



4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft of complaint here attached, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent: (1) issue its complaint corresponding in form and substance with the draft of complaint attached hereto and its decision containing the following order to cease and desist in disposition of the proceeding; and (2) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to proposed respondent's address as stated in this agreement shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the proposed complaint and order contemplated hereby. It understands that once the order has been issued, it will be required to file one or more compliance reports showing that it has fully complied with the order. Proposed respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

## ORDER

### I.

IT IS ORDERED that respondent, World Media T.V., Inc., its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, promotion, offering for sale, sale, or distribution of any device, as "device" is defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, in any manner, directly or by implication:

- A. That use of the device will significantly reduce, relieve, or eliminate musculoskeletal pain, including but not limited to pain in the back, feet, knees, wrists, knuckles, elbows, shoulders, ankles, joints, or calves; carpal tunnel syndrome; muscle spasms or strains; or sciatica;
- B. That use of the device will significantly reduce, relieve, or eliminate abdominal pain or pain or discomfort caused by allergies, sinus conditions, diverticulosis, cramps, or menstrual cramps;
- C. That use of the device will eliminate the pain caused by severe headaches, including but not limited to occipital, frontal, migraine, cluster, or stress headaches, or headaches caused by benign tumors;
- D. That the pain relief or pain elimination provided by the device is immediate;
- E. That use of the device provides long-term pain relief;
- F. That, for the treatment of pain, the device is as effective as, or more effective than, prescription or over-the-counter medications, including but not limited to aspirin, acetaminophen, Darvon, Darvocet, or codeine;
- G. That, for the treatment of pain, the device is as effective as, or more effective than, physical therapy, massage therapy, chiropractic treatment, acupuncture, acupressure, or reflexology; or
- H. About the efficacy or relative efficacy of the product in reducing, relieving, or eliminating pain from any source;

unless, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation. For purposes of this provision, "competent and reliable scientific evidence" shall mean adequate and well-controlled clinical testing conforming to acceptable designs and protocols and conducted by a person or persons qualified by training and experience to conduct such testing.

Provided that, for any representation that any device is effective for:

- (1) the temporary relief of minor aches and pains due to fatigue and overexertion, or
- (2) easing and relaxing of tired muscles, or
- (3) the temporary increase of local blood circulation in the area where applied,

"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.

## II.

IT IS FURTHER ORDERED that respondent, World Media T.V., Inc, its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, promotion, offering for sale, sale, or distribution of any product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, in any manner, directly or by implication, about the health or medical benefits of any such product unless, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation. For purposes of this provision, "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 have 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.

## III.

IT IS FURTHER ORDERED that respondent, World Media T.V., Inc., its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, promotion, offering for sale, sale, or distribution of any product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that any endorsement (as "endorsement" is defined in 16 C.F.R. § 255.0(b)) of the product represents the typical or ordinary experience of members of the public who use the product, unless:

- A. at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates such representation, or
- B. respondent discloses, clearly and prominently, and in close proximity to the endorsement or testimonial, either:
  - (1) what the generally expected results would be for users of such product, or
  - (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 provision, "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 have 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.

#### IV.

Nothing in this Order shall prohibit respondent from making any representation for any drug that is permitted in labeling for any 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.

#### V.

IT IS FURTHER ORDERED that for five (5) years after the last date of dissemination of any representation covered by this Order, respondent, or its successors and assigns, shall maintain and upon request make available to the Federal Trade Commission or its staff for inspection and copying:

- A. All materials that were relied upon in disseminating such representation; and
- B. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis for such representation, including but not limited to complaints from consumers and complaints or inquiries from governmental organizations.

VI.

IT IS FURTHER ORDERED that respondent shall notify the Commission at least thirty (30) days prior to any proposed change in its corporate structure, including but not limited to dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or affiliates, the planned filing of a bankruptcy petition, or any other change in the corporation that may affect compliance obligations arising out of this Order.

