

Complaint

87 F.T.C.

IN THE MATTER OF

SIMEON MANAGEMENT CORPORATION, ET AL.

ORDER, OPINION, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket 8996. Complaint, Oct. 15, 1974—Final Order,* April 29, 1976*

Order requiring five independent California weight reduction clinic operators, among other things to cease failing to make conspicuous disclosure statements in advertising, and to potential purchasers that drugs used in weight reducing programs have not been approved by the Food and Drug Administration as safe and effective for weight control; drugs do not cause more attractive redistribution of weight; and treatment required adherence to a 500 calorie daily diet.

Appearances

For the Commission: *Alfred Lindeman, Harvey M. Freed and Paul D. Hodge.*

For the respondents: *Grayson & Gross*, Los Angeles, Calif., for Simeon Management Corporation, John D. Howell, Simeons Weight Clinics Foundation, Robert Van Dine, J. William Byrd and Medical Weight Loss, Inc. *Robert M. Aran*, Beverly Hills, Calif., for Darrel P. Simpson. *David L. Cunningham*, Sausalito, Calif., for Bariatric Medical Clinics Management Corporation and David L. Cunningham. *Lee Shaw*, San Diego, Calif., for Harvey J. Lobelson and Weight Reduction Medical Clinic. *Cooper & Scarpulla*, San Francisco, Calif., for C.M. Norcal, Inc., HCG Weight Clinics Foundation, Peter J. Marengo, III and Joseph Costa.

Complaint

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Simeon Management Corporation, a corporation, and John D. Howell, individually and as principal investor in Simeon Management Corporation; Simeons Weight Clinics Foundation, a corporation, and Robert Van Dine and J. William Byrd, individually and as officers of Simeons Weight Clinics Foundation; Medical Weight Loss, Inc., a corporation, and Darrel P. Simpson, individually and as an officer of Medical Weight Loss, Inc.; Bariatric Medical Clinics Management Corporation, a corporation, and David L. Cunningham, individually and as an officer of Bariatric

* Reported as corrected by Commission order dated July 7, 1976.

Medical Clinics Management Corporation; Harvey J. Lobelson, an individual doing business as Weight Reduction Medical Clinic; C. M. Norcal, Inc., a corporation, HCG Weight Clinics Foundation, a corporation, and Peter J. Marengo, III and Joseph Costa, individually and as officers of C. M. Norcal, Inc. and HCG Weight Clinics Foundation, hereinafter referred to as respondents, have violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. (A) Respondent Simeon Management Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its principal office and place of business located at 7712 Densmore Ave., Van Nuys, California.

Respondent John D. Howell is the principal investor in said corporate respondent Simeon Management Corporation, which has not yet named officers and directors or issued stock. He formulates, directs and controls the acts and practices of said corporate respondent, including the acts and practices hereinafter set forth. His business address is the same as that of said corporate respondent.

Respondent Simeons Weight Clinics Foundation is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its principal office and place of business located at 7712 Densmore Ave., Van Nuys, California.

Respondents Robert Van Dine and J. William Byrd are officers of said corporate respondent Simeons Weight Clinics Foundation. Their business address is the same as that of said corporate respondent. Said individual respondents and respondents Howell and Simeon Management Corporation cooperate and act together to bring about the acts and practices hereinafter set forth, including the operation of numerous clinics known by the name Simeons Weight Clinics Foundation located in the State of California, and by other names located elsewhere in other States in the United States.

(B) Respondent Medical Weight Loss, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of California with its principal office and place of business located at 1901 Avenue of the Stars, Suite 470, Los Angeles, California.

Respondent Darrel P. Simpson is an officer of Medical Weight Loss, Inc. Said individual respondent formulates, directs and controls the acts and practices of said corporate respondent, including the acts and practices hereinafter set forth. His business address is the same as that of said corporate respondent. He and respondent Medical Weight Loss, Inc. cooperate and act together to bring about the acts and practices

hereinafter set forth, including the operation of numerous clinics known by the name Medical Weight Loss located in the State of California and by the same name or other names located elsewhere in other States in the United States.

(C) Respondent Bariatric Medical Clinics Management Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its principal office and place of business located at 560 Battery St., San Francisco, California.

Respondent David L. Cunningham is an officer of Bariatric Medical Clinics Management Corporation. Said individual respondent formulates, directs and controls the acts and practices of said corporate respondent, including the acts and practices hereinafter set forth. His business address is 680 Beach St., San Francisco, California. He and respondent Bariatric Medical Clinics Management Corporation cooperate and act together to bring about the acts and practices hereinafter set forth, including the operation of numerous clinics known by the name Bariatric Medical Clinics located in the State of California.

(D) Respondent Harvey J. Lobelson is an individual trading and doing business under the name of Weight Reduction Medical Clinic, with his principal office and place of business located at 6505 Alvarado Rd., San Diego, California, and with numerous other clinics known by the same name located elsewhere in the State of California.

(E) Respondent C. M. Norcal, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its principal office and place of business located at 6 West Swain Rd., Stockton, California.

Respondent HCG Weight Clinics Foundation is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its principal office and place of business located at 6 West Swain Rd., Stockton, California.

Respondents Peter J. Marengo, III, and Joseph Costa are officers of C. M. Norcal, Inc. and HCG Weight Clinics Foundation. Their business address is the same as that of said corporate respondents. Said individual respondents formulate, direct and control the acts and practices of said corporate respondents, including the acts and practices hereinafter set forth. They and said corporate respondents cooperate and act together to bring about the acts and practices hereinafter set forth, including the operation of numerous clinics known by the name HCG Weight Clinics Foundation located in the State of California.

PAR. 2. Each of the respondents is engaged in the business of operating weight reduction clinics, and the advertising, offering for

sale and sale of weight reduction treatments by said clinics, which treatments are purported to produce significant loss of weight by persons who desire to lose weight. Said treatments are sometimes referred to as the "Simeon" method or "Simeons" method, and consist of five or six daily injections per week of a prescription drug, human chorionic gonadotropin (hereinafter referred to as HCG), which is a hormone derived from the urine of pregnant women, and adherence to a 500 calorie diet daily, both for a period of about four to six weeks. Said drug falls within the classification of "drug" as said term is defined in the Federal Trade Commission Act.

PAR. 3. In the course and conduct of their businesses as aforesaid, each of the respondents has disseminated and caused the dissemination of certain advertisements concerning the said reducing clinics and treatments in newspapers which are distributed by United States mails and by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, for the purpose of inducing and which are likely to induce, directly or indirectly, the purchase of said treatments including the drug HCG.

PAR. 4. Typical of such advertisements disseminated as aforesaid, but not all inclusive thereof, are the following:

SIMEON WEIGHT CLINICS FOUNDATION DECLARES WAR ON WEIGHT

MEDICALLY SUPERVISED WEIGHT LOSS

Lose weight safely, quickly and effortlessly through our proven weight reduction program developed by Medical Doctors and supervised by our Physicians and Nurses. Simeon Weight Clinics, its Doctors, Nurses and professionally trained staff, bring you a quick and safe way to melt away unwanted pounds. Start today by calling for your free consultation.

Important Facts to Know About

SIMEON Weight Clinics Foundation

- OVER 265 PROFESSIONALLY TRAINED EMPLOYEES
- OVER 17 MEDICAL DOCTORS
- OVER 75 LICENSED NURSES
- OVER 45 CLINICS IN CALIFORNIA ALONE
- TOTAL MEDICAL SUPERVISION
- APPROVED AS A THERAPY HEALTH PLAN
- NO SURGERY OR STARVATION REQUIRED
- MASTER CHARGE AND BANKAMOUNT CARD ACCEPTED
- ABSOLUTE NO CHARGE FOR CONSULTATIONS
- SUPERBLY TRAINED AND CAREFUL MONITORING

SEE OUR DOCTORS NOW

Start today by calling for your free consultation. We are now accepting new patients for our medically supervised weight reduction program.

LOSE WEIGHT UNDER STRICT MEDICAL SUPERVISION.

SIMEON
Weight Clinics
Foundation

Weekdays 8 to 7 • Saturdays 9 to 1

**CALL THE CLINIC
NEAR YOU TODAY.**

BAY AREA CLINICS

S.F. 2266 GEARY BLVD.	667-2513	REDWOOD CITY	365-4264
S.F. 656 SUTTER STREET	928-5928	SAN JOSE	267-8000
S.F. 2005 MISSION STREET	620-8461	OAKLAND	465-8845
S.F. VERA PORTAL	648-7134	EL CERRILLO	525-2342
DAILY CITY	718-8098	HAYWARD	527-6822
SAN MATEO	547-8223	SAN RAFAEL	456-5930

CALL A CLINIC IN YOUR AREA

LOSING WEIGHT IS A DOCTOR'S BUSINESS

HOW YOU CAN LOSE WEIGHT...

THROUGH A PROVEN METHOD—FAST ...



...using the safe and practical Dr. A. T. W. Simeons method of weight reduction. Expect dramatic results in just weeks. Call your nearest clinic today for a consultation at no charge. You'll also receive a copy of Dr. Simeons book,

"POUNDS AND INCHES," at no charge. Enroll in the world's largest group of Doctor owned, Doctor operated medical weight loss clinics.

Summer's here ... Special rates for groups of 6 or more

NO CONTRACTS TO SIGN...42 CLINICS OPEN IN THIS AREA

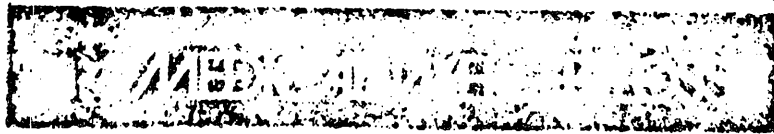


Look for the World Globe ... you'll know your at Medical Weight Loss.

SO. SAN FRANCISCO 586-7117	REDWOOD CITY 369-2935	FREMONT 786-9232
DALY CITY 894-6446	MOUNTAIN VIEW 965-4308	SAN LORENZO/ HAYWARD 228-4134
SAN CARLOS 591-9681	MILPITAS 263-8181	PETALUMA 763-4178
SAN MATEO 347-3051	CASTRO VALLEY/ SAN LEANDRO 581-5070	LOS GATOS/ SARATOGA 356-1118
MILL VALLEY 332-6560	DUBLIN 829-2424	EAST SAN JOSE 926-2737

BankAmericard or Master Charge Welcome

FOR INFORMATION CALL (415) 697-0600



Complaint

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**medical
weight®
reduction**

**NEW CLINIC
NOW OPEN
DUBLIN
829-2626**

 (C-74)

Bariatric's individual program is a safe and practical method for the entire family to lose weight and learn how to maintain proper weight ... under the strict supervision of Medical Doctors. Call for information Mon. thru Friday 8 a.m. to 6 p.m.

Bariatric Medical Clinics

OAKLAND 1419 Broadway 465-7800	SAN FRANCISCO Post & Powell 433-2333	PLEASANT HILL 1222 Contra Costa 798-7090	HAYWARD 21561 Foothill 888-8623
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14 San Francisco Chronicle Mon., June 24, 1974

6 ~~San Francisco Chronicle~~ ★★★ Tues., June 11, 1974

LOOK AT ME NOW!



**I lost 26 lbs in
6 weeks!**

"I didn't sign any contracts or take any pills! I didn't even do any exercises! Also, my husband liked the money-back guarantee! The doctors and nurses were just great! Life really changes when you slim down!"

Chris Mishak, patient.

San Jose

296-2000

South San Jose

267-3131

Los Altos/Mt. View

941-6440

San Mateo

347-9901

Redwood City

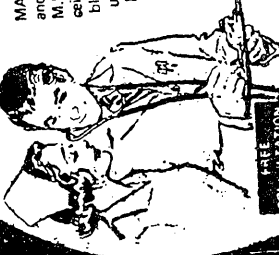
369-0333



WEIGHT REDUCTION MEDICAL CLINIC

Already helping thousands in southern California!

LOSE WEIGHT-NOW

-to look better
-to feel better
-to perform better

MANDATORY, that all examinations, tests and treatments are medically supervised by M.D., R.N.'s and L.V.N.'s. You will receive a one-time complete blood count and a blood chemistry. Also thyroid test and a urinalysis. Plus a complete computerized EKG and full physical exam given by the Doctor. This is all part of the program, before you are accepted. IT'S EASY — You'll be astounded how easy it is... Formerly available only to the very wealthy. The weight reduction plan is completely professional and now can be yours at a very modest cost. Terms are available.

