

ROBERT J. DEL TUFO
ATTORNEY GENERAL OF NEW JERSEY

FILED

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MAR 8 1990

PAID BY THE STATE OF NEW JERSEY
ORDER TO BE FILED
OF THE SUPERIOR COURT

SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION: MONMOUTH COUNTY
DOCKET NO. C-2656-89

PETER N. PERRETTI, JR., ATTORNEY :
GENERAL OF NEW JERSEY and STATE :
BOARD OF MEDICAL EXAMINERS, :

Plaintiffs, :

v. :

RAYMOND J. SALANI, JR. and :
NUTRI-CARE HEALTH CENTER, INC., :

Defendants. :

Civil Action

SETTLEMENT ORDER

This matter was opened to the Court by Peter N. Perretti, Jr., Attorney General of New Jersey and the State Board of Medical Examiners, Linda S. Ershow-Levenberg, Deputy Attorney General, appearing. Defendants have been charged by the State with (1) engaging in the unlicensed practice of medicine in violation of N.J.S.A. 45:9-5.1 and 9-18, (2) performing unlicensed bioanalytic laboratory testing in violation of N.J.S.A. 45:9-42.28 and 45:9-42.42, (3) engaging in insurance fraud in violation of N.J.S.A. 17:33A-4a, 5a, (4) engaging in consumer fraud and (5) failing to comply with subpoenas. An interlocutory restraint *enjoining*

defendants from engaging in activities constituting the unlicensed practice of medicine was entered by the Court on March 27, 1989.

It appearing that the parties desire to settle this matter without the necessity for further proceedings and that all parties are satisfied with the terms of this settlement, and it being agreed that this settlement resolves all civil issues pertaining to conduct that occurred prior to the entry of this Order and that was raised or addressed in either the amended complaint, the appendix thereto or the within Order, and it further being agreed that no further civil actions will be initiated by the Division of Law of the State of New Jersey on behalf of the Attorney General or the agencies which administer the statutes and regulations referenced in the amended complaint, pertaining to conduct that occurred prior to the entry of this Order which was raised or addressed in the amended complaint, its appendix or this Order, and it being further acknowledged that appropriate directives have been issued by the Director of the Division of Consumer Affairs in conformance with this Order, and for good cause shown;

IT IS therefore, on this 8th day of March, 1990,

ORDERED:

1.(a) Raymond J. Salani, (hereinafter "Salani") and Nutri-Care may continue to engage in the independent practice of nutrition including assessing nutrition needs; recommending appropriate dietary regimens, nutritional support and nutrient intake; providing general information about diet, nutrition and the use of supplements, consistent with paragraphs 2 and 3; marketing

or distributing food supplements, foods, vitamins, minerals or other supplements; engaging in the explanation of the nature and use of those products; conducting community education programs to provide general information concerning nutrition and supplements; and developing, implementing and managing nutrition care systems to evaluate, modify and maintain appropriate standards of high quality in food and nutrition services, provided that such practice of nutrition conforms to the restrictions set forth in paragraphs 2 through 9 below.

1.(b) When providing general information to the public in the context of community education programs and speaking engagements, Salani shall disclose the sources of the information he relates and shall not be limited in the sources of information he relates, but he shall not knowingly conceal, suppress or omit material facts necessary to avoid the presentation of misleading information.

2. With respect to the selling or recommending of supplementation with vitamins and minerals specifically, Salani and Nutri-Care shall conform their recommendations to those set forth in the chart below, and shall not in any event exceed the lowest figure listed for a given item in the column headed "Estimated Daily Adult Oral Minimum Toxic Dose." They shall explain to the client the health risks of ingesting quantities of vitamins and minerals in excess of the U.S. Recommended Dietary Allowance ("RDA") as well as all reactions or side effects known by them to possibly occur. They shall also inform the client that the Estimated Daily Adult Oral Minimum Toxic Dose ("ESAADI") is merely an

estimate, that individual sensitivities may vary, and that an adverse reaction could occur at a significantly lower level than that in the Estimate. Additionally, they shall unambiguously inform the clients that the need and usefulness in human nutrition for quantities of vitamins and minerals in excess of the USRDA or ESAADDI have not been recognized by the Food and Drug Administration ("FDA"). They shall also obtain a signed written acknowledgement from each client (using the form attached hereto as Exhibit "A" and made a part hereof), which acknowledgement shall reiterate the oral representation and list the products recommended or sold to the client. A copy of the form shall be given to the client and the original maintained in the client's file.