VII.

IT IS FURTHER ORDERED that respondent shall:

- A. Within thirty (30) days after service of this Order, distribute a copy of this Order to each of its operating divisions and to each of its officers, agents, representatives, or employees engaged in the preparation or placement of advertisements or other materials covered by this Order.
- B. For a period of five (5) years from the date of entry of this Order, provide a copy of this Order to each of its future principals, officers, directors, and managers, and to all personnel, agents, and representatives having sales, advertising, or policy responsibility with respect to the subject matter of this Order who are associated with it or any subsidiary, successor, or assign, within ten (10) days after the person assumes his or her position.

VIII.

IT IS FURTHER ORDERED that this Order will terminate twenty (20) years from the date of its issuance, 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 paragraph 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 Paragraph.

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 Paragraph as though the complaint was never 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.

IX.

IT IS FURTHER ORDERED that respondent shall, within sixty (60) days after service of this Order, and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this Order.

Signed this \_\_\_\_\_ day of \_\_\_\_\_, 1996.

WORLD MEDIA T.V., INC.

BY: \_\_\_\_\_  
Michael Clark  
President

\_\_\_\_\_  
Edward F. Glynn, Jr.  
Venable, Baetjer, Howard & Civiletti  
Counsel for Respondent World Media T.V., Inc.

\_\_\_\_\_  
Lesley Anne Fair  
Counsel for the Federal Trade Commission

APPROVED:

\_\_\_\_\_  
C. LEE PEELER  
Associate Director for Advertising Practices

\_\_\_\_\_  
JOAN Z. BERNSTEIN  
Director  
Bureau of Consumer Protection



headaches because I have an osteoma right up here. That's a non-malignant tumor that's just going to be there forever unless I have it surgically removed. And I get pressure headaches from it. You just feel like your whole head is just going to explode. They get so bad that I can take Darvocets and it doesn't relieve it. You know, I can be taking them for days and it doesn't relieve it. He puts the Stimulator here and here, it's gone within seconds. (Exhibit A, p. 6)

- B. RUTH MINARD (Consumer Endorser): I started out with a stomach ache and I had a stomach ache for, oh, a couple, maybe three, months. It was diagnosed through my internist that it was diverticulosis. And so I had heartburn and gas like you wouldn't believe -- 24 hours, all the time. I couldn't believe, after having pain that long, and I had tried everything that I knew to try over the counter, and [the Stimulator] did the trick. I mean, I got results immediately. It's still unbelievable what it did for me. Today I have no stomach ache. (Exhibit A, p. 5)
- C. RON HARTLINE (Consumer Endorser): And the lower back, it's unreal how it worked down there. Because, like, my low back on the one side has always bothered me. And I zap it and it's like it relieves it, you know? It's like taking back ten years on my body. This is something that works on me. (Exhibit A, p. 4)
- D. DR. GANDEE: I've been using the Stimulator on many people for different problems, like headaches. All they have to do, wherever the pain is, stimulate the head, right around the area of pain. (Exhibit A, p. 6)
- E. UNIDENTIFIED WOMAN #5 (Consumer Endorser): That was the biggest surprise to me -- that a little thing like that Stimulator could help that sinus in that day. No hot and cold packs, no bend over and feel like your eyes are going to fall out. (Exhibit A, p. 3)
- F. JAMES LARIMORE (Consumer Endorser): [The Stimulator] works for me in the area of the sinus problem. (Exhibit A, p. 3)
- G. DR. GANDEE: Sinuses. The Stimulator works very well with sinuses. (Exhibit A, p. 6)
- H. RON HARTLINE (Consumer Endorser): It's just aches and pains. Carpal tunnel in the wrist, which I didn't think anything but surgery could take care of that. But [the Stimulator] works real well. I mean it loosens -- it's like instantly -- it loosens up the wrist. (Exhibit A, p. 4)