CALL NOW
938-2565
1409 HUNSEY LANE
Walnut Creek



FREE
This book
with each
consultation

FEATURING
DR. A.T.W. SIMEON'S
"POUNDS & INCHES" METHOD
 ... Obesity affects 4 out of 5 families... whether you are male or female, 18 or 80, HCG Weight Clinics Foundation can improve your appearance and attractiveness - and help you stay that way!

...lose weight in weeks... you can't afford not to... and we make it easy with our new Credit Plan!

HCG Weight Clinics Foundation

Sacramento 927-2201	Modesto 521-8030
Stockton 478-5000	Walnut Creek 938-2565
Mother Lode 736-2142	

Oakland Tribune, June 16, 1973

PAR. 5. Through the use of the advertisements set forth in Paragraph Four, and others similar thereto but not specifically set forth herein, each of the respondents directly or indirectly invites and induces persons seeking to lose weight to attend its respective clinics and purchase its respective treatments to achieve this purpose. Said advertising fails to disclose the following material facts to prospective consumers:

1. The treatment offered by each respondent involves injections of the drug HCG;
2. The drug HCG is not approved by the Food and Drug Administration as safe and effective for the treatment of obesity or weight control.

Therefore, each respondent's advertisements were and are misleading in material respects and constituted, and now constitute "false advertisements" as that term is defined in the Federal Trade Commission Act; and the aforesaid advertisements were, and are, false, misleading, deceptive and unfair.

PAR. 6. The drug laws of the United States have been established by Congress to protect consumers from being subjected to certain drugs before such drugs have been approved by the Food and Drug Administration as both safe and effective for specific uses. Each respondent's advertising, promotion and marketing has the capacity to induce potentially large numbers of persons who desire to lose weight to be subjected to its respective treatments. Said treatments include numerous injections of the prescription drug HCG, which has not been approved by the Food and Drug Administration as safe and effective for the treatment of obesity or weight control, as provided for in the Federal Food, Drug and Cosmetic Act. Furthermore, the total cost of said treatments to each patient is substantial. Therefore, each respondent's advertising, promotion and marketing of a costly treatment which involves the use of a prescription drug prior to approval by the Food and Drug Administration as both safe and effective for its intended use is unfair.

PAR. 7. The aforesaid acts and practices of respondents as herein alleged, including the dissemination of "false advertisements," were and are all to the prejudice and injury of the public and constituted, and now constitute, unfair or deceptive acts or practices in violation of Sections 5 and 12 of the Federal Trade Commission Act.

INITIAL DECISION BY JOSEPH P. DUFRESNE, ADMINISTRATIVE LAW
JUDGE AS TO J. WILLIAM BYRD, MEDICAL WEIGHT LOSS, INC.,
AND DARREL P. SIMPSON JANUARY 7, 1975

PRELIMINARY STATEMENT

[2] In a complaint issued on October 15, 1974, in accord with its Rule 3.11, the Federal Trade Commission instituted a proceeding charging respondents with false, misleading, deceptive and unfair advertising for their weight reduction clinics where the "Simeon" or "Simeons" Method is used.

In the complaint it was alleged (1) that the method includes numerous injections of the prescription drug human chorionic gonadotropin (HCG) which has not been approved by the Food and Drug Administration (FDA) as safe and effective for the treatment of obesity or for weight control (complaint, Pars. Two and Six), and (2) that the total cost of the treatments per patient is substantial (complaint, Par. Six).

Therefore, it was alleged, it is unfair and violative of Sections 5 and 12 of the Federal Trade Commission Act (15 U.S.C. §§45 and 52) for respondents to advertise, promote and market their method prior to FDA approval of HCG as being both safe and effective for its use in treating either obesity or weight control (complaint, Pars. Six and Seven).

[3] Commission records show that respondent J. William Byrd received a copy of the Complaint on November 21, 1974 (pp. 9 and 10, transcript of prehearing conference). Respondents Medical Weight Loss, Inc., and Darrel P. Simpson received their copies on October 21, 1974 (p. 8, transcript of prehearing conference). However, none of these three respondents filed an answer to the complaint within the thirty (30) days allowed under Commission Rule 4.3, nor have they done so to date. The other respondents in this matter have filed answers to the allegations.

The failure by the three respondents to file an answer constitutes a waiver of their right to appear and contest the allegations. This is noted in the notice section* of the complaint (pp. 6 and 7). The same section also alerts respondents to the fact that failure to answer authorizes the administrative law judge to find the facts as alleged and to enter an initial decision (see also Commission Rule 3.12(c)).

On the basis of the allegations, it is clear that this proceeding is concerned with risks to which members of the public are exposed, particularly if they contract with respondents for obesity or weight

* Not reproduced herein.

control treatments in accord with the Simeon Method. Such proceedings are within the purview of Sections 12 and 13 of the Federal Trade Commission Act (15 U.S.C. §§ 52 and 53) which, in pertinent part, have to do with bringing an end, as promptly as possible, to the false advertising of drugs; and HCG is a drug (complaint, Par. Two).

Consequently, I am of the opinion that my initial decision in this matter, insofar as the three nonanswering respondents are concerned, should be rendered as promptly as possible, consistent with their being accorded due process. My view that the decision should be rendered as promptly as possible is buttressed by the fact that the Commission sought to obtain a preliminary injunction in the United States District Court for the Northern District of California (C74-2226 WHO) to bring an end to the offensive practices pending litigation of the allegations made in the complaint.

[4] With regard to their rights to due process, deferral of the rendition of this decision as to these three respondents until after the prehearing conference, which none of the three attended, has accorded them more than the right to due process requires. They have had ample notice both of the charges and of their opportunity to contest them. 5 U.S.C. §554(b) and (c), (formerly the Administrative Procedure Act); *United States v. San Juan Lumber Co., Inc.*, 313 F. Supp. 703 (U.S. Dist. Ct. Colo. - 1969); *Goldberg v. Kelly*, 397 U.S. 254 (1970); *Golden Grain Macaroni Company v. Federal Trade Commission*, 472 F.2d 882 (9th Cir. 1972), *cert. denied*, 412 U.S. 918 (1973).

Accordingly, complaint counsel's motion that these three respondents be declared in default and that an initial decision, conclusion and order against them should issue, which motion was made to me at the prehearing conference (p. 7, transcript of prehearing conference), is granted.

Complaint counsel's motion for a summary decision against respondents Harvey J. Lobelson and Weight Reduction Clinic (p. 44, transcript of prehearing conference) is denied because those respondents have amended their answer to deny the key charge in Paragraph Six of the complaint which formed the primary basis for that motion.

Any motions not heretofore or herein specifically ruled upon, either directly or by the necessary effect of the conclusions in the initial decision, are hereby denied. The findings of fact made herein are based on the failure to answer, on a review of the allegations made in the complaint and on an examination of the transcript of the prehearing conference which was held in San Francisco on December 2, 1974.

In accord with Rule 3.12(c), the undersigned hereby makes the following findings of fact, conclusions and order.

FINDINGS OF FACT AS TO RESPONDENTS J. WILLIAM BYRD,
MEDICAL WEIGHT LOSS, INC., AND DARREL P. SIMPSON.

(1) Respondent J. William Byrd is, or when the complaint was filed was, an officer of said corporate respondent Simeons Weight Clinics Foundation. His business address is, [5] or was, the same as that of said corporate respondent. Respondent J. William Byrd and respondents John D. Howell and Simeon Management Corporation cooperated and acted together to bring about the acts and practices hereinafter set forth, including the operation of numerous clinics known by the name Simeons Weight Clinics Foundation located in the State of California, and by other names located elsewhere in other States of the United States.

Respondent Medical Weight Loss, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of California with its principal office and place of business located at 1901 Avenue of the Stars, Suite 470, Los Angeles, California.

Respondent Darrel P. Simpson is an officer of Medical Weight Loss, Inc. Said individual respondent formulates, directs and controls the acts and practices of said corporate respondent, including the acts and practices hereinafter set forth. His business address is the same as that of said corporate respondent. He and respondent Medical Weight Loss, Inc. cooperate and act together to bring about the acts and practices hereinafter set forth, including the operation of numerous clinics known by the name Medical Weight Loss located in the State of California and by the same name or other names located elsewhere in other States in the United States.

(2) Each of the respondents is, or was, engaged in the business of operating weight reduction clinics and the advertising, offering for sale and sale of weight reduction treatments by said clinics, which treatments were and are purported to produce significant loss of weight. Said treatments are sometimes referred to as the "Simeon" or "Simeons" method, and include (a) five or six daily injections per week of HCG, which is a hormone derived from the urine of pregnant women, and (b) adherence to a 500 calorie diet daily, both for a period of about four to six weeks. HCG falls within the classification of "drug" as said term is defined in the Federal Trade Commission Act.

[6] (3) In the course and conduct of their business each of the three respondents has disseminated and caused the dissemination of certain advertisements concerning the said reducing clinics and treatments in newspapers which are distributed by United States mails and by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, for the purpose of inducing and which are

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Initial Decision

likely to induce, directly or indirectly, the purchase of said treatments including the drug HCG.

(4) Typical of such advertisements, but not all inclusive thereof, are the following:

SIMEON WEIGHT CLINICS FOUNDATION DECLARES WAR ON WEIGHT

MEDICALLY SUPERVISED WEIGHT LOSS

Lose weight safely, quickly and effortlessly through our proven weight reduction program developed by Medical Doctors and supervised by our Physicians and Nurses. Simeon Weight Clinics, its Doctors, Nurses and professionally trained staff, bring you a quick and safe way to melt away unwanted pounds. Start today by calling for your free consultation.

Important Facts to Know About

SIMEON Weight Clinics Foundation

- OVER 200 PROFESSIONALLY TRAINED EMPLOYEES
- OVER 12 MEDICAL DOCTORS
- OVER 75 LICENSED NURSES
- OVER 15 CLINICS IN CALIFORNIA ALONE
- TOTAL MEDICAL SUPERVISION
- APPROVED AS A FULLY ACCREDITED PLAN
- NO SHAMEFUL STAINLESS SURGERY
- MASTER CHARGE AND BANKAMERICAN ACCEPTED
- ABSOLUTELY NO CHARGE FOR CONSULTATIONS
- 12 WEEKS OF TREATMENT, NO TWO CLASSES MONTHLY

SEE OUR DOCTORS NOW

Start today by calling for a free consultation. We will tell you if you are a good candidate for our medically supervised weight reduction program.



LOSE WEIGHT UNDER STRICT MEDICAL SUPERVISION.

**SIMEON
Weight Clinics
Foundation**

Weekdays 8 to 7 • Saturdays 9 to 1

**CALL THE CLINIC
NEAR YOU TODAY.**

BAY AREA CLINICS

S.F. 2266 GEARY BLVD.	587-2543	REDWOOD CITY	365-4264
S.F. 655 SUTTER STREET	622-6008	SAN JOSE	267-8600
S.F. 2065 MISSION STREET	626-4461	OAKLAND	465-5845
S.F. WEST PORTAL	606-7154	EL CERRITO	525-2342
DALY CITY	798-0075	HAYWARD	537-6822
SAN MATEO	347-0213	SAN RAFAEL	456-5930

CALL A CLINIC IN YOUR AREA

Datebook, Sunday, June 23, 1974
S. F. Sunday Examiner & Chronicle

Page 20—S.F. Examiner ☆☆ Wed., June 19, 1974

LOSING WEIGHT IS A DOCTOR'S BUSINESS

NOW YOU CAN LOSE WEIGHT...

THROUGH A PROVEN METHOD—FAST ...



...using the safe and practical Dr. A. T. W. Simeons method of weight reduction. Expect dramatic results in just weeks. Call your nearest clinic today for a consultation at no charge. You'll also receive a copy of Dr. Simeons book, "POUNDS AND INCHES," at no charge. Enroll in the world's largest group of Doctor owned, Doctor operated medical weight loss clinics.

Summer's here ... Special rates for groups of 6 or more

NO CONTRACTS TO SIGN...42 CLINICS OPEN IN THIS AREA



Look for the World Globe ... you'll know your at Medical Weight Loss.

