diverticulitis	Psoriasis
Eczema	Rashes *
Edema	Seborrhea
Energy, Low	Sjogren's Syndrome
Fibromyalgia	Ulcerative Colitis
Gout	varicose veins
Heart Attack	Vitality & Vigor
Heart Disease	

4

\* SEE TABLE 8 ALOE VERA GEL AND COLLOIDAL SILER

\*\* SEE TABLE 9 EMU OIL PAIN CREAM

C-37

## Complaint

TABLE 2 MARITIME PINE & ALOE VERA JUICE CONCENTRATE				
DIRECTIONS:				
1. Start at DETOXIFICATION dosages. Take several days to build up to SATURATION, according to your weight Pycnogenol® see Table DETOX 1. Aloe Vera Juice see Table DETOX 2.				
2. Maintain SATURATION for 30 days. If your progress is satisfactory, stay on SATURATION until attaining your desired health. If your progress is not satisfactory, increase your dose to DOUBLE SATURATION as noted below. Take Maritime Pine total daily dose 1/2 morning, 1/2 late afternoon. Portion out the Aloe Vera juice concentrate throughout the day, maximum 2 ounces at a time. Drink plenty of pure water.				
3. Once you have attained satisfactory health, slowly decrease your dose until you reach a MAINTENANCE dose. Do not decrease so low that your symptoms of poor health come back				
WEIGHT	MARITIME PINE @20mg/tab SATURATION	ALOE VERA JUICE CONCENTRATE SATURATION	MARITIME PINE @20mg/tab DOUBLE SATURATION	ALOE VERA JUICE CONCENTRATE DOUBLE SATURATION
20#	1 tab	.5 oz	2 tabs	1 oz
40#	2 tabs	1 oz	4 tabs	2 oz
60#	3 tabs	1.5 oz	6 tabs	3 oz
80#	4 tabs	2 oz	8 tabs	4 oz
100#	5 tabs	3 oz	10 tabs	8 oz
120#	6 tabs	4 oz		
140#	7 tabs	4 oz		
160#	8 tabs	4 oz	16 tabs	
180#	9 tabs	4 oz	18 tabs	8 oz
200#	10 tabs	4 oz	20 tabs	8 oz
220#	11 tabs	4 oz	22 tabs	8 oz
240#	12 tabs	4 oz	24 tabs	8 oz

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36

## Complaint

TABLE 3 MARITIME PINE, ALOE VERA JUICE CONCENTRATE AND COLLOIDAL SILVER	
<b>DIRECTIONS:</b>	
<p>1. Start at DETOXIFICATION dosages. Take several days to build up to SATURATION, according to your weight.  Maritime Pine see Table DETOX 1. Aloe Vera Juice see Table DETOX 2.  Colloidal Silver take 1/4 to 1/2 teaspoon dosages to build up to SATURATION.</p> <p>2. Maintain SATURATION for 30 days. If your progress is satisfactory, stay on SATURATION until attaining your desired health. If your progress is not satisfactory, increase your dose to DOUBLE SATURATION. Take Maritime Pine and Colloidal Silver total daily dose 1/2 morning, 1/2 late afternoon. Portion out the Aloe Vera juice concentrate throughout the day, maximum 2 ounces at a time. Drink plenty of pure water.</p> <p>3. Once you have attained satisfactory health, slowly decrease your dose until you reach a MAINTENANCE dose. Do not decrease so low that your symptoms of poor health come back.</p>	
<p>Bronchitis  Chronic Fatigue Syndrome  Colds  Cough  Crest Syndrome  Epstein-Barr Virus  Flu  Genital Herpes  Gingivitis  Hepatitis  Hodgkin's Disease  Influenza  Lupus  Lyme Disease  Prostatitis  Rheumatoid Arthritis  Scleroderma  Systemic candidiasis  Vasculitis</p>	
<div style="text-align: right;">CONTINUE</div>	



## Complaint

**TABLE 3 MARITIME PINE, ALOE VERA JUICE  
CONCENTRATE AND COLLOIDAL SILVER**

WEIGHT	MARITIME PINE @20mg/tab SATURATION	ALOE VERA JUICE CONCENTRATE SATURATION	COLLOIDAL SILVER SATURATION	MARITIME PINE @20mg/tab DOUBLE SATURATION	ALOE VERA JUICE CONCENTRATE DOUBLE SATURATION	COLLOIDAL SILVER DOUBLE SATURATION
20#	1 tab	.5 oz	1/4 tsp	2 tabs	1 oz	1/2 tsp
40#	2 tabs	1 oz	1/2 tsp	4 tabs	2 oz	1 tsp
60#	3 tabs	1.5 oz	1/2 tsp	6 tabs	3 oz	1 tsp
80#	4 tabs	2 oz	1 tsp	8 tabs	4 oz	2 tsp
100#	5 tabs	3 oz	1 tsp	10 tabs	6 oz	2 tsp
120#	6 tabs	4 oz	1 tsp	12 tabs	8 oz	2 tsp
140#	7 tabs	4 oz	1 tsp	14 tabs	8 oz	2 tsp
160#	8 tabs	4 oz	1 tsp	16 tabs	8 oz	2 tsp
180#	9 tabs	4 oz	1 tsp	18 tabs	8 oz	2 tsp
200#	10 tabs	4 oz	1 tsp	20 tabs	8 oz	2 tsp
220#	11 tabs	4 oz	1 tsp	22 tabs	8 oz	2 tsp
240#	12 tabs	4 oz	1 tsp	24 tabs	8 oz	2 tsp




## Complaint

**TABLE 4 MARITIME PINE AND MARITIME PINE PLUS OTHER NUTRIENTS**

WEIGHT	MARITIME PINE PLUS OTHER NUTRIENTS SATURATION	MARITIME PINE @20mg/tab SATURATION	MARITIME PINE PLUS OTHER NUTRIENTS MAINTENANCE	MARITIME PINE @20mg/tab MAINTENANCE
20#	1 tab	1 tab	1 tab	0
40#	2.5 tabs	2 tabs	2.5 tabs	0
60#	3 tabs	3 tabs	3 tabs	1 tab
80#	4 tabs	4 tabs	4 tabs	1 tab
100#	5 tabs	5 tabs	5 tabs	1 tab
120#	5 tabs	6 tabs	5 tabs	1 tab
140#	7 tabs	7 tabs	7 tabs	0
160#	8 tabs	8 tabs	8 tabs	0
180#	8 tabs	9 tabs	8 tabs	1 tab
200#	8 tabs	10 tabs	8 tabs	2 tabs
220#	8 tabs	11 tabs	8 tabs	2 tabs
240#	8 tabs	12 tabs	8 tabs	2 tabs

## Complaint

TABLE 4 MARITIME PINE AND MARITIME PINE PLUS OTHER NUTRIENTS
<p><b>DIRECTIONS:</b></p> <p>1. Start at DETOXIFICATION dosage. See Table DETOX 1. Take several days to build up to SATURATION, according to your weight.</p> <p>2. Maintain SATURATION for at least 60 days. If your progress is satisfactory, stay on SATURATION until attaining your desired health. If your progress is not satisfactory, increase your dose to 1 or 2 tablets more of each product. Take both products total daily dose 1/2 morning, 1/2 late afternoon. Drink plenty of pure water.</p> <p>3. Once you have attained satisfactory health, slowly decrease your dosage until you reach a MAINTENANCE dose. Do not decrease so low that your symptoms of poor health come back.</p>
<p>Alzheimer's Attention Deficit Disorder Attention Deficit Hyperactive Disorder Autism Dementia Depression Emphysema Manic Depressive Memory, Sluggish Senility</p> <p>CONTINUED </p>

40

## Complaint

**TABLE 4 MARITIME PINE AND MARITIME PINE PLUS OTHER NUTRIENTS**

WEIGHT	MARITIME PINE PLUS OTHER NUTRIENTS SATURATION	MARITIME PINE @20mg/tab SATURATION	MARITIME PINE PLUS OTHER NUTRIENTS MAINTENANCE	MARITIME PINE @20mg/tab MAINTENANCE
20#	1 tab	1tab	1 tab	0
40#	25 tabs	2 tabs	25 tabs	0
60#	3 tabs	3 tabs	3 tabs	1 tab
80#	4 tabs	4 tabs	4 tabs	1 tab
100#	5 tabs	5 tabs	5 tabs	1 tab
120#	5 tabs	6 tabs	5 tabs	1 tab
140#	7 tabs	7 tabs	7 tabs	0
160#	8 tabs	8 tabs	8 tabs	0
180#	8 tabs	9 tabs	8 tabs	1tab
200#	8 tabs	10 tabs	8 tabs	2 tabs
220#	8 tabs	11 tabs	8 tabs	2 tabs
240#	8 tabs	12 tabs	8 tabs	2 tabs

41

## Complaint

**TABLE 5 MARITIME PINE, MARITIME PINE PLUS OTHER NUTRIENTS, ALOE VERA JUICE CONCENTRATE & COLLOIDAL SILVER**

**DIRECTIONS:**

1. Start at DETOXIFICATION dosages. Take several days to build up to DAILY DOSAGE.  
 Maritime Pine see Table DETOX 1. Aloe Vera Juice see Table DETOX 2. Colloidal Silver take 1/4 to 1/2 teaspoon dosages to build up to DAILY DOSAGE.
2. Maintain DAILY DOSAGE until attaining your desired health. Drink plenty of pure water.  
 Maritime Pine : 10 tablets.  
 Maritime Pine Plus Other Nutrients: 5 tablets.  
 Aloe Vera juice concentrate: 10 ounces.  
 Colloidal Silver: 2 teaspoons.
3. Ideal total daily dose: 2 Maritime Pine, 1 Maritime Pine Plus Other Nutrients, 2 oz Aloe Vera juice concentrate 5 times a day, every 2 hours (ex: 9AM-11AM-1PM-3PM-5PM). Colloidal Silver: 1 tsp AM, 1 tsp PM.

Acquired Immune Deficiency Syndrome (AIDS)  
 Cancer, Internal  
 Cancer, External  
 (See Table 8 ALOE VERA GEL AND COLLOIDAL SILVER)  
 Leukemia

42

**CONFIDENTIAL**

Complaint

## **EXHIBIT D**

**REDACTED**

## **EXHIBIT E**

**AUDIO CASSETTE TAPE**

## Complaint

**1' AIRBORNE PYCNOGENOL MONOGRAPH #2**  
**Relative To Attention Deficit Disorder & ADHD**

The data within this monograph was created for our Fairborne Association's member - physicians who practice in the field. This information is to further disclose facts obtained regarding the compound Pycnogenol, and particularly its efficacy for alleviation of the signs and symptoms of Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder or ADHD.

For all other health applications of Pycnogenol, please refer to our separate, "FAIRBORNE PYCNOGENOL MONOGRAPH #1"

**INTRODUCTION:**

Pycnogenol is a patented and trademarked, naturally occurring compound that is produced in its basic form by Harphag Research Ltd. in France. It is a water processed extract from the bark of the French Maritime Pine tree. The compound is not a drug. Moreover, it is not herbal. Composed of forty-plus subcompounds, reports demonstrate that Pycnogenol is the single, most potent nutritional antioxidant discovered by science.

**UNIVERSITY STUDIES:**

The compound is relatively new to physicians - and consumers - in North America. However, due to overwhelmingly positive anecdotal clinical results individual physicians have obtained thus far, three major universities in the U.S. have (as of this 7-10-98 printing), already begun full-scale, double-blind research studies.

Clinical studies relating to Pycnogenol's effectiveness for such conditions as Alzheimer's disease, immune system dysfunctional conditions and others.