- I. BILL RAMSELL (Consumer Endorser): I had excruciating pain in my knees. And [the Stimulator] was fantastic. I couldn't believe what it did for me. You know, it just felt wonderful. As a matter of fact, I golfed 18 holes yesterday and walked quite a bit and it never bothered me at all. (Exhibit A, p. 5)
- J. EVEL KNIEVEL: When I wake up in the morning, my wrist tends to hurt me very badly. When I put [the Stimulator] on and I click it, and use it, say, half a dozen or a dozen times on different parts of my wrist, my wrist begins to feel good. . . . [Friends] know that if I use it after all I've been through and all the things that I've tried to kill pain -- that if I use it and they don't see me taking any kind of a drug for pain -- everybody that knows me knows that I do not take drugs -- and they just absolutely know that if I've got a product and I'm using it to help me, then it must be working for me and you can keep things that do not belong in your system out of your system. (Exhibit A, pp. 7-8)
- K. DR. GANDEE: But I'll tell you, when I first saw the Stimulator, I personally needed something in my office to help me. And the reason is the knuckle on the forefinger of my hand hurt so bad for the last two years I thought I was going to have to quit chiropractic. I could not work on my patients the way I wanted to. I had to change techniques. I think, seriously, if I hadn't had the Stimulator, I wouldn't be in chiropractic right now. Or I would've had to cut back dramatically on the patients I was seeing. (Exhibit A, p. 3)
- L. KEVIN CULVER (Consumer Endorser): I'm up at the club there and I'm bragging about this thing and that's how I ended up here. I said, "That thing worked." You know, I haven't had any pain since. (Exhibit A, p. 8)
- M. RUTH MINARD (Consumer Endorser): I got up this morning and I wasn't feeling very well. My feet were hurting me so bad. And I came to sit down to eat my breakfast and Nan got the zapper and she come and zapped me good. Before I could eat my breakfast, my feet were better. It doesn't take me too long to eat either. (Exhibit A, p. 11)
- N. BILL WALTON: I had approximately 30 operations on my feet. I was in physical therapy on a constant basis. I worked with people who practiced all sorts of medicine. Orthopedists at the top. Massage therapist, chiropractors, acupuncture, acupressure, reflexology, tremendous amounts of yoga. You name it, I did it. If you have a life where you sit around and are in pain, you're going to be thinking all day long about the things that cause those pains. One of the things I try to do with my life is help people who are also in that chronic pain. That's why I recommend the Stimulator. So that they can move on and have a productive and happy life. And that smile will return to their face, the way it has to mine. (Exhibit A, p. 9)

- O. JAMES LARIMORE (Consumer Endorser): Consequently, I get cramps in the hands, cramps in the arms, shoulders, across the top of the neck, back, lower back. And from crawling in and out, I get it in the knees. It's just, it just goes along with the job. Now I don't have to tolerate it anymore. If I have a cramp in my hand or something like that, I can relieve the cramp within 30 seconds. I use it in the evenings when I'm home after work. I use it on the balls of my feet, around my ankles, knees. (Exhibit A, p. 6)
- P. RON HARTLINE (Consumer Endorser): When you do as much lifting like I do -- like a weight lifter -- and your wrists get swelled, your hands get swelled. The swelling in my hands is actually going down. I can't explain that but the swelling in my hands has actually gone down. My watch actually slides now whereas it's always been tight. (Exhibit A, p. 4)
- Q. DR. GANDEE: Allergies, the runny eyes, the runny nose. [The Stimulator] really seems like it gives a lot of relief for that. (Exhibit A, p. 6)
- R. BILL WALTON: If I had the Stimulator available to me my entire career, I would've had a better career. The short term and long term pain relief that the Stimulator provides would have helped me -- would have helped me work harder -- would've helped me play better. (Exhibit A, p. 4)
- S. DR. GANDEE: You can do it wherever you have pain. The knuckle, your elbow, your shoulder, your knees, your feet, your ankles, your wrist, the calves. It does not matter. And what it does is allows the body to help itself. The Creator put us here with a body that was supposed to be healthy. I believe that and most people believe that. And this Stimulator helps the body help itself. (Exhibit A, p. 4)
- T. DR. GANDEE: The Stimulator may sound too good to be true. But it is true. The Stimulator works. It helps your body help itself naturally. What you've seen here are exactly the results that people have gotten. As a matter of fact, if anything, we've understated the relief people get. (Exhibit A, p. 10)
- U. UNIDENTIFIED WOMAN #6 (Consumer Endorser): Oh, I think it works much faster than any medication. (Exhibit A, p. 3)
- V. LINDA ANTHONY (Consumer Endorser): He puts the Stimulator here and here, it's gone within seconds. The pain is so excruciating and the relief is so wonderful. I mean, it's like no aspirin, no pain medication, no nothing can take that -- give you that instant relief. I mean I'm talking instant. (Exhibit A, p. 6)