SO. SAN FRANCISCO 588-7117	REDWOOD CITY 369-2935	FREMONT 796-9232
DALY CITY 994-6446	MOUNTAIN VIEW 965-4300	SAN LORENZO/ HAYWARD 278-4114
SAN CARLOS 591-9681	MILPITAS 263-8181	PETALUMA 763-4178
SAN MATEO 347-3051	CASTRO VALLEY/ SAN LEANDRO 581-5070	LOS GATOS/ SARATOGA 356-1118
MILL VALLEY 332-6560	DUBLIN 829-2424	EAST SAN JOSE 926-2737

BankAmericard or Master Charge Welcome

FOR INFORMATION CALL (415) 697-6600

MEDICAL WEIGHT LOSS

[9] (5) Through the use of the advertisements set forth in Paragraph Four, and others similar thereto but not specifically set forth herein, each of the three respondents directly or indirectly invited and induced persons seeking to lose weight to patronize their clinics and to purchase the Simeon method of treatment. Said advertising, however, fails to disclose the following material facts to prospective consumers:

1. The treatment offered by each of the three respondents involves injections of the drug HCG;

2. The drug HCG is not approved by the Food and Drug Administration as safe and effective for the treatment of obesity or weight control.

Therefore, each of the three respondents' advertisements were and are misleading in material respects and constituted, and now constitute "false advertisements" as that term is defined in the Federal Trade Commission Act; and the aforesaid advertisements were, and are, false, misleading, deceptive and unfair.

(6) The drug laws of the United States were established by Congress to protect consumers from being subjected to certain drugs before such drugs have been approved for specific uses. Each of the three respondents' advertising, promotion and marketing has the capacity to induce potentially large numbers of persons who desire to lose weight to purchase and undergo the three respondents' respective treatments. The treatments include numerous injections of the prescription drug HCG, which has not been approved by the Food and Drug Administration as safe and effective for the treatment of obesity or weight control, as provided for in the Federal Food, Drug and Cosmetic Act (21 U.S.C. §321). Furthermore, the total cost of said treatments to each patient is substantial. Therefore, each of the three respondents' advertising, promotion and marketing of a costly treatment which involves the injection into persons of a prescription drug prior to approval by the Food and Drug Administration as both safe and effective for its intended use is unfair.

[10] (7) The aforesaid acts and practices of the three respondents including the dissemination of "false advertisements," were and are all to the prejudice and injury of the public and constituted, and now constitute, unfair or deceptive acts or practices in violation of Sections 5 and 12 of the Federal Trade Commission Act.

CONCLUSIONS

1. The Federal Trade Commission has jurisdiction of and over respondents and the subject matter of this proceeding.

2. The complaint herein states a cause of action, and this proceeding is in the public interest.

3. The acts and practices charged in the complaint took place in commerce as "commerce" is defined in the Federal Trade Commission Act.

4. The three respondents have engaged in unfair or deceptive acts and practices in commerce in that they have disseminated false and misleading advertisements in violation of Sections 5 and 12(a) of the Federal Trade Commission Act (15 U.S.C. §§45 and 52).

ORDER

It is ordered, That respondents J. William Byrd, individually and as an officer of Simeons Weight Clinics Foundation, a corporation, Medical Weight Loss, Inc., a corporation, its successors and assigns and its officers, and Darrel P. Simpson, individually and as an officer of Medical Weight Loss, Inc., respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the offering for sale, sale or distribution of the "Simeon" or "Simeons" method for weight reduction or of any other weight reducing service or treatment, do forthwith cease and desist from:

[11] 1. Disseminating, or causing the dissemination of any advertisement, by means of the United States mails, or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act, promoting any service or treatment which involves the use of HCG or any other drug required under the Federal Food, Drug and Cosmetic Act to be approved by the Food and Drug Administration (FDA) as both safe and effective for the treatment of the conditions for which it is to be used, until such drug has received the required FDA approval.

2. Disseminating, or causing to be disseminated, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of any such weight reducing service or treatment in commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which fails to comply with the requirements of paragraph 1 hereof.

It is further ordered, That each of the three respondents is to deliver a copy of this order to cease and desist to all persons now engaged, or who become engaged, in the management, [12] advertising, promotion, or marketing of weight reducing treatments as their agents, salesmen, representatives, or employees and to secure from each of said persons a signed statement acknowledging receipt of a copy thereof.

It is further ordered, That the corporate respondent Medical Weight Loss, Inc. is to notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent, such as dissolution,

Initial Decision

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assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, licensees, or franchisees, or any other change in the corporation which may affect compliance obligations arising out of this order.

It is further ordered, That each of the individual respondents named herein is to promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment. Such notice shall include his current business address and a statement as to the nature of the business or employment in which he is engaged as well as a description of his duties and responsibilities.

INITIAL DECISION BY JOSEPH P. DUFRESNE, ADMINISTRATIVE LAW
JUDGE JUNE 18, 1975

PRELIMINARY STATEMENT

[2] In a complaint dated October 15, 1974, the Commission charged respondents with violations of Sections 5 and 12 of the Federal Trade Commission Act (15 U.S.C. §§45 and 52).

[3] The gravamen of the charges was that respondents' advertising in newspapers distributed by the United States mails and various other means in commerce invited and induced persons seeking to lose weight to attend their clinics and to purchase treatments without disclosing in the advertising that the treatments used, *i.e.*, the Simeon or Simeons method, involve injections of the drug, human chorionic gonadotropin (HCG).

It also was alleged that HCG has not been approved by the Food and Drug Administration (FDA) as safe and effective for the treatment of obesity and weight control, that the advertisements were misleading in material respects in that they failed to disclose lack of FDA approval, constituted "false advertisements" and were, and are, misleading, deceptive and unfair.

Lastly, it was alleged that it is unfair for respondents to promote and market a costly treatment involving use of HCG—a prescription drug—prior to its approval by the Food and Drug Administration as safe and effective for its intended use by respondents in treating obesity and weight control.

After issuance of the complaint and prior to the start of the adjudicative hearings on the charges, counsel for the Commission sought a preliminary injunction in the United States District Court for the Northern District of California (No. C-74-225 WHO) to enjoin, pending the completion of the Commission proceedings, the dissemination by respondents of the advertisements alleged to be false and

misleading. In a memorandum opinion dated March 11, 1975, the court declined to issue the injunction.

Three of the respondents named in the Commission's complaint (J. William Byrd, individually and as an officer of Simeons Weight Clinics Foundation; Medical Weight Loss, Inc.; and Darrel P. Simpson, individually and as an officer of Medical Weight Loss, Inc.) did not answer the complaint. Consequently, an initial decision predicated on their default was filed by me on January 7, 1975, in accord with Commission Rule 3.12(c). By order dated March 7, 1975, the Commission stayed the effective date of that initial decision until its further order issues.

[4] The remaining respondents (*i.e.*, those listed in the caption hereof) answered in timely fashion. In addition to denying that they were violating Sections 5 and 12 of the Federal Trade Commission Act, various defenses were asserted. These defenses, in essence, were that: (1) This matter lies within the jurisdiction of the Food and Drug Administration rather than the Federal Trade Commission; (2) The advertisements are not violative of Sections 12 and 15 of the F.T.C. Act because (a) it is not customary or usual for a doctor to advertise the use of HCG, (b) it is customary and usual for a doctor to use HCG for weight control purposes, and (c) it is not customary to tell a patient that HCG has approval for other purposes but not for weight control; (3) California law precludes a finding of violation of the Federal Trade Commission Act in that California's Knox-Mills Act regarding prepaid medical plans, under which respondents are registered, calls for submittal of advertisements to the Attorney General of the State, and prohibits their use if disapproved by him. Respondents' advertisements have not been disapproved; (4) The treatments are administered by medical doctors and the Federal Trade Commission has no jurisdiction to interfere with the doctor-patient relationship; (5) No "sale" of the drug HCG takes place within the meaning of Section 12 of the F.T.C. Act; (6) HCG is safe and not harmful as used by respondents; (7) A substantial number of doctors in the United States have used HCG as an integral part of their weight reduction programs for a substantial period of time and the failure of the F.T.C. to challenge such use has estopped the Commission "* * *" from prosecuting this action based on the doctrine of laches;" and (8) HCG is exempt from the new drug requirements of the Federal Food, Drug and Cosmetic Act (FFDCA). Each of these defenses is addressed below in this initial decision.

Complaint counsel and counsel for Norcal, et al., filed cross motions for summary decision on January 27 and February 4, 1975, respectively. These were denied by me on February 10, 1975. Complaint counsel's

request for reconsideration was also denied in an order issued on February 21, 1975.

[5] Adjudicative hearings were held in San Francisco and Los Angeles, California, on February 25, 26 and 27, and March 6 and 7, 1975, respectively. The record was closed for the reception of evidence on March 24, 1975. Thereafter, in accord with Commission Rule 3.46, proposed findings, conclusions and order, together with reasons and briefs in support thereof were filed by the parties on May 9, 1975.

The findings of fact made herein are based on a review of the allegations made in the complaint, respondents' answers, stipulations entered by counsel, written admissions by respondents, the evidentiary record of this matter and upon consideration of the demeanor of the witnesses at the hearings in this proceeding. In addition, the proposed findings of fact, conclusions and order, together with reasons and briefs in support thereof, which have been filed by the parties, have been given careful consideration. To the extent not adopted by this decision in the form proposed or in substance, they are rejected as not supported by the record or as immaterial.

References to the record are intended to serve as guides to the testimony, evidence and exhibits supporting the findings of fact. They do not necessarily represent complete summaries of the evidence considered in arriving at such findings. The following abbreviations have been used:

CX — Commission's Exhibit, followed by number of exhibit being referenced.

RX — Respondents' Exhibit, followed by number of exhibit being referenced.

Tr. — Transcript, preceded by the name of the witness testifying and followed by the page number being referenced. [6]

FINDINGS OF FACT

1. RESPONDENTS' IDENTITIES

(A) Respondent Simeon Management Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its principal office and place of business located at 7712 Densmore Ave., Van Nuys, California. The corporation has not yet named officers and directors or issued stock.

Respondent John D. Howell is the principal investor in Simeon Management Corporation. He formulates, directs and controls the acts and practices of said corporate respondent, including the acts and practices set forth in the complaint. His business address is the same as that of said corporate respondent.

Respondent Simeons Weight Clinics Foundation is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its principal office and place of business located at 7712 Densmore Ave., Van Nuys, California.

Respondent Robert Van Dine is an officer of corporate respondent Simeons Weight Clinics Foundation. His business address is the same as that of said corporate respondent. He and respondents Howell and Simeon Management Corporation cooperate and act together to bring about the acts and practices set forth in the complaint, including the operation of numerous clinics known by the name Simeons Weight Clinics Foundation located in the State of California, and by other names located elsewhere in other States in the United States. (All the findings in (A) were admitted since these facts were set forth in the complaint but Simeon did not address them in its answer. See Commission Rule 3.12(b)(1)(ii).)

[7] (B) Respondent Bariatric Medical Clinics Management Corporation (Bariatric) is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its principal office and place of business located at 560 Battery St., San Francisco, California.

Respondent David L. Cunningham is an officer of Bariatric Medical Clinics Management Corporation. He formulates, directs and controls the acts and practices of said corporate respondent, including the acts and practices set forth in the complaint (Cunningham, Tr. 102); however, he does not personally engage in any practices that may be regarded as medical treatment (Bariatric Answer p. 2; Cunningham, Tr. 108). His business address is 680 Beach St., San Francisco, California. He and respondent Bariatric cooperate and act together to bring about the acts and practices set forth in the complaint, including the operation of numerous clinics known by the name Bariatric Medical Clinics located in the State of California (Bariatric Answer, p. 2; Cunningham, Tr. 102).

(C) Respondent Harvey J. Lobelson (Lobelson) is an individual trading and doing business under the name of Weight Reduction Medical Clinic, with his principal office and place of business located at 6505 Alvarado Rd., San Diego, California. He also operates numerous other clinics known by the same name located elsewhere in the State of California (Lobelson Answer, p. 1).

(D) Respondent C. M. Norcal, Inc. (Norcal) is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its principal office and place of business located at 6 West Swain Rd., Stockton, California (Norcal Answer, p. 2).