Also, an internationally-respected Midwest psychiatric center has started a landmark research study to document the compound's efficacy for use with ADD and ADHD.

However, professional courtesy restrains us from revealing the identities of these institutions until their results are actually completed and published. Which, we've been informed, may require a year or two.

**COMMERCIAL SOURCE OF THE COMPOUND:**

The commercial source for the compound we continue to utilize, is the same formulator in Colorado referred to in our first monograph. The only reason we continue to use that source is because their proprietary, blended formulations of Pycnogenol have significantly greater bioavailability than basic Pycnogenol sold over the counter in pharmacies and other sources. ("Bioavailability" refers to the total percentage of a dose that first can be absorbed by the intestine, then - of equal importance - actually absorbed and utilized by the body's cells).

However, physicians in the field may prefer to obtain the basic Pycnogenol from local pharmacies or stores. If using those as your source, simply keep in mind the differences in bioavailability mentioned above.

Thus, you may need to increase the patient's daily dosage by a factor of as much as 3.5 to 4.5 times more of your locally-obtained brands, to achieve the same degree and speed of patient relief. You may perform your own, in-practice comparative trials to confirm that fact.

**INDICATIONS**

As explained in our monograph #1 on general use, Pycnogenol has been efficacious for a wide variety of health problems, particularly of the chronic degenerative type. However, regarding the signs and symptoms of ADD/ADHD refer to separate professional literature.

For further study on the compound (as well as additional, more in-depth safety documentation than stated below) you may obtain the following book: "Pycnogenol, The Super Protector Nutrient" by Richard A. Passwater, Ph.D., published by Keats Publishing.

**BASIC SAFETY INFORMATION:**

According to researchers at the Pasteur Institute and the Huntington Institute, Pycnogenol is virtually nontoxic to humans and mammals. Water-soluble, it is also non-carcinogenic, non-mutagenic, non-antigenic and non habit forming. Consumed in Europe under medical supervision for more than a decade, it is now available in the U.S. and Canada without a prescription.

Chronic toxicity studies reveal no adverse effects in man, even from massive daily doses of up to 36,000 milligrams for more than six months. Considering that recommended daily dosage of Pycnogenol for a 300 pound patient and at "double saturation" level would still only involve 840 milligrams, (as an example), this compound should be viewed as completely safe. Pharmacologically, Pycnogenol is classified within the same, safe-to-use class of therapeutic compounds as is vitamin C.

**KEY FACTS:**

Interesting to note is the fact that even though, over the years, many so called "nutritional" approaches to ADD have been attempted, no nutritional methods had heretofore produced significant alleviation of symptoms.

However, not only is Pycnogenol proving to be exceedingly efficacious for ADD, from the anecdotal results reported from the field it is becoming a very attractive first-line method of choice by many physicians, in preference to conventional drug administration. Also, in most cases, traditional drug therapy can eventually be discontinued - or significantly reduced - provided the patient continues to consume Pycnogenol.

**MODE OF BIOLOGICAL ACTION**

First, remember that Pycnogenol is not a drug. However, with Pycnogenol, there is much the same situation as with traditional drugs such as Ritalin, Dexedrine and Cylert...there is as yet, no conclusive explanation as to

EXHIBIT F

Please turn to side 2

ASSOCIATE: Unless you initially explain that sufficient dosage is CRUCIAL, then actually pass a copy of these directions to clients, they will usually follow the dosages shown on the BOTTLES, which is virtually certain to create a dissatisfied client! Also, doubly-confirm client dosage compliance later, during follow-up calls! (write this out before making copies).

ASSOCIATE: U setase mailing the m uple - doctor ADD tape with govern or letter. per at a quick print shop. MAIL TO PHOSPEC IS AS A FOLLOW

## Complaint

ASSOCIATE: You should make a follow up service call to each customer about three days after they have received their first order...to be sure they understand PROPER DOSAGE TO THE LETTER (While this out before making copies).

required to maintain maximum relief of symptoms. That may - in fact - prove to be "saturation" dosage (as shown in the chart) in many cases. In others, that may be the average "maintenance" dosage indicated on the chart, or somewhat more.

Finding the ideal, minimum daily Pycnogenol dosage for ADD, is solely to render the lowest possible cost to the patient. Realize Pycnogenol is so safe to use, some of our Association's physicians suggest ongoing "saturation" dosage for disease preventative purposes. Moreover, some even recommend ongoing double "saturation" dosage for serious health challenges. Knowing that complete safety to the patient is assured.

## BODY TOXINS ELIMINATION

As explained on page 2, the gradual 10-day buildup to daily "saturation" Pycnogenol dosage prevents body toxins - elimination healing reactions in practically all cases. However, a very rare few may still experience that. Such as mild diarrhea, skin rash, light-headedness, slight headache, gas or stomach upset. Or even feeling as though their health problem is getting worse...

Actually a positive sign, it indicates large volumes of health-retarding, stored toxins being cleansed from the body. If such complaints are TOLERABLE, maintain "saturation" dosage level but include at least 8 to 10 eight-ounce glasses of water per day to accelerate toxins elimination. Discomfort then usually ceases within 2 or 3 days and the patient will then feel energized and renewed.

IF NOT TOLERABLE to the patient, simply cut back Pycnogenol dosage to very low "day 1" level. Then, very gradually build up to daily "saturation" dosage over a 30-day period or even longer. Also maintain high water intake as explained above.

## A WORD OF CAUTION:

Several years ago, the nutritional products supplier-company in Colorado -- that our Fairborne Association's doctors currently recommend -- introduced Pycnogenol to North America. Since then, doctors have proven it to be a historically effective health-restoring compound. Due to its success, many other companies have attempted to capitalize on the health trend that the Colorado supplier's blends of Pycnogenol are setting. Other companies now promote compounds such as grape seed extracts (not from grape skins and grape seeds)...extracts from soybeans... and inferior grades of pine bark extract...And claim they are equal to, or even more effective than, Pycnogenol.

Our Fairborne Association's doctors (and many

others) have proven that those claims are simply not true. However, you should not merely accept that statement...You may do the same, simple comparative test. Our physicians in the field have performed as follows...

You will then have actual experience. In addition, you will understand why we currently recommend the Colorado supplier.

Realize that basic Pycnogenol from France is now in many pharmacies and other stores. However, the Colorado-based supplier developed a proprietary, plant-based *enzyme delivery system* that is blended with their Pycnogenol formulations.

The clinical importance of that is this: Their Pycnogenol formulations are demonstrating 3.5 to 4.5 times more biological effectiveness than store-obtained basic Pycnogenol. Which is to say, a patient would need to consume from 3.5 to 4.5 times more store-obtained basic Pycnogenol to produce the same health results.

## SIMPLE TEST FOR COMPARATIVE CLINICAL EFFECTIVENESS:

First obtain maximum relief and health results using the recommended Colorado-supplied Pycnogenol. Then substitute any store-purchased Pycnogenol brand. Or--for that matter--you may substitute any other company's highly-publicized antioxidant compounds. What's more, have the patient consume at least a two times higher daily dosage of the substituted compound. The patient's symptoms will gradually start to return after having done so. You would then, of course, switch the patients back to the Colorado-obtained tablets.

## PATIENT COST CONSIDERATIONS:

After obtaining those test results, realize that the currently-recommended Colorado Pycnogenol will represent a considerable savings in cost to the patient.

Another reason why our Fairborne physicians suggest the Colorado-supplied Pycnogenol: There is no financial risk to the patient. As a professional courtesy, when a patient -- or, for that matter, any consumer -- orders Pycnogenol it is shipped with a 90-day, cost returned certification of assured satisfaction.

Which means that the supplier ships their Pycnogenol on an on-trial basis. Thus, if one is not satisfied with the health results obtained -- during the 90-day, experimental trial of the compound -- they simply return the empty bottles within 90 days and the Colorado supplier directly returns their cost. In addition, that supplier charges no fee for the privilege of being able to place relatively small orders with them, at wholesale cost.

THE FAIRBORNE INST. & ASSOCIATION was founded in March 1995. It is an independent, national professional association composed primarily of Medical Doctors plus other physicians and health care professionals whose practices include the use of alternative or complimentary health-promoting compounds; inclusive of but not limited to Pycnogenol and other valid health-restoring, natural compounds. Due to tens-of-thousands of copies of these professional directions now in circulation, member-physicians generally prefer that their names and phone numbers remain confidential, as they maintain very busy health-care practices. However, the Association has registered its credentials plus the names, professional degrees and backgrounds of its thirteen founding member-physicians with the currently-recommended, Colorado Pycnogenol supplier. Professional inquiries from physicians only, may be mailed to: Fairborne Inst. & Association, Box 125, Maassena, Iowa 50853.



## 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 of complaint which the Western Region 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 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 aforesaid draft of 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 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.a Respondent J & R Research Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of Iowa , with its office and principal place of business at 109 Main Street, Massena, Iowa 50853.

1.b. Respondent Gerald G. McCarthy is an officer of said corporation. He formulates, directs and controls the policies, acts



## Decision and Order

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. Unless otherwise specified, "respondents" shall mean J & R Research Corporation, a corporation, its successors and assigns and its officers; Gerald McCarthy, individually and as an officer of the corporation; and each of the above=s agents, representatives, and employees.
3. "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 pycnogenol or any other food,

## Decision and Order

drug, or dietary supplement, as Afood@ and Adrug@ are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that such product:

- A. will treat or improve rheumatoid arthritis, osteoarthritis or rheumatism, including the elimination or reduction of inflammation or pain associated with these disorders;
- B. will reduce the amount of insulin needed to treat diabetes;
- C. will treat or improve health disorders associated with diabetes, including neuropathy, retinopathy, osteomyelitis, circulatory problems or heart problems;
- D. will help treat lupus, Parkinson=s Disease, multiple sclerosis or fibromyalgia;
- E. will treat or improve digestive disorders, including Crohnes Disease or irritable bowel syndrome;
- F. will help prevent strokes or the recurrence of strokes;
- G. will improve physical disabilities caused by stroke;
- H. will help prevent heart disease, including arterial sclerosis;
- I. will reduce blood pressure;
- J. will improve or help prevent circulatory problems, including phlebitis, thrombophelbitis, blood clots, or varicose veins;
- K. will promote the shrinkage of tumors or help prevent tumor formation;
- L. will treat cancer or prolong the life of cancer victims;
- M. will reduce or eliminate inflammation of the prostate;

## Decision and Order

- N. will eliminate or reduce the incidence of asthma attacks and symptoms caused by allergies;
- O. will improve eyesight or treat disorders of the retina;
- P. will help rebuild joints and soft tissue;
- Q. will accelerate the healing time of injuries;
- R. will improve or cure skin conditions such as psoriasis and acne;
- S. will treat Attention Deficit Disorder or Attention Deficit Hyperactive Disorder;
- T. will reduce or eliminate the need for medication in individuals with Attention Deficit Disorder or Attention Deficit Hyperactive Disorder; or
- U. is more protective as an antioxidant than Vitamin C or Vitamin E;

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 food, drug, or dietary supplement, as Afood@ and Adrug@ are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, shall not make any representation, in any manner,

## Decision and Order

expressly or by implication, about the benefits, performance, or efficacy of such product, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

**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 any product 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.

**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 food, drug, or dietary supplement, as Afood@ and Adrug@ are defined in Section 15 of the Federal Trade Commission Act, 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 represents the typical or ordinary experience of members of the public who use the product, 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, Aendorsement@ shall mean as defined in 16 C.F.R. ' 255.0(b).

**V.**

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.

**VI.**

Nothing in this order shall prohibit respondents 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.