Vitamin and Mineral Safety Indexes^a

Nutrient	Highest Recommended Adult Intake ^b	Source of Recommended Intake	Estimated Daily Adult Oral Minimum Toxic Dose	References
Vitamin A	5,000 IU	USRDA	25,000 to 50,000 IU	Miller and Hayes, 1982
Vitamin D	400 IU	USRDA	50,000 IU	Miller and Hayes, 1982
Vitamin E	20 IU	USRDA	1,200 IU	Miller and Hayes, 1982
Vitamin C	60 mg	RDA	1,000 to 5,000 mg	Miller and Hayes, 1982
Thiamin	1.5 mg	USRDA	300 mg	Itokawa, 1978; Miller and Hayes, 1982
Riboflavin	1.7 mg	USRDA	1,000 mg	Miller and Hayes, 1982; Rivlin, 1978
Niacin (nicotinamide)	20 mg	USRDA	1,000 mg	Miller and Hayes, 1982; Waterman, 1978
Pyridoxine	2.2 mg	RDA	2,000 mg ^c	Schaumburg et al., 1983
Folic acid	0.4 mg	USRDA	400 mg	Miller and Hayes, 1982
Biotin	0.3 mg	USRDA	50 mg	Miller and Hayes, 1982
Pantothenic acid	10 mg	USRDA	1,000 mg	Miller and Hayes, 1982
Calcium	1,200 mg	RDA	12,000 mg	Goto, 1973
Phosphorus	1,200 mg	RDA	12,000 mg	Draper and Bell, 1978
Magnesium	400 mg	USRDA	6,000 mg	Lipsitz, 1978
Iron	18 mg	USRDA	100 mg	Crosby, 1978
Zinc	15 mg	USRDA	500 mg	Lantzsch and Schenkel, 1978
Copper	3 mg	ESAADDI	100 mg	Moffitt, 1978
Fluoride	4 mg	ESAADDI	4 to 20 mg	Miller and Hayes, 1982
Iodine	0.15 mg	USRDA	2 mg	Vidor, 1978
Selenium	0.2 mg	ESAADDI	1 mg	Miller and Hayes, 1982

^aAdapted from Hatchcock, 1985.

^bFigures represent the highest published value for each nutrient, either the Recommended Dietary Allowances (RDA) (except those for pregnancy and lactation) or Estimated Safe and Adequate Daily Dietary Intakes (ESAADDI) (JRC, 1980) or the U.S. Recommended Daily Allowances (USRDA).

^cMore recent data suggest that the toxic dose of pyridoxine for some individuals is much lower. See text.

3. As to all products or their components recommended and sold which are not listed in the USRDA and ESAADDI (see chart in paragraph 2) Salani and Nutri-Care shall unambiguously inform the clients that the need and usefulness in human nutrition for the product or its components has not been recognized by the FDA and shall provide a copy of the chart in paragraph 2. In addition, Salani and Nutri-Care shall obtain a signed written acknowledgement from each client following the above oral representation (using the form attached hereto and made a part hereof), which acknowledgement shall reiterate the oral representation and list the products recommended or sold to the client. The original of the acknowledgement form shall be kept in the client's file and a copy of the form will be given to the client.

4. Notwithstanding the provisions of paragraphs 1, 2 and 3 above, Salani and Nutri-Care shall not recommend the use of supplements to any clients who tell him that they are pregnant or that they believe they may be pregnant, except with the express approval, in writing, of the patient's obstetrician-gynecologist or family physician.

5. Salani and Nutri-Care are enjoined from engaging in any of the following conduct until such time, if ever, as Salani is licensed as a physician in the State of New Jersey:

(a) Ordering or performing any bioanalytic laboratory tests for clients of his nutritional practice including but not limited to blood tests, urine tests, Live Cell analysis, crystal analysis, sublingual or saliva tests, and hair analysis.

(b) Billing for the bioanalytic lab tests listed in (a).