[8] Respondent HCG Weight Clinics Foundation is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its principal office and place of business located at 6 West Swain Rd., Stockton, California (Norcal Answer, p. 2).

Respondents Peter J. Marengo, III, and Joseph Costa are officers of C. M. Norcal, Inc. and HCG Weight Clinics Foundation. Their business address is the same as that of said corporate respondents (Norcal Answer, p. 2).

Other than those activities related to the doctor-patient relationship (Norcal Answer, p. 2), the individual respondents Marengo and Costa formulate, direct and control the acts and practices set forth in the complaint. These include the operation of numerous clinics known by the name HCG Weight Clinics Foundation located in the State of California (Norcal Answer, p. 2).

2. RESPONDENTS' ACTIVITIES

(A) Each of the respondents is involved in the business of operating weight reduction clinics, and in the advertising, offering for sale and sale of weight reduction treatments by the clinics, which treatments are designed to produce significant loss of weight through use of the Simeon or Simeons method (complaint Par. 2, respondents Simeon, et al. Answer, Commission Rule 3.12(b)(1)(ii); Cunningham, Tr. 102, 108, 110-111; Lobelson Answer, pp. 1-2; Norcal Answer, p. 2).

(B) Respondents' weight reduction treatments are not unreasonably "costly." Their cost is comparable to physicians' charges for office visits for medical attention of various types including other weight reduction treatments (Parker, Tr. 658-659; Polsky, Tr. 669-670).

Simeons Clinics charge patients anywhere from \$188 to \$368 or more per set of treatments (Simeon Stipulations #4). HCG Weight Clinics charge from \$195 to \$395 or more, with the average cost having been calculated to be \$302 (Norcal Stipulations #4). Weight Reduction Medical Clinic's charges to patients are \$170 for 23-shot treatments and \$240 for 40-shot treatments (Lobelson Requests for Admissions and Responses #4). Bariatric's clinics charge \$165-\$170 per set of six-week treatments (Tr. p. 98). [9]

3. THE SIMEON(S) METHOD (CX's 1-3)

The "Simeon" or "Simeons" method is followed in the treatments respondents advertise. That method includes five or six injections per week, one injection per visit, for from four to six weeks, of human chorionic gonadotropin (HCG), a prescription drug. HCG is a hormone

derived from the urine of pregnant women and is a "drug" as that term is defined in the Federal Trade Commission Act (15 U.S.C. §55(c)). The method also calls for adherence to a 500 calorie a day diet (CX 22; Respondents Simeon, et al. Answer, Commission Rule 3.12(b)(1)(ii); Bariatric et al. Answer, p. 2; Lobelson et al. Answer, p. 2; Norcal Answer, p. 2).

(Note: Pursuant to Commission Rule 3.15, in order to make it clear that the Simeon(s) method is not limited absolutely merely to five or six injections per week, on a daily basis, of HCG, and a 500 calorie a day diet, both for a period of about four to six weeks, at a prehearing conference on December 2, 1974, the words "consist of" were deleted and "include" was substituted in paragraph two of the complaint with the agreement of both sides (Tr. 31-35).)

4. THE COMMISSION'S JURISDICTION

Each of the respondents has disseminated and caused the dissemination of advertisements concerning the reducing clinics and treatments (admitted in each respondent's Answer). These have appeared in newspapers of intra and interstate circulation. In addition, each respondent except Bariatric has advertised on television (Simeon Stipulation, Norcal Stipulation and Lobelson Stipulation).

[10] The newspapers in which their advertisements were placed have interstate circulations, *e.g.*, *The San Francisco Chronicle*, *The Los Angeles Times* and *The Sacramento Bee* (Simeon, Lobelson and Norcal Stipulations and/or Admissions). Similarly, the television stations over which each but Bariatric advertised are interstate in range.

In addition, respondents, in the course of operating the weight reduction clinics, purchase HCG from drug manufacturers located throughout the United States and have it shipped to their receiving points for distribution to the clinics at which it is injected into persons who have subscribed for the course of treatments. Therefore, respondents are "in commerce" within the meaning of the Federal Trade Commission Act (Marengo, Tr. 397-398).

5. ADVERTISEMENTS USED

Typical advertisements each of the respondents has disseminated follow on pages 10a-10d. Each of the advertisements was disseminated by a different respondent; however, they are sufficiently alike in their representations and omissions to be considered and discussed together (see page 11, *infra*).

SIMEON WEIGHT CLINICS FOUNDATION DECLARES WAR ON WEIGHT

MEDICALLY SUPERVISED WEIGHT LOSS

Lose weight safely, quickly and effortlessly through our proven weight reduction program developed by Medical Doctors and supervised by our Physicians and Nurses. Simeon Weight Clinics, its Doctors, Nurses and professionally trained staff, bring you a quick and safe way to melt away unwanted pounds. Start today by calling for your free consultation.

Important Facts to Know About

SIMEON Weight Clinics Foundation

- OVER 200 PROFESSIONALLY TRAINED EMPLOYEES
- OVER 17 MEDICAL DOCTORS
- OVER 75 LICENSED NURSES
- OVER 45 CLINICS IN CALIFORNIA ALONE
- TOTAL MEDICAL SUPERVISION
- APPROVED AS A PREPAID HEALTH PLAN
- NO GIMMICKS OR STRENUOUS EXERCISE
- MASTER CHARGE AND BANQUAMERICA ACCEPTED
- ABSOLUTELY NO CHARGE FOR CONSULTATIONS
- SUCCESSFULLY TREATING THOUSANDS MONTHLY

SEE OUR DOCTORS NOW

Start losing weight safely, quickly and without strenuous exercise through our proven weight reduction program.



LOSE WEIGHT UNDER STRICT MEDICAL SUPERVISION.

SIMEON Weight Clinics Foundation

Weekdays 8 to 7 • Saturdays 9 to 1

**CALL THE CLINIC
NEAR YOU TODAY.**

BAY AREA CLINICS

S.F. 2266 GEARY BLVD.	567-2543	REDWOOD CITY	365-4264
S.F. 655 SUTTER STREET	928-5888	SAN JOSE	267-8600
S.F. 2065 MISSION STREET ...	626-3461	OAKLAND	465-5845
S.F. WEST PORTAL	665-7034	EL CERRITO	525-2342
DALY CITY	756-0406	HAYWARD	537-6822
SAN MATEO	347-8223	SAN RAFAEL	456-5930

CALL A CLINIC IN YOUR AREA

S. F. Sunday Examiner & Chronicle Datebook, Sunday, June 23, 1974

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**medical
weight®
reduction**

**NEW CLINIC
NOW OPEN
DUBLIN
829-2626**



Bariatric's individual program is a safe and practical method for the entire family to lose weight and learn how to maintain proper weight ... under the strict supervision of Medical Doctors. Call for information Mon. thru Friday 8 a.m. to 6 p.m.

Bariatric Medical Clinics

OAKLAND 1419 Broadway 465-7000	SAN FRANCISCO Post & Powell 433-2333	PLEASANT HILL 1222 Contra Costa 798-7090	HAYWARD 21651 Redline 888-8623
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14 San Francisco Chronicle Mon., June 24, 1974

LOOK AT ME NOW!



I lost 26 lbs in 6 weeks!

"I didn't sign any contracts or take any pills! I didn't even do any exercises! Also, my husband liked the money-back guarantee! The doctors and nurses were just great! Life really changes when you slim down!"

Chris Mishak, patient.

San Jose
296-2000
South San Jose
267-3131
Los Altos/Mt. View
941-6440
San Mateo
347-9901
Redwood City
369-0333



**WEIGHT REDUCTION
MEDICAL CLINIC**

Already helping thousands in southern California!

1184

Initial Decision

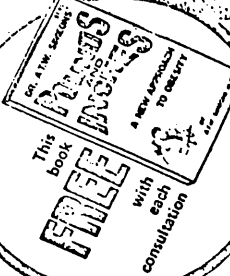
LOSE WEIGHT - NOW




-to look better
-to feel better
-to perform better

MANDATORY, that all examinations, tests and treatments are medically supervised by M.D., R.N.'s and L.V.N.'s. You will receive a one time complete blood count and blood chemistry. Also thyroid test and a urinalysis. Plus a complete computerized EKG and full physical exam given by the Doctor. This is all part of the program, before you are accepted. IT'S EASY - You'll be astounded how easy it is... Formerly available only to the very wealthy. The weight reduction plan is completely professional and now can be yours at a very modest cost. Terms are available.

CALL NOW
938-2565
 1409 NURSERY LANE
 Walnut Creek



FREE
This book
with each
consultation

FEATURING
DR. A.T.W. SIMEON'S
"POUNDS & INCHES" METHOD
 ... Obesity affects 4 out of 5 families... whether you are male or female, 18 or 80, HCG Weight Clinics Foundation can improve your appearance and attractiveness - and help you stay that way!

...lose weight in weeks... you can't afford not to... and we make it easy with our new Credit Plan!

CALL NOW
938-2565
 1409 NURSERY LANE
 Walnut Creek

Sacramento 927-2201	Modesto 521-8030
Stockton 478-5000	Walnut Creek 938-2565
Mother Lode 735-2142	

HCG
Weight Clinics
Foundation

Oakland Tribune, June 10, 1974

[11] The impression conveyed by respondents' advertisements is that the weight reduction plan offered involves doctors using a method whereby those taking the treatments will lose weight. The advertisements are an inducement to subscribe to the regimen offered but no information is given as to its specifics.

Each of the advertisements reproduced above, as well as others in the record, fails to disclose the material facts that:

(1) the treatments offered by each respondent involve injections of the drug HCG; or that

(2) HCG is not approved by the Food and Drug Administration as safe *and* effective for the treatment of obesity or weight control. (See Simeon Stipulations, Exhibits A and B, Norcal Stipulations A, B and C (RX 3), Lobelson Responses to Requests for Admissions #5 (Exhibit A) and CX 17a-17m (Bariatric).)

6. EFFECT OF THE ADVERTISEMENTS

(A) By use of such advertisements, and others, each of the respondents directly or indirectly invites persons to attend its clinics and to purchase treatments in order to lose weight. (Simeon stipulated it advertised in newspapers and on television, and as noted before, admitted (par. 5, above) disseminating the advertisements reproduced on page 10a hereof. Admitted by Bariatric, et al., Commission Rule 3.12(b)(1)(ii); Lobelson Answer, par. 5, p. 3; Norcal Answer, par. 5, p. 3.)

(B) Each respondent's advertising, promotion and marketing effort has the capacity to induce potentially large numbers of persons who desire to lose weight to purchase its respective treatments.

[12] (C) Each respondent's advertising, promotion and marketing of a treatment which involves the injection of HCG prior to its approval by the Food and Drug Administration as being both safe *and* effective is unfair to rivals of respondents who offer other methods, devices or texts for the purpose of losing weight.

DISCUSSION

JURISDICTION

Respondents have at all times relevant hereto been engaged in interstate commerce within the intent and meaning of Sections 4 and 5 of the Federal Trade Commission Act. (See Findings, pp. 9-11 above, regarding newspaper advertisements and interstate shipments.)

The Commission's jurisdiction over the advertising of treatments or services as well as products under Section 5 is clearly established under existing case law. *Abel Allan Goodman v. Federal Trade Commission*,

244 F.2d 584 (9th Cir. 1957); *Federal Trade Commission v. Civil Service Training Bureau, Inc.*, 79 F.2d 113 (6th Cir. 1935).

It is sufficient for establishing the "in commerce" jurisdictional requirement of Section 5 of the Federal Trade Commission Act, if the advertisements of the respondents have been disseminated interstate. Intent to attract out-of-State customers is not necessary. Jurisdiction under Section 12 of the F.T.C. Act exists if the U.S. mails have been used by respondents in the dissemination of their advertisements. *John A. Guziak v. Federal Trade Commission*, 361 F.2d 700 (8th Cir. 1966); *S. Klein Dept. Stores, Inc.*, Dkt. 7891, 57 F.T.C. 1543, 1544 (1960) Interlocutory Order; *Surrey Sleep Products*, 73 FTC 523, 553-554 (1968); *Sidney J. Mueller v. United States*, 262 F.2d 443, 446-448 (5th Cir. 1958); *Kenneth W. Shafe, et al. v. Federal Trade Commission*, 256 F.2d 661 (6th Cir. 1958). (Note: The "in commerce" jurisdictional requirements of Sections 5 and 12 of the F.T.C. Act were changed to "in or affecting commerce" in essence by the Magnuson-Moss Warranty—Federal Trade Commission Improvement Act (88 Stat. 2193—Jan. 4, 1975), some months after instant complaint issued.)

