STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF PROFESSIONAL REGULATION, BOARD OF MEDICAL EXAMINERS,	)	
Petitioner,	)	
vs	)	CASE NOS. 86-2054
	)	87-1599
ROBERT D. WILLNER, M. D.,	)	
Respondent.	)	

RECOMMENDED ORDER

This matter was heard by William R. Dorsey, Jr., the Hearing Officer designated by the Division of Administrative Hearings, on August 31, 1987, through September 2, 1987, in Miami, Florida and on November 2, 1987, in Tallahassee, Florida.

APPEARANCES

For Petitioner: Joel S. Fass, Esquire
COLONY, FASS, & TALENFELD
626 N.E. 124th Street
North Miami, Florida 33161

For Respondent: Joseph C. Jacobs, Esquire
Kelly Overstreet Johnson, Esquire
ERVIN, VAN, JACOBS, ODOM and ERVIN
Post Drawer 1170
Tallahassee, Florida 32302-1170

STATEMENT OF THE ISSUES

This proceeding involves two administrative complaints filed against Dr. Willner. In Case 86-2054, the complaint sought disciplinary action for

> (1) Violating Section 458.331(1)(u) Florida Statutes, (1981) by performing a procedure or prescribing a therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed and written consent by treating patients for obesity with a product known as "NatureSlim" which had not been proven safe and effective for human use (Count 1);
> (2) Violating Section 458.331(1)(d)

Florida Statutes, (1983) by being guilty of false, deceptive or misleading advertisement with respect to claims made for a diet program known as "Forever Thin" (Count 2);
(3) Violating Section 458.331(1)(h) Florida Statutes, (1983) by failing to perform a statutory or legal obligation placed upon a licensed physician by distributing a new drug that did not have a Federal or Florida investigational drug permit on file, in violation of 21 U.S.C. Section 355 and Section 429.023 Florida Statutes (1983) (Count 3);
(4) Violating Section 458.331(1)(t) Florida Statutes, (1983) by gross or repeated malpractice or the failure to practice medicine with that level of care, skill and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances by failing to obtain full, informed written consent from patients who were sold glucomannan, which the department contends was an unapproved new drug (Count 4); and
(5) Violating Section 458.331(1)(u) Florida Statutes, (1983) by performing any procedure or prescribing any therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed and written consent from those who used the drugs included in the "Forever Thin" diet program (Count 5).

The administrative complaint in Case 87-1599 sought to discipline Dr. Willner for

(1) Violating Section 458.331(1)(d) Florida Statutes, (1985) by false, deceptive or misleading advertisement with respect to claims made for products marketed under the name of the "Ultimate Solution Diet Program" (Count 1, paragraph 22);
(2) Violating Section 458.331(1)(1) Florida Statutes, (1985) by making deceptive, untrue, or fraudulent representations in the practice of medicine, or employing a trick or scheme in the practice of medicine when that scheme or trick fails to conform to the generally prevailing standards of

treatment in the medical community in connection with the promotion of the "Ultimate Solution Diet Program"; [Count 2, paragraph 24]

(3) Violating Section 458.331(1)(n) Florida Statutes, (1985) by failing to keep written medical records justifying the course of treatment of patients, including, but not limited to, patient histories, examination results, and test results for persons who were told they were part of a select group of persons offered the new drugs contained in the "Ultimate Solution Diet Program"; [Count 3, paragraph 26]

(4) Violating Section 458.331(1)(u), Florida Statutes, (1985) by performing any procedure or prescribing any therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed, and written consent from persons offered the new drugs contained in the "Ultimate Solution Diet Program [Count 4, paragraph 28]

(5) Violating Section 458.331(1)(h) Florida Statutes, (1985) by failing to perform any statutory or legal obligation placed upon a licensed physician by failing to comply with Federal and Florida law governing the use of new or investigational drugs; [Count 5, paragraph 30] and

(6) Violating Section 458.331(1)(t) Florida Statutes, (1985) by gross or repeated malpractice or the failure to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances by his course of conduct in the marketing of the "Ultimate Solution Diet Program." [Count 6, paragraph 32]

PRELIMINARY STATEMENT

A transcript of the proceedings was filed, and proposed recommended orders were received by July 6, 1988. Ruling on proposed findings of fact are made in the appendix to this Recommended Order.

FINDINGS OF FACT

INTRODUCTION

1. Dr. Robert D. Willner is a licensed Florida medical doctor. He maintains a Florida medical practice which includes weight management, and he has authored a book on dieting. Publication of that book put him into contact with a promoter of mail order products, including books and diet programs, Frank Sarcone. Dr. Willner conducted studies at his medical office for Mr. Sarcone after advertising for volunteers in the Miami Herald to evaluate the effectiveness of certain substances in enhancing weight loss. He also was retained as a consultant and obtained the contractual right to review advertising materials which Mr. Sarcone distributed over Dr. Willner's signature promoting Sarcone's diet programs, or under the imprimatur of a board of medical advisors Dr. Willner had assembled at Mr. Sarcone's request to review mail-order diet programs. Sarcone paid Dr. Willner for his work on behalf of Sarcone and his companies. Sarcone promoted Dr. Willner's clinical studies with advertising materials which form the basis of these disciplinary proceedings against Dr. Willner.

I. Spirulina and Glucomannan - what are they?

2. This proceeding involves the use of two substances, spirulina and glucomannan, in conjunction with diet programs sold through the mail.

A. Spirulina

3. Spirulina is a blue-green algae which grows in saline or brackish water and in lakes. It is a dietary fiber which has some value as a food supplement because the algae has a protein content and a polysaccharide content. Its protein content makes it a useful source of protein. It is harvested and consumed in some underdeveloped parts of the world. It is not commonly consumed in the United States, although it is sold in health food stores. It can be added to such foods as biscuits, cakes, noodles, breads, candies or pastas. By itself, spirulina is an unappetizing powder. Due to its unpalatablity, it is often sold in tablet or capsule form for use as a protein supplement.

4. There was no scientific evidence extant, at the times pertinent to this proceeding, of spirulina's usefulness in enhancing weight loss in a diet regimen. In 1979 the U.S. Food and Drug Administration Advisory Panel on Over-the-Counter Drugs reviewed spirulina and found no scientific evidence to demonstrate that it was safe and effective for use as an appetite suppressant. FDA Release, attached to Willner deposition of 8/24/87 as Ex. 8.

5. Dr. Willner did conduct a study of spirulina's effectiveness in enhancing weight loss which is discussed below. Since that time, one study of the use of spirulina in dieting was published in 1986, in a journal so obscure that the parties could only locate a 12-line abstract of it. The abstract is too brief to assess the study's methodology or to determine whether its conclusion that spirulina can cause a small but statistically significant increase in a dieter's weight loss is valid. Its publication after the representations made about spirulina in advertisements for its use in Mr. Sarcone's diet programs make the article irrelevant to the issue of whether the advertising which is the subject of this proceeding was misleading or false when distributed. The article was not the basis for any claim made by Mr. Sarcone for his diet programs.

B. Glucomannan

6. Glucomannan is the name given to long-chain, non-digestible polysaccharides made up of the simple sugars glucose and mannose. It is a dietary fiber. When ingested, it swells to absorb water within the stomach and intestines and forms a gelatin-like mass. That mass also takes up other nutrients in the stomach. The glucomannan bolus, including the nutrients bound to it, is not absorbed through the intestinal wall. The bolus moves slowly through the stomach and intestines, generating a feeling of fullness. It has the dual effects of impairing nutrient absorption and increasing the time the user experiences a feeling of fullness. Glucomannan occurs naturally as a component of baker's yeast, making up part of the yeast cell wall. It can also be derived from the konjac root, a plant which grows in the Orient, especially Japan.

7. Due to its bulking properties, glucomannan has been used in diet programs to promote stool, for some diets result in constipation or diarrhea. Glucomannan can also inhibit the reabsorption of serum cholesterol which is secreted into the intestines as a component of bile from the liver. This cholesterol would otherwise be reabsorbed by the body. Cholesterol is a fat in the blood, and to the extent that cholesterol reabsorption is inhibited, glucomannan can be said to inhibit the body's ingestion of fat. This does not mean, however, that glucomannan burns or otherwise reduces those fats stored in the body as fatty tissue.

8. No valid scientific studies demonstrate that the use of glucomannan in a diet enhances weight loss. One study of glucomannan was done at the Harvard Medical school. A principal investigator for that study was George Blackburn, M.D., who testified as an expert witness for the Department in this case by deposition. The Harvard study found no statistical difference in weight loss among 83 healthy adult women who were given glucomannan or a different dietary fiber over nine weeks, in conjunction with a daily 1,250 calorie, low fat, complex carbohydrate diet.

9. In 1982 the U.S. Food and Drug Administration Advisory Review Panel on Over-the-Counter Miscellaneous Internal Drug Products published a report presenting recommendations about weight control drug products for over-the-counter human use. 47 Fed. Reg. 8466 (February 26, 1982). The Advisory Review Panel analyzed the usefulness of anorectic drugs, i.e., drugs used to suppress appetite and thus reduce or control weight by reducing calorie intake below energy output. 47 Fed. Reg. 8466, at 8472. Dr. Hegenhaur, an expert witness for Dr. Willner, referred to the report in his testimony. The Advisory Review Panel Report found benzocaine to be generally recognized as safe and effective, and not misbranded, when consumed for weight control at a dosage of 3 to 5 milligrams in gum, lozenges or candy just prior to eating. Id. at 8474. One other drug, phenylpropanolamine hydrochloride, was similarly approved. Id. at 8475.

10. On the other hand, the FDA Advisory Review Panel was unable to determine whether a number of other substances discussed in the report were both safe and effective weight control drugs. Among these was xanthan gum, described as a "hydrophilic colloidal polysaccharide gum containing d-gulcose, d-mannose and d-glucuronic acid as either a potassium or sodium salt." 47 Fed. Reg. at 8479. This substance meets Dr. Heghehaur's definition of glucomannon. The Advisory Panel judged xanthan gum safe, at a dosage of 1.1 grams taken before each meal with 8 oz. of water, but found "the value of bulk producers in reducing weight by controlling appetite have not been established." Id. The

panel recommended additional testing of xanthan gum and other substances according to a very specific protocol set out in the report "to determine whether or not it is effective for weight control." Id. A total sample of at least 100 subjects was prescribed. 47 Fed. Reg. at 8481. Certain limited labeling claims for xanthan gum were approved by the panel. 47 Fed. Reg. 8476, 8479.

II. Dramatis Personae

A. Dr. Willner and His Writings

11. Robert D. Willner, M.D., has been licensed as a medical doctor in the State of Florida since 1959, holding license number ME0008519. He is Board-certified in family medicine and practices in Miami, Florida. His practice is includes pain management, weight management, and nutrition. Thirty percent of his practice is devoted to family medicine, an area in which he is Board-certified.

12. Dr. Willner has never before had a substantiated complaint filed against him and has never been found guilty of malpractice.