(c) Recommending vitamin, mineral, enzyme, tissue or food supplements for prevention of, or as a remedy for, a specific medical condition, medical symptom(s) or medical complaint(s), or making such recommendations in conjunction with a diagnosis of a client or in response to a client's personal bioanalytic lab test results, except in response to a direct referral from a plenary licensed physician or a dentist. Such referral shall be confirmed and authorized in writing within five days of its receipt. Salani and Nutri-Care shall keep a record of all such referrals and of the recommendations made in response thereto. "Condition" as used herein and elsewhere in this Order includes but is not limited to chronic fatigue syndrome, Temporomandibular Joint Dysfunction (TMJ), Premenstrual Stress Syndrome (PMS) and hypoglycemia.

(d) Advertising or otherwise representing to the public that Salani and Nutri-Care can treat or address by nutritional means (including supplements) any specific medical conditions, medical symptoms or medical complaints experienced by or previously diagnosed in prospective clients.

(e) Representing Salani as "Dr." or "doctor" in conjunction with any health-related activities of his nutritional practice including community education seminars and speaking engagements, advertising and his office practice. Salani shall instruct his employees to immediately cease

referring to him as "doctor Salani" when speaking with or in the presence of clients or prospective clients of Nutri-Care. All signs and literature posted or present in the office or its environs which describe Salani as "Dr. Salani" shall be immediately removed. Salani shall immediately notify the telephone company and any other publisher of a directory which lists Salani and the Nutri-Care service so as to ensure that future listings conform to this Order.

(f) Rendering a diagnosis of a client's medical condition or medical symptoms.

(g) Representing that the Nutri-Care program and supplements can ameliorate, or make a person free of, his or her medical symptoms or complaints.

(h) Listing a diagnosis on statements of services or billing statements, including but not limited to documents provided to clients for submission with insurance claim forms for services rendered after March 27, 1989. However, a diagnosis may be recorded on other documentation in the client's file, such as on a physician's referral, record as long as the physician who rendered the diagnosis is identified therein. A copy of that referral record may be attached to the client's billing statement to documents provided to clients for submission to insurance carriers, or to claim forms submitted by defendants directly to insurance carriers.

(i) Writing or printing or otherwise showing the name of a physician on the bills they issue for the services rendered by Salani or Nutri-Care after March 27, 1989, or on

insurance claim forms or other documents that only reflect the services Salani or his employees provide after the date of this Order.

6. Salani and Nutri-Care shall provide full advance disclosure of all costs of the Nutri-Care program recommended for a given client including all charges that will be assessed for the initial consultation, for the supplements and for services to be provided later, including ancillary services that are performed by other employees than Raymond J. Salani Jr. The duty to disclose any and all costs is a continuing obligation.

7. Salani and Nutri-Care shall maintain an accurate and detailed record (including bills for charges) of services performed for each client.

8. Salani and Nutri-Care shall not represent to clients or potential clients (e.g. in community education forums, advertising or personal consultations) that Nutri-Care's services are reimbursable by health insurance unless that individual client or potential client's specific policy provides such coverage.

9. Salani and Nutri-Care shall not advertise that Nutri-Care provides medical services, preventive medicine, or a medically-supervised program, and shall not use any other similar words to imply that medicine is being practiced.

10. If the State of New Jersey enacts legislation creating a State Board or committee to license or certify nutritionists, and Raymond J. Salani, Jr. becomes licensed or certified by said body such that any conduct prohibited herein is permitted by virtue of his license or certification, the particular prohibition shall

be inoperative to the extent that it conflicts with the licensing law.

11.(a) Salani and Nutri-Care, Inc. shall pay \$15,000 in costs for the use of the State, a portion of which shall be distributed to the persons identified on the list annexed hereto as Exhibit "B" and made a part hereof, in the amounts there indicated, without prejudice to any rights of private action held by such persons.

11.(b) The costs set forth above shall be paid to the Board of Medical Examiners, 28 West State Street, Trenton, New Jersey 08625 as follows: \$300 upon tendering of the Order, and \$300 per month thereafter, to be paid no later than the 1st day of each month.

11.(c) Documents reflecting that Raymond J. Salani, Jr., and Brian Robinson are giving the Board a mortgage on the property owned by them located at 816 3rd Street, Union Beach, New Jersey are being held in the file pending receipt by the Deputy Attorney General of documentation which establishes to the Attorney General's satisfaction the value of the property, the identity and amount of all existing encumbrances and the state of the title. If said documentation is received by March 1, 1990, and the Attorney General is satisfied that the property can support a mortgage in favor of the Board, said mortgage will be executed before March 30, 1990, in the amount of \$15,000 less payments made to date.