[13] All the acts and practices which were and are part of the mode of operation of respondents in effecting the sale of treatments for the purpose of losing weight were methods of competition or acts and practices in commerce within the purview of the Federal Trade Commission Act. *Standard Oil Co. v. Federal Trade Commission*, 340 U.S. 231, 236-238 (7th Cir. 1951); *Holland Furnace Company v. Federal Trade Commission*, 269 F.2d 203 (7th Cir. 1959), *cert. denied*, 361 U.S. 932; *John A. Guziak v. Federal Trade Commission*, *supra*; *United States v. South-Eastern Underwriters Association et al.*, 322 U.S. 533, 549-553 (1944).

F.T.C. and FDA Responsibilities

The determinations as to (1) whether HCG is a new drug, and (2) whether HCG is safe and effective, insofar as its use for treating obesity and weight control are concerned, are for the Food and Drug Administration to make. That, however, does not deprive the Federal Trade Commission of its authority to take action to bring an end to false, misleading, deceptive or unfair advertising or unfair trade practices used in connection with the offering of treatments involving the administration of HCG to ultimate consumers of the drug.

Except for jurisdictional exclusions not pertinent here (see Sec. 5(a)(6) of the F.T.C. Act), Sections 5 and 12 of the F.T.C. Act (15 U.S.C. §§45 and 52) authorize the Commission to initiate proceedings to bring an end to *any* unfair method of competition or unfair or deceptive act or practice in commerce when it is to the interest of the public to do so.

The Food and Drug Administration operates primarily pursuant to authority contained in the Federal Food, Drug and Cosmetic Act (FFDCA) which deals with the introduction and delivery for introduction into interstate commerce of foods, drugs and cosmetics by manufacturers, packers and distributors (21 U.S.C. §331).

[14] Since there was no indication prior to the initiation of these proceedings, or since, that respondents state anything specifically about HCG in their advertising, the Food and Drug Administration determined respondents' advertising is not subject to FDA regulation (Dr. Temple, Tr. 152-153). Moreover, there is no evidence to suggest that respondents are manufacturers or distributors; and FDA corrective actions focus on violations of the FFDCA by manufacturers or distributors (Dr. Temple, Tr. 164).

To avoid duplication or overlapping of their regulatory functions, the Food and Drug Administration and the Federal Trade Commission have entered into a Liaison Agreement (*Trade Reg. Rep.* ¶9850 and ¶9851; 36 F.R. 18539, September 16, 1971; also see F.T.C. Rules of Practice Section 4.6). By its terms, the FDA has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising. However, even if respondents' practices in some respects were clearly within the FDA's power to challenge, there is ample precedent for the proposition that the Food and Drug Administration and the Federal Trade Commission may assert jurisdiction *concurrently* in their respective areas of responsibility.

The Federal Trade Commission's responsibility is to bring an end to false or misleading advertising or to those trade practices which are unfair. The representations of and the advertising of the medicinal qualities or properties of HCG itself would be primarily within the purview of the FDA's responsibilities. *United States v. Research Laboratories, Inc.*, 126 F.2d 42, 45 (9th Cir., 1942), *cert. denied*, 317 U.S. 656; *United States v. Various Quantities of Articles of Drug Labeled in Part: "Instant Alerty Food * * *," etc.*, 83 F. Supp. 882, 887 (D.D.C., 1949).

The Commission's jurisdiction and power to enforce the F.T.C. Act has been consistently sustained against challenges that statutes enforced by other agencies should be construed to preclude such jurisdiction. *Federal Trade Commission v. Cement Institute, et al.*, 333 U.S. 683 (7th Cir. 1948); [15] *Charles of the Ritz Distributors Corporation v. Federal Trade Commission*, 143 F.2d 676, 679 (2d Cir. 1944); *Irwin et al. v. Federal Trade Commission*, 143 F.2d 316, 325 (8th Cir. 1944); *Waltham Watch Company et al. v. Federal Trade Commission*, 318 F.2d 28, 31-32 (7th Cir. 1963), *cert. denied*, 375 U.S. 944; *Carl Brandenfels v. J. Edward Day, Postmaster General et al.*, 316

F.2d 375, 378 (D.C. Cir. 1963), *cert. denied*, 375 U.S. 824; *American Cyanamid Co. v. Federal Trade Commission*, 363 F.2d 757, 769 (6th Cir. 1966), 401 F.2d 574 (6th Cir. 1968), *cert. denied*, 394 U.S. 920 (1969).

U.S. Drug Laws

The drug laws of the United States, and the Federal Food, Drug and Cosmetic Act in particular, were enacted by the Congress to protect consumers from being subjected to certain drugs before the drugs had been approved by the Food and Drug Administration as both safe *and* effective for specific use.

Senate Report 1744, p. 8, 87th Cong. 2nd Sess. (1962) makes it clear that this, in fact, was the Congressional purpose:

The purpose of the proposed legislation, as amended, is to strengthen and broaden existing laws in the drug field so as to bring about better, safer medicine and to establish a more effective system of enforcement of the drug laws.

The amended bill would help assure a safer and more reliable drug supply for the Nation by requiring registration of all prescription drug manufacturers and more effective inspection of their plants to determine whether such drugs are being manufactured in accordance with the law. In addition, the bill requires the installation and maintenance of acceptable drug manufacturing and control procedures and a pre-marketing showing that all new drugs are effective—as well as safe—for their intended uses.

* * * * *

In short, the purpose of this bill, as amended, is to strengthen the laws designed to keep unfit drugs [16] off the market in the first instance and speed their removal should they reach the market.

And from page 16 of the Report:

* * * the Committee wants to make sure that safe new drugs become available for use by the medical profession so long as they are supported as to effectiveness by a responsible body of opinion.

As described by the FDA:

The major objective of the drug provisions of the Federal Food, Drug and Cosmetic Act is to assure that drugs will be safe and effective for use under the conditions of use prescribed, recommended, or suggested in the labeling thereof. Thus, new drug approval and antibiotic drug certification are regulated by law, both in the prescriber's and the patient's interest.

* * * * *

Thus although it is clear that Congress did not intend the Food and Drug Administration to regulate or interfere with the practice of medicine, it is equally clear that it did intend that the Food and Drug Administration determine those drugs for which there exists substantial evidence of safety and effectiveness and thus will be

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available for prescribing by the medical profession, and additionally what information about the drugs constitutes truthful, accurate and full disclosure to permit safe and effective prescription by the physician. As the law [FFDCA] now stands, therefore, the Food and Drug Administration is charged with the responsibility for judging the safety and effectiveness of drugs and the truthfulness of their labeling. [17] The physician is then responsible for making the final judgment as to which, if any, of the available drugs his patient will receive in the light of the information contained in their labeling and other scientific data available to him. (37 F.R. 158, August 15, 1972, pp. 16503-16504)

The Status of HCG with FDA

On December 5, 1974, the FDA announced in the *Federal Register* (CX 6; 39 F.R. 235, pp. 42397-42403) that HCG is a "new drug" (at p. 42401) and subject to the terms of the FFDCA insofar as the use of HCG for treating obesity and weight control are concerned. Thus, HCG is a drug which has not been approved by the Food and Drug Administration as safe and effective for the treatment of obesity or weight control, as provided for in the Federal Food, Drug and Cosmetic Act (Dr. Temple, Tr. 120, 126, 130, 147-148, 212).

A "new drug" by definition in the FFDCA (21 U.S.C. 321(p)(1) and (2)) is:

Any drug * * * the composition of which is such that such a 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, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

[18] Any drug * * * the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

As for when a drug is "generally recognized" as being safe and effective, in *Weinberger, Secretary of Health, Education and Welfare v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629, 632 (4th Cir. 1973), the Supreme Court had this to say:

In the absence of any evidence of adequate and well-controlled investigation supporting the efficacy of * * * [a drug] *a fortiori* * * * [the drug] would be a "new drug" subject to the provisions of the Act.

* * * * *

We accordingly have concluded that a drug can be "generally recognized" by experts as effective for intended use within the meaning of the Act only when that expert consensus is founded upon "substantial evidence" as defined in § 505(d). (21 U.S.C. 355(d), *i.e.*, that needed to support a new drug application.)

The FDA has regulations (21 C.F.R. §130.12(a)(5)(ii)) which describe what is required for an investigation to be adequate and well controlled. These regulations have been upheld by the Supreme Court (*Weinberger v. Hynson, Westcott & Dunning, Inc., supra*).

[19] Anecdotal evidence, such as is mentioned in the record here (Presley, Tr. 484; Lobelson, Tr. 536-37; Eisenberg, Tr. 616) consisting of the impressions and beliefs of physicians is not substantial evidence of efficacy or of safety. *Pharmaceutical Manufacturers Association v. Elliot L. Richardson, et al.*, 318 F. Supp. 301, 306-311 (D. Del. 1970); *The Upjohn Company v. Robert H. Finch, et al.*, 422 F.2d 944, 950-954 (6th Cir. 1970).

The Federal Food, Drug and Cosmetic Act provides in Section 355 (21 U.S.C. §355) that approvals of drugs for particular uses may be obtained by submitting a new drug application (NDA) together with supporting documentation to the Secretary of the Department of Health, Education and Welfare (HEW) who is to take action on the application within specified times.

In the December 5, 1974 announcement the Food and Drug Administration made it clear, however, that “* * * there is a lack of substantial evidence in the form of adequate and well-controlled studies meeting the requirements of 21 C.F.R. §314.111(a)(5) showing that (1) HCG is safe *and* effective * * *” for use in the treatment of obesity (p. 42397), and (2) for its use “* * * as an adjunct to diet in weight reduction programs.”

Thus, HCG in FDA parlance is a “new drug” insofar as its use in treating obesity and for weight control are concerned because the Food and Drug Administration has not approved HCG for such use (Temple, Tr. 120). At the same time, however, HCG is not a “new drug” insofar as it is used in treating (1) sterility, (2) cryptorchidism, *i.e.*, undescended testicles not due to anatomical obstruction, and (3) in inducing ovulation (FDA Notice, 39 F.R. 235, December 5, 1974, p. 42397).

[20] The result of this “new”/“not new” status is that HCG is available to respondents simply because it legally may be marketed in the United States for the FDA approved uses, and under the FFDCA, thereafter may be put to such use as the purchaser chooses (37 F.R. 16503, August 15, 1972).

Omission of Material Facts from Advertisements

Section 15 of the F.T.C. Act defines “false advertisement” so that both affirmative representations which are misleading in material respects *and* the failure to reveal facts material in the light of the representations made in an advertisement constitute a false advertisement (15 U.S.C. §55).

It is well established that it is an unfair trade practice to make statements in advertising which have the tendency and capacity to deceive the prospective customer. *Carter Products, Inc. v. Federal Trade Commission*, 323 F.2d 523 (5th Cir. 1963); *Spiegel, Inc. v. Federal Trade Commission*, 494 F.2d 59, 62 (7th Cir. 1974). It is not essential that the Commission find actual deception to support its complaint when the representations have the capacity to deceive. *Charles of the Ritz Dist. Corp. v. Federal Trade Commission*, 143 F.2d 676 (2d Cir. 1944); *The Regina Corporation v. Federal Trade Commission*, 322 F.2d 765 (3d Cir. 1963); *Montgomery Ward & Co. v. Federal Trade Commission*, 379 F.2d 666 (7th Cir. 1967).

Where the advertisements themselves sufficiently demonstrate their capacity to deceive, the Commission can find the requisite deception or capacity to deceive on a visual examination of the exhibits without evidence that the public was actually deceived. *Federal Trade Commission v. Colgate-Palmolive Co., et al.*, 380 U.S. 374 (1st Cir. 1965); *Double Eagle Lubricants, Inc., et al. v. Federal Trade Commission*, 360 F.2d 268, 270 (10th Cir. 1965); *Mitchell S. Mohr, et al. v. Federal Trade Commission*, 272 F.2d 401, 405 (9th Cir. 1959), *cert. denied*, 362 U.S. 920 (1960).