13. Dr. Willner's work in weight management led him to author a book on dieting in 1977, The Pleasure Principle Diet. Dr. Willner took a dim view of fad diets in that book. For example, in chapter two 1/ of his book, Dr. Willner wrote:

> Americans are an incredible people. They have incredible ideas, incredible energies, incredible wealth and power, and, oh yes, an incredible need to believe in miracles because of their incredible achievements. This, of course, makes them incredibly gullible. Charlatans and quacks have been around for a long time. Quacks of all sorts have claimed to cure people by radio waves, electrical waves, magnetic waves, thought waves, and an assortment of unheard-of waves that were unheard of and never heard of again. All kinds of gadgets have been sold, leased, and franchised; boxes to sit on, boxes to sit in, boxes to sit under, rings for your fingers, bracelets for your wrists, and collars for your neck made out of copper, brass, hair from horsetails, and tails from asses. Mysterious, undetectable beams have been bounced on people, off people, in people, through people, and back at people. The miracle merchants sold pills, tonics, nostrums, brews, garments, and you-name-its to millions of people for millions of dollars. Some of the great fakers even had streets, boulevards, and buildings named after them.
> The perpetrators of these frauds

invariably use testimonials to support their claims. You will never find carefully documented and controlled studies. Look through almost any magazine on the stands today and you will see advertisements for all sorts of medicines and gadgets for which testimonials are the only "proof." There will always be some people to give a testimonial that Preparation "X" cured them. In almost every instance, it is an unsubstantiated illness cured by an unsubstantiated drug. Frequently, unfortunate individuals who are suffering from terminal illnesses are subject to the most unspeakable kinds of fraud. They are robbed of their funds, their dignity, their hope, and a chance for legitimate therapy. Actually, I can't blame the public too much for jumping on every fad bandwagon that comes along. A large amount of new knowledge is being discovered by the scientific community at a rapid rate. Most of this knowledge is published only in medical and scientific journals. Much of it can only be understood by highly-trained, specialized individuals. It may take many years before the significance of new discoveries can be fully comprehended and their role in our every day lives determined. The public becomes confused and frustrated when new information reaches the media. Often it appears to be contradictory and at times may challenge well-established concepts. Laws and safeguards may be thoughtlessly discarded because public pressure and impatience may force the premature disclosure and application of new information before its impact on our way of life is fully and correctly interpreted.

In the field of nutrition and dieting, food faddists get the most publicity. They achieve their fame through their ability to attract public notice. The statements made by most faddists are unfounded, designed to startle, attract attention, and make big profits. They start with a small truth, which they exaggerate into a big lie. Their claims are baseless and backed by testimonials that are in turn backed by coincidence, imagination, or fantasy. Very few aspects of living have attracted the merchants of magic, myths,

> and miracles as much as nutrition and dieting. When a particular diet is the "current rage," it arouses a serious interest and enthusiasm on the part of the fat or potentially fat population. Everybody wants to try it, everybody wants their problem to disappear--pooff! Willner, The Pleasure Principle Diet (Reward Books, 1985) at 65-68

14. The book contains an overview of what Dr. Willner characterized as "fad diets," including high protein, high fat, low carbohydrate diets; starvation diets; starvation and fasting diets; and protein-sparing, modified fast diets; he also reviews pills used in conjunction with diets, including amphetamines, thyroid hormones, metabolic stimulants, bulk preparations and human chorionic gonadotropin. With respect to bulk preparations he says:

> Bulk preparations contain methyl-cellulose and have not proven to be effective in weight control to any substantial degree. The Pleasure Principle Diet, supra, at 79.

This is consistent with the findings of the FDA Advisory Review Panel on Over-the-Counter Miscellaneous Internal Drug Products Report on Weight Control Drug Products, 47 Fed. Reg. 8466, 8478 (Feb. 26, 1982)

B. Mr. Frank Sarcone

15. Dr. Willner met Frank Sarcone in 1981 through a mutual acquaintance. Sarcone contacted Dr. Willner to discuss distribution of his book by mail. Mr. Sarcone's company, Milburn Books published Dr. Willner's book, The Pleasure Principle Diet, for approximately six months to a year. 2/

16. Mr. Sarcone is an entrepreneur who has had no formal education since he dropped out of high school. After leaving school, Mr. Sarcone worked for Plymouth Publishing Company for two years and then began his own company, Robert Collier Book Corporation, which went bankrupt. He then started the Nancy Prior Book Corporation which went bankrupt and then started the Milburn Book Corporation which has pled guilty to mail fraud. Although Dr. Willner heard that Sarcone had been the subject of criminal charges, he did nothing to follow up on it because "the matter had nothing to do with him."

17. Sarcone told Dr. Willner he was interested in mail order sale of products containing spirulina. Dr. Willner was familiar with it from patients who mentioned that they used it when dieting, and he had seen it in health food and drug stores. Dr. Willner did not know if it was effective for dieting, and agreed with Mr. Sarcone to conduct a study on spirulina.

III. Dr. Willner's Double-Blind Studies.

A. Spirulina Study

18. An agreement was memorialized by a letter dated November 20, 1981, by which Dr. Willner was employed by Clinical Testing Center, one of Mr. Sarcone's companies, as its Medical Director to test the appetite suppression qualities of Naturalean 1000, a spirulina product sold by Sarcone under the trade name

Natureslim. Dr. Willner was paid $500 per week during the month of October, 1981 to conduct the study, plus expenses and $1,000 per week beginning November 1, 1981 while the Natureslim program was marketed. He agreed that his name and photo could be used in marketing the product.

19. Dr. Willner conducted a double-blind study 3/ on spirulina using Natureslim tablets. Dr. Willner regarded spirulina as a food, not a drug, so he sought no permission for his study from the U.S. Food and Drug Administration or from the Florida Department of Health and Rehabilitative Services. He titled his report Spirulina as an Appetite Suppressant. The study was not submitted to any scientific journals. Its design was so flawed by problem such as the use of too small a number of participants to support any valid statistical inferences, that the study could not have been accepted for publication in any reputable medical journal. The design does not begin to approach the rigor of the general regulations published by the U.S. Food and Drug Administration to determine whether there is substantial evidence to support claims of effectiveness for new drugs found at 21 C.F.R. Section 130.12(a)(5), or of the study protocol later described by the FDA Advisory Review Panel on Over-the-Counter Weight Control Drug Products published at 47 Fed. Reg. 8466, 8480 (Feb. 26, 1982)

20. The subjects in the double-blind study Dr. Willner performed on spirulina were obtained through newspaper advertisements in the Miami Herald to come to Dr. Willner's medical office in Dade County. Twenty subjects responded and participated in the studies. The subjects were few because Dr. Willner's efforts were limited by funding and time considerations.

21. According to the report Dr. Willner wrote at the close of the spirulina study, subjects "were to be treated as regular office patients." Their histories were taken and physical exams were performed if Dr. Willner deemed them necessary. No written informed consent to participation in the study was obtained from the subjects.

22. All twenty participants received diets of approximately 1000 calories for four days a week and 500 calories for three days per week. They then were divided into two groups. One group received spirulina, three tablets were to be taken one-half hour before meals; the size of the tablets is undisclosed. The other group received placebos. Neither Dr. Willner nor the subjects knew who had received the spirulina. Participants filled out daily a questionnaire containing a rating scale Dr. Willner had constructed. It asked them if the pills they received stopped their hunger (value +3), modified their hunger (value +2), took the edge off their hunger (value +1), or had no noticeable effect (value -3). The subjects' answers to the questions for two weeks were summed, as was the weight loss they achieved, and the number of days they reported they actually followed the diet. The group which received spirulina lost a total of 66-1/2 pounds overall, while the placebo group only lost a total of 29-3/4 pounds. On the average, both groups of subjects said they followed the diet for about the same number of days. Those given spirulina reported a greater effect on their hunger than those who received the placebo. Dr. Willner then concluded that spirulina appeared to have a significant effect on appetite suppression if taken in the dose of three tablets one-half hour before meals.

23. The spirulina study is so weak in its methodology, due to the self-selection of the participants, the failure to establish comparability between the two groups of subjects, the failure to specify the dose of spirulina used, the uselessness of the non-continuous rating scale for summing the responses of subjects and the very small number of people involved, that it never could have been published in any reputable medical journal.

24. Dr. Willner did not consider the participants in the spirulina double-blind study to be his patients; he kept no office records for them. He did not believe he had a doctor-patient relation with them. He failed to obtain written informed consent from them to participate in the study. The report he wrote shows, however, they were to be treated as other office patients, had histories taken and in some cases were given physical examinations. They were seeing Dr. Willner for treatment for obesity, were put on a diet and followed by him. A doctor-patient relationship was established, requiring Dr. Willner to maintain records on those patients.

B. Glucomannan Study

25. In approximately April, 1983, at the request of Mr. Sarcone, Dr. Willner conducted another study, this one on glucomannan as an appetite suppressant. Apparently fad diets are short-lived, and Mr. Sarcone needed a new diet to sell by mail. Again an advertisement was placed in the Miami Herald in March, 1983 requesting volunteers. Because Dr. Willner regarded glucomannan as a food rather than a drug, no permission for the investigation was sought from the U.S. Food and Drug Administration or from the Florida Department of Health and Rehabilitative Services. According to his study report "this kind of study fell into the same kind of category as would a study on the use of bananas in checking diarrhea in children." Twenty subjects participated in the experiment. None were asked for, or gave, written informed consent to participate in the study. The participants were placed on a diet of 800 calories for three days a week and 500 calories every fourth day. They received a booklet in which to record whether they had taken their pills and followed the diet, and in which to make any subjective comments about their hunger. The amount of glucomannan taken by those who received it (as opposed to the placebo) is not stated in the study. These subjects used a different scale to evaluate their pills for appetite suppression than Dr. Willner had used in his spirulina study. In this study the scale used was: stopped hunger (value +3), modified hunger (value +2), took the edge off hunger (value +1), no noticeable effect (value 0). Although no statistical analysis is reported in the study, it states that there was an "obvious .... significant statistical difference between the effectiveness" of the glucomannan and the placebo because three of the pill "A" subjects [who received glucomannan] scored its effectiveness as 3, three scored its effectiveness as 2, two scored its effectiveness as 1, and two scored it at 0. Of the seven subjects completing the study on pill "B", one scored the effectiveness of the pill as 3, and three of the remaining six rated it at 0. Dr. Willner concluded that glucomannan "does suppress the appetite." The small number of persons involved in the study, the weakness of the study design, and the primitive method of reporting the statistical analysis of the results means that no such inference could validly be drawn from Dr. Willner's report.

26. As with the spirulina study, no written consent was obtained by Dr. Willner for experimentation on the participants, and no office records were made for these patients because Dr. Willner did not regard them as having a doctor-patient relationship with him. The doctor was wrong in this, for the subjects came to him at his medical office for treatment of their obesity, received a diet and the supposed appetite suppressant or placebo from him, and were followed by him. They had become his patients and patient records should have been kept.

27. One study on the use of glucomannon was published by David Walsh and others at 2 International Journal of Obesity 289, in July, 1983. The study was commissioned by a chain of health food stores, the General Nutrition Mills,

which sells products containing glucomannan. It is not clear whether the International Journal of Obesity is a scientific publication which subjects articles to peer review before they are accepted for publication. In this study, twenty overweight females selected from a group which had responded to a newspaper ad were placed into two groups comparable in weight and height distribution. One group took 2 capsules containing 500 milligrams of glucomannan with 8 oz. of water 1 hour before meals; the other group was given capsules containing starch to be consumed under similar instructions. All participants were told not to deviate from their previous eating and exercise patterns. According to the publication, after eight weeks the mean weight loss from the glucomannan group was 5.5 pounds, while the group receiving the starch gained 1.5 pounds.

28. Dr. Blackburn's harsh criticism of the Walsh study's conclusion that "the results support the use of glucomannan food supplement for the purpose of weight reduction" is well-founded. The number of subjects in the Walsh study is too small to permit a reader to draw any valid scientific conclusion from it. That it was conducted by a seller of glucomannan products, which provided the glucomannan for free, also clouds the study's conclusions. The study design does not meet the FDA protocol for studies of the effectiveness of anorectic drugs published at 47 Fed. Reg. 8480 (Feb. 26, 1982). The Walsh study proves nothing about the effectiveness of glucomannan as an appetite suppressant in a weight control program.

IV. Forever Thin Weight Loss Clinic

A. The Clinic

29. Frank Sarcone owns the Forever Thin Weight Loss Clinic, Inc. In spite of its name, the entity owns no clinic, rather, it is a direct marketing company. The corporate headquarters for the Clinic are in Hawaii, but orders for the diet program were processed by a fulfillment center in the State of Utah. Dr. Willner holds the title of "Program Medical Director" for the Clinic, but he has no ownership interest in it. The Clinic marketed a weight loss program known as the Forever Thin Weight Loss Diet consisting of a low calorie diet and glucomannan. Dr. Willner provided Sarcone with a diet to be used as part of the program. It is a well known diet published by the American Hospital Association. Dr. Willner also agreed to answer telephone calls from customers seeking additional information about the program. The Clinic used Dr. Willner's office in North Miami Beach as one of its addresses. The glucomannan was promoted in the program as an aid to suppress the appetite of dieters.