**VII.**

**IT IS FURTHER ORDERED** that respondent J & R Research Corporation, and its successors and assigns, and respondent Gerald McCarthy 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 came into their possession from a distributor or any other source 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.

**VIII.**

**IT IS FURTHER ORDERED** that respondent J & R Research Corporation, and its successors and assigns, and respondent Gerald McCarthy 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 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. Respondents shall maintain and upon request make available to the Federal Trade Commission for inspection and copying a copy of each signed statement acknowledging receipt of the order.

**IX.**

**IT IS FURTHER ORDERED** that respondent J & R Research Corporation 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

## Decision and Order

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.

**X.**

**IT IS FURTHER ORDERED** that respondent Gerald McCarthy, 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.

**XI.**

**IT IS FURTHER ORDERED** that respondent J & R Research Corporation, and its successors and assigns, and respondent Gerald McCarthy 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.

## Decision and Order

**XII.**

This order will terminate on July 19, 2020, 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 to Aid Public Comment***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 J & R Research, Inc., and its principal, Gerald G. McCarthy ("respondents"). Respondents were general partners in a distributorship of Kaire International, Inc., a multi-level marketing company. Respondents also created and marketed to Kaire distributors audio tapes and other promotional materials touting a Kaire product containing pycnogenol, a substance derived from the bark of the maritime pine tree.

The proposed consent order has been placed on the public record for sixty (60) days for the reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and any 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.

Respondents' advertisements claimed that pycnogenol could mitigate or cure the effects of numerous diseases or disorders. The proposed complaint alleges that respondents could not substantiate claims that pycnogenol: (1) alleviates rheumatoid arthritis, osteoarthritis and rheumatism; (2) reduces the amount of insulin needed to treat diabetes; (3) treats and/or improves health disorders associated with diabetes, including neuropathy, retinopathy, osteomyelitis, circulatory problems and heart problems; (4) helps treat lupus, Parkinson=s Disease, multiple sclerosis and fibromyalgia; (5) treats or improves digestive disorders, including Crohnes Disease and irritable bowel syndrome; (6) helps prevent strokes and the reoccurrence of strokes; (7) dramatically improve physical disabilities caused by stroke; (8) dramatically helps prevent heart disease, including arterial sclerosis; (9) reduces blood pressure; (10) dramatically improves and helps prevent circulatory problems, including

## Analysis to Aid Public Comment

phlebitis, thrombophlebitis, blood clots, and varicose veins; (11) dramatically promotes the shrinkage of tumors and helps prevent tumor formation; (12) treats cancer and/or prolongs the life of cancer victims; (13) reduces or eliminates inflammation of the prostate; (14) eliminates or reduces the incidence of asthma attacks and symptoms caused by allergies; (15) improves eyesight and treats disorders of the retina; (16) helps rebuild joints and soft tissue; (17) greatly accelerates the healing time of injuries; (18) improves or cures skin conditions such as psoriasis and acne; (19) treats Attention Deficit Disorder and Attention Deficit Hyperactive Disorder; (20) reduces or eliminates the need for medication in individuals with Attention Deficit Disorder and Attention Deficit Hyperactive Disorder; and (21) is twenty times more protective as an antioxidant than Vitamin C, and fifty times more protective than Vitamin E.

The complaint further alleges that respondents falsely claimed that scientific research demonstrates that pycnogenol products can alleviate or cure many of these diseases or disorders. Finally, the complaint alleges that respondents could not substantiate its claim that testimonials from consumers appearing in the advertisements for pycnogenol products reflect the typical or ordinary experience of members of the public who use pycnogenol products.

Part I of the proposed consent order would require respondents, when advertising pycnogenol or any other food, drug, or dietary supplement, to possess competent and reliable scientific evidence before making any of the claims that were alleged as unsubstantiated in the complaint. Part II of the proposed order would require respondents to possess competent and reliable scientific evidence before making any claim regarding the benefits, performance, or efficacy of any food, drug, or dietary supplement. Part III of the proposed order would prevent respondents from misrepresent the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research in an advertisement for any product.

*Analysis to Aid Public Comment*

Part IV of the proposed order addresses claims made through endorsements or testimonials. Under Part IV, respondents may make such representations if they possess and rely upon competent and reliable evidence that substantiates the representations; or the respondents must disclose either what the generally expected results would be for users of the advertised products, or the limited applicability of the endorser's experience to what consumers may generally expect to achieve. The proposed order's treatment of testimonial claims is in accordance with the Commission's "Guides Concerning Use of Endorsements and Testimonials in Advertising," 16 C.F.R. 255.2 (a).

Part V of the proposed order contains language permitting respondents to make drug claims that have been approved by the FDA pursuant to either a new drug application or a tentative final or final standard. Part VI states that respondents would be permitted to make claims that the FDA has approved pursuant to the Nutrition Labeling and Education Act of 1990.

Part VII of the proposed order requires respondents to retain, and make available to the Commission upon request, all advertisements and promotional materials containing any representation covered by the order, as well as any materials that it relied upon in disseminating the representation and any materials that contradict, qualify, or call into question the representation.

The remainder of the proposed order contains standard requirements that respondents distribute the order to relevant personnel, that the corporate respondent notify the Commission of any changes in corporate structure that might affect compliance with the order; that the individual respondent notify the Commission of changes in his employment status, and that respondents file one or more reports detailing their compliance with the order.

*Analysis to Aid Public Comment*

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

**RILEY MANUFACTURED HOMES, INC., ET AL.**CONSENT ORDER, ETC., IN REGARD TO ALLEGED  
VIOLATIONS OF THE TRUTH IN LENDING ACT*Docket C-3963; File No. 992 3202**Complaint, July 24, 2000 -- Decision, July 24, 2000*

This consent order addresses Riley Manufactured Homes, Inc.'s, and its president, Dennis Ohnstad's failure to fully disclose financing terms when selling manufactured homes. The complaint alleges that respondents' advertisements stated a rate of finance charge for financing the purchase of manufactured homes but did not properly disclose the rate as an annual percentage rate, as required by Regulation Z. Additionally, respondents' credit advertisements stated a monthly payment amount or other triggering terms, but failed to disclose the amount or percentage of the down payment; the terms of repayment; and the annual percentage rate. The consent order prohibits respondents from: (A) stating a rate of finance charge without disclosing the APR; (B) using triggering terms without providing the additional disclosures required by Regulation Z; and (C) failing to comply with TILA and Regulation Z.

*Participants*

For the Commission: *John C. Hallerud*, and *BE*.

For the Respondents: *Evan D. Coobs; Meyer, Capel, Hirschfeld, Muncy, Jahn & Aldeen*.

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Riley Manufactured Homes, Inc., a corporation, and Dennis Ohnstad, individually and as an officer of the corporation ("respondents"), have violated the provisions of the Truth in Lending Act, 15 U.S.C. ' ' 1601-1667e, as amended, and its implementing Regulation Z, 12 C.F.R. ' 226, as amended, and it

## Complaint

appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Riley Manufactured Homes, Inc., is an Illinois corporation with its principal office or place of business at 2610 N. Cunningham Avenue, Urbana, Illinois 61801.

2. Respondent Dennis Ohnstad is an officer of the corporate respondent. Individually or in concert with others, he formulates, directs, or controls 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 Riley Manufactured Homes, Inc.

3. Respondents have disseminated advertisements to the public that promote extensions of closed-end credit in consumer credit transactions, as the terms Aadvertisement,@ and Aconsumer credit@ are defined in Section 226.2 of Regulation Z, 12 C.F.R. ' 226.2, as amended.

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, 15 U.S.C. ' 44.

**CREDIT ADVERTISING**

5. Respondents have disseminated or have caused to be disseminated advertisements for homes in the print media, including but not necessarily limited to the attached Exhibit A. These advertisements contain statements such as the following:

Interest rates from 5.78%

6. Respondents have disseminated or have caused to be disseminated advertisements for homes in the print media, including but not necessarily limited to the attached Exhibit B. These advertisements contain statements such as the following:

## Complaint

**\$279 PER Month\***

\* \* \*

\*based on \$29,900 SP plus ST, less \$1589 DP for  
300 months at 10.25% VAR interest.

**TRUTH IN LENDING ACT AND REGULATION Z**  
**VIOLATIONS:**

**Failure to Disclose Required Information**

7. In advertisements, including, but not necessarily limited to, Exhibits A and B, respondents have stated a rate of finance charge for financing the purchase of the advertised homes.

8. These advertisements, described in Paragraph 7, have failed to state the rate of finance charge as an annual percentage rate as required by Regulation Z, 12 C.F.R. ' 226.24(b).

9. Respondents' failure to state the rate of finance charge as an annual percentage rate as set forth in Paragraph 8 violates Section 144 of the Truth in Lending Act, 15 U.S.C. ' 1664, as amended, and Section 226.24(b) of Regulation Z, 12 C.F.R. ' 226.24(b).

10. In advertisements, including, but not necessarily limited to, Exhibit B, respondents have stated the amount or percentage of any downpayment; the number of payments or the period of repayment; the amount of any payment; or the amount of any finance charge.

11. These advertisements have failed to state the amount or percentage of the downpayment; the terms of repayment; and the "annual percentage rate," using that term or the abbreviation "APR," as required by Regulation Z, 12 C.F.R. ' 226.24(c).

## Complaint

12. Respondents' failure to state the amount or percentage of the downpayment; the terms of repayment; and the "annual percentage rate," using that term or the abbreviation "APR," as set forth in Paragraph 11 violates Section 144 of the Truth in Lending Act, 15 U.S.C. ' 1664, as amended, and Section 226.24(c) of Regulation Z, 12 C.F.R. ' 226.24(c).

THEREFORE, the Federal Trade Commission this twenty-fourth day of July, 2000, has issued this complaint against respondents.





By the Commission.



## Complaint

## EXHIBIT A

**YOUR BEST HOUSING  
VALUE-GUARANTEED!**  
*...Has Been Since 1967!*

 <p><b>Doublewides</b> from <b>\$299,900</b><sup>*1*2</sup></p>	 <p><b>Modular Ranches</b> from <b>\$39,900</b><sup>*1*2</sup></p>
 <p><b>Cape Cods</b> from <b>\$59,900</b><sup>*1*2</sup></p>	 <p><b>2 Stories</b> from <b>\$69,900</b><sup>*1*2</sup></p>

• **PRICE GUARANTEE** - \*1\*2 back to you if we aren't always your best housing value.  
 • **ON SITE MORTGAGE DEPARTMENT** - Interest rates from 5.78%<sup>\*1</sup>  
 • **IN HOUSE SITE DEVELOPMENT DEPARTMENT** - to insure your building site is properly prepared - garages, wells, septic, basements, foundations, concrete flat work... etc. we've always done it all for you!  
 • **ILLINOIS' LARGEST DISPLAY OF MODEL HOMES** - Over 9 acres of models open for your inspection.  
 • **HUNDREDS OF PLANS TO CHOOSE FROM**  
 • **OPEN SEVEN DAYS** - We match your schedule, not ours!

\*Rates subject to change without notice. Subject to credit approval. \*1 base price \*2 optional interior

**RILEY HOMES**  
Since 1967  
RT. 45N, URBANA • 800-798-1541  
www.rileyhomes.com    rileyhome@aol.com

COMPLAINT  
EXHIBIT A

## Complaint

## EXHIBIT B

**\$279 PER Month\***  
New 1998 1200  
sq.ft. home on  
display and can be  
delivered to your  
location. 3  
bedrooms, 2 full  
baths, center island  
kitchen, and deluxe  
master bath. Riley  
Homes. Rt 45 N  
Urbana, 1-800-305-  
9761. \* based on  
\$29,900 SP plus  
ST, less \$1509 DP  
for 300 months at  
10.25% VAR  
interest.