- W. UNIDENTIFIED MAN #2 (Consumer Endorser): It's always there. It's handy. You don't have to go make a call or set an appointment. It just helps relieve the pain instantly. (Exhibit A, p. 10)
- X. JOHN TRIPPE (Consumer Endorser): I've been on Darvocets and other pain killers all this time. Darvocets and Darvons and codeines, Tylenol with codeine. And since I've been introduced to this I haven't used any of it. (Exhibit A, p. 3)
- Y. UNIDENTIFIED WOMAN #4 (Consumer Endorser): Some things are addictive. You don't want to -- you end up relying on something that it causes other health problems. And I look for a natural way to deal with any health problems that I have. (Exhibit A, p. 3)
- Z. GLEN MATZ (Consumer Endorser): Some of us can't just take aspirin. Some of us just can't take certain medications or anti-inflammatory drugs because they upset our stomach. This, I can relieve that pain and I don't have to swallow anything. (Exhibit A, p. 3)

PARAGRAPH FIVE: Through the use of the statements contained in the advertisements referred to in PARAGRAPH FOUR, including but not necessarily limited to the advertisement attached as Exhibit A, respondent has represented, directly or by implication, that:

- A. Use of the Stimulator will significantly reduce, relieve, or eliminate musculoskeletal pain, including pain in the back, feet, knees, wrists, knuckles, elbows, shoulders, ankles, joints, and calves; carpal tunnel syndrome; muscle spasms and strains; and sciatica.
- B. Use of the Stimulator will significantly reduce, relieve, or eliminate abdominal pain and pain and discomfort caused by allergies, sinus conditions, diverticulosis, cramps, and menstrual cramps.
- C. Use of the Stimulator will significantly reduce, relieve, or eliminate the pain caused by severe headaches, including but not limited to occipital, frontal, migraine, cluster, and stress headaches, and headaches caused by benign tumors.
- D. The pain relief or pain elimination provided by the Stimulator is immediate.
- E. Use of the Stimulator provides long-term pain relief.

- F. For the treatment of pain, the Stimulator is as effective as, or more effective than, prescription and over-the-counter medications, including aspirin, acetaminophen, Darvon, Darvocet, and codeine.
- G. For the treatment of pain, the Stimulator is as effective as, or more effective than, physical therapy, massage therapy, chiropractic treatment, acupuncture, acupressure, and reflexology.
- H. Testimonials from consumers appearing in the advertisements for the Stimulator reflect the typical or ordinary experience of members of the public who have used the product.

PARAGRAPH SIX: Through the use of the statements contained in the advertisements referred to in PARAGRAPH FOUR, including but not necessarily limited to the advertisement attached as Exhibit A, respondent has represented, directly or by implication, that at the time they made the representations set forth in PARAGRAPH FIVE, respondent possessed and relied upon a reasonable basis that substantiated such representations.

PARAGRAPH SEVEN: In truth and in fact, at the time it made the representations set forth in PARAGRAPH FIVE, respondent did not possess and rely upon a reasonable basis that substantiated such representations. Therefore, the representation set forth in PARAGRAPH SIX was, and is, false and misleading.