[21] It is no defense to a charge of engaging in unfair trade practices to assert that the customer was advised of the truth or of all material facts before making his choice of purchase. The initial contact, if deceptive, may be prohibited under the Federal Trade Commission Act. *Exposition Press, Inc., et al. v. Federal Trade Commission*, 295 F.2d 869, 873 (2d Cir. 1961), *cert. denied*, 370 U.S. 917 (1962); *Carter Products, Inc., et al. v. Federal Trade Commission*, 186 F.2d 821, 824 (7th Cir. 1951).

The failure to disclose material facts which if known to prospective purchasers would influence their decision as to whether to purchase, is an unfair trade practice in violation of Section 5. *Haskelite Mfg. Corporation v. Federal Trade Commission*, 127 F.2d 765 (7th Cir. 1942); *L. Heller & Son, Inc., et al. v. Federal Trade Commission*, 191 F.2d 954 (7th Cir. 1951); *Federal Trade Commission v. Colgate-Palmolive Co. et al.*, 380 U.S. 374 (1st Cir. 1965); *The J. B. Williams Company, Inc., et al. v. Federal Trade Commission*, 381 F.2d 884 (6th Cir. 1967); *S.S.S. Company, Inc., et al. v. Federal Trade Commission*, 416 F.2d 226, 231 (6th Cir. 1969). The Commission may utilize its accumulated expertise to determine what facts are material to consumers and whether such information has been withheld. *Pfizer Inc.*, F.T.C. Dkt. 8819, 81 F.T.C. 23 (1972).

There is ample precedent for the proposition that the Commission may require affirmative disclosures where necessary to prevent

deception. Accordingly, the Commission has the authority to require disclosure of material facts when a respondent advertises misleadingly due to a failure to reveal facts material in the light of the representations made. *All-State Industries of North Carolina, Inc., et al. v. Federal Trade Commission*, 423 F.2d 423 (4th Cir. 1970); *Portwood Co., et al. v. Federal Trade Commission*, 418 F.2d 419, 424 (10th Cir. 1969); *Leon A. Tashof v. Federal Trade Commission*, 437 F.2d 707, 714, n.37 (D.C. Cir. 1970); *Ward Laboratories, Inc., et al. v. Federal Trade Commission*, 276 F.2d 952, 954 (2d Cir. 1960), *cert. denied*, 364 U.S. 827.

[22] It is not a violation of a respondent's First Amendment rights to require affirmative disclosure of material facts. They are free to advertise; but they are prohibited from making false or misleading statements—*i.e.*, failing to disclose material facts. No one has the constitutional right to disseminate false or misleading representations in advertisements. *The Regina Corporation v. Federal Trade Commission*, 322 F.2d 765, 770 (3d Cir. 1963); *S.S.S. Company, Inc., et al. v. Federal Trade Commission*, 416 F.2d 226, 231 (6th Cir. 1969).

Is there an Inducement to Buy or an Actual Purchase of
HCG?

Advertisements are to be interpreted on the basis of the net general impression conveyed to the reader of the advertisement. *National Bakers Services, Inc. v. Federal Trade Commission*, 329 F.2d 365 (7th Cir. 1964); *Rhodes Pharmacal Co., Inc. v. Federal Trade Commission*, 208 F.2d 382, 387 (7th Cir. 1953), *F.T.C. affirmed* 348 U.S. 940 (1955). Respondents' ads induce the purchase of HCG.

Section 12(a) of the Federal Trade Commission Act, in pertinent part, prohibits dissemination of a false advertisement which is likely to induce the purchase of a drug. An advertisement which does not disclose material facts is false per Section 15 (15 U.S.C. §55). Section 12(b) provides that such dissemination violates Section 5 of the Act.

There is no question as to whether a purchase, or from the other perspective a sale, takes place when a product is injected into a person paying for it. There can be no serious question as to whether the advertisements in newspapers with extensive circulation is likely to induce the purchase of respondents' treatments which include the injection of HCG; and the drug does not need to be personally handled by the buyer. *Ratigan v. United States*, 88 F.2d 919 (9th Cir. 1937); *Sidney J. Mueller v. United States*, 262 F.2d 443, 447 (5th Cir. 1958).

[23] The injection of HCG in the course of the treatments offered by respondents contains all of the elements within the definition of "purchase" found in *Corpus Juris Secundum* (73 CJS 286): "A

'purchase' in the popular acceptance of the term is the transfer of property from one person to another by his voluntary act and agreement founded on a valuable consideration." *Shepard Paint Company, et al. v. Board of Trustees of Franklin County Veterans Memorial et al.*, 100 N.E. 2d 248, 251 (Court of Appeals of Ohio, Franklin County, 1950).

The Doctor-Patient Relationship

After a purchaser of a course of respondents' treatments enrolls, he is examined by a physician before he actually begins the treatments (Presley, Tr. 480). The injections of HCG are given by nurses at the clinics (Harris, Tr. 418).

The Food and Drug Administration has made it clear that, insofar as that agency is concerned, a physician in treating his patients may lawfully prescribe a dosage differing from that indicated in the labeling of a drug. The physician also may vary the conditions of use from those approved in the package inserts without informing the Food and Drug Administration or obtaining their approval (37 F.R. 16503)(Aug. 15, 1972). "The labeling is not intended either to preclude the physician from using his best judgment in the interest of his patient, or to impose liability if he does not follow the package insert (37 F.R. *supra*, at 16504). (Dr. Temple, Tr. 163-164, 184).

With regard to F.T.C. jurisdiction, however, the focus of the Commission's complaint is on the advertising, primarily in newspapers, by respondents, each of whom has denied being involved in the medical aspects of the operation of the weight reduction clinics. Thus, these F.T.C. proceedings are *not* focused on what a physician may in his professional judgment conclude is the appropriate treatment for a particular patient.

[24] The fact that a physician-patient relationship may be involved in respondents' operations does not preclude assertion of F.T.C. jurisdiction to bring an end to violation of the Federal Trade Commission Act. *American Medical Association v. United States*, 317 U.S. 519 (1943); *Northern California Pharmaceutical Association, et al. v. United States*, 306 F.2d 379 (9th Cir. 1962), *cert. denied*, 371 U.S. 862; also see Sections 5 and 12 of the F.T.C. Act (15 U.S.C. §§ 45(a)(b) and 52(a)).

The Impact of Respondents' Practices on Competitors

Although I do not agree with complaint counsel's position that the treatments respondents offer are unduly costly (*supra* par. 2B), I am of

the view that respondents' advertising promotion and marketing of the Simeon(s) method of weight control is unfair.

The reason is that since respondents do not disclose in their advertising that their treatments involve the injection of HCG or that HCG has not been approved for such use by the Food and Drug Administration, respondents' operations injure or tend to divert trade from competitors for the trade of those who are interested in fat reduction and who disclose all the material facts pertinent to their remedies. Such competitors would include those engaged in the sale of medicines, preparations, systems, methods, books of instruction, and other articles and means designed, intended and used for the purpose of reducing weight. *Raladam Co. v. Federal Trade Commission*, 316 U.S. 149, 151 (1942).

A competitor is prejudiced when business that would have come to him is diverted to another who is unscrupulous in the conduct of his business. *Federal Trade Commission v. Algoma Lumber Co., et al.*, 291 U.S. 67, 78 (1934). [25]

California's Knox-Mills Act and Its Effect

Respondents are registered under California's Knox-Mills Health Plan Act. The Act was passed by the State legislature to provide a means whereby private organizations, very much like insurance companies, could enroll so that they could be registered by the State as having complied with the requirements of the Act. For example, the registrants are companies and doctors, which furnish health care to individuals who formerly had been covered under the State's Medical program and who now pay for the care either through prepayment or periodic payment plans. The Act was designed essentially to cover the financial aspects of such plans and to determine whether the contracts with subscribers are fair. It was not designed to cover all aspects of their operation (Elkins, Tr. 734-740; RX 4 - 4y).

The Act also calls for submittal of the advertisements of an organization or physician registered under the Knox-Mills Act to the Attorney General of the State. The Deputy Attorney General responsible for administering the Act (Elkins, Tr. 732) testified that his office's actions in examining such advertisements do not constitute a judgment that a particular advertisement is not violative of either the State or Federal law (Elkins, Tr. 742-745). He also testified that review of an advertisement by his office and expression of an opinion as to its propriety or impropriety would not constitute a determination binding on the State of California (CX 19, 20, 21; Elkins, Tr. 748, 762, 790-791), and would not foreclose action by the Federal Trade Commission to challenge respondents' advertising. *United States v. California*, 297

U.S. 175 (1936). The Deputy Attorney General also testified that as a practical matter the State probably would not challenge an advertisement regarding which his office had given no adverse opinion (Elkins, Tr. 762), provided all facts had been truthfully disclosed when the advertisement was submitted for approval.

[26] The Federal Government in comparable circumstances is neither bound nor estopped by acts of its officers or agents. It is not irrevocably bound by a Federal employee entering an arrangement or agreement to do or cause to be done what the law does not sanction or permit. *United States Immigration and Naturalization Service v. Hibi*, 414 U.S. 5, 8 (1973). The Government is not in a position identical to a private litigant with respect to its enforcement of laws enacted by the Congress. *Utah Power & Light Co. v. United States*, 243 U.S. 389, 409 (1917). Certainly, the activities of employees in the office of the Deputy Attorney General of the State of California would be of no greater effect in foreclosing action by the Federal Trade Commission.

Estoppel-Laches

The Federal Trade Commission Act does not prescribe a minimum period within which the Commission must challenge a practice or lose the right to challenge it. To the contrary, Section 5(b) authorizes the Commission to take action to bring an end to apparent violations of the Act *whenever* it has reason to believe that doing so would be “to the interest of the public” (15 U.S.C. §45).

The Commission, in fact, acted promptly in this matter to challenge respondents’ advertisements by issuing its complaint and by seeking a preliminary injunction pending the trial of this matter. (See “Preliminary Statement,” *supra*.)

As for the law on the subject, the general rule is that an administrative agency charged with protection of the public interest is not precluded from taking appropriate action because of mistaken action or a lack of any action on its part in the past. *Federal Trade Commission v. Algoma Lumber Co., et al.*, 291 U.S. 67, 78-79 (1934); *National Labor Relations Board v. Baltimore Transit Co., et al.*, 140 F.2d 51-55 (4th Cir. 1944); *P. Lorillard Co. v. Federal Trade Commission*, 186 F.2d 52 (4th Cir. 1950). The principle of equitable estoppel—laches—may not be applied to deprive the public of the protection of a statute because of mistaken action or lack of action on the part of public officials. *United States v. City and County of San Francisco*, 310 U.S. 16, 31-32 (9th Cir. 1940). [27]

CONCLUSIONS

1. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents under both Section 5 and Section 12 of the Federal Trade Commission Act.

2. Respondents have been at all times relevant hereto engaged in interstate commerce within the meaning of Section 5 of the Federal Trade Commission Act and have caused to be disseminated false advertisements by United States mails, or in commerce, within the meaning of Section 12, which are likely to induce, directly or indirectly, the purchase of the drug human chorionic gonadotropin (HCG).

3. Respondents have been at all times relevant hereto in substantial competition in commerce with others engaged in the sale of medical and other treatments, and other means of weight reduction.

4. The aforesaid acts and practices of respondents were and are all to the prejudice and injury of the public and of respondents' competitors, and constituted and now constitute unfair methods of competition in commerce and unfair or deceptive acts or practices in commerce in violation of Section 5 of the Federal Trade Commission Act.

THE REMEDY

It is well settled that the Commission may, and should, enter an order of sufficient breadth to insure that a respondent will not engage in future violations of the law. To this end the Commission has wide discretion in fashioning an appropriate order. *See Jacob Siegel Co. v. Federal Trade Commission*, 327 U.S. 608, 611-13 (1946); *Federal Trade Commission v. Ruberoid Co.*, 343 U.S. 470, 473 (1952); *Federal Trade Commission v. National Lead Co.*, 352 U.S. 419, 428-30 (1957); *Federal Trade Commission v. Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965). Commission orders have been consistently upheld whenever the orders are reasonably related [28] to the unlawful practices found to exist and are clear and precise so that they may be understood by those against whom they are directed. *Jacob Siegel, supra*, at 611-13; *Ruberoid, supra*, at 473; *Federal Trade Commission v. Cement Institute*, 333 U.S. 683, 726 (1948).