30. Forever Thin is the brand name Mr. Sarcone used for glucomannan.

31. To market the Forever Thin Weight Loss diet program, Mr. Sarcone identified potential buyers through industry brokers who compile lists of individuals who show an interest in purchasing weight loss products.

B. Marketing by Forever Thin Weight Loss Clinic

32. The Forever Thin Weight Loss Clinic distributed nationally a packet to potential buyers of its products which contained: 1) a cover letter bearing Dr. Willner's signature; 2) a business card bearing Dr. Willner's name and giving his address as 4357 Airport Plaza, Ogden, Utah 84403; 3) a preprinted brochure for a product called "Forever Thin"; and 4) a brief questionnaire.

33. A letter bearing Dr. Willner's signature as Program Medical Director and a medical doctor represents that:

(a) Glucomannan is a safe, natural diet product that contains absolutely no drugs, chemicals, or absorbable calories whatsoever;

(b) Glucomannan is made from a special plant that is grown only in a remote region of southern China;

(c) For thousands of year it has been safely eaten by the Chinese people and may prove to be the reason why the Chinese people are generally a thin race while enjoying one of the most widely diversified menus in the world;

(d) Only recently have unique powers of the special plant been revealed by science;

(e) A recent scientifically controlled double-blind study conducted in the United States proved the safety and effectiveness of this natural food substances clinically beyond a shadow of a doubt;

(f) The group studied was not put on any kind of low calorie restricted diet, yet the group given glucomannan lost five times the amount of weight as the group given the placebo on a pound for pound basis;

(g) The company is conducting a nation-wide test, which Dr. Willner is personally supervising, to determine the effectiveness of Forever Thin [glucomannan] when used at home without medical supervision;

(h) If the person does not wish to participate in the test, he should return the enclosed envelope unopened so that someone else could be included in the test; and

(i) The test Dr. Willner is conducting is a restricted test. The implication was that the test was a medical test.

34. Almost everything in the letter is untrue. Dr. Willner has never had an office in Utah. The letter was not sent to a specially selected group of people, but to people whose names appeared on lists Sarcone purchased from brokers. Glucomannan is not derived from a plant grown only in southern China. It has nothing to do with thinness or girth of the Chinese people. Glucomannan has no unique powers which were revealed in any scientifically controlled double-blind study. Neither the Walsh study or any other study proved the safety and effectiveness of glucomannan as a diet aid beyond a shadow of a doubt. The Walsh study provides no scientific basis for the assertion that ingesting glucomannan permits weight loss without calorie restriction. There was no test which Dr. Willner, or anyone else, was conducting; the reference to a test was part of a scheme to generate interest in the product.

35. Mr. Sarcone wrote the letter, but Dr. Willner did review it before it was distributed. Dr. Willner gave Sarcone permission to use Willner's signature in advertising materials. Dr. Willner agreed that a person reading the letter would assume that Dr. Willner had written it. According to Dr. Willner, the substance of the letter is fine. (Tr. 817).

36. The reference in the letter to a double-blind study of the safety and effectiveness of glucomannan treats glucomannan as if it were a drug.

37. The preprinted brochure contained in the envelope under cover of Dr. Willner's letter (see paragraph 32 above) contained the following misrepresentations:

> a) Forever Thin is an effective new way to lose weight quickly;
> b) When Forever Thin enters the digestive tract it first absorbs water and expands into a high viscosity jelly. This increases bulk, and gives a safe and natural feeling of fullness which controls the desire to overeat;
> c) When Forever Thin enters the small intestines it retards glucose absorption and blocks cholesterol absorption, prevents a sudden increase in blood glucose levels, reduces and absorbs the production of harmful substances, shortens the time harmful matter is in contact with the intestinal membrane and prevents constipation;
> d) If the consumer would "help" the Forever Thin Weight Loss Clinic with their testing, the clinic would give the consumer a "free" 10-day supply of Forever Thin, or pay thee consumer $5.00;
> e) Forever Thin "has proven itself extremely safe and obviously effective", and has no side effects; and
> f) Forever Thin simply does its work and then leaves the system forever.

This preprinted brochure makes claims for glucomannan that are drug claims, including that it affects the digestive functions of the body when it allegedly retards glucose absorption, retards cholesterol absorption and reduces blood glucose levels, that it is safe and effective and that it has no side effects. Glucomannan has never been approved by the U.S. Food and Drug Administration as a drug which is safe and effective for the treatment of obesity or for any other medical purpose.

V. The Ultimate Solution Diet program

38. The Ultimate Solution Diet program is a weight loss program marketed by Amerdream Corporation, which also is owned by Mr. Sarcone. Its corporate headquarters are also in Hawaii, but it received its mail in Nevada and at Dr. Willner's medical office in North Miami Beach. Inquires about its programs were directed to Dr. Willner's office in Florida. The Ultimate Solution Diet is a weight loss plan sold through the mail.

A. The Program and Its Components

39. The diet plan is based in part upon the restriction of caloric consumption. Purchasers of this program divide the week into "diet days" and "normal eating days." On diet days, the dieters consume servings of food products marketed with the program such as chicken soup, onion soup, beef soup, chocolate fiber shakes, vanilla fiber shakes, banana fiber shakes, chocolate pudding, banana pudding, vanilla pudding, dessert diet wafers, Super Energy Plus Diet Pills, containing spirulina and minerals, Eat-Less Diet Lozenges containing benzocaine, and glucomannan tablets marketed under the name of "Night Trim."

Dieters consume only about 350 calories on diet days by using the diet products provided. For example, on diet days a participant may consume a serving of pudding for breakfast, one shake made with skim milk for lunch, a serving of soup and specified vegetables for dinner, and the program's dietary supplements. The program (including the supplements) was said to provide 100% of all nutrients for which United States recommended daily allowances have been established. On normal eating days, the dieters eat a 1200 calorie diet plan and are instructed to take the program's supplements, to eat sparingly, and to follow the diet recommendations in Dr. Willner's The Pleasure Principle Diet Book. They are also encouraged to increase their exercise. When they purchase the weight loss program, dieters receive an instructional cassette tape, a nutrition manual, charts and written instructions.

40. The Super Energy Plus Diet Pills contain 500 mg. of spirulina, as well as other vitamins. The Night-Trim tablets contain 500 mg. of glucomannan.

B. Promotion of the Program

41. As the director of research for Amerdream, Dr. Willner was responsible to assist in the design of the diet program, provide nutritional advice to the company, and respond to telephone inquiries from customers. The Ultimate Solution Diet program was advertised nationwide, in newspapers and magazines, as well as through direct mail solicitations.

42. Mr. Sarcone wanted to have Dr. Willner and other doctors involved in the marketing of the Ultimate Solution Diet Program because his competitors had incorporated testimonial statements in their advertising of doctors purportedly given by boards of doctors. Mr. Sarcone needed the prestige of a similar group including medical doctors in its membership to endorse his mail order diet program to remain competitive. Dr. Willner signed a contract to become a member of what became known as the Board of Medical Advisors for Amerdream. Dr. Willner received one percent of the remittances from the mail order sales of the diet plan for the use of his name and his service as the director of research.

1. The Board of Medical Advisors

43. Dr. Willner's contract with Amerdream Corporation stated that he would be listed as a member of the corporation's Board of Medical Advisors so long as he had reviewed the sales literature and had no objections to it. Dr. Willner saw the letter distributed under the name of the Board of Medical Advisors, saw no problem with it, and signed the contract allowing his name to be used.

44. The Board of Medical Advisors apparently did little or nothing with respect to the diet program other than lending their names to it for advertising purposes. One of the members listed is a Mauricio Rubio, M.D., identified as a physician in general medicine. The only Dr. Rubio licensed in the state of Florida testified that he had nothing to do with Amerdream or the Ultimate Solution Diet Plan and never heard of it before being contacted by the Department of Professional Regulation. He had never entered into any contract with Frank Sarcone. The Dr. Rubio involved may be a doctor in Columbia. What that doctor did for the Amerdream Corporation is unclear. Dr. Gehl was also on Amerdream' Board of Medical Advisors and is identified as the Assistant Research Director. By the time of the hearing, the Board of Medical Advisors's letter still was being distributed, but Dr. Gehl had been dead for over two years. The posthumous distribution of the letter is consistent with the casual attitude to the truth reflected in the program's advertisements.

45. Another member of the Board was a Dr. Ronald Drucker, a doctor of chiropractic, who was to evaluate the diet for nutrition. After he was questioned by investigators of the Department of Professional Regulation about statements contained in the Board of Medical Advisors' letter, Dr. Drucker contacted Dr. Willner. Dr. Willner then wrote a letter to Dr. Drucker acknowledging that all Drucker had done was to review the diet to determine that the diet regimen, and the products sold as part of the program, were safe and wholesome, that Dr. Drucker had nothing to do with the content of the advertising material for the diet program and played no role in its formulation.

2. Advertisement of the Program

46. To generate interest in the Ultimate Solution Diet Program ads were purchased in newspaper throughout the United States, including south Florida. The advertisement promised to pay a $1,000 government bond to persons who would try a diet program "that cannot fail," that participants could lose weight "without ever counting a single calorie" and that the diet program was "the most natural, effective, new and safe way to lose weight and inches that has ever been announced." The ad did not mention that to qualify for the bond, it was necessary to purchase a 60-day supply of the Ultimate Solution Diet Program for $229.95. The bond purchasers would receive would not mature for twenty years. After responding to the ad, persons would receive an envelope which would include a business card from the Board of Medical Advisors, a color brochure, a test application form, a return envelope, and a letter on stationary of the Board of Medical Advisors which was signed by the five members of the Board, including Dr. Willner. Mr. Sarcone had drafted this letter also. The letter made the following representations:

(a) The letter was sent to a specially selected group of people to participate in a most unusual test;

(b) if the addressee participated in the test, the company would pay a $1,000 U.S. Government Treasury Bond for the person's efforts;

(c) the bond would be free;

(d) as doctors, Board members recognized that the major threat to health is being overweight;

(e) the Board chose the recipient to participate in the test because the person had tried at least one popular diet plan in the past;

(f) enclosed was a sealed brown envelope containing a test application as well as information based on a clinical study;

(g) the Board members "fully endorsed" the program "for its safety and effectiveness";

(h) the diet allows one to lose weight "without dieting at all in the conventional sense, such as every day following a boring regimented diet plan."

47. These representations are false, because those sent the information were not selected in a special manner, but received the advertisement because their name was contained on a list of people who had tried diet programs prepared by brokers; the offer of the $1,000 bond was deceptive in that it did not explain that the bond had a very low value unless it was held for twenty years or that recipients had to purchase almost $230 worth of products to

qualify for the "free" bond. The information contained in the sealed brown envelope was not based on any valid clinical study, but was merely advertisement material masquerading as scientific material. The members of the board of the medical advisor had no valid basis for endorsing the diet and the associated pills for their safety and effectiveness in weight loss, and the diet did require dieting in a conventional sense.

48. The color brochure asserted that

(a) the Ultimate Solution Diet Program was the most natural, effective, new and safe way to lose weight that has ever been announced;

(b) participants in the test have reported a greater amount of energy after taking the Super Energy Plus Diet pills (spirulina and minerals), which makes dieting easier;

(c) After the first week, some individuals will lose up to 35 pounds;

(d) The all natural Night Slim Diet Tablet (glucomannan) will safely stimulate natural hormone production in the body at night so that "your body actually burns up fat while "you sleep";

(e) Testing so far has produced incredible results so that it is possible for a very overweight person to lose 1 1/2 pounds of fat and fluid daily in the first seven days of the diet and in some cases dieters lost five pounds of fat and fluid in the first 72 hours;

(f) The Eat Less Diet Chewables, (benzocaine) when combined with dessert diet wafers, "safely and effectively suppresses your appetite." There is a color picture in the brochure of Dr. Willner, M.D., identifying him as Director of Research for the diet program.