**\$211 PER Month\***  
beautiful front  
kitchen home with 2  
bedrooms, 1 bath,  
ready to live in on  
your lot. Riley  
Homes. Rt 45 N  
Urbana, 1-800-305-  
9761. \* based on  
\$22,500 SP plus  
ST, less \$1196 DP  
for 300 months at  
10.25% VAR  
interest.

**\$233 PER Month\***  
Own your own  
home. Now  
luxurious home with  
3 bedrooms, 2 full  
baths delivered and  
set on your lot.  
Riley Homes. Rt 45  
N. Urbana, 1 800  
305-9761 \* based  
on \$24,900 SP plus  
ST, less \$1324 DP  
for 300 months at  
10.25% VAR  
interest.

COMPLAINT  
EXHIBIT B

## 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 of complaint which the Midwest Region proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of the Federal Trade Commission Act; 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 aforesaid draft of 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, 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 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 Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1.a. Respondent Riley Manufactured Homes, Inc., is an Illinois corporation with its principal office or place of business at 2610 North Cunningham Avenue, Urbana, Illinois 61801.

## Decision and Order

1.b. Respondent Dennis Ohnstad is an officer of the corporate Respondent. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of the corporation. His principal office or place of business is the same as that of Riley Manufactured Homes, Inc.

2. The acts and practices of the Respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act.

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

## DEFINITIONS

1. ACommerce@ shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. ' 44.

2. Unless otherwise specified, ARespondents@ shall mean Riley Manufactured Homes, Inc., a corporation, its successors and assigns and its officers; Dennis Ohnstad, individually and as an officer of the corporation; and each of the above's agents, representatives, and employees.

## I.

**IT IS ORDERED** that Respondents, directly or through any corporation, subsidiary, division, or any other device, in connection with any advertisement to promote, directly or indirectly, any extension of consumer credit in or affecting commerce, as Aadvertisement@ and Aconsumer credit@ are defined in Section 226.2 of Regulation Z, 12 C.F.R. ' 226.2, as amended, shall not, in any manner, expressly or by implication:

## Decision and Order

- A. State a rate of finance charge without stating the rate as an annual percentage rate as required by Section 144 of the Truth in Lending Act (ATILA@), 15 U.S.C. ' 1664, as amended, and Section 226.24(b) of Regulation Z, 12 C.F.R. ' 226.24(b), as amended.
- B. State the amount or percentage of any downpayment, the number of payments or period of repayment, the amount of any payment, or the amount of any finance charge, without disclosing clearly and conspicuously all of the terms required by Section 144 of the Truth in Lending Act, 15 U.S.C. ' 1664, as amended, and Section 226.24(c) of Regulation Z, 12 C.F.R. ' 226.24(c), as amended, as more fully set out in Section 226.24(c) of the Federal Reserve Board's Official Staff Commentary to Regulation Z, 12 C.F.R. ' 226.24(c), as amended, as follows:
  - 1. the amount or percentage of the downpayment;
  - 2. the terms of repayment; and
  - 3. the annual percentage rate, using that term or the abbreviation "APR." If the annual percentage rate may be increased after consummation of the credit transaction, that fact must also be disclosed.
- C. Fail to comply in any other respect with Regulation Z, 12 C.F.R. ' 226, as amended, and the TILA, 15 U.S.C. ' ' 1601-1667, as amended.

**II.**

**IT IS FURTHER ORDERED** that Respondents shall, for five (5) years after the last date of dissemination of any advertisement covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection

## Decision and Order

and copying all records that will demonstrate compliance with the requirements of this order.

## Decision and Order

**III.**

**IT IS FURTHER ORDERED** that Respondents 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 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.

**IV.**

**IT IS FURTHER ORDERED** that Respondent Riley Manufactured Homes, 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 necessarily 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 Director, Midwest Region, Federal Trade Commission, 55 East Monroe, Suite 1860, Chicago, Illinois 60603.

## Decision and Order

**V.**

**IT IS FURTHER ORDERED** that Respondent Dennis Ohnstad, for a period of three (3) 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 involving the advertising and/or extension of "consumer credit," as that term is defined in the TILA and its implementing Regulation Z. 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 Director, Midwest Region, 55 East Monroe, Suite 1860, Chicago, Illinois 60603.

**VI.**

**IT IS FURTHER ORDERED** that Respondents 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.**

**IT IS FURTHER ORDERED** that this order will terminate on July 24, 2020, 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



Analysis to Aid Public Comment

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 of Proposed Consent Order to Aid Public Comment**

The Federal Trade Commission has accepted an agreement to a proposed consent order from Riley Manufactured Homes, Inc., and its president, Dennis Ohnstad (Arespondents@).

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 alleges that respondents= credit advertisements violated Section 144 of the Truth in Lending Act, (ATILA@), 15 U.S.C. ' 1664, and Section 226.24 of Regulation

## Analysis to Aid Public Comment

Z, 12 C.F.R. ' ' 226.24. Congress established statutory disclosure requirements for credit advertising under the TILA and directed the Federal Reserve Board (ABoard@) to promulgate a regulation implementing such statute - - Regulation Z. See 15 U.S.C. ' ' 1601-1667e; 12 C.F.R. Part 226.

According to the complaint, respondents= advertisements stated a rate of finance charge for financing the purchase of manufactured homes but did not properly disclose the rate as an annual percentage rate, as required by Regulation Z. The complaint also alleges that respondents= credit advertisements stated a monthly payment amount or other Atriggering@ terms (the amount or percentage of any downpayment; the number of payments or the period of repayment; the amount of any payment; or the amount of any finance charge), but failed to disclose the following information required by Regulation Z: the amount or percentage of the downpayment; the terms of repayment; and the annual percentage rate.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the proposed respondents from engaging in similar acts in the future. In particular, Part I of the proposed order prohibits respondents from: (A) stating a rate of finance charge without disclosing the APR; (B) using triggering terms without providing the additional disclosures required by Regulation Z; and (C) failing to comply with TILA and Regulation Z. Part II of the proposed order requires respondents to maintain and make available records of compliance for five years. Part III requires respondents to distribute copies of the order to company personnel. Part IV requires respondents to notify the Commission of changes in corporate structure that may affect compliance obligations under the proposed order. Part V requires the individual respondent to notify the Commission of changes in his employment status for three years. Part VI requires respondents to file compliance reports. Finally, Part VII sunsets the proposed order after twenty years.

*Analysis to Aid Public Comment*

*Analysis to Aid Public Comment*

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

**PFIZER INC. AND WARNER-LAMBERT  
COMPANY**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF  
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT AND  
SECTION 7 OF THE CLAYTON ACT

*Docket C-3957; File No. 0010059  
Complaint, June 19, 2000--Decision, July 27, 2000*

This consent order addresses the \$90 billion acquisition by Pfizer Inc. of Warner-Lambert Company. The complaint alleges that the proposed merger, if consummated, would constitute a violation of Section 7 of the Clayton Act and Section 5 of the FTC Act in the markets for: (1) SSRI/SNRI antidepressants; (2) pediculicides; (3) drugs for the treatment of Alzheimer=s disease; and (4) EGFr-tk inhibitors for the treatment of cancer. The consent order requires the companies to terminate Warner=s agreement with Forest Laboratories, Inc. to co-promote the antidepressant Celexa; divest Pfizer=s RID pediculicide (used to treat head lice) business to Bayer Corporation; divest all of Warner=s assets relating to the Alzheimer=s drug, Cognex, to First Horizon Pharmaceutical Corporation; and transfer and surrender, to OSI Pharmaceuticals, Inc., all of Pfizer=s assets relating to the Epidermal Growth Factor receptor tyrosine kinase inhibitor, CP-358,774, for the treatment of cancer.

*Participants*

For the Commission: *Elizabeth A. Jex, Randall A. Long, Laura I. Bren, Ann Malester, David Von Nirschl, Elizabeth A. Piotrowski, Debra J. Holt, Daniel O=Brien, and Gregory S. Vistnes.*

For the Respondents: *Mark D. Godler, David Klingsberg, and Michael Malina, Kaye Scholer, Fierman, Hays & Handler, Alec Y. Chang and Clifford N. Aronson, Skadden, Arps, Slate, Meagher & Flom LLP. Christopher R. Manning, Burke, Warren, Mackay & Serritella, Robert E. Bell, Wilmer, Cutler & Pickering, Howard Adler, Baker & McKenzie, and Herschel S. Weinstein, Dornbush, Mensch, Mandelstham & Schaeffer, LLP.*

## Complaint

**COMPLAINT**

The Federal Trade Commission (ACommission@), having reason to believe that Respondent Pfizer Inc. (APfizer@), a corporation subject to the jurisdiction of the Commission, has agreed to merge with Respondent Warner-Lambert Company (AWarner@), 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. "Forest" means Forest Laboratories, Inc., 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 909 Third Avenue, New York, New York 10022.
2. AMerger Agreement@ means the Agreement and Plan of Merger among Pfizer, through its wholly-owned subsidiary, Seminole Acquisition Sub Corp., and Warner, dated February 6, 2000.
3. "Commission" means the Federal Trade Commission.
4. AFDA@ means the United States Food and Drug Administration.
5. AOTC pediculicides@ means all over-the-counter products manufactured, developed, or sold for the treatment of lice infestation.

## Complaint

6. ASSRI@ means selective serotonin reuptake inhibitor.
7. ASNRI@ means serotonin norepinephrine reuptake inhibitor.
8. ASSRI/SNRI drugs for the treatment of depression@ means the SSRI/SNRI pharmaceutical preparations approved by the FDA for the treatment of depression.
9. ADrugs for the treatment of Alzheimer=s disease@ means any acetylcholinesterase inhibitor pharmaceutical preparation approved by the FDA for the treatment of Alzheimer=s disease.
10. AEGFr-tk inhibitors for the treatment of cancer@ means any small molecule pharmaceutical preparation which inhibits the tyrosine kinase activity of the epidermal growth factor receptor in development or approved by the FDA for the treatment of cancer.
11. ACelexa@ means any pharmaceutical preparation containing the drug substance citalopram HBr.
12. AZoloft@ means any pharmaceutical preparation containing the drug substance sertraline hydrochloride.
13. ACognex@ means any pharmaceutical preparation containing the drug substance tacrine hydrochloride.
14. AAricept@ means any pharmaceutical preparation containing the drug substance donepezil hydrochloride.

**II. RESPONDENTS**

15. Respondent Pfizer 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 235 East 42<sup>nd</sup> Street, New York, New York 10017. Pfizer, among other things, is engaged in the research, development,

## Complaint

manufacturing and sale of human pharmaceutical products, including OTC pediculicides, SSRI/SNRI drugs for the treatment of depression, drugs for the treatment of Alzheimer=s disease, and EGFr-tk inhibitors for the treatment of cancer.

16. Respondent Warner 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 201 Tabor Road, Morris Plains, New Jersey 07950. Warner, among other things, is engaged in the research, development, manufacturing and sale of human pharmaceutical products, including OTC pediculicides, SSRI/SNRI drugs for the treatment of depression, drugs for the treatment of Alzheimer=s disease, and EGFr-tk inhibitors for the treatment of cancer.

17. Respondents are, and at all times relevant herein have been, engaged in commerce, as Acommerce@ 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 Acommerce@ is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. ' 44.

### III. THE PROPOSED MERGER

18. On February 6, 2000, Pfizer and Warner entered into a Merger Agreement whereby Pfizer agreed to acquire, through its wholly-owned subsidiary, Seminole Acquisition Sub Corp., 100 percent of all issued shares of Warner for approximately \$90 billion (AMerger@). Upon completion of the transaction the merged entity will be known as Pfizer.