It is also firmly established that, where appropriate, the Commission is authorized to require affirmative action in its orders. *S & S Pharmaceutical Co., Inc. v. Federal Trade Commission*, 408 F.2d 487, 489 (5th Cir. 1969); *All-State Industries of North Carolina, Inc. v. Federal Trade Commission*, 423 F.2d 423, 425-426 (4th Cir. 1970), *cert. denied*, 400 U.S. 828; *Tashof v. Federal Trade Commission*, 437 F.2d 707 (D.C. Cir. 1970).

In drafting the order in this proceeding, I have been influenced by the fact that it must be designed to protect all members of the consuming public which includes both the sophisticated and intelligent as well as the unthinking and the credulous. See *Aronberg, et al. v. Federal Trade Commission*, 132 F.2d 165, 167 (7th Cir. 1942); *Charles of the Ritz Distributors Corporation v. Federal Trade Commission*, 143 F.2d 676, 679 (2d Cir. 1944).

I also am not unmindful of the precept that “* * * once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as to the remedy are to be resolved in its favor.” *United States v. E. I. du Pont de Nemours & Co. et al.*, 366 U.S. 316, 334 (1961); *Ford Motor Co. v. United States et al.*, 405 U.S. 562, 575 (1972). I have deleted, however, the notice order* provision proposed by complaint counsel prohibiting any advertising of treatments involving use of a drug required under the Federal Food, Drug and Cosmetic Act to be approved for such use until the drug has received the required FDA approval. The notice order immediately raises First Amendment questions in that it would effect an absolute prohibition of advertising rather than require respondents simply to advertise in a manner which is not false, misleading or unfair. An obligation [29] to advertise truthfully bears no resemblance to a restriction on the exercise of free speech. *Grosjean, Supervisor of Public Accounts of Louisiana v. American Press Co., Inc., et al.*, 297 U.S. 233, 250 (1936); *Rodale Press, Inc., et al.*, Dkt. 8619, 71 F.T.C. 1184, 1234 (1967). I believe that an absolute prohibition of advertising does.

* * * the Court must always keep in mind the conflicting impact of the constitutional right of freedom of speech with the limitation upon the right if there is false advertising. If the advertisement is not false, defendants have a constitutional right to utilize it even though its content and blatancy may annoy both the Commission and the general public.

Federal Trade Commission v. Sterling Drug, Inc., et al., 215 F. Supp. 327, 332 (D.C.S.D.N.Y., 1963), *aff'd*, 317 F.2d 669 (2d Cir. 1963).

The Commission may, of course, prohibit false statements or true statements which in total effect are misleading. *Murray Space Shoe Corp. v. Federal Trade Commission*, 304 F.2d 270, 272 (2d Cir. 1962); *Ward Laboratories v. Federal Trade Commission*, 276 F.2d 952, 954, *cert. denied*, 364 U.S. 827 (1960). But the Commission may not prohibit the telling of a true statement. See *Crosley v. Bradstreet Co.*, 312 F.2d 483 (2d Cir. 1963), *cert. denied*, 373 U.S. 911 (1963); *Scientific Mfg. Co. v. Federal Trade Commission*, 124 F.2d 640 (3d Cir. 1941).

Instead of the notice order provision, I have substituted provisions calling for (1) disclosure in advertising of (a) the fact that the

* Not reproduced herein.

treatment involves injections of HCG and, usually, adherence to a 500 calorie daily diet, and (b) HCG's unapproved-by-FDA status for use in treating obesity and weight control, and (2) a statement in the receipt or contract provided to subscribers to respondents' treatment plans as to the nature of the treatments and HCG's status with FDA.

[30] I have also deleted the notice order provision calling for notification to the Commission of all changes in employment by individual respondents. I see no useful purpose in requiring an individual respondent in this case to report that he has entered some totally dissimilar line of business. The Commission should follow the individual's career in the weight reduction business but need not have such information regarding other businesses he may enter. The order now calls for notification only when the individual leaves or reenters the weight reduction business.

ORDER

It is ordered, That respondents Simeon Management Corporation, Simeons Weight Clinics Foundation, Bariatric Medical Clinics Management Corporation, C. M. Norcal, Inc., and HCG Weight Clinics Foundation, corporations, their successors and assigns and their officers, and Harvey J. Lobelson, individually and trading and doing business as Weight Reduction Medical Clinic, or under any other name or names, his successors and assigns, and John D. Howell, Robert Van Dine, David L. Cunningham, Peter J. Marengo, III, and Joseph Costa, individually and as officers, respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the offering for sale, sale or distribution of the "Simeon" or "Simeons" treatment for [31] weight reduction, or of any other weight reducing service or treatment, do forthwith cease and desist from:

1. Disseminating, or causing the dissemination of any advertisement, by means of the United States mail, or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act, promoting any service or treatment which involves the use of HCG or any other drug required under the Federal Food, Drug and Cosmetic Act to be approved by the Food and Drug Administration as both safe and effective for the treatment of the conditions for which it is to be used without disclosing in the advertisement in print equally conspicuous to that in the bulk of the text that:

- (1) The treatments include injections of HCG and, usually, adherence to a 500 calorie daily diet; and that (2) HCG is a drug which has not been approved by the Food and Drug Administration as safe and effective for the treatment of obesity or weight control.

[32] 2. Disseminating, or causing to be disseminated, by any means, for the purpose of inducing or which is likely to induce, directly or indirectly, the purchase of any such weight reducing service or treatment in commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which fails to comply with the requirements of paragraph 1 hereof.

It is further ordered, That each respondent is to forthwith cease and desist from failing to furnish each subscriber to the course of weight reduction treatments he offers with a fully completed receipt and/or copy of any contract executed when the treatments are subscribed for, which receipt and contract is to bear in boldface type of a minimum size of 10 points in close proximity to the signature element(s) thereon, a statement in substantially the following form:

THESE WEIGHT REDUCTION TREATMENTS INCLUDE THE INJECTION OF HCG, A DRUG WHICH HAS NOT BEEN APPROVED BY THE FOOD AND DRUG ADMINISTRATION AS SAFE AND EFFECTIVE IN THE TREATMENT OF [33] OBESITY OR WEIGHT CONTROL. THERE IS NO SUBSTANTIAL EVIDENCE THAT HCG INCREASES WEIGHT LOSS BEYOND THAT RESULTING FROM CALORIC RESTRICTION, THAT IT CAUSES A MORE ATTRACTIVE OR "NORMAL" DISTRIBUTION OF FAT, OR THAT IT DECREASES THE HUNGER AND DISCOMFORT ASSOCIATED WITH CALORIE-RESTRICTIVE DIETS.

It is further ordered, That each respondent and its successor or assignee is to deliver a copy of this order to cease and desist to all persons now engaged, or who become engaged, in the management, advertising, promotion, or marketing of weight reducing treatments as respondent's agents, salesmen, representatives, or employees, and secure from each of said persons a signed statement acknowledging receipt of a copy thereof.

It is further ordered, That each respondent and its successor and assignee is to notify the Commission at least thirty (30) days prior to any proposed change in their respective corporate respondent, successor or assignee, such as dissolution, assignment, or sale resulting in the emergence [34] of a successor corporation, the creation or dissolution of subsidiaries, licensees, or franchisees, or any other change in the corporation which may affect compliance obligations arising out of this order.

It is further ordered, That each of the individual respondents named herein is to promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment involved in the offering of treatments or other methods for reduction of weight. Such notice shall include respondents' current business address and a statement as to the nature of the

business or employment in which he is engaged as well as a description of his duties and responsibilities.

It is further ordered, That the respondents herein shall within sixty (60) days after service upon them of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

OPINION OF THE COMMISSION

By DOLE, *Commissioner*:

[2] Respondents are corporations and individuals in the business of setting up, operating and promoting weight reduction clinics.¹ They provide management and support services to licensed physicians and nurses who administer the treatments offered by the clinics. The clinics advertise in newspapers that their programs are safe, effective and medically approved.² The cost of respondents' treatment programs ranges from \$165 to more than \$395.³

All of the clinics use the "Simeon" or "Simeons" method for weight reduction. After an initial examination by a licensed physician, patients are given a four to six week treatment program consisting of a 500 calorie daily diet, medical counseling and five or six injections per week of human chorionic gonadotropin ("HCG"), a prescription drug.⁴ HCG is approved by the Food and Drug Administration ("FDA") for some purposes⁵ but not for treatment of obesity.⁶ Indeed, the FDA has found that there is a lack of substantial evidence that HCG is safe and effective in the treatment of obesity.⁷ FDA, accordingly, ordered [3] that effective on February 3, 1975,⁸ labeling reveal the "material" fact "that there is a lack of substantial evidence that the drug is effective as adjunctive therapy in the treatment of obesity* * *."⁹ All advertisements for the drug HCG must include the following disclosure:

HCG has not been demonstrated to be effective adjunctive therapy in the treatment of obesity. There is no substantial evidence that it increases weight loss beyond that resulting from

¹ The following abbreviations will be used throughout this opinion in citations to the record: CX — Commission Exhibits; RX — Respondents' Exhibits; Compl. — Complaint; Tr. — Transcript of Testimony; I.D. — Initial Decision of the Administrative Law Judge (June 18, 1975); RB — Respondents' appeal brief; CAB — Complaint Counsel's answer brief.

² I.D. 9, 10a-10d, 11, RB 2. All but one of the respondents have also advertised on television. I.D. 9.

³ I.D. 8 (Stipulation, RX 3a).

⁴ I.D. 9.

⁵ Treatment of sterility and cryptorchidism and inducing ovulation.

⁶ I.D. 19.

⁷ 39 F. R. 42397 (Dec. 5, 1974), CX 6-a.

⁸ Tr. 170.

⁹ 39 F. R. at 42402, CX 6-f.

caloric restriction, that it causes more attractive or "normal" distribution of fat, or that it decreases the hunger and discomfort associated with calorie-restricted diets.¹⁰

In October 1974, the Commission issued a complaint alleging that respondents had engaged in false, deceptive and unfair advertising, in violation of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45, 52, by failing to disclose in their advertising that their treatments involve injections of the drug HCG and that the drug is not approved by FDA for weight reduction purposes. The complaint also alleged unfairness in advertising, marketing and promoting a costly treatment involving a prescription drug required to be approved by FDA, but unapproved by FDA for that purpose.¹¹

Respondents J. William Byrd, Medical Weight Loss, Inc., and Darrel P. Simpson failed to answer the complaint. Administrative Law Judge Joseph P. Dufresne found against them on all [4] charges and imposed on them the order requested by complaint counsel.¹² Judge Dufresne subsequently found the other respondents liable for failing to disclose material facts in their advertising.¹³ He declined, however, to find that respondents had acted unfairly in advertising, marketing and promoting a "costly" treatment involving a prescription drug required to be approved by FDA, but unapproved by FDA for that purpose.¹⁴

The law judge accordingly denied complaint counsel's request for a broad order prohibiting respondents from advertising any service or treatment which involves the use of a drug required to be approved by FDA until it has been approved. He instead prohibited advertisements for respondents' weight reduction treatment unless they disclose the facts that the treatments include injections of HCG and adherence to a 500 calorie daily diet and that HCG has not been approved by FDA for weight reduction purposes. He further ordered respondents to furnish their customers the following disclosure as a part of each contract or as a receipt:

THESE WEIGHT REDUCTION TREATMENTS INCLUDE THE INJECTION OF HCG, A DRUG WHICH HAS NOT BEEN APPROVED BY THE FOOD AND DRUG ADMINISTRATION [5] AS SAFE AND EFFECTIVE IN THE TREATMENT OF OBESITY OR WEIGHT CONTROL. THERE IS NO SUBSTANTIAL EVIDENCE THAT HCG INCREASES WEIGHT LOSS BEYOND THAT RESULTING FROM CALORIC RESTRICTION, THAT IT CAUSES A MORE

¹⁰ *Id.*

¹¹ Compl., Paragraphs 5, 6.

¹² Initial Decision, January 7, 1975. See 16 C.F.R. §3.12(c). The Commission has stayed the effective date of the law judge's order. 16 C.F.R. §3.51(a). Respondent Simpson subsequently moved to reopen the default decision entered in this matter as to him [See, 86 F.T.C. 895 and 1568]. On remand, the law judge denied the motion. Order Denying Motion to Reopen the Default Decision, February 26, 1976.