The cost of producing the title search, and certified photocopies of current appraisals and of lien documents secured by

the property at 816 3rd Street, Union Beach, New Jersey shall be borne by defendants.


11.(d) If the mortgage described in paragraph 11(c) is not executed by March 30, 1990, defendants may, in the alternative, tender a certified check for \$11,000 less payments made to date, by April 2, 1990. If the Board of Medical Examiners receives from defendants by April 2, 1990 said certified check for \$11,000 less payments made to date, the balance of the debt shall be deemed waived, and the monetary obligations arising under this Order shall be deemed satisfied. A short extension will be granted by plaintiffs if the Board receives prior to April 2, 1990 a request by defendants for an extension supported by formal commitment from a third party that the money will be forthcoming by a date certain within one month after April 2, 1990, and that the only reason for delay is circumstances in control of said third party, i.e., the lender's closing date later than April 2, 1990.


11.(e) If the mortgage described in section 11(c) above is not executed by March 30, 1990 and if the Board does not receive a certified check from defendants for \$11,000 less payments made to date by the April 2 or extended deadline set forth in paragraph 11(d) above, defendants shall be deemed to be in default of their obligations under this Order, and this Order may be docketed as a judgment against Raymond J. Salani, Jr. and Nutri-Care Health Center, Inc. jointly and severally upon the filing of an affidavit by the Attorney General with the clerk of the Superior Court. The amount of the judgment shall be \$15,000 less payments made to date, with interest on the judgment at 8% per annum.


12. The entry of this Order does not constitute an admission of wrongdoing on defendants' part or an admission of the truth of any of the allegations of the Amended Complaint.


Patrick J. McGann, J.S.C.

We consent to the form and entry of the within Order.


Raymond J. Salani, Jr.,
for himself and Nutri-Care Health
Center, Inc.


ROBERT J. DEL TUFO
ATTORNEY GENERAL OF NEW JERSEY
By: Linda S. Ershow-Levenberg
Deputy Attorney General
Counsel for Plaintiffs


Frank Ciesla, Esq.
Counsel for Defendants

ACKNOWLEDGEMENT

I have been informed by Raymond J. Salani, Jr., and Nutri-Care that the Food and Nutrition Board of the National Research Council has established Recommended Dietary Allowances (RDAs), which are the amounts of various vitamins and minerals considered adequate for healthy adults. I have been given a copy of this chart. I understand that the National Research Council has published a chart devised by Dr. John Hathcock concerning the safety of vitamins and minerals. I understand that this chart lists "highest recommended adult intakes" and "estimated minimum toxic doses" for various vitamins and minerals. Mr. Salani has advised me never to take more of any vitamin or mineral than he tells me is safe to take.

I understand that many of the products sold or recommended by Mr. Salani and Nutri-Care contain amounts of one or more vitamins or minerals that exceed the RDAs.

I understand that the FDA has not recognized the need or usefulness in human nutrition for quantities of vitamins and minerals that exceed the RDAs.

I understand that some of the products recommended or sold by Mr. Salani and Nutri-Care contain food extracts, herbs, animal organs and/or enzymes that are not vitamins or minerals. I understand that the FDA does not recognize any need or usefulness for these substances in a person's daily nutrition.

I understand that the products sold or recommended to me by Mr. Salani and Nutri-Care are intended for general nutritional enhancement. No one at Nutri-Care has represented that the nutritional program recommended for me can prevent, cure, or relieve any medical condition or symptom.

The Nutri-Care Health Center agrees to provide nutritional and dietary advice and educational services to facilitate the practical changes in lifestyle necessary to improve the client's nutritional state.

It is expressly understood that the Nutri-Care Health Center is providing nutritional advice only, and at no time is offering medical advice, or the diagnosis of any condition or ailment.

It is understood that nutritional products including, but not limited to vitamins, minerals, and accessory nutrients are not included in the cost of the client's program.

Name of Client

Witnessed by:

Raymond J. Salani, Jr.

Restitution to be made by the State of New Jersey
to:

1) Phoenix Mutual Ins. Co.	\$408
2) Chris Ann Brewer	\$183
3) Antoinette Fagliarone	\$56
4) Government Employees Hospital Ass'n., Inc.	\$516
5) Celia Spring	\$100
6) Pat Sepe	\$200
7) Prudential Ins. Co./Raritan Valley Group Health Division	\$224
8) Judith Ann Kozma	<u>\$100</u>

\$1,787