### IV. THE RELEVANT MARKETS

19. 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 OTC pediculicides;



### Complaint

- b. the research, development, manufacture and sale of SSRI/SNRI drugs for the treatment of depression;
- c. the research, development, manufacture and sale of drugs for the treatment of Alzheimer=s disease; and
- d. the research, development, manufacture and sale of EGFr-tk inhibitors for the treatment of cancer.

20. 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

21. The market for OTC pediculicides is highly concentrated as measured by the Herfindahl-Hirschman Index (HHI@). Pfizer and Warner are the two leading suppliers of OTC pediculicides in the United States. Pfizer and Warner each have approximately 30 percent of the market, and the pre-merger HHI is 2223. As a result of the Merger, Pfizer would have a 60 percent share of the market, and the post-merger HHI would be 4024.

22. The market for SSRI/SNRI drugs for the treatment of depression is concentrated as measured by the HHI. Pfizer=s Zoloft has 23 percent of the market, while Celexa, which Warner co-promotes with Forest, has a 10 percent market share, and the pre-merger HHI is 1834. As a result of the Merger, Pfizer/Forest would have a 33 percent share of the market, and the post-merger HHI would be 2294.

23. The market for drugs for the treatment of Alzheimer=s disease is highly concentrated as measured by the HHI. Pfizer=s Aricept has over 98 percent of the market, while Warner=s Cognex has about one percent market share, and the pre-merger

## Complaint

HHI is 9801. As a result of the Merger, Pfizer would obtain a monopoly position and post-merger HHI would be 10,000.

24. In the market for EGFr-tk inhibitors for the treatment of cancer, the FDA has yet to approve any product. If approved by the FDA, these products would offer a significant improvement in the treatment of solid tumor cancers. The market for the research, development, manufacture and sale of EGFr-tk inhibitors for the treatment of cancer is highly concentrated; currently only four companies, including Pfizer and Warner, have EGFr-tk inhibitors in human clinical testing. The proposed Merger would reduce the number of companies to three.

**VI. ENTRY CONDITIONS**

25. Entry into the market for OTC pediculicides is unlikely and would not occur in a timely manner to deter or counteract the adverse competitive effects described in Paragraph 29, because, among other things, the time and expense necessary to develop a product capable of successful entry are disproportionate to the likely available sales opportunity.

26. Entry into the market for SSRI/SNRI drugs for the treatment of depression will not occur in a timely manner to deter or counteract the adverse competitive effects described in Paragraph 29, because of, among other things, the time and expense necessary to develop an FDA-approved antidepressant.

27. Entry into the market for drugs for the treatment of Alzheimer=s disease will not occur in a timely manner to deter or counteract the adverse competitive effects described in Paragraph 29, because of, among other things, the time and expense necessary to develop an FDA-approved Alzheimer=s disease treatment.

28. Entry into the market for the research, development, manufacture and sale of EGFr-tk inhibitors for the treatment of cancer will not occur in a timely manner to deter or counteract the

### Complaint

adverse competitive effects described in Paragraph 29, because of, among other things, the time and expense necessary to develop an FDA-approved cancer treatment.

## Complaint

**VII. EFFECTS OF THE MERGER**

29. The effects of the Merger, if consummated, may be substantially 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 increasing the ability of the merged entity to unilaterally increase prices, and reduce innovation and promotional activities, in the market for OTC pediculicides;
- b. by increasing the likelihood of coordinated interaction in the market for SSRI/SNRI drugs for the treatment of depression;
- c. by increasing the likelihood that the merged entity would unilaterally increase prices and reduce innovation in the market for drugs for the treatment of Alzheimer=s disease; and
- d. by increasing the likelihood that the merged entity would unilaterally delay, deter or eliminate competing programs to research and develop EGFr-tk inhibitors for the treatment of cancer, potentially reducing the number of drugs reaching the market and thus resulting in higher prices for consumers.

**VIII. VIOLATIONS CHARGED**

30. The Merger Agreement described in Paragraph 18 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. ' 45.

## Order to Maintain Assets

31. The Merger described in Paragraph 18, 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 nineteenth day of June, 2000, issues its Complaint against said Respondents.

By the Commission.

**ORDER TO MAINTAIN ASSETS**

The Federal Trade Commission (ACommission@) having initiated an investigation of the proposed merger between Pfizer Inc. (APfizer@) and Warner-Lambert Company (AWarner@), hereinafter referred to as ARespondents,@ and the Respondents having been furnished thereafter with a copy of a draft of Complaint which the Bureau of Competition presented to the Commission for its consideration and which, if issued by the Commission, would charge the 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 (AConsent Agreement@), containing the proposed Decision and Order, an admission by the Respondents of all of 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

## Order to Maintain Assets

the Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than the 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 has 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 the Consent Agreement on the public record for a period of thirty (30) days, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent Pfizer 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 235 East 42<sup>nd</sup> Street, New York, New York 10017.
2. Respondent Warner is a 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 201 Tabor Road, Morris Plains, New Jersey 07950.
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.**

## Order to Maintain Assets

**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 competitiveness of the Celexa Assets, the Cognex Divestiture Assets, the RID Divestiture Assets, and the EGFr-tk Assets, hereinafter collectively referred to as AAssets,@ and to prevent the destruction, removal, wasting, or deterioration, of the Assets, except for ordinary wear and tear and as would otherwise occur in the ordinary course of business.
- B. Pending the divestiture or transfer of each of the respective Assets, Respondents shall adhere to and abide by the Celexa Termination Agreement, the Cognex Divestiture Agreement, the RID Divestiture Agreement, and the EGFr-tk Divestiture Agreement, which agreements are incorporated by reference into this Order to Maintain Assets and made a part hereof, and are also appended to the attached Decision and Order.

**III.**

**IT IS FURTHER ORDERED** that at any time after the Commission issues this Order to Maintain Assets, the Commission may appoint an Interim Trustee as provided in the attached Decision and Order.

**IV.**

**IT IS FURTHER ORDERED** that Respondents shall notify the Commission at least thirty (30) days prior to any proposed change in Respondents that may affect compliance obligations arising out of this Order to Maintain Assets, such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation.

## Order to Maintain Assets

**V.**

**IT IS FURTHER ORDERED** that for the purposes of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States office, 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 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 all of the divestitures or transfers of the Assets, as described in and required by the Decision and Order, are completed.

By the Commission.



## Decision and Order

**DECISION AND ORDER**

The Federal Trade Commission (ACommission@) having initiated an investigation of the proposed merger of Respondent Warner-Lambert Company (AWarner@) and Respondent Pfizer Inc. (APfizer@), hereinafter referred to as ARespondents,@ 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 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 (AConsent 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, 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 Order:

## Decision and Order

1. Respondent Pfizer 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 235 East 42<sup>nd</sup> Street, New York, New York 10017.

2. Respondent Warner 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 201 Tabor Road, Morris Plains, New Jersey 07950.

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. "Pfizer" means Pfizer Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Pfizer Inc. and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "Warner" means Warner-Lambert Company, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Warner-Lambert Company (including, but not limited to, the Parke-Davis Division), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Respondents" means Pfizer and Warner, individually and collectively.

## Decision and Order

D. AMerger@ means the proposed merger of Pfizer and Warner by means of an Agreement and Plan of Merger dated as of February 6, 2000 among Pfizer, Seminole Acquisition Sub. Corp., and Warner.

E. "Commission" means the Federal Trade Commission.

F. "Forest" means Forest Laboratories, Inc., 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 909 Third Avenue, New York, New York 10022.

G. AFirst Horizon@ means First Horizon Pharmaceutical 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 660 Hembree Parkway, Suite 106, Roswell, Georgia 30076.

H. ABayer@ means Bayer Corporation, a corporation organized, existing and doing business under and by virtue of the laws of the State of Indiana, with its offices and principal place of business located at 36 Columbia Road, Morristown, New Jersey 07962-1910.

I. AOSI@ means OSI Pharmaceuticals, Inc., 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 106 Charles Lindbergh Boulevard, Uniondale, New York, 11553-3649.

J. ACelexa@ means any pharmaceutical preparation containing the drug substance citalopram HBr that is the subject of the Celexa Co-Promotion Agreement and the Celexa Amendment. Celexa includes any and all of its constituent

## Decision and Order

elements, active ingredients or intermediaries, and all rights relating to the research, development, manufacture and sale of Celexa.

K. ACelexa Co-Promotion Agreement@ means the Agreement dated March 27, 1998 by and between Forest and the Parke-Davis Division of Warner attached hereto as non-public Appendix I.

L. ACelexa Amendment@ means the Amendment to the Celexa Co-Promotion Agreement between Forest and the Parke-Davis Division of Warner, dated September 1, 1999, attached hereto as non-public Appendix II.

M. ACelexa Assets@ mean all rights granted to Warner pursuant to the Celexa Co-Promotion Agreement and Celexa Amendment.

N. ACelexa Termination Agreement@ means the Amendment No. 2 and Termination Agreement terminating the Celexa Co-Promotion Agreement and Celexa Amendment by and between Forest and Warner, dated May 11, 2000, attached hereto as non-public Appendix III.

O. AKnow-how@ means all technological, technical, scientific, chemical, biological, pharmacological, toxicological, regulatory and marketing materials and information used to develop, make, use, sell, offer for sale, import or seek regulatory approval in any country to market a Product, including without limitation all: formulae; trade secrets; inventions; techniques; intellectual property (including patents and patent applications) whether or not patentable; discoveries; compounds; compositions of matter, assays, reagents, and biological materials; trademarks; research data; technical data and information; testing data; preclinical and clinical data; toxicological and pharmacological data; regulatory files; statistical analyses; analytical data; clinical protocols; specifications; designs; drawings; processes; testing and quality assurance/quality control data; manufacturing data and information; regulatory submissions; and any other information and experience, whether recorded on paper or electronically.

Decision and Order

## Decision and Order

P. ACelexa Know-how@ means all Confidential Business Information and Know-how in the possession or control of Warner as of the date Warner signed the Celexa Termination Agreement that relates in whole or in part to Celexa, including without limitation information and documents stored on all computer files and management information systems; written, recorded and graphic materials of every kind; proprietary software used in connection with Celexa; all data, contractual rights, materials, documents and information relating to obtaining FDA approvals and other government or regulatory approvals for Celexa; and any other information, documents and experience relating to Celexa. Celexa Know-how shall be deemed to include all information comprised by Celexa Assets. Celexa Know-how includes, but is not limited to:

1. notes, minutes and other documents relating to speaker programs, Alunch and learn@ programs, and meetings with medical advisers to Forest or Warner in connection with the Celexa Co-Promotion Agreement (and Celexa Amendment), including plans for future programs and meetings, market research data and proposals relating to Celexa;
2. all marketing plans including written fiscal year and contract year marketing plans, media placement plans, public relations plans, convention plans, symposia plans, publication plans, pricing plans, and line extension plans related to Celexa;
3. minutes of all Celexa meetings, and intracompany and intercompany correspondence related to such meetings;
4. all advisory board and consultants= correspondence related to Celexa;
5. all correspondence with advertising, public relations and medical education agencies related to Celexa;

## Decision and Order

6. speaker training materials and all other medical education materials related to Celexa;
7. all market research, including both primary and secondary, whether conducted by Forest or Warner= Parke-Davis Division related to Celexa;
8. all forecasts and assumptions, including sample production forecasts related to Celexa;
9. all presentation materials used at national sales meetings or manager meetings related to Celexa;
10. all physician targeting data and call plans including reach and frequency plans related to Celexa;
11. all communications with the FDA and DDMAC related to Celexa;
12. all Phase IV clinical study plans and protocols provided to Warner related to Celexa;
13. all regulatory and development information including information on Celexa line extensions, tablet strengths and SKUs related to Celexa;
14. any and all information provided from the Celexa NDA, investigators= brochures or study reports;
15. all professional affairs letters related to Celexa utilized to respond to physician inquiries; and
16. all information related to Celexa pertaining to managed care, government accounts, hospitals, long-term care

## Decision and Order

and other channels. This includes all contracts and contracting templates and strategies.