¹³ I.D. 20-22, 27.

¹⁴ I.D. 24, 27.

ATTRACTIVE OR "NORMAL" DISTRIBUTION OF FAT, OR THAT IT DECREASES THE HUNGER AND DISCOMFORT ASSOCIATED WITH CALORIE-RESTRICTIVE DIETS.

Complaint counsel and respondents Simeons Weight Clinics Foundation, John D. Howell, Simeon Management Corporation, Robert Van Dine, C.M. Norcal, Inc., HCG Weight Clinics Foundation, Peter J. Marengo, III, Joseph Costa, Bariatric Medical Clinics Management Corporation and David L. Cunningham appeal from the order of the administrative law judge.¹⁵

RESPONDENTS' APPEAL

Respondents assert that complaint counsel failed to meet their burden of proving the lack of safety and effectiveness of respondents' weight reduction program. However, the complaint does not allege that respondents' treatment is in fact [6] unsafe or ineffective for treatment of obesity. Instead, it claims that respondents violated Sections 5 and 12 by failing to disclose in their advertising the material facts that the treatments involve injections of the drug HCG and that HCG is not approved by FDA as safe and effective for weight reduction purposes.

The Commission believes that the failure to disclose that respondents' treatments involve the administration of a drug which has not been approved by FDA for weight reduction renders respondents' advertising false, deceptive and unfair.

FALSITY AND DECEPTION

Capacity to deceive and not actual deception is the criterion by which practices are tested under the Federal Trade Commission Act. *See, e.g., Goodman v. Federal Trade Commission*, 244 F.2d 584 (9th Cir. 1957). "Advertising capable of being interpreted in a misleading way should be construed against the advertiser. Neither actual damage to the public nor actual deception need be shown." *Resort Car Rental System, Inc. v. Federal Trade Commission*, 518 F.2d 962, 964 (9th Cir. 1975).

What constitutes deception in advertising is clearly within the realm of the Commission's expertise. *Fedders Corp. v. Federal Trade Commission*, 529 F.2d 1398, No. 75-4051 (2d Cir., Jan. 21, 1976). The Commission may utilize its accumulated expertise in analyzing the facts of each case to determine what [7] direct and implied representations are contained in advertising. It may also use its

¹⁵ Subsequent to the issuance of the complaint, the Commission sought an injunction in the United States District Court for the Northern District of California against advertising by respondents' weight reduction clinics. The district court denied the injunction, 391 F. Supp. 697 (1975), and the district court's order has been affirmed by the Court of Appeals. 532 F.2d 708, No. 75-2363 (9th Cir., March 2, 1976).

expertise in evaluating what facts are material to consumers, and thereby to determine the situations in which material facts have not been disclosed. See *Pfizer, Inc.*, 81 F.T.C. 23, 58 (1972).

It is deceptive, and, therefore, a violation of Section 5, to fail to disclose in advertisements promoting respondents' weight reduction program that the treatments employ prescription drugs not approved for weight reduction by FDA. Some consumers will reasonably believe, and indeed have a right to assume, that controls are exercised by the government over the promotion and use of prescription drugs. This assumption is understandable in view of the elaborate regulatory scheme established by the Federal Food, Drug, and Cosmetic Act ["FFDCA"] and FDA's implementing regulations.¹⁶

[8] Moreover, the consumer's expectations in these respects are intensified by the challenged advertisements which represent respondents' treatments as safe, effective and medically approved. For these reasons, we find that advertising for a treatment involving the use of the prescription drug, HCG, representing that it is safe and effective, may reasonably lead consumers into a mistaken belief that these claims are based, not on the advertisers' opinions alone, but on a determination by the Federal agency responsible for drug regulation and approval. That implication, under the circumstances here before us, is clearly false.¹⁷ In addition, in view of the public's belief that the government strictly regulates therapeutic drugs, we find that the fact a weight reduction treatment involves the administration of a drug lacking FDA approval for weight reduction therapy may materially affect a consumer's decision to undergo the treatment. Respondents' failure to disclose this fact, therefore, renders their advertising deceptive.

Further, under Section 15 of the F.T.C. Act defining "false advertisement" for the purposes of Section 12, it is a violation to fail to disclose in advertisements promoting, directly or indirectly, the sale of a drug "facts material in the light of [the] representations [made] or

¹⁶ "Few other products are legally required to undergo such extensive pre-market testing and approval." Merrill, *Compensation for Prescription Drug Injuries*, 59 *Va. L. Rev.* 1, 8 (1973). The FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any "new drug," "unless an approval of an application . . . is effective with respect to such drug." 21 U.S.C. §355(a). A "new drug" is a drug not generally recognized among experts as effective as well as safe for its intended use. 21 U.S.C. §321(p)(1). A new drug may not be marketed unless a new drug application filed with FDA is in effect and FDA is directed to refuse approval of an application if "substantial evidence" that the drug is effective for its intended use is lacking. 21 U.S.C. §§355(d) and (e). A drug may be "new" even if it has already been approved for another use. See, *Merritt Corp. v. Folsom*, 165 F. Supp. 418, 421 (D.D.C. 1958).

¹⁷ Respondents acknowledge that their advertisements "suggest that the treatment method is safe, effective and medically approved." RB 2.

material with respect to consequences which may result from the use of the commodity to [9] which the advertisement relates.”¹⁸ The lack of FDA approval for a drug used in the advertised treatments is obviously material “in the light of [the] representations” that the treatments are safe, effective and medically approved. The lack of an FDA determination that the drug is safe and effective for weight reduction is also obviously material “with respect to consequences which may result from the use” of the drug, especially in view of the belief held by many consumers that any drugs used are being employed only for government approved uses.¹⁹

On the other hand, we disagree with the law judge that the name of the drug is a material fact to consumers that must be included in order to prevent advertising of the treatments from being false or deceptive. [10]

UNFAIRNESS

Among the factors the Commission considers in determining whether a practice is “unfair” within the meaning of Section 5 is “whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise — whether, in other words, it is within at least the penumbra of some common law, statutory, or other established concept of unfairness* * *.”²⁰

Food and Drug Administration regulations, promulgated pursuant to the FFDCA, provide that advertisements for prescription drugs approved by FDA may not recommend or suggest any use that is not indicated in the labeling as approved by the FDA in the new drug application.²¹ Respondents, therefore, cannot advertise the use of HCG in connection with weight reduction therapy. To advertise a *treatment* that involves the use of HCG for weight reduction without any qualifying language is to circumvent the FDA prohibition. We, therefore, conclude that respondents’ advertising offends public policy as it has been established by the Federal Food, Drug, and Cosmetic Act. [11]

¹⁸ F.T.C. Act, §15(a)(1); 15 U.S.C. §55(a)(1).

¹⁹ Subsequent to the issuance of the complaint, FDA issued a statement that became effective on February 3, 1975, which found that there was lack of substantial evidence that HCG was safe and effective in the treatment of obesity. However, no evidence was introduced that respondents have disseminated advertising after February 3, 1975, that failed to disclose the FDA finding.

²⁰ “Statement of Basis and Purpose of Trade Regulation Rule 406, Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking,” 29 F. R. 8355 (1964), cited in *Federal Trade Commission v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244-45 n. 5 (1972).

²¹ 21 C.F.R. §202.1(e)(4).

RESPONDENTS' OTHER CONTENTIONS

We reject respondents' other claims. Respondents assert that HCG is not a "new drug" as defined by the Food, Drug, and Cosmetic Act and, therefore, did not have to be pre-cleared by FDA before being marketed. FDA has determined that, when used for weight reduction, HCG is a "new drug." We see no reason to challenge this finding, especially in view of the "absence of any evidence of adequate and well-controlled investigation supporting" HCG's efficacy.²²

Respondents also argue that, even if HCG is a "new drug," the prior approval requirement applies only to manufacturers and distributors of the drug and not to physicians or clinics that administer the drug. However, the fact that the drug cannot be introduced or distributed in commerce for weight [12] reduction purposes is itself material to consumers.²³ [13]

COMPLAINT COUNSEL'S APPEAL

Complaint counsel contend that the law judge erred in failing to find that, even with disclosures, any advertising of a treatment involving a drug which is required to be approved by FDA but which has not received FDA approval for the advertised purpose is inherently unfair. They ask us to reverse this finding and to remedy the alleged violation by imposing an unconditional ban on all advertising for treatments involving any drug required to be approved by FDA until it has received approval for the advertised purpose.

In this contention, complaint counsel place their primary reliance on

²² See *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 629 (1973).

²³ We reject respondents' argument that the instant complaint improperly intrudes on the physician-patient relationship. We are not challenging the physician's right to administer or prescribe any medication he deems appropriate in the treatment of his patients. See "Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration," 37 F. R. 16503 (1972) (physician may prescribe drug for uses other than those approved by FDA). The Commission is, instead, prohibiting deceptive and unfair advertisements. That respondents provide medical services does not immunize them from liability under Sections 5 and 12. See, *Goldfarb v. Virginia State Bar*, 421 U.S. 773, 787-88 (1975); *American Medical Ass'n v. United States*, 317 U.S. 519, 528-29 (1943).

We also reject respondents' claim that, because their advertising has not been disapproved by the California Attorney General, pursuant to the Knox-Mills Health Plan Act, Cal. Gov't Code §12530-39.7 (West Supp. 1975), it is not subject to review by the Commission. The Attorney General's office advised counsel for certain respondents that, in administering the Knox-Mills Health Plan Act, it does not determine that the plans "are in compliance with other statutes and regulations." CX 19. Moreover, the Attorney General has made it clear that his failure to disapprove the advertisements of certain respondents did not constitute an approval of the advertisements. CX 20. In any event, the actions of a State agency would not be dispositive of whether respondents have violated Federal law.

Nor are we persuaded by respondents' claim that their patients do not "purchase" HCG, within the meaning of Section 12(a), since the injections of HCG are merely one segment of the treatment program. See, *Mueller v. United States*, 262 F.2d 443 (5th Cir. 1958). Of course, respondents' argument has no bearing on the allegation that their advertisements violated Section 5.

Finally, the Commission's jurisdiction is not pre-empted by the FFDCA. The statute provides that "no advertisement of a prescription drug" shall with respect to matters covered by the statute or FDA regulations be subject to Sections 12 to 17 of the F.T.C. Act, 15 U.S.C. §52-57. However, none of the parties has claimed that respondents' advertisements, which did not mention the drug HCG, were advertisements of a prescription drug. In any event, the Commission would retain jurisdiction under Section 5.

Sperry & Hutchinson, supra, holding that the Commission has broad authority to prohibit “unfair” commercial practices. Here, however, we are faced with competing policies. On the one hand, there is a clear policy in the FFDCa to prevent drugs such as HCG from being marketed for unapproved purposes until FDA approval for that purpose has been received. On the other hand, there is a policy to allow physicians to utilize, for any purpose, any drug which has lawfully come into their hands.²⁴ Balancing these competing considerations, we cannot conclude that there is a clear public policy against allowing these physicians to advertise their treatments in a nondeceptive manner. We believe that, circumscribed as they will [14] be by our order, any advertisements run by respondents will sufficiently apprise consumers of the negative features of respondents’ services.²⁵

REMEDY

Advertising Disclosure

Since we have found that respondents’ advertising has run afoul of the law by failing to disclose a material fact, it is obviously appropriate for us to require disclosure of that fact in the future. We have determined, however, that substantial variations from the law judge’s disclosure should be made. As Judge Dufresne recognized, advertising disclosures should not be limited to advertisements for treatments involving HCG, but should apply to advertisements for treatments which involve the use of any drug required to be approved by FDA which has not received that approval.²⁶ Judge Dufresne, however, failed [15] to word his disclosure to provide for the possibility that respondents might switch to the use of another drug unapproved by FDA. We have reworded the disclosure to this end and have also expanded it, drawing on the FDA warning which is required in prescription drug advertising,²⁷ so that it will effectively convey the

²⁴ See note 23 *supra*.

²⁵ It is arguable that the mere advertising of a treatment program involving the use of a drug for purposes unapproved by FDA may be inconsistent with the FDA prohibition against advertisements for prescription drugs that recommend or suggest a use