49. This information was false because the Ultimate Solution Diet Program is not the most natural, effective, new and safe way to lose weight ever announced. There is no reason to believe that spirulina and minerals in the Super Energy Diet Pills would give dieters greater energy. The implication that all dieters will lose thirty five pounds on the diet is generally misleading. There is no reason to believe that glucomannan contained in the Night Slim Diet Tablets would stimulate hormone production or permit one taking the pills to burn fat while they sleep. There has been no testing of the product which produced incredible results showing that use of the pills would result in a loss of one and one-half pounds per day during the first week of the diet or five pounds of fat and fluid within seventy two hours. The use of benzocaine in the Eat Less Diet Chewables could safely and effectively suppress the appetite based upon the conclusion of the Food and Drug Administration Advisory Review Panel on Over-the-Counter Miscellaneous Internal Drug Products published at 47 Fed. Reg. 8474 (Feb. 26, 1982).

50. Also included was a letter on the letterhead of Amerdream which, in general, repeated the false representations contained in the Board of Medical Advisor's letter and the color brochure. It also included other misrepresentations, such as (a) there was a nationwide test to determine the effectiveness of the Ultimate Solution Diet Program and that once the data was collected that it would be made available through distributors nation-wide, (b) tests conducted prior to the time of the letter had been limited to closely

monitored groups, (c) if the person receiving the letter would help with the testing he would receive a $1,000 U.S. Government bond with "no gimmicks and no strings" and (d) The Ultimate Solution Diet Program had absolutely no side effects, which is a drug-type claim.

51. Despite the presence of a test card and extensive test survey booklets in the material sent to potential purchasers, no test was actually being conducted. In fact, the test number on all of the mailings was identical. This was deceptive and misleading to those who received the material, who would reasonably conclude that by purchasing the product and returning the test booklets, they were participating in a scientific test.

52. Just how much money Dr. Willner received for his association with Mr. Sarcone is unclear because Dr. Willner had no records to indicate how much he had received. He estimated he had received about $60,000 over six years from Mr. Sarcone. Mr. Sarcone was evasive about how much Dr. Willner had been paid and refused to produce records about those payments.

CONCLUSIONS OF LAW

53. The Division of Administrative Hearings has jurisdiction over this matter. Sections 120.57(1) and 120.60, Florida Statutes (1987).

54. Several of the charges made against Dr. Willner depend on the determination of whether the spirulina and glucomannan used in the double-blind studies and diet programs are drugs, which are highly regulated, or merely food, in which case Dr. Willner would have no obligation to comply with state and federal statutes and rules regulating the testing and marketing of drugs. This is a question of statutory construction involving labyrinthine statutes and rules that have their genesis in federal legislation.

I. The Regulation of Drugs by the State of Florida

55. Chapter 499, Florida Statutes, the Florida Food Act and Chapter 500, Florida Statutes, the Florida Drug and Cosmetic Act, are relevant to the decision here.

56. The Florida Food Act defines food at Section 500.03(1)(g) in the following way:

> (g) "Food" means:
> 1. Articles used for food or drink for man or other animals;
> 2. Chewing gum; and
> 3. Articles used for components of any such article. Section 500.03(1)(g), Florida Statutes.

The Florida Drug and Cosmetic Act defines "drug" as follows:

> (8) "Drug" means an agent or product:
> (a) Recognized in the official United States Pharmacopoeia, official Homeopathetic Pharmacopoeia of the United States, or official National Formulary, or any supplement thereto;
> (b) Intended for use in the diagnosis,

cure, mitigation, treatment, therapy, or prevention of disease in man or other animals;
(c) Intended to affect the structure or any function of the body of man or other animals; or
(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), but does not include devices or their components, parts, or accessories. Section 499.003(8), Florida Statutes (1985).

57. The term "new drug" means:

Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; Section 499.003(17)(a) Florida Statutes (1985).

58. Substantive Florida law provides that if a food is misbranded it may be detained or destroyed. Sections 500.11(1)(a), 500.172, Florida Statutes (1985). Similarly, any drug which is misbranded may be seized and condemned. Section 499.062, Florida Statutes (1985). A drug is misbranded if its label is false or misleading in any particular, has inadequate directions for use, or inadequate warnings about unsafe dosages. Section 499.007, Florida Statutes (1985).

59. No new drug can be sold, distributed, or given away in Florida unless a new drug application has been filed with the Secretary of the U.S. Department of Health and Human Services for the drug under section 505 of the Food, Drug and Cosmetic Act, [21 U.S.C. Section 355], Section 499.023, Florida Statutes (1985). The Florida Drug and Cosmetic Act is to be interpreted so far as practicable in conformity with the federal Food, Drug and Cosmetic Act, and in conformity with the Federal Trade Commission Act with respect to false advertisement of drugs, devices and cosmetics. Section 499.002(2), Florida Statutes (1985). The Florida Food Act is also to be administered as far as practicable in conformity with the federal Food, Drug and Cosmetic Act and the Federal Trade Commission Act to prohibit the false advertisement of food. Section 500.02(2) Florida Statutes (1985). It is therefore necessary to examine carefully the federal scheme for the regulation of drugs and food.

II. The Regulation of Drugs By the Federal Government

A. The Statutory Definition of a Drug

60. The federal Food, Drug and Cosmetic Act of 1938 provides different levels of regulation depending on whether a product is classified as a food, a drug or a cosmetic. Foods are exempt from pre-marketing review, while drugs must undergo a lengthy and expensive pre-marketing testing and review process.

United States v. An Article of Drug ... Bacto-Unidisk, 394 U.S. 784, 785, 89 S.Ct. 1410, 1411, 22 L.Ed.2d. 726 (1969). These distinctions can be highly significant to a manufacturer marketing a new product. The U.S. Supreme Court has recognized that Congress intended the definition of drug to be very broad, broader than a medical definition of the term would otherwise reach. Bacto-Unidisk, supra 394 U.S. at 798, 89 S.Ct. at 14.

61. The distinctions between a food and drug under the federal Food, Drug and Cosmetic Act can be elusive, but Congress intended that a product may be both a food and a drug.

62. The terms "food" and "drug" were defined in Section 201 of the federal Food, Drug and Cosmetic Act of 1938 as follows:

> The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. [Codified as 21 U.S.C. Section 321(f),)
> The term "drug" means (A) articles recognized in the Official United States Pharmacopoeia, Official Homoeopathic Pharmacopoeia of the United States, or Official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C); but does not include devices or their components, parts, or accessories . [Codified as 21 U.S.C. Section 321(1)(g)]

63. A food is misbranded if its label "is false or misleading in any particular," 21 U.S.C. Section 343(a)(1), and may be seized, 21 U.S.C. Section 334(a)(1). A drug is misbranded if its labeling is false or misleading in any particular, 21 U.S.C. Section 352(a), and is subject to seizure, 21 U.S.C. Section 334.

64. The third component of the definition of drug found in Section 201 of the 1938 Act [codified as 21 U.S.C. Section 321(g)(1)(C), quoted above] expanded the definition of "drug" over that found in the Pure Food and Drug Act of 1906. Because obesity was not considered a disease, weight-reduction products and compounds had escaped regulation under the 1906 act. The expansion of the definition of "drug" is explained, in part, by remarks made during the 1933 Senate Hearings on what became the Food, Drug and Cosmetic Act of 1938:

> The purpose of the drafters of this bill in the formulation of that part of this section, Mr. Chairman, was to make possible' the regulation of a great many

> products that have been found on the market that cannot be alleged to be treatments for diseased conditions. I have in mind such products as anti-fat remedies. Obesity may not be a disease. There has been lately a tendency to market products on the claim that they will have slenderizing effects. Some of these products are definitely harmful. One of those which the Federal Trade Commission undertook to control was characterized by the Supreme Court as a dangerous product. There can be no question about the necessity of the protection of public health by the extension of the provisions of this Act to cover those articles. (Food Drug, and Cosmetics Hearings before a subcommittee of the Senate Committee on Commerce on Senate Bill 1944, 73d Cong., 2d Sess. 16 (1933), reported in A Legislative History of the Federal Food, Drug and Cosmetic Act and its Amendments (F.D.A. 1979) Vol. 1, 107-08 [hereinafter Legislative History].

A similar explanation also was given during House hearings on the bill. "The primary purpose of that particular definition ... is to reach the use of fat reducers, particularly since obesity may not be a disease." Food, Drug, and Cosmetics Hearings on H.R. 6906, H.R. 8805, H.R. 8941 and S.5. before a subcommittee of the House Committee on Interstate and Foreign Commerce, 74th Cong., 1st Sess. 55 (1935), Legislative History, Vol. IV at 370. Another reference to the Congressional purpose in expanding the definition of "drug" to include obesity products was made in the 1934 Senate report, which states:

> Such expansion of the definition of the term "drug" is essential if the consumer is to be protected against a multiplicity of devices and such preparations as "slenderizers", many of which are worthless at best and some of which are distinctly dangerous to health,. [S. Rep. No. 493, 73d Cong., 2d Sess. 2 (1934)]. Legislative History, Vol. II at 722.

See also Federal Trade Commission v. Liggett and Neyers Tobacco Co., 108 F. Supp. 573 (S.D.N.Y.), aff'd., 203 F.2d 955 (2d Cir. 1952). Only slenderizers were given as examples of products which would fall within the expanded definition of drugs during the congressional debates. Hutt, Government Regulation of Health Claims in Food Labeling and Advertising, 41 Food, Drug and Cosmetic Law Journal 3, 22 (1986). Products which disrupt digestion affect the body's functioning, while products which make it thinner or leaner affect the body's structure, hence the definition of "drug" Congress enacted. Rodriguez, Cosmetic or Drug? The Minotaur's Labvrinth Revisited, 44 Food, Drug and Cosmetic Law Journal 63, 70 (1989).

65. The 1938 Act initially had a provision stating that the definitions of "food" and "drug" were not mutually exclusive, but this provision was eliminated on the grounds that it was superfluous. Nutrilab Inc. v. Schweiker, 713 F.2d 335, 336 (7th Cir. 1983); S. Rep. No. 493, 73d Cong., 2d Sess. 2 (1934), Legislative History, Vol. II at 722.

66. The Congressional debates also show an understanding that the claims made for a substance, and not its common use, determine whether a substance is a food or drug under the 1938 Act:

> The use to which the product is to be put will determine the category into which it will fall. If it is to be used only as a food, it will come within the definition of food and none other. If it contains nutritive ingredients but is sold for drug use only, as clearly shown by the labeling and advertising, it will come within the definition of drug, but not that of food. If it is sold to be used both as a food and for the prevention or treatment of disease, it would satisfy both definitions and be subject to the substantive requirement for both. The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put. For example, the manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing the article fairly and unequivocally as a drug product. S. Rep. No. 493, 73d Cong., 2d Sess. 2-3. (1934). Legislative History, Vol. II at 722-23.

67. The text of the federal Food, Drug and Cosmetic Act does not state clearly why food was exempted from subsection (C) of 21 U.S.C. Section 321(g)(1), which sweeps into the definition of "drugs" all articles intended to affect the structure or function of the body of man or other animals. According to commentators "[p]resumably, this exclusion was designed to reflect the fact that all food is intended to, and in fact does, affect the structure and function of the body." Hutt, Governmental Regulation of Claims in Food Labeling and Advertising, 41 Food, Drug, and Cosmetic Law Journal 3, 24 (1986). A similar view is expressed in Note, Food, Drug or Both?: Dual Classification under the Federal, Food, Drug and Cosmetic Act (1984) Univ. of Ill. L.R. 987, 1002. Thus even if spirulina and glucomannan are foods, they may be regulated as drugs if the distributor or manufacturer makes claims that their use will affect the structure or a function of the body.