*Provided, however,* that Celexa Know-how does not include information which becomes or became available to Respondents on a non-confidential basis from a source other than Forest, if such source is not under obligation (whether contractual, legal or fiduciary) to Forest to keep such information confidential.

Q. AConfidential Business Information@ means all information that is not in the public domain concerning the research, development, marketing, distribution, cost, pricing, sale and commercialization of a Product or of a Product in development.

R. "Celexa Material Confidential Information@ means any information not in the public domain obtained by Respondents directly or indirectly from Forest pursuant to the Celexa Co-Promotion Agreement and Celexa Amendment prior to the date this Order becomes final, and includes, but is not limited to, Celexa Know-how and Confidential Business Information relating to Celexa.

S. AFDA@ means the United States Food and Drug Administration.

T. ADDMAC@ means the Division of Drug Marketing, Advertising and Communication of the FDA.

U. ANDA@ means a New Drug Application filed or to be filed with the FDA, any preparatory work, drafts and data necessary for the preparation thereof, and Know-how, and includes without limitation both supplemental and abbreviated NDAs.

V. AZoloft@ means any pharmaceutical preparation containing the drug substance sertraline hydrochloride, any of its constituent elements, active ingredients or intermediaries, and all



## Decision and Order

rights relating to the research, development, manufacture and sale of Zoloft, which is manufactured, marketed and distributed by Pfizer.

W. ASSRI/SNRI@ means any selective serotonin reuptake inhibitor/serotonin norepinephrine reuptake inhibitor, including, but not limited to, branded, generic or isomer forms of the following drugs: Paxil, Prozac, Zoloft, Luvox, Effexor, and Celexa.

X. ACognex@ means any pharmaceutical preparation containing the drug substance tacrine hydrochloride. Cognex includes any of its constituent elements, active ingredients, intermediaries, and all rights relating to the research, development, manufacture and sale of Cognex and the once daily controlled release formulation containing Tacrine as the HCl salt and using the gastrointestinal therapeutic system technology from ALZA Corporation.

Y. ATacrine@ means the active pharmaceutical ingredient produced at Warner=s chemical manufacturing facility in Holland, Michigan.

Z. ACognex Divestiture Assets@ mean all assets relating to Cognex and Tacrine as defined in the Cognex Divestiture Agreement.

AA. ACognex Divestiture Agreement@ means the asset purchase agreement between Warner and First Horizon relating to the sale of the Cognex Divestiture Assets, dated April 14, 2000, attached hereto as non-public Appendix IV.

BB. AEGFr-tk@ means any pharmaceutical preparation containing the drug substance Epidermal Growth Factor receptor tyrosine kinase inhibitor, CP 358,774. EGFr-tk shall also include all salts and prodrug forms of CP 358,774.

## Decision and Order

CC. AEGFr-tk Assets@ means all assets relating to EGFr-tk to be licensed or transferred to OSI pursuant to the EGFr-tk Divestiture Agreement. *Provided, however,* that if OSI requests such assets, the EGFr-tk Assets shall also include intellectual property and technology (including Joint Technology) arising under the OSI/Pfizer Collaboration Research Agreements and OSI/Pfizer License Agreements which relate to CP 358,774 and to salts and prodrug forms of CP 358,774, and which are reasonably necessary to research, develop, manufacture, or sell EGFr-tk.

DD. AOSI/Pfizer Collaboration Research Agreements@ means the Agreement dated April 1, 1986, the Agreement dated April 1, 1991 and the Agreement dated April 1, 1996, by and between OSI and Pfizer, attached hereto as non-public Appendix V.

EE. AOSI/Pfizer License Agreements@ means the Agreements dated December 14, 1990 and April 1, 1996, by and between OSI and Pfizer, attached hereto as non-public Appendix VI.

FF. AEGFr-tk Divestiture Agreement@ means the Agreement between Pfizer and OSI dated May 23, 2000, attached hereto as non-public Appendix VII.

GG. AJoint Technology@ means all technology and technical information relating to EGFr-tk pursuant to the OSI/Pfizer Collaboration Research Agreements.

HH. AOwnership Interest@ means any right(s), present or contingent, to hold voting or nonvoting interest(s), equity interest(s), and/or beneficial ownership(s) in the capital stock of OSI.

II. ARID@ means Pfizer=s rights and assets relating to any Product containing the active ingredient pyrethrum that is a lice treatment or related Product, including all rights relating to the research, development, manufacture and sale of lice treatments or related Products, including but not limited to individual, kit,

## Decision and Order

advance systems and bulk SKUs containing RID spray, shampoo, egg loosener gel, mousse or comb.

JJ. ARID Assets@ means all assets relating to RID as defined in the RID Divestiture Agreement.

KK. ARID Divestiture Assets@ means:

1. all intellectual property, including pending patent applications, licenses, inventions, technology, Know-how, patents, trademarks, brand names, trade names, trade dress, trade secrets, and copyrights;
2. all research materials, formulations, new product formulations, line extensions, patent rights, trade secrets, specifications, protocols, technical information, regulatory information and approvals, manufacturing information, management information systems, software, specifications, designs, drawings, processes and quality control data;
3. all customer lists, vendor lists, medical marketing lists, catalogs, sales promotion literature, promotional materials, displays, tokens, advertising materials, marketing plans and strategies, price and discount strategies, price lists, sales forecasts, distribution information, trade booths, medical marketing convention floor space and related items, telephone and facsimile numbers, as well as other customer support materials (including, without limitation, web sites);
4. inventory and storage capacity;
5. all third party agreements and contracts that are related to the research, development, manufacture, marketing, sale or use of RID, including but not limited to contract manufacturing arrangements;

## Decision and Order

6. inventories, including finished goods inventory of RID, works in progress, raw material and packaging materials for RID, including but not limited to the active ingredient pyrethrum;

7. all rights, titles and interests in and to the contracts entered into in the ordinary course of business with customers (together with associated bid and performance bonds), suppliers, sales representatives, distributors, agents, personal property lessors, personal property lessees, licensors, licensees, consignors and consignees;

8. all rights under warranties and guarantees, express or implied;

9. all books, records and files; and

10. all items of prepaid expense.

*Provided, however,* that the RID Divestiture Assets shall also include all research, development and manufacturing assets necessary to produce RID in a government-approved facility if the person acquiring the RID Divestiture Assets requests such assets.

LL. ARID Divestiture Agreement@ means the asset purchase agreement between Bayer and Pfizer dated April 11, 2000, attached hereto as non-public Appendix VIII.

MM. AProduct@ means any finished pharmaceutical composition containing any formulation or dosage of a compound as its pharmaceutically active ingredient.

NN. ARID Closing@ means the date that Bayer acquires the RID Assets from Pfizer.

OO. APublic Record Date@ means the date that the Commission places the Consent Agreement on the public record pursuant to Commission Rule 2.34, 16 C.F.R. ' 2.34.

## Decision and Order

PP. AEPA@ means the United States Environmental Protection Agency.

QQ. ASKU@ means stock keeping unit.

RR. AKey Employees@ means the individuals identified in public Appendix IX attached hereto.

**II.****IT IS FURTHER ORDERED** that:

A. Not later than (10) days after the Public Record Date, Respondents shall terminate, absolutely and in good faith, the Celexa Co-Promotion Agreement and Celexa Amendment, pursuant to and in accordance with the terms of the Celexa Termination Agreement. The Celexa Termination Agreement is incorporated by reference into this Order and made a part hereof as non-public Appendix III. Failure to comply with all of the terms of the Celexa Termination Agreement shall constitute a failure to comply with this Order.

B. Respondents shall return and submit to Forest at its New York corporate office, at Respondents' expense, all Celexa Know-how pursuant to the terms of the Celexa Termination Agreement. Respondents shall not retain any copies of Celexa Know-how except as required by law.

C. Respondents shall provide Forest with the opportunity to enter into employment contracts with the Key Employees listed in Appendix IX attached to this Order through March 31, 2001. Respondents shall provide Forest an opportunity to inspect the personnel files and other documentation relating to these employees, to the extent permissible under applicable laws, at the request of Forest any time after execution of the Celexa Termination Agreement. Respondents shall not interfere with the

## Decision and Order

employment by Forest of these employees and shall remove any impediments that may deter such employees from accepting employment with Forest, 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 Forest.

## Decision and Order

D. Respondents shall not use, disclose or convey, directly or indirectly, any Celexa Know-how or any Confidential Business Information relating to the research, development, manufacturing or marketing of Celexa to any other person.

E. Respondents shall require each Key Employee to sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Celexa Know-how (including, without limitation, all field experience) strictly confidential, including from all other employees, executives or other personnel of Respondents. (A copy of this confidentiality agreement is appended hereto as public Appendix X). Respondents shall ensure that Key Employees (listed in Appendix IX) shall not be involved in the marketing, sale or promotion of Zoloft or any SSRI/SNRI Product other than Celexa through March 31, 2001.

F. Respondents shall also provide written notification of the restrictions on the use of Celexa Know-how by former Warner personnel and of the restrictions on the Warner personnel from selling Zoloft, or accompanying Pfizer personnel involved with the sale or marketing of Zoloft, for the time periods set forth in the Celexa Termination Agreement, to all Warner employees involved in the sale or marketing of Celexa (other than the Key Employees) and all Pfizer employees involved with the sale or marketing of Zoloft. Respondents shall provide such notification by email with return receipt requested or similar transmission. (A copy of this confidentiality notification is appended hereto as Appendix XI). Respondents shall also obtain from each employee covered by the requirements of this subparagraph an agreement to abide by these restrictions. Respondents shall maintain complete records of all such statements at Respondents' corporate headquarters and shall provide an officer's certificate 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 these restrictions, including the provision of written reminders to all

## Decision and Order

sales personnel at three (3) month intervals until the expiration of the time periods set forth in the Celexa Termination Agreement, and take corrective actions for the failure of sales personnel to comply with such restrictions or to furnish the written acknowledgments required by this Order.

G. Pending the termination of the Celexa Co-Promotion Agreement and the Celexa Amendment, Respondents shall take such actions as are necessary to maintain the viability and marketability of Celexa and to prevent the destruction, removal, wasting, deterioration, or impairment of any Celexa Assets, except for ordinary wear and tear.

H. Except as required by law, Respondents shall not receive or have access to, or use or continue to use, any Celexa Material Confidential Information.

I. The purpose of Paragraph II of this Order is to ensure the continued use of the Celexa Assets in the same business in which the Celexa Assets are engaged at the time of the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.

**III.****IT IS FURTHER ORDERED** that:

A. Not later than ten (10) days after the Public Record Date, Warner shall divest the Cognex Divestiture Assets to First Horizon pursuant to and in accordance with the Cognex Divestiture Agreement, and such agreement is incorporated by reference into this Order and made part hereof as non-public Appendix IV.

B. Failure to comply with all terms of the Cognex Divestiture Agreement shall constitute a failure to comply with this Order.

C. Pending divestiture of the Cognex Divestiture Assets, Respondents shall take such actions as are necessary to maintain



## Decision and Order

the viability and marketability of the Cognex Divestiture Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Cognex Divestiture Assets except for ordinary wear and tear.