PARAGRAPH EIGHT: Respondent knew or should have known that the misrepresentation set forth in PARAGRAPH SIX was, and is, false and misleading.

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

THEREFORE, the Federal Trade Commission, on this \_\_\_\_\_ day of \_\_\_\_\_, 1996, has issued this complaint against respondent.

By the Commission.

DONALD S. CLARK  
Secretary

[Exhibit A attached to paper copies of complaint, but not available in electronic form.]

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

The Federal Trade Commission has accepted, subject to final approval, agreements to a proposed consent order from Natural Innovations, Inc. ("Natural Innovations") and its officer and director, Ohio chiropractor William S. Gandee ("Dr. Gandee"), and a proposed consent from World Media T.V., Inc. ("World Media") (collectively "respondents").

The proposed consent orders have been placed on the public record for sixty (60) days for 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 agreements and the comments received and will decide whether it should withdraw from the agreements or make final the agreements' proposed orders.

The Commission's complaint against respondents Natural Innovations and Dr. Gandee alleges that they deceptively advertising the Stimulator, a purported pain relief device, primarily through an infomercial entitled "Saying No To Pain." The Stimulator is a syringe-shaped device that purports to relieve pain by emitting an electrical spark when applied to the skin. The complaint against World Media TV alleges that it served as an advertising agency, production company, and media buyer for Natural Innovations, Inc., and participated in the creation and dissemination of advertisements for the Stimulator.

The complaints further allege that respondents made unsubstantiated representations that the Stimulator will significantly relieve or eliminate a wide variety of pain, including musculoskeletal pain, carpal tunnel syndrome, abdominal pain, pain caused by allergies and sinus conditions, diverticulosis, menstrual cramps, and headaches, including but not limited to occipital, frontal, migraine, cluster, and stress headaches, and headaches caused by benign tumors.

The complaints also allege that respondents represented without substantiation that pain relief from the device is immediate; that the device provides long-term relief; and that the device is as effective as, or more effective than, prescription and over-the-counter medications, physical therapy, chiropractic treatment, acupuncture, acupressure, and reflexology.

The proposed consent orders contain provisions designed to remedy the violations charged and to prevent respondents from engaging in similar acts and practices in the future. Part I of both orders requires respondents to possess well-controlled clinical testing to support any claim that a device relieves or eliminates pain, relieves pain immediately, or is as effective as or better than over-the-counter pain medication or physical treatments. For representations that a device is effective for temporary relief of minor aches and pains due to fatigue or overexertion, easing and relaxing tired muscles, or temporary increase of local blood circulation, Part I requires that respondents possess competent and reliable scientific evidence.

Part II requires respondents to possess competent and reliable scientific evidence for any claims about the health or medical benefits of any product.

Part III of both orders forbids respondents from representing that an endorsement represents the typical experience of users of the product unless respondents possess competent and reliable scientific evidence substantiating that representation or they disclose clearly and prominently either the results that consumers can generally expect or that consumers should not expect to achieve results similar to the endorsers.

Part IV allows respondents to make representations for any drug that are permitted in labeling for that drug under any tentative or final FDA standard or under any FDA-approved new drug application.

Parts V through VIII and X of the Natural Innovations Order and Parts V through VII and IX of the World Media Order relate to respondents' obligations to make available to the Commission materials substantiating claims covered by the order; to notify the Commission of changes in Natural Innovation's or World Media's corporate structure; to notify the Commission of changes in Dr. Gandee's employment or business affiliations; to provide copies of the orders to certain Natural Innovations and World Media personnel; and to file compliance reports with the Commission. Part IX of the Natural Innovations Order and Part VIII of the World Media Order provide that the orders will terminate after twenty years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed orders, and it is not intended to constitute an official interpretation of the agreements and proposed orders or to modify in any way their terms.