68. Under section 505 of the Food, Drug and Cosmetic Act of 1938, as amended, a new drug cannot be introduced into interstate commerce until a new drug application is filed with the U.S. Food and Drug Administration and becomes effective, 21 U.S.C. Section 355(a). The Food and Drug Administration will not permit a new drug application to become effective unless there is "substantial

evidence" that the drug is both safe and effective 4/ for its intended use. 21 U.S.C. Section 355 (d)(1),(5). The requirements for demonstrating efficacy are rigorous, for Congress determined, after hearings, that "impressions or beliefs of physicians, no matter how fervently held, are treacherous." Weinberger v. Hynson, Westcott and Dunning, Inc., 412 U.S. 609, 619, 93 S.Ct. 2469, 2478, 37 L.Ed.2d 207 (1973); Hearings on Senate Bill 1552 before the subcommitte on Antitrust and Monopoly of the Senate Committe on the Judiciary, 87th Cong., 1st Sess. pt. 1, at 195, 285, 411-12; Legislative History, Vol. 17 at 759, Vol. 18 at 41, 166-67. Procedures for classifying over-the-counter drugs as generally recognized as safe and effective and not misbranded are found at 21 C.F.R. Section 330.10. They were not followed here. No new drug application was filed for the spirulina and glucomannan contained in the diet programs at issue here under the general investigational new drug provisions of 21 C.F.R. Part 312. Consequently, they cannot be introduced into interstate commerce as drugs and cannot be given away as drugs in Florida, Section 499.023, Florida Statutes.

B. Distributors Claims and Their Effect in Federal Drug Regulation

69. The Food and Drug Administration adopted the view early on that a food for which drug claims are made in advertising becomes a drug as well as a food. For example, honey is undoubtedly a food, but if the seller intends the retail purchaser to use it as a remedy for ailments, it has been held to fall into the 21 U.S.C. Subsection 321(g)(1)(B) definition of a drug. U.S. v. 250 Jars of U.S. Fancy Pure Honey, 218 F. Supp. 208 (E.D. Mich. 1963), aff'd., 344 F.2d 288 (6th Cir. 1965). According to that decision, the act is meant to ensnare those who prey upon the weakness, gullibility and superstition of human nature." 218 F. Supp. at 212. Courts have embraced the Food and Drug Administration's view that a product's labeling can bring what would otherwise be a food within the drug provisions of the Act. The addition of a flavoring to cigarettes, which were then sold as aids to weight reduction when smoked before meals, was held to make the cigarettes drugs which could not be sold unless an effective new drug application was filed for them with the U.S. Food and Drug Administration. U.S. vs. 354 Bulk Cartons, 178 F.Supp. 847, 853 (D. N.J. 1959). Vitamins are usually regarded as foods for special dietary use, but if therapeutic claims are made in advertising for them, they fall both within the definition of food under 21 U.S.C. Section 321(f) and of drugs under 21 U.S.C. Section 321(g)(1)(C). U.S. v. Vitasafe Formula M, 226 F.Supp. 266, 278 (D. N.J. 1964), aff'd. in relevant part and rev'd. in part, 345 F.2d 864, 867 (3d. Cir. 1965)(finding vitamins misbranded as food and drugs due to the seller's claims for them).

70. Courts have fashioned a two-prong test for determining whether the manufacturer intends the purchaser to use a product for therapeutic purposes. First, the court considers how the ignorant, unthinking or credulous consumer might understand the claim; it then asks whether the claim, as so understood, constitutes a representation that the product will affect the structure or a function of the body. U.S. v. An Article Consisting of 216 Cartoned Bottles of Sudden Change, 409 F. 2d 734, 740-42 (2d Cir. 1969); United States v. An Article of Drug Consisting of 47 Shipping Cartons, 331 F.Supp. 912, 917 (D.Md. 1971). Courts apply an objective test to determine whether therapeutic claims are made because of the difficulty inherent in determining a manufacturer's subjective' intent. National Nutritional Foods Ass'n. v. Mathews, 557 F.2d. 325, 334 (2d Cir. 1977); National Nutritional Food Ass'n. v. Food and Drug Administration, 504 F.2d 761, 789 (2d Cir. 1974), cert. denied, 420 U.S. 946 (1975). Intent may be inferred from claims made in promotional material, advertising, or from any relevant source. Id., 557 F.2d at 334.

71. The most complete analysis of the interplay between the definitions of "food" and "drug" under the federal Food, Drug and Cosmetic Act was made in litigation about the sale of starch blockers. These products were represented to inhibit the body's digestion of starch and thus to enhance weight loss programs. The Food and Drug Administration determined that these products were drugs, and declaratory judgment actions were filed to contest this decision. The first case to consider the issue was Nutrilab, Inc. v. Schweiker, 547 F.Supp. 880 (N.D. Ill. 1982) aff'd. 713 F.2d 335 (7th Cir. 1983). The district court rejected the manufacturer's arguments that starch blockers were food because they were derived from a food product (kidney beans); the court held that a product which occurs naturally or was derived from a food may still be a drug. Moreover, that an item might be regarded as a food generally does not prevent it from being regulated as a drug if used as a drug. The question is one of the intent of the manufacturer, to be determined from the promotional materials and labeling of the product. In that case, the manufacturer's materials claimed the product was "totally natural and safe" "absolutely safe and exceptionally effective... no side effects" and "tested; approved" 547 F.Supp. at 883. 5/ It also claimed that starch blockers aid in prevention of certain degenerative diseases. Such claims usually are associated with drugs, not foods. The district court therefore found that the products were drugs. The court also noted that as a product marketed to treat an overweight condition, starch-blockers might have been "foods for special dietary use," but found that they were not food because they were not marketed for taste, aroma, or nutritional value. The court of appeals affirmed. 713 F.2d at 339. It too rejected the idea that the material could not be a drug because it was derived from a food, noting that some things that are drugs clearly are derived from foods, such as caffeine and penicillin. The appellate court also rejected the manufacturer's argument that Congress intended that foods for special dietary uses (such as foods used for treating weight conditions) come solely within the statutory definition of "food" in Section 321(f) of the Food, Drug and Cosmetics Act and cannot be drugs. The Seventh Circuit found that Section 343(j) of the Act, on foods for special dietary use, merely requires that if a product is a food and purports to be for special dietary uses, it must also contain additional information on its label, lacking which it will be considered misbranded and subject to seizure. The court also observed that starch blockers were sold in the form of tablets and pills which are not consumed primarily for their taste, aroma, or nutrient-value but for their ability to block the digestion of food and aid in weight loss. The starch blockers affect a structure or function of the body by affecting digestion in people who take them, and thus were drugs under the Food, Drug and Cosmetic Act, 21 U.S.C. Section 321(g)(1)(C)

72. A second decision also found starch blockers were drugs, American Health Products Co. v. Hayes, 574 F.Supp. 1498 (S.D.N.Y. 1983), aff'd., 744 F.2d 912 (2d Cir. 1984). In this case, the Food and Drug Administration argued that starch blockers were not common foods and therefore were not exempted from the third component of the definition of a drug found in 21 U.S.C. Section 321(g)(1)(C), and that that portion of the definition of drug does not exempt a food sold with specific representations as to its physiological effects. This district court agreed with the FDA's first contention but disagreed with the second, thereby also disagreeing with the legal analysis of the Nutrilab courts. The district court's decision was affirmed by the Second Circuit on the first ground, but the Court of Appeals expressly declined to approve that portion of the district court's opinion which found that a manufacturer's claim for a specific physiologic purpose would not bring a food within the sweep of the third component of the drug definition.

73. With respect to the spirulina and glucomannan which are components in the diets at issue, the representations made by the distributor under Dr. Willner's signature make those substances drugs. When a diet program includes drugs, representations in advertisements for the program form part of the labeling for the drugs. Misrepresentations in those advertisements render the drug mislabeled and subject to seizure or to an injunction against its distribution. Cf. U.S. v. Urbuteit, 335 U.S. 355, 69 S.Ct. 112 (1948)(leaflets related to a medical device form part of the labeling of the device, false statements in the leaflets render the device misbranded and subject to seizure). See also U.S. v. Lanpar Co., 293 F.Supp. 147, 152-3 (N.D. Tex. 1968); U.S. v. CDC Capsules, 204 F.Supp. 280 (E.D.N.Y. 1962); U.S. v. Sekov Reducer, 45 F.Supp. 52 (S.D. Tex. 1942), aff'd., 139 F.2d 197 (5th Cir. 1943); but see U.S. v. Vitasafe Formula M, 226 F.Supp. 266 (D.N.J. 1964), rev'd. in part, 345 F.2d 864 (3d Cir. 1965) (undistributed literature is not labeling). Representations in the labeling of the Forever Thin diet, that the "safety and effectiveness" of Forever Thin was "clinically proven beyond a shadow of a doubt" make claims ordinarily associated with drugs, not foods. Similar claims were made about the Ultimate Solution Diet's components. These components are drugs under the Food, Drug and Cosmetics Act.

74. Moreover, the representation to potential buyers that study subjects who ingested Forever Thin's pills lost five times the weight of those taking a placebo, while no one was put on any kind of a low calorie diet, indicate that the substance, not dieting, has an effect upon the body and causes the weight loss. The representation that when the product enters the small intestines it "retards glucose absorption and blocks cholesterol absorption, prevents a sudden increase in blood glucose levels, reduces and absorbs the production of harmful substances" are drug claims. The further claim that it has no side affects reinforces this conclusion.

75. With respect to the "Ultimate Solution" diet program, the representations made that the program was safe and effective, that users report greater energy after taking the Super Energy Plus Diet pills, that the "Night Slim" diet tablets safely stimulate natural hormone production in the body at night, and that the "Night Slim" diet tablets give people the ability to "burn up fat like teenagers" are all drug claims. While food may provide energy, pills do not, unless they are affecting a structure or function of the body. The stimulation of hormone production by pills is uniquely a drug function, not the ordinary result of ingesting food. Similarly, pills that would give people the ability to "burn fat like teenagers" are not pills which contain what would ordinarily be thought of as food.

76. Spirulina and glucomannan are not generally recognized as safe and effective for suppressing appetite and causing weight loss. They are therefore new drugs under 21 U.S.C. Section 321(p)(2) and Section 499.023 Florida Statutes (1985). See generally, U.S. v. Articles of Drug ... Promise Toothpaste, 826 F.2d 564 (7th Cir. 1987)(combination of drugs which are individually recognized as safe and effective became a new drug, and required a new drug application).

C. Participation in Distribution as the Basis for Liability

77. A person may be held liable under the Food, Drug and Cosmetic Act even if he does not physically participate in the production, labeling or other act which violates the statute. It is enough if the person "stand[s] in a responsible relationship to such activity." U.S. v. Sene X. Eleemosynary, Corp. Inc., 479 F. Supp. 970, 977 (S.D. Fla. 1979). By combining with Mr. Sarcone to test the effectiveness of spirulina and glucomannan on patients at his office

and to advertise and offer these new drugs for sale while trading on his status as a medical doctor, without obtaining an effective new drug application from the Food and Drug Administration, Dr. Willner violated 21 U.S.C. Section 355 and Section 499.023, Florida Statutes. This is the predicate for finding Dr. Willner guilty of violating Section 458.331(1)(h) Florida Statutes (1985) by failing to perform a statutory obligation placed upon a physician.

III. Experimentation

78. Before the double-blind study which Dr. Willner conducted, there was no research on the effect of spirulina as an appetite suppressant. Dr. Willner says as much in his Pleasure Principle Diet book at page 208: "in view of the fact that no one, to my knowledge, has ever tested spirulina..." he therefore preformed his double-blind study on it. By using spirulina not as a food, but as a potential anorectic drug or appetite suppressant, Dr. Willner engaged in experimentation on the volunteers who came to his office. The same is true with respect to the volunteers in the glucomannan study. Under Section 458.331(1)(u), Florida Statues, a physician is subject to discipline for

> Performing any procedure or prescribing any therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed, and written consent.