D. The purpose of Paragraph III of this Order is to ensure the continued use of the Cognex Divestiture Assets in the same business in which the Cognex Divestiture Assets are engaged at the time of the Merger, 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) days after the Public Record Date, Pfizer shall divest the RID Assets to Bayer pursuant to and in accordance with the RID Divestiture Agreement, and such agreement is incorporated by reference into this Order and made part hereof as non-public Appendix VIII. *Provided, however*, that if Respondents have divested the RID Assets to Bayer 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 Bayer is not an acceptable purchaser of the RID Assets or that the manner in which the divestiture was accomplished is not acceptable, then Respondents shall immediately rescind the transaction with Bayer and shall divest the RID Divestiture Assets within six (6) months from the date the Order becomes final, absolutely and in good faith, at no minimum price, to an acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission.

B. Failure to comply with all terms of the RID Divestiture Agreement shall constitute a failure to comply with this Order.

## Decision and Order

C. Pending divestiture of the RID Divestiture Assets, Respondents shall take such actions as are necessary to maintain the viability and marketability of the RID Divestiture Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the RID Divestiture Assets except for ordinary wear and tear.

D. The purpose of Paragraph IV of this Order is to ensure the continued use of the RID Assets or RID Divestiture Assets in the same business in which the RID Assets or RID Divestiture Assets are engaged at the time of the Merger, 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. Not later than ten (10) days after the Public Record Date, Respondents shall transfer and surrender, absolutely and in good faith, all of Pfizer's EGFr-tk Assets, pursuant to and in accordance with the EGFr-tk Divestiture Agreement to OSI, and such agreement is incorporated by reference into this Order and made a part hereof as non-public Appendix VII. Failure by Respondents to comply with the requirements of the EGFr-tk Divestiture Agreement shall constitute a failure to comply with this Order.

B. Upon reasonable notice and request from OSI to Respondents, Respondents shall provide to OSI, in a timely manner and at no cost to OSI, any assistance, advice or EGFr-tk Assets as may be reasonably necessary for OSI to obtain FDA approvals to manufacture and sell EGFr-tk.

C. Respondents shall not, directly or indirectly: (i) exercise dominion or control over, or otherwise seek to influence, the management, direction or supervision of the business of OSI; (ii) seek or obtain representation on the Board of Directors of OSI; (iii) exercise any voting rights attached to any ownership of OSI

## Decision and Order

shares of stock; (iv) seek or obtain access to any Confidential Business Information of OSI relating to EGFr-tk and not otherwise necessary to comply with this Order; or (v) 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 OSI. The requirements of Paragraph V.C. shall continue and remain in effect so long as the Respondents retain any Ownership Interest in OSI.

D. Pending the completion of the transfer of the EGFr-tk Assets, Respondents shall take such actions as are necessary to maintain the viability and marketability of the EGFr-tk Assets, and to prevent the destruction, deterioration, or impairment of any of the EGFr-tk Assets. Respondents shall also take such actions as are necessary to maintain the viability and marketability of the EGFr-tk Assets, and to prevent the destruction, deterioration, or impairment of any of the EGFr-tk Assets.

E. The purpose of Paragraph V of this Order is to ensure the continued use of the EGFr-tk Assets in the same business in which the EGFr-tk Assets are engaged at the time of the Merger, and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's complaint.

**VI.****IT IS FURTHER ORDERED** that:

A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint an Interim Trustee to assure that Respondents expeditiously perform their responsibilities as required by this Order and the EGFr-tk Divestiture Agreement.

B. If an Interim Trustee is appointed pursuant to Paragraph VI of this Order, Respondents shall consent to the following terms

## Decision and Order

and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Trustee:

1. The Commission shall select the Interim Trustee, 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 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. The Interim Trustee shall have the power and authority to monitor Respondents= compliance with the terms of this Order and with the terms of the EGFr-tk Divestiture Agreement, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Trustee in a manner consistent with the purposes of this Order and in consultation with the Commission.

3. Within ten (10) days after appointment of the Interim Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, confers on the Interim Trustee all the rights and powers necessary to permit the Interim Trustee to monitor Respondents= compliance with the terms of this Order and with the terms of the EGFr-tk Divestiture Agreement in a manner consistent with the purposes of this Order.

4. The Interim Trustee shall serve until the last obligation under the EGFr-tk Divestiture Agreement has been fully performed; *provided, however*, the Commission may extend this period as may be necessary or appropriate to accomplish the purposes of this Order.

5. The Interim Trustee shall have full and complete access to Respondents= personnel, books, records, documents, facilities and technical information relating to the research,

## Decision and Order

development and manufacture of EGFr-tk, or to any other relevant information, as the Interim Trustee may reasonably request, including, but not limited to, all documents and records kept in the normal course of business that relate to the manufacture of EGFr-tk and all materials and information relating to FDA and other government or regulatory approvals. Respondents shall cooperate with any reasonable request of the Interim Trustee. Respondents shall take no action to interfere with or impede the Interim Trustee's ability to monitor Respondents' compliance with this Order and the EGFr-tk Divestiture Agreement.

6. The Interim Trustee 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 Commission may, among other things, require the Interim Trustee to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with performance of the Interim Trustee's duties. The Interim Trustee shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Trustee's duties and responsibilities. The Interim Trustee shall account for all expenses incurred, including fees for his or her services, subject to the approval of the Commission.

7. Respondents shall indemnify the Interim Trustee and hold the Interim Trustee harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection with, the performance of the Interim Trustee's duties, including all reasonable fees of counsel and other 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

## Decision and Order

negligence, willful or wanton acts, or bad faith by the Interim Trustee.

## Decision and Order

8. If the Commission determines that the Interim Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Trustee in the same manner as provided in Paragraph VI.A. of this Order.

9. The Commission may on its own initiative or at the request of the Interim Trustee issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order and the EGFr-tk Divestiture Agreement.

10. The Interim Trustee shall obtain and evaluate reports submitted to it by OSI with respect to the performance of Respondents' obligations under the EGFr-tk Divestiture Agreement. The Interim Trustee shall report in writing to the Commission every two (2) months from the date the Interim Trustee is appointed concerning compliance by Respondents and OSI with the provisions of this Order and the EGFr-tk Divestiture Agreement until the last obligation under the EGFr-tk Divestiture Agreement has been fully performed.

**VII.****IT IS FURTHER ORDERED** that:

A. If Respondents have not fully complied with the obligations specified in Paragraph IV of this Order, the Commission may appoint an individual to serve as a trustee to divest the RID Divestiture Assets. 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 trustee in such action to divest the RID Divestiture Assets. 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

## Decision and Order

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 enforced by the Commission, for any failure by the Respondents to comply with this Order.

B. If a trustee is appointed by the Commission or a court pursuant to Paragraph VII.A. 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 the 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 the RID Divestiture Assets.

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 Paragraph IV of this Order.

4. The trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in Paragraph VII.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 trustee



## Decision and Order

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 trustee, by the court; *provided, however*, the Commission may extend the divestiture period only two (2) times.

5. The trustee shall have full and complete access to the personnel, books, records and facilities related to RID 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 at no minimum price. The divestiture shall be made in the manner and to an acquirer as set out in Paragraph IV of 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) 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

## Decision and Order

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 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 direction of the Respondents, and the trustee=s power shall be terminated. The compensation of the trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture all of Respondents= RID Divestiture Assets.

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 VII.B. 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.

## Decision and Order

11. The trustee shall have no obligation or authority to operate or maintain the RID Divestiture Assets.

12. The trustee shall report in writing to Respondents and the Commission every sixty (60) days concerning the trustee=s efforts to accomplish the divestiture.

**VIII.****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 the provisions of Paragraphs II, III, IV, and V.A. of this Order, 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 Trustee if any Interim Trustee 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 Paragraphs II through V of the Order, including a description of all substantive contacts or negotiations for the divestitures 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 five (5) 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.

## Decision and Order

**IX.**

**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 the Order.

**X.**

**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 office, 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 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.

**XI.**

**IT IS FURTHER ORDERED** that this Order shall terminate on July 27, 2020.

By the Commission.

Appendices

**APPENDIX I (non-public)**  
**Celexa Co-Promotion Agreement**

**APPENDIX II. [non-public]**  
**Amendment to Celexa Co-Promotion Agreement**

**APPENDIX III. [non-public]**  
**Celexa Termination Agreement**

**APPENDIX IV. [non-public]**  
**Cognex Divestiture Agreement**

**APPENDIX V. [non-public]**  
**OSI/Pfizer Collaboration Agreements (1986, 1991 and 1996)**

**Appendix VI [non-public]**  
**OSI/Pfizer License Agreements (1990 and 1996)**



Appendices

**Appendix VII (non-public)**  
**EGFr-tk Divestiture Agreement**

**Appendix VIII (non-public)**  
**RID Divestiture Agreement**

**Appendix IX (public)**  
**Key Employees**

**PARKE-DAVIS CELEXAJ TEAM MEMBERS**

<u>John Woychick</u>	<u>VP NE CBU</u>
<u>Doug Saltel</u>	<u>VP CNS Marketing</u>
<u>Tim George</u>	<u>Dir. Strategic Alliances</u>
<u>Katie MacFarlane</u>	<u>Dir. Marketing</u>
<u>Garry Callendar</u>	<u>Dir., Strategic Planning &amp; Information Management</u>
<u>Jim LaMartina</u>	<u>Dir., Sales Training</u>
<u>Scott Van Acker*</u>	<u>Dir., Health Care Management (Field)</u>
<u>Rich Weiss *</u>	<u>Dir., Health Care Management (Marketing)</u>
<u>Ken Massey</u>	<u>Sr. Dir., Medical &amp; Scientific Affairs</u>
<u>Victor Delimata</u>	<u>Sr. Product Manager-CNS Disease Team</u>
<u>Patrick Runde*</u>	<u>Sr. Marketing Manager</u>
<u>George Cavic*</u>	<u>VP Health Care Management</u>
<u>John Richter*</u>	<u>Dir., CNS &amp; Anti-Infective Marketing, Health Care Mgmt.</u>
<u>Ginny Ludwig</u>	<u>Sr. Mgr., Health Care Mgmt.</u>
<u>Ron Preblich, Pharm.D.</u>	<u>Mgr., Health Care Economics</u>

## Appendices

<u>Debra Schramm *</u>	<u>Dir., Contracts and Pricing, Health Care Management</u>
<u>Lynne Fredericks</u>	<u>Market Research</u>
<u>Rick Wantees</u>	<u>Market Research</u>
<u>Lene Ulrich*</u>	<u>VP, SC CBU</u>
<u>John Howard*</u>	<u>VP, NC CBU</u>
<u>Daniel Green*</u>	<u>VP, West CBU</u>
<u>Les Slater*</u>	<u>VP, SE CBU</u>
<u>Laura Johnson*</u>	<u>Marketing Mgr., NE CBU</u>
<u>Andrew Purcell</u>	<u>VP, West CBU</u>
<u>Janice Hall</u>	<u>Senior Product Manager</u>
<u>Allison Fannon</u>	<u>Product Manager</u>
<u>Tim Amato</u>	<u>Product Manager</u>

\* These individuals are signing as to confidentiality only

**Appendix X (public)**  
**Key Employee Confidentiality Agreement**

I, \_\_\_\_\_, hereby acknowledge that I will maintain all Celexa Know-how (as defined in the Consent Order, including, without limitation, all field experience) regarding Celexa strictly confidential, including from all other employees, executives, or other personnel of Warner-Lambert, its Affiliates and successors.

I also hereby agree that I will not be involved in the marketing, sale, or promotion of Zoloft or any SSRI/SNRI Product (as defined in the Consent Order) other than Celexa through March 31, 2001.