79. Dr. Willner failed to obtain written consent from the 40 study volunteers, and thus violated Section 458.331(1)(u), Florida Statutes. Dr. Willner's objection that spirulina and glucomannan are used as foods, so that their use does not constitute experimentation, is too facile. It is undisputed that spirulina and glucomannan can be food. Under prevailing standards of medical practice, use of the substances as a course of treatment which is being evaluated in a double-blind study is nothing if not experimentation. The whole reason for the double-blind studies was to assess the effectiveness of those substances in enhancing weight loss. Drugs not generally recognized as safe and effective can be tested after obtaining an effective investigational new drug permit, but those using investigational new drugs on humans must inform the subjects that they are being given investigational drugs, and obtain the consent of the subjects. 21 U.S.C. Section 355(i). Dr. Willner correctly points out that the risk posed for the volunteers was slight. That is a different issue, however, from whether the studies constituted human experimentation. They did, and full, informed, and written consent was required. Note, Experimentation on Human Beings, 20 Stanford L.R. 99, 100 & n.5 (1967)(doctors engaging in cancer research involving no risk of harm to patient, but which was undisclosed, disciplined for fraud, deceit and unprofessional conduct). See also, Silva, Informed Consent in Human Experimentation, 16 Trial 37 (Dec. 1980); Woody, Legal and Ethical Concepts Involved in Informed Consent to Human Research, 18 Cal. West L.R. 50 (1981).

80. The nature of the required consent is somewhat problematic, however. Spirulina and glucomannan have no risks associated with their use, whether as food or as a potential anorectic drug. The FDA Advisory Review Panel on Over-the-Counter Miscellaneous Internal Drug Products has recognized that glucomannan is safe (though not effective) when used as an anorectic drug to achieve weight loss. 47 Fed. Reg. 8466, 8479 (Feb. 28, 1982). The greatest risk a subject

undergoes, when given one of those substances in conjunction with a diet, is that the subject loses no more weight with the substance than without it.

IV. Misrepresentation Claims

81. Anti-fat remedies long have been sources of regulatory litigation, for sellers have often made extravagant representations on which "credulous persons, eager to reduce, were entitled to rely." Reilly v. Pinkus, 338 U.S. 269, 70 S.Ct. 110, 113 (1949). The Federal Trade Commission historically has used its authority to prohibit the sale of weight-reduction products by misrepresentations. Federal Trade Commission v. Raladam Co. 316 U.S. 149, 62 S.Ct. 966 (1942).

82. It was during the same session of Congress which enacted the federal Food, Drug and Cosmetics Act that the jurisdiction of the Federal Trade Commission was expanded by the Wheeler-Lea Amendments of 1938, 52 Statutes-At-Large 111 (1938). Under that law

> Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful. Codified as 15 U.S.C. Section 45(a).

83. False or misleading labeling or advertising of food or drugs is an unfair method of competition. Under the Federal Trade Commission Act, the distinction between whether a product is a food or drug is irrelevant. A misrepresentation in labeling or advertising is all that is required. Hobbs and McCall, Health Claims -- What Food Marketers Should Know about Current FTC, NAD, State and Lanham Act Precedents, 43 Food Drug Cosmetic Law Journal 223, 225 (1988). To avoid duplication of agency efforts in regulating drugs, the federal Food and Drug Administration and the Federal Trade Commission have entered into a memorandum of understanding which provides that the Food and Drug Administration has primary jurisdiction over labeling matters, and the Federal Trade Commission has primary jurisdiction over advertising. Hobbs, Health Claims -- What Food Marketers Should Know, supra at 223; Hutt, Government Regulation of Health Claims and Food Labeling and Advertising, 41 Food, Drug and Cosmetic Law Journal 3 (1986) at 26. To remedy the same evils Congress recognized, the Florida Legislature has enacted provisions in the Florida Drug and Cosmetic Act and in the Florida Food Act requiring that both acts be administered in conformity with the provisions of the federal Food, Drug and Cosmetic Act and the Federal Trade Commission Act. See Sections 499.002(2) and 500.02(2), Florida Statutes, respectively.

84. In Department of Legal Affairs v. Rogers, 329 So.2d 257 (Fla. 1976) the Supreme Court of Florida considered whether Florida's little FTC Act, Sections 501.204 and 501.205, Florida Statutes, (1975) were unconstitutionally vague and indefinite when they adopted the broad language of the Federal Trade Commission Act, which proscribed unfair methods of competition and unfair or deceptive acts and practices in the conduct of any trade or in commerce. The Florida enactment specifically provided that "due consideration and great weight" shall be given to interpretations of the Federal Trade Commission and the federal courts in interpreting the Federal Trade Commission Act, 15 U.S.C. Section 45. Section 501.204(2), Florida Statutes, (1975). The Florida Supreme Court followed the analysis made by the Supreme Court of Washington in the State of Washington v. Reader's Digest Association, Inc., 81 Wash.2d. 259, 501 P.2d 90 (1972) and found that the statutory language was neither unfairly vague or

indefinite. Thirty years of federal implementation of the Federal Trade Commission Act had made the phrases "unfair methods of competition" and "unfair or deceptive acts or practices" sufficiently definite to allow citizens to guide their conduct. 329 So.2d at 265.

85. The Florida Supreme Court's decision in the Rogers case is significant here. The report of the U.S. Food and Drug Administration Advisory Review Panel on Over-the-Counter Miscellaneous Internal Drug Products on weight control drug products, published at 47 Fed. Reg. 8466, included a discussion of labeling claims which the panel found to be vague, misleading, or unsupported by scientific data, id. at 8476, and contrasted them with labeling claims that would be appropriate in part II, paragraph D and part III, paragraphs A, 2. and B.2 of that report. Any physician (or for that matter, any advertiser), looking for a safe harbor with respect to advertising claims for diet products or programs could tailor his advertising around those approved or disapproved statements. Dr. Willner's advertising claims exceeded those guidelines.

86. Federal decisional law on what constitutes misrepresentations in advertising is also instructive. Advertising that a weight loss program is safe, effective and medically approved when it uses a drug that has not been approved by the Food and Drug Administration as safe and effective for weight loss is deceptive, false and unfair, and violates section 5 of the Federal Trade Commission Act, 15 U.S.C. Section 45 (a). Simeon Management Corp. v. Federal Trade Commission, 579 F.2d 1137 (9th Cir. 1978). This is so even when the advertisements do not mention specifically that the weight loss program uses drugs. Id., at 1141. Consumers believe the government regulates drug use closely, and representations of safety and effectiveness "reasonably lead consumers into the mistaken belief that claims of safety and effectiveness are based" on governmental evaluations, not merely on the seller's opinion. Id. at 1145. This holding is highly persuasive authority in Florida.

87. The Court of Appeals of Maryland has considered whether statements made in advertisements for mail order diet programs violated that state's Consumer Protection Act, Section 13-301 of the Maryland Commercial Law Article, which forbids deceptive practices in a manner similar to the Federal Trade Commission Act. Consumer Protection Division v. Consumer Publishing Co., Inc., 304 Md. 731, 501 A.2d 48 (1986). The decision prohibited a seller from advertising that (1) a diet plan consists primarily of taking a pill, when the plan includes a low-calorie diet; (2) use of the plan or pill will cause weight reduction without the exercise of will power; (3) the pills will prevent hunger or excessive food consumption; (4) the pills are recent medical discoveries or have only recently been used in diet programs; (5) the pills increase the body's metabolic rate or otherwise convert fat to energy; (6) use of the plan or pills will cause weight loss for substantially all users; (7) users of the plan or pill will lose certain amounts of weight or inches of girth; (8) the pill or plan had been the subject of scientific, academic or clinical testing which proves their value in a weight loss program. 501 A.2d at 53. These material misrepresentations are strikingly similar to the representations previously found to be false or misleading in this case. Dr. Willner has argued that the representations in the advertisements prepared by Mr. Sarcone were only puffing, and similar to advertisements distributed by competing sellers of diet products or programs. The similarity to misrepresentations or deceptive statements by others does not render the advertising harmless. The misleading and deceptive impressions conveyed by the promotional material would influence a purchaser's decision to buy; indeed, that is why the statements were made. Such deceptive statements would subject Dr. Willner to an enforcement action under the Federal Trade Commission Act, Federal Trade Commission v. Colgate Palmolive Co., 380

U.S. 374, 386, 85 S.Ct. 1035, 1043 (1965) and under the Food, Drug and Cosmetics Act, U.S. vs. Article consisting of 216 Cartoned Bottles of Sudden Change, 406 F.2d 734, 740 (2d. Cir. 1969). That the federal authorities had taken no action against Dr. Willner or Mr. Sarcone is irrelevant.

88. Dr. Willner granted Mr. Sarcone the right to use Dr. Willner's name in advertising for Sarcone's diet programs, and also ceded to him the right to make claims in Dr. Willner's name. Having done so, Dr. Willner is subject to discipline for any deceptive or untrue representations Sarcone made using Dr. Willner's name. There is no reason to treat the prohibition found in Section 458.331(1)(d) of the Florida Medical Practice Act against false, deceptive or misleading advertising as having a shorter reach than the prohibitions against misleading advertising with respect to food or drug products found in Sections 499.007(1) and 500.04(5), Florida Statutes, in the federal Food, Drug and Cosmetics Act, or in the Federal Trade Commission Act.

89. The false statements in the advertising materials distributed by Mr. Sarcone under Dr. Willner's name are set out in the findings of fact. They are numerous. They are not merely statements which might be misunderstood by ignorant, unthinking or credulous consumers, but are statements meant to mislead reasonable consumers. Dr. Willner is subject to discipline for those misrepresentations.

V. SUMMARY

90. Dr. Willner is guilty of two violations of Section 458.331(1)(u), Florida Statutes by prescribing a procedure which constitutes experimentation on humans without first obtaining a full informed and written consent when he used the Natureslim spirulina and the glucomannan as drugs in conducting two double-blind studies on patients who came to his office. The substances were being used in ways which made them drugs, and because those drugs were not generally regarded as safe and effective when used in weight loss programs they were new drugs under Section 499.03(17)(a), Florida Statutes.

91. Dr. Willner had no federal or Florida investigational new drug permit on file as required by 21 U.S.C. Section 355(a) and Section 499.023, Florida Statutes when he distributed the spirulina and glucomannan in those double-blind studies. He thereby violated Section 458.331(1)(h), Florida Statutes on both those occasions.

92. The failure to obtain the written informed consents from the patients participating in the two double-blind studies constituted gross or repeated malpractice or the failure to practice medicine with the level of care, skill and treatment recognized by reasonably prudent similar physicians as acceptable under similar conditions and circumstances violated Section 458.331(1)(t), Florida Statutes. Both spirulina and glucomannan are generally recognized as safe for use as food, but neither are generally recognized as effective drugs in enhancing weight loss. Dr. Willner failed to meet applicable standards of practice when he failed to obtain written, informed consent from the study participants. Two instances of violation of the statute have been proven.

93. Dr. Willner is guilty of violating Section 458.331(1)(d), Florida Statutes, by false, deceptive or misleading advertising based on the claims made with his permission and in his name as the Medical Director for the Forever Thin Diet, and as the Research Director for the Ultimate Solution Diet. Dr. Willner must have understood the unscrupulous nature of the false or fraudulent representations made in his name in connection with those diets, as evidenced by

his own writings. He understood that Mr. Sarcone wanted to use his name in promoting the Forever Thin Diet and to use his name, along with the names of the other members of the Board of Medical Advisors, in promoting the Ultimate Solution Diet program because testimonials or endorsements from physicians such as Dr. Willner were essential to Sarcone's marketing program. Two instances of violation of the statute have been proven.

94. The statements attributed to Dr. Willner in the advertisements for the Ultimate Solution Diet also constitute deceptive, untrue or fraudulent representations in the practice of medicine in violation of Section 458.331(1)(1), Florida Statutes.

95. Dr. Willner is guilty of violation of Section 458.331(1)(n), Florida Statutes by failing to keep written medical records justifying his course of treatment on those who participated in the double-blind study on glucomannan. No portion of the administrative complaints makes a similar charge about the spinulina study. He is not guilty of a violation of this section, however, with respect to those who purchased the Ultimate Solution Diet Program. They did not come to his office, were not examined by him, and were not treated and followed by him, as were the participants in the two double-blind studies. Section 458.331(1)(n), Florida Statutes, simply does not reach Dr. Willner's action with respect to those purchasers. Similarly, he is not guilty of violation of Section 458.331(1)(u), Florida Statutes, by prescribing a procedure or therapy which, by prevailing standards of medical practice in the community is experimentation on human subjects, without having obtained full and informed written consent from all the people offered opportunity to buy the "drugs" contained in the Ultimate Solution Diet Program. Those advertising recipients were not his patients, and Section 458.331(1)(u), Florida Statutes, does not reach that conduct.

96. Dr. Willner is not guilty of violation of Section 458.331(1)(t), Florida Statutes, by gross or repeated malpractice with respect to all those who purchased the Ultimate Solution Diet Program. Those people were not his patients, so he cannot be guilty of malpractice in their care. The charges with respect to improper advertising represent the furthest reach of the disciplinary statutes in regard to those purchasers.

VI. PENALTY

97. During the hearing, the Board of Medicine argued that the appropriate penalty was revocation of licensure (Tr. 23). In its proposed recommended order, the Board recommended a maximum of a three-year suspension, a fine of $50,000 and probation. Dr. Willner's proposed recommended order contained no penalty discussion, but argued instead that Dr. Willner is guilty of no violations of the Medical Practice Act.

98. The Board of Medicine has adopted disciplinary guidelines in Rule 21M-20.001, Florida Administrative Code. Those penalties ranges are "based upon a single count violation of each provision listed; multiple counts of the violated provisions or a combination of violations may result in a higher penalty than that for a single, isolated violation." Rule 21M-20.001(1), Florida Administrative Code. As a result, the penalty guidelines are unhelpful here, for Dr. Willner is guilty of multiple violations. This is not particularly significant, for the guidelines do little more than restate the maximum penalty range available. For example, the suggested penalty for false or misleading advertising is "from reprimand to one year's suspension ... and an administrative fine from $500 to $5,000." See Clark vs. Dept. of Professional

Regulation, 463 So.2d 328 (Fla. 5th DCA 1985)(Upchurch, J. dissenting). A fine of 5,000 per count for each of Dr. Willner's ten violations is appropriate. Rule 21M-20.001(3)(c), Florida Administrative Code.

99. It is also significant that Dr. Willner made $60,000 by engaging in his course of conduct, which is an aggravating factor in assessing a penalty under Rule 21M-20.001(3)(f), Florida Administrative Code. Under Section 458.331(2)(i), Florida Statutes (1988 Supp.), the penalty for the violation of the Medical Practice Act may include a requirement to refund fees billed to and collected from patients. That is not directly applicable here, but it does reflect a legislative intention to require physicians violating the Medical Practice Act to disgorge any monetary benefit they received in connection with their misconduct. Dr. Willner has profited by at least $60,000 from his actions, which is more than the maximum fine for his violations.

100. Under Section 458.331(2)(f), Florida Statutes (1988 Supp.), the Board of Medicine has the authority to place a physician on probation for a period of time "subject to such conditions as the Board may specify including, but not limited to" education, re-examination, supervision and other conditions. It is appropriate, in addition to the $50,000 fine imposed above, to suspend the license of Dr. Willner for one year, and thereafter place his licensure on probation, subject to the special condition that Dr. Willner pay $60,000 to the Office of the Attorney General, Division of General Legal Services, which is responsible for consumer protection. See Rule 2-1.005(2)(d), Florida Administrative Code. It is appropriate to utilize the profits from false and misleading advertising to enforce the provisions of Florida law prohibiting such advertising.

RECOMMENDATION

It is recommended that Dr. Willner be found guilty of ten counts of violation of the Medical Practice Act, that he be fined $50,000, and that his license be suspended for a period of one year, and that his licensure then be placed on probation for two years subject to the special condition that he pay $60,000 to the Department of Legal Affairs, Division of General Legal Services, for use in consumer protection.

DONE and ORDERED this 7th day of June, 1989, in Tallahassee, Florida.

WILLIAM R. DORSEY, JR.
Hearing Officer
Division of Administrative Hearings
The DeSoto Building
1230 Apalachee Parkway
Tallahassee, FL 32399-1550
(904) 488-9675

Filed with the Clerk of the
Division of Administrative Hearings
this 7th day of June, 1989.

ENDNOTES

1/ Actually, Dr. Willner's book is broken into the theatrical divisions of "acts" and "scenes" instead of the more familiar divisions of chapters.

2/ The book was later published by Reward Books, a subsidiary of Prentice-Hall, Inc., after updating in 1984.

3/ In a double-blind study, some participants receive the substance being tested, while others do not. During the test period neither the participants nor the investigator know who received the substance or who received a placebo. The study evaluates the effectiveness of the substance based on measurable differences between the two groups of participants.

4/ When first enacted in 1938, the Food, Drug and Cosmetic Act focused only on whether a drug was safe. The Harris-Kefauver drug Amendments Act of 1962 added the efficacy requirement. Weinberger v. Hynson, Westcott and Dunning, Inc. 412 U.S. 609, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973). Dr. Willner's focus on the safety of spirulina and glucomannan due to their use as foods overlooks the significance of these amendments.

5/ Those claims are similar to the claims made for the diets at issue here. See findings of fact 33(a)(e), 37(e)(f), 46(g), 48(a)(f), 49.

APPENDIX

The following constitute my rulings on proposals by the Board of Medicine:

1. Covered in Finding of Fact 11.
2. Covered in Finding of Fact 4.
3. Covered in Finding of Fact 18.
4. Covered in the Conclusions of Law.
5. Covered in Finding of Fact 24.
6. Covered in Finding of Fact 29.
7. Covered in Finding of Fact 29.
8. Covered in Finding of Fact 32.
9. Covered in Finding of Fact 34.
10. Covered in Finding of Fact 33.
11. Covered' in Finding of Fact 34.
12. Covered in Finding of Fact 37.
13. Covered in Finding of Fact 37.
14. Covered in Finding of Fact 30.
15. Covered in Findings of Fact 6 and 7.
16. Covered in Finding of Fact 37.
17. Covered in Finding of Fact 43, for Dr. Willner reviewed the mail order representations to be made under his name.
18. Covered in Finding of Fact 36.
19-20. Covered in Finding of Fact 37.
21. Covered in Finding of Fact 32.
22-23. Covered in Finding of Fact 25.
24. Covered in Findings of Fact 21, 24 and 25.
25. Covered in the Conclusions of Law.
26. Covered in Finding of Fact 25.
27. Covered in Finding of Fact 42.
28. Covered in Finding of Fact 38.
29. Rejected as irrelevant.

30. Covered in Finding of Fact 39.
31-32. Covered in Finding of Fact 50.
33. Covered in Finding of Fact 46.
34. Covered in Finding of Fact 47.
35-36. Covered in Finding of Fact 50.
37. Covered in the Conclusions of Law.
38-39. Rejected as subordinate to other Findings of Fact.
40. Rejected because the persons who purchased the Ultimate Solution Diet Program were not participating in the experiments. The representation that they would be participating in a test was false.
41. Rejected because there was no experiment for which purchasers of the Ultimate Solution Diet Program needed to give informed written consent.
42. Covered in Findings of Fact 9 and 10.
43. Rejected as subordinate.
44. Covered in Findings of Fact 25 and 26.

Rulings on Proposed Findings of Dr. Willner

1-3. Covered in Finding of Fact 11.
4. Covered in Finding of Fact 12.
5. Covered in Finding of Fact 15.
6. Covered in Finding of Fact 17.
7. Covered in Finding of Fact 25.
8. Covered in Finding of Fact 20.
9. Covered in Finding of Fact 29, except for the second sentence which is rejected as unproven.
10-11. Covered in Finding of Fact 29.
12. Rejected as irrelevant.
13. The first sentence rejected because Dr. Willner reviewed the marketing literature before his name was used, and the second sentence covered in Finding of Fact 31.
14. Covered in Finding of Fact 38.
15-17. Covered in Finding of Fact 39.
18. Covered in Findings of Fact 38 and 41.
19. Covered in Finding of Fact 41.
20. Rejected as irrelevant.
21. Covered in Finding of Fact 21.
22. Rejected because the percentage of income received from his activities is not relevant.
23. Covered in Finding of Fact 3.
24. To the extent necessary, covered in Finding of Fact 3.
25. Covered in Finding of Fact 3.
26. The first clause covered in Finding of Fact 3. The second clause is rejected because even if spirulina is advertised as an aid to weight loss, it would have to be approved for use as a drug for that to be legal.
27. Rejected as irrelevant.
28. Rejected as silly, for spirulina would not be included in the Ultimate Solution Diet Program unless it contributed to weight loss, but the focus of the Ultimate Solution Diet Program is not on the plan, but on the pills, which included spirulina.
29. Rejected because the Becker abstract is too vague to support any finding.
30. Rejected, see Finding of Fact 23.
31. Rejected, see Conclusions of Law. The use of spirulina was experimentation, and written consent was statutorily required.
32. Rejected as argument, informed consent was statutorily required.
33-36. Covered in Finding of Fact 6.

37. Rejected because glucomannan was represented as a drug here.

38. Covered in Finding of Fact 6.

39. Rejected because glucomannan was promoted in a way which made it a drug, and its use in the double-blind study was experimentation which required written consent.

43. Rejected as unnecessary.

47. Rejected because, while they have some factual basis, these findings are essentially legal arguments.

48. Rejected as legally erroneous. See Conclusions of Law.

49. Rejected because common usage is not the touch-stone of whether a substance is a drug. See Conclusions of Law.

50. Rejected as argument.

51. Rejected. See Conclusions of Law.

52. Rejected because the statute requires written consent.

53. Rejected as irrelevant.

54. Rejected because the statute requires written informed consent.

55. Rejected as irrelevant and unnecessary. Both Drs. Blackburn and Ayres were sufficiently familiar with the programs to support their testimony.

56. Rejected because the statute requires written informed consent.

57. Rejected because the statute requires written informed consent.

58. Rejected because I do not accept the testimony of Mrs. Gomes that written consent was provided by study subjects.

59. Rejected because no consent forms were ever executed by the study participants. Mrs. Gomes' testimony to the contrary is unpersuasive. No written consent forms were produced at the hearing, because none ever existed.

60. Rejected because if Dr. Willner made the representation, he treated the food product as a drug; written informed consent is statutorily required.

61-64. Rejected as unnecessary.

65. Rejected as legal argument.

66. Rejected as unnecessary. See also Finding of Fact 10.

67. Rejected as unnecessary.

68. Rejected as argument.

69. Rejected as unnecessary.

70-71. Rejected as irrelevant.

72. Rejected because there is no proof that either substance is effective for use as an anorectic drug.

73. Rejected as irrelevant.

74. Rejected because the substances were used as drugs.

75. Rejected as a recitation of testimony.

76. Rejected as argument.

77. Rejected because the substance has an effect on the structure or function of the body if they are used as anorectic drugs.

78-80. Rejected as irrelevant.

81. Rejected as unnecessary.

82. Rejected because Dr. Willner did treat the patients with a diet and followed their progress.

83. Rejected because medical treatment in the form of a diet, and the use of "drugs" was provided here.

84. Rejected because the matter must be determined by objective evidence, not a licensee's after-the-fact characterization of his intent. Furthermore, the concept that payment for services is required for there to be a doctor-patient relationship is rejected. It may be customary, but it is not necessary.