## Appendices

**Appendix XI (public)**  
**Warner/Pfizer Notice****I.**

Pursuant to a Consent Order entered into between Warner-Lambert Company, Pfizer Inc. and the Federal Trade Commission on May 24, 2000, members of the Warner-Lambert PC-2 salesforce, CNS, Hospital, Managed Care, and Governmental salesforces, who directly participated in the marketing of Celexa within the twelve month period immediately prior to the termination date of April 30, 2000, are prohibited from performing services for Pfizer, or any affiliate of Pfizer, in connection with the marketing or promotion of Zoloft through November 30, 2000. In addition, such employees are prohibited from accompanying Pfizer personnel on Zoloft detailing calls.

In addition, these employees shall maintain all Celexa Know-how (as defined in the Consent Order) in their possession strictly confidential from any person or entity, including from all other employees, executives, or other personnel of Warner-Lambert, its Affiliates and successors.

**II.**

Pursuant to a Consent Order entered into between Warner-Lambert Company, Pfizer Inc. and the Federal Trade Commission on May 24, 2000, Morris Plains New Jersey and Warner-Lambert Central Business Unit-based Warner-Lambert marketing executives and personnel and administrative and sales personnel, who directly participated in the marketing of Celexa within the twelve month period immediately prior to the termination date of April 30, 2000, are prohibited from performing services for Pfizer, or any affiliate of Pfizer, in connection with the marketing or promotion of Zoloft through March 31, 2001. In addition, such employees are prohibited from accompanying Pfizer personnel on Zoloft detailing calls.

*Analysis to Aid Public Comment*

In addition, such employees shall maintain all Celexa Know-how (as defined in the Consent Order) strictly confidential from any person or entity, including from all other employees, executives, or other personnel of Warner-Lambert, its Affiliates and successors.

**Analysis of Proposed Consent Order to Aid Public Comment**

The Federal Trade Commission (ACommission@) has accepted, subject to final approval, an agreement containing a proposed Consent Order from Pfizer Inc. (APfizer@) and Warner-Lambert Company (AWarner@) which is designed to remedy the anticompetitive effects of the merger of Pfizer and Warner. Under the terms of the agreement, the companies would be required to: (1) terminate Warner=s agreement with Forest Laboratories, Inc. (AForest@) to co-promote the antidepressant Celexa; (2) divest Pfizer=s RID pediculicide (used to treat head lice) business to Bayer Corporation (ABayer@); (3) divest all of Warner=s assets relating to the Alzheimer=s drug, Cognex, to First Horizon Pharmaceutical Corporation; and (4) transfer and surrender to OSI Pharmaceuticals, Inc. (AOSI@) all of Pfizer=s assets relating to the Epidermal Growth Factor receptor tyrosine kinase inhibitor, CP-358,774, for the treatment of cancer.

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 Consent Order.

In their merger agreement of February 6, 2000, Pfizer and Warner propose to combine their two companies in a transaction

*Analysis to Aid Public Comment*

valued at approximately \$90 billion. Thereafter, the merged entity will be renamed Pfizer 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) SSRI/SNRI antidepressants; (2) pediculicides; (3) drugs for the treatment of Alzheimer=s disease; and (4) EGFr-tk inhibitors for the treatment of cancer. The proposed Consent Order would remedy the alleged violations by replacing the lost competition that would result from the merger in each of these markets.

**SSRI/SNRI Antidepressants**

Selective serotonin reuptake inhibitors (ASSRIs@) and selective norepinephrine reuptake inhibitors (ASNRIs@) are used to treat depression. Both SSRIs and SNRIs have the same effect on the neurotransmitter serotonin, which is believed to be an important mood regulator. SSRIs and SNRIs are favored by physicians because they offer once-a-day dosing and a lower side effect profile compared to earlier generation antidepressants. Annual U.S. sales of SSRI/SNRI antidepressants total approximately \$7 billion.

The market for SSRI/SNRIs is highly concentrated. Pfizer and Warner compete directly against each other in the market for SSRI/SNRI antidepressants. Pfizer markets Zoloft, while Warner co-promotes Celexa with Forest. In 1999, Pfizer=s Zoloft was the second-leading SSRI, with sales in the United States of over \$2 billion, while Warner and Forest=s Celexa was the fastest-growing SSRI with sales of \$210 million.

There are significant barriers to entry into the SSRI/SNRI market. New entry into the manufacture and sale of drugs for the treatment of depression is difficult, expensive and time-consuming. It requires identifying a preclinical compound,

## Analysis to Aid Public Comment

performing animal safety tests, clinically developing the product in humans, and submitting a New Drug Application for approval by the Food and Drug Administration (AFDA@). In order to enter the market, a firm must incur substantial sunk costs to research, develop, manufacture and sell a SSRI/SNRI. De novo entry has been estimated to take between 8-12 years and cost upwards of \$250 million. New entry sufficient to deter or counteract the anticompetitive effects of the merger would not occur in a timely manner. Nor would such entry be likely to occur in the face of a 5 to 10 percent increase in the prices of these drugs.

The proposed merger of Pfizer and Warner is likely to cause significant anticompetitive effects in the U.S. SSRI/SNRI market by increasing the likelihood of coordinated interaction among the remaining firms in the market and by eliminating Celexa, an aggressive new market entrant, as an independent competitor. As a result, American consumers of these drugs would likely pay higher prices and have fewer alternatives for SSRI/SNRI drugs for the treatment of depression.

The proposed Consent Order maintains competition in the SSRI/SNRI market by requiring that: (1) Warner terminate, absolutely and in good faith, the Celexa Co-Promotion Agreement and Celexa Amendment in accordance with the terms of the Celexa Termination Agreement with Forest; (2) Warner return all confidential information regarding Celexa to Forest; (3) the former Warner sales personnel who participated in the marketing of Celexa maintain the confidentiality of this information; and (4) the former Warner sales personnel involved in marketing Celexa be prohibited from selling Zoloft for a period of time.

**Pediculicides**

Over-the-counter (AOTC@) pediculicides are used to treat head-lice infestation. While prescription products and home remedies may also be used for the treatment of head lice, OTC pediculicides are more effective, cheaper and safer than any

Analysis to Aid Public Comment

available alternatives. Annual U.S. sales of OTC pediculicides total over \$150 million.

The market for OTC pediculicides is highly concentrated. Pfizer and Warner are the two leading suppliers of OTC pediculicides in the United States, with approximately 30 percent of the market each. Thus, as a result of the merger, Pfizer would have a 60 percent share of the market. There are significant barriers to entry and expansion into this market. In order to enter the market, a firm must incur substantial sunk costs to research, develop, manufacture and sell OTC pediculicides. Existing private label and small branded suppliers of pediculicides are not likely to effectively reposition themselves in order to counteract a post-merger price increase because of their minimal market presence, lack of scale economies and lack of consumer brand loyalty. The proposed merger is likely to lead to unilateral anticompetitive effects in the OTC pediculicide market by eliminating the actual, direct, and substantial competition between Pfizer and Warner and allowing the combined firm to raise prices.

The proposed Consent Order remedies the merger's anticompetitive effects by requiring that Pfizer divest its entire RID brand of pediculicide and all assets associated with this product line to Bayer.

### **Drugs for the Treatment of Alzheimer=s Disease**

Pfizer and Warner market the only two products sold in the United States for the treatment of Alzheimer=s disease, Aricept and Cognex, respectively. Aricept dominates the market with more than 98 percent market share, while Cognex accounts for the remainder of the market. While the FDA has recently approved one new product, Novartis AG=s Exelon, for the treatment of Alzheimer=s disease, Novartis has yet to market its product. Even taking into account Novartis=s entry into the market, the market will still be highly concentrated. There are significant

## Analysis to Aid Public Comment

barriers to entry into this market. New entry into the manufacture and sale of drugs for the treatment of Alzheimer=s disease is difficult, expensive and time-consuming because of the lengthy development periods, the need for FDA approval, and the substantial sunk costs required to research, develop, manufacture and sell these drugs. As a result, entry likely to deter or counteract the likely anticompetitive effects of the proposed merger is unlikely.

The merger would result in Pfizer=s having a monopoly in the market for drugs for the treatment of Alzheimer=s disease, with that monopoly position lessening only slightly when Exelon is launched in the United States. Accordingly, the merger would increase Pfizer=s dominant position in the market, allowing it to increase prices and potentially eliminate Cognex, the smaller competitor, from the market. The proposed Consent Order remedies the merger=s anticompetitive effects by requiring Warner to divest Cognex to First Horizon Pharmaceutical Corporation.

**EGFr-tk Inhibitors for the Treatment of Cancer**

Pfizer and Warner are developing Epidermal Growth Factor receptor tyrosine kinase (AEGFr-tk@) inhibitors for the treatment of solid cancerous tumors. Solid tumor cancer targets include head and neck, non-small-cell lung, breast, ovarian, pancreatic and colorectal cancers. Currently, over 1.2 million Americans are diagnosed with solid tumor cancers each year. It is anticipated that EGFr-tk inhibitors will be used in conjunction with surgery, radiation and chemotherapy to treat cancer patients.

EGFr-tk inhibitors target the EGFr oncogene that regulates cancer cell growth. The EGFr has been identified as being over-expressed (too prevalent) in as many as 700,000 of the 1.2 million Americans diagnosed with a solid tumor cancer each year. Patients with an over-expression of EGFr are believed to have a worse prognosis than other cancer patients. Accordingly, scientists have developed drugs that attempt to inhibit the EGFr

## Analysis to Aid Public Comment

activity of cell division signal transduction that results in cancer cell proliferation.

The most advanced EGFr-tk inhibitors include those being developed by Pfizer and Warner. Pfizer and Warner are two of only a few companies in clinical development of EGFr-tk inhibitors for solid tumor cancers. There are significant barriers to entry into the market. In order to enter the market, a firm must incur substantial sunk costs to research, develop, manufacture and sell EGFr-tk inhibitors.

The proposed merger is likely to create anticompetitive effects in the EGFr-tk inhibitor market by potentially eliminating one of the few research and development efforts in this area. As a result of the merger, the combined entity could unilaterally delay, terminate or otherwise fail to develop one of the two competing EGFr-tk drugs, resulting in less product innovation, fewer choices, and higher prices for consumers.

To resolve these concerns, the proposed Consent Order requires Pfizer to return its EGFr-tk inhibitor, CP-358,774, to its development partner, OSI. OSI holds a contractual right to obtain CP-358,774 should Pfizer terminate development efforts. Thus, while other companies have expressed interest in acquiring the rights to CP-358,774, none may do so without the prior approval of OSI.

The proposed Consent Order maintains competition in the research and development of EGFR-tk inhibitors for the treatment of cancer by requiring that Pfizer fulfill its obligations under the May 23, 2000 agreement between Pfizer and OSI to (1) transfer and surrender its rights to CP-358,774 to OSI; (2) grant OSI a royalty-free, irrevocable worldwide license, including the right to sublicense, to all of its rights in, and to, the patents currently owned jointly by OSI and Pfizer relating to EGFr-tk inhibitors; (3) complete, at Pfizer's cost, ongoing clinical trials of CP-358,774; (4) provide OSI with a manufacturing and supply

*Analysis to Aid Public Comment*

agreement for the continued supply of CP-358,774, pending transfer of manufacturing technology to a new manufacturer; (5) assume liability for all completed clinical trials; and (6) transfer all know-how and technology relating to CP-358-774 to OSI. The Consent Order also provides for an Interim Trustee to be appointed to oversee Pfizer=s obligations under the Order and to ensure the continued development and viability of CP-358,774.

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.