85. Rejected as unnecessary.

86. Those who received advertisements did not become Dr. Willner's patients through that solicitation.

87. Rejected, those who participated in the studies were Dr. Willner's patients.

88. Rejected because Dr. Willner's actions, viewed objectively, made those study participants his patients.

89. Generally accepted, but whether Dr. Willner wrote the advertisements is not dispositive.

90. Covered in Findings of Fact 31 and 47.

91. Rejected because complaints are irrelevant.

92. Rejected because, as presented, the number's use was reasonably calculated to give the consumer the impression that a medical test was involved, not an internal test of marketing effectiveness.

93. Rejected as subordinate to the finding that Mr. Sarcone drafted the material sent out in Dr. Willner's name.

94. Rejected as argument.

95. Rejected as irrelevant.

96. Rejected as irrelevant.

97-98. Rejected as irrelevant.

99. Rejected because the advertising clearly gives the impression that the glucomannan, rather than the diet, is what is effective in promoting weight loss.

100. Rejected for the reasons given by Dr. Blackburn for criticizing the Walsh study.

101. Rejected because no nationwide test has actually been conducted. The test materials returned are useless information which have not been compiled in any way, and were never intended to be so compiled.

102. Rejected as specious.

103. Rejected because what is standard advertising practice is irrelevant. Doctors are held to a higher standard than the morals of the advertising marketplace.

104. Rejected because Dr. Willner is responsible for advertising distributed under his name.

105. Rejected because Dr. Willner had control over the use of his name in the marketing for the Ultimate Solution Diet Program.

106. Rejected as unnecessary.

107. Covered in Finding of Fact 44.

108. Implicit in Findings of Fact 43 and 44.

109. Covered in Finding of Fact 42.

110. Covered in Finding of Fact 44.

111. Rejected as unnecessary.

112. Rejected as inconsistent with my view of the evidence. Dr. Willner's involvement was significant to the programs' marketing.

113. Generally adopted in Finding of Fact 52.

114. Rejected as irrelevant.

115. Rejected as unsupported by the citations given.

116. Rejected because Dr. Blackburn was sufficiently familiar with the Ultimate Solution Diet Program to give the opinions found in his deposition.

117. Rejected as unnecessary. No finding is made that the diet program, viewed alone, is dangerous.

118. Rejected because rather than flamboyant, the ads are deceptive, misleading, and false.

119. Rejected because whether others make similar statements is no indication of whether they are forbidden under the Medical Practice Act, the Food, Drug and Cosmetics Act, or the Federal Trade Commission Act.

120. Rejected for the reasons given in the preceding ruling.

121. Rejected because the advertising is misleading.

122. Rejected because whether the material is promotional is irrelevant. Promotional material is part of labeling and if misleading, renders the food or drug misbranded, at the very least.

123. Rejected because the implication of material is misleading.

124. Rejected because the failure to specify the maturity date is designed to mislead and does mislead.

125. Rejected as argument.

126. Rejected as argument.

127. Rejected as unnecessary. Injury is not the touchstone for determining whether Dr. Willner violated the Medical Practice Act. At most, it relates to penalty.

COPIES FURNISHED:

Joel S. Fass, Esquire
626 Northeast 124th Street
North Miami, Florida 33161

Kelly Overstreet Johnson, Esquire
Post Office Drawer 1170
Tallahassee, Florida 32302-1170

Kenneth D. Easley, General Counsel
Department of Professional Regulation
1940 North Monroe Street, Suite 60
Tallahassee, Florida 32399-0729

Dorothy Faircloth, Executive Director
Department of Professional Regulation
1940 North Monroe Street, Suite 60
Tallahassee, Florida 32399-0729

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AGENCY FINAL ORDER

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DEPARTMENT OF PROFESSIONAL REGULATION
BOARD OF MEDICINE

DEPARTMENT OF PROFESSIONAL
REGULATION,

Petitioner,

DPR CASE NUMBERS: 0049222
0073220

vs

DOAH CASE NUMBERS: 86-2054, 87-1599

LICENSE NUMBER: ME 0008519

ROBERT E. WILLNER, M.D.,

Respondent.
_____/

FINAL ORDER

This cause came before the Board of Medicine (Board) pursuant to Section 120.57(1)(b)9, Florida Statutes on August 4, 1989, in Orlando Florida, for the

purposes of considering the Hearing Officer's Recommended Order, Respondent's Exceptions to the Recommended Order, and Petitioner's Response to Respondent's Exceptions (copies of which are attached hereto as Exhibits A, B, and C, respectively) in the above-styled cause. Petitioner, Department of Professional Regulation, was represented by Stepahnie A. Daniel, Attorney at Law. Respondent was present and represented by Gregory Seely and Margaret McCall, Attorneys at Law.

Upon review of the Recommended Order, the argument of the parties, and after a review of the complete record in this case, the Board makes the following findings and conclusions.

FINDINGS OF FACT

1. Findings of fact set forth in the Recommended Order are approved and adopted and incorporated herein, with the exception of the assertion in paragraph 34, "It has nothing to do with thinness or girth of the Chinese people."

2. There is competent substantial evidence to support the findings of fact by the Board.

CONCLUSIONS OF LAW

1. The Board has jurisdiction of this matter pursuant to Section 120.57(1), Florida Statutes, and Chapter 458, Florida Statutes.

2. The conclusions of law set forth in the Recommended Order are approved and adopted and incorporated herein.

3. There is competent substantial evidence to support the conclusions of law.

RULINGS ON EXCEPTIONS TO FINDINGS OF FACT

1. Respondent's Exception A.1. is REJECTED for the reasons stated in the arguments of the Petitioner.

2. Respondent's Exception A.2. is REJECTED for the reasons stated in the arguments of the Petitioner.

3. Respondent's Exception B. is REJECTED for the reasons stated in the arguments of the Petitioner.

4. Respondent's Exception C. is REJECTED for the reasons stated in the arguments of the Petitioner.

5. Respondent's Exception D. is REJECTED for the reasons stated in the arguments of the Petitioner.

6. Respondent's Exception E. is REJECTED for the reasons stated in the arguments of the Petitioner.

7. Respondent's Exception F.1. is REJECTED for the reasons stated in the arguments of the Petitioner.

8. Respondent's Exception F.2. is GRANTED. There is no competent substantial evidence in the record to support the finding, "It has nothing to do with thinness or girth of the Chinese people." Since the burden of proof is on the Petitioner, a lack of evidence by the Respondent on a point cannot be, itself, the basis for a finding of fact against Respondent.

9. Respondent's Exception F.3. is REJECTED for the reasons stated in the arguments of the Petitioner.

10. Respondent's Exception F.4. is REJECTED for the reasons stated in the arguments of the Petitioner.

11. Respondent's Exception F.5. is REJECTED for the reasons stated in the arguments of the Petitioner.

12. Respondent's Exception G.1. is REJECTED for the reasons stated in the arguments of the Petitioner.

13. Respondent's Exception G.2. is REJECTED for the reasons stated in the arguments of the Petitioner.

14. Respondent's Exception G.3. is REJECTED for the reasons stated in the arguments of the Petitioner.

15. Respondent's Exception G.4. is REJECTED for the reasons stated in the arguments of the Petitioner.

16. Respondent's Exceptions H.1. through H.3. are REJECTED for the reasons stated in the arguments of the Petitioner.

17. Respondent's Exception I.1. is REJECTED for the reasons stated in the arguments of the Petitioner.

18. Respondent's Exception I.2. is REJECTED for the reasons stated in the arguments of the Petitioner.

19. Respondent's Exception I.3. (first) is REJECTED for the reasons stated in the arguments of the Petitioner.

20. Respondent's Exception I.3. (second) through I.5. are REJECTED for the reasons stated in the arguments of the Petitioner.

21. Respondent's Exception J.1. is REJECTED for the reasons stated in the arguments of the Petitioner.

22. Respondent's Exception J.2. through J.3. are REJECTED for the reasons stated in the arguments of the Petitioner.

23. Respondent's Exception J.4. is REJECTED for the reasons stated in the arguments of the Petitioner.

RULINGS ON EXCEPTIONS TO CONCLUSIONS OF LAW

1. Respondent's Exception A.1. is REJECTED on the basis that the Hearing Officer's analysis is correct. The Board is authorized and required to rule on federal laws and rules, as well as Florida Statutes, such as Chapter 499, which set forth the requirements that licensed medical doctors must meet but which are

not within the Medical Practice Act, Chapter 458, Florida Statutes. This Exception is also REJECTED based on the reasons set forth in the Petitioner's argument.

2. Respondent's Exception A.2. is REJECTED based on the written argument of the Petitioner.

3. Respondent's Exception A.3. is REJECTED based on the Department's oral argument and its written arguments to Exceptions A.1. and A.3. to the conclusions of law.

4. Respondent's Exception B.1. is REJECTED based on the arguments set forth by Petitioner.

5. Respondent's Exception C.1. is REJECTED for the reasons stated in the oral argument by the Petitioner and the written argument by the Petitioner in response to Exceptions in C.1 in Exceptions to Findings of Fact and C.1. in Exceptions to Conclusions of Law.

6. Respondent's Exception D. is REJECTED for the reasons set forth by the Petitioner.

7. Respondent's Exception E. is REJECTED for the reasons set forth by the Petitioner.

8. Respondent's Exception F.1. is REJECTED for the reasons set forth by the Petitioner. Petitioner's reliance on the Rodgers case is misplaced because that case involved full informed consent of the patients and did not involve fraud.

9. Respondent's Exception F.2. through F.3. are REJECTED based on the reasons set forth by the Petitioner.

10. Respondent's Exception G.1. is REJECTED for the reasons set forth by the Petitioner.

11. Respondent's Exception set forth as "IV. SUMMARY" is REJECTED as cummulative. See Rule 21M-18.004, Florida Administrative Code.

RESPONDENT'S EXCEPTION TO PENALTY

1. Respondent's Exception to penalty is REJECTED.

PENALTY

Upon a complete review of the record in this case, the Board determines that the penalty recommended by the Hearing Officer be ACCEPTED and ADOPTED. WHEREFORE,

IT IS HEREBY ORDERED AND ADJUDGED that

1. Respondent shall pay an administrative fine in the amount of $50,000.00 to the Executive Director within thirty days.

2. Respondent's license to practice medicine in the State of Florida is SUSPENDED for a period of one year.

3. Upon reinstatement from suspension, Respondent's license to practice medicine in the State of Florida is placed on PROBATION for a period of two years, subject to the special condition that Respondent pay $60,000.00 to the Department of Legal Affairs Division of General Legal Services, for use in consumer protection.

This Order takes effect upon filing with the Clerk of the Department of Professional Regulation.

DONE AND ORDERED this 17th day of August, 1989.

BOARD OF MEDICINE

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FUAD S. ASHKAR, M.D.
CHAIRMAN

NOTICE OF RIGHT TO JUDICIAL REVIEW

A PARTY WHO IS ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW PURSUANT TO SECTION 120.68, FLORIDA STATUTES. REVIEW PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF A NOTICED OF APPEAL WITH THE AGENCY. CLERK OF THE DEPARTMENT OF PROFESSIONAL REGULATION AND A SECOND COPY, ACCOMPANIED BY FILING FEES PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEAL, FIRST DISTRICT, OR WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by certified mail to Robert D. Willner, M.D. , 999 N. Miami Beach Boulevard, N. Miami Beach, Florida 33162 and Joseph C. Jacobs and Margaret McCall, Attorneys at Law, P.O. Drawer 1170, Tallahassee, Florida 32302-1170, and by U.S. Mail to William R. Dorsey, Jr., Hearing Officer, Division of Administrative Hearings, The DeSoto Building, 1230 Apalachee Parkway, Tallahassee, Florida 32399-1550; interoffice delivery to Stephanie A. Daniel, Attorney at Law, Department of Professional Regulation, 1940 North Monroe street, Tallahassee, Florida 32399-0792, at or before 5:00 P.M., this 21st day of August, 1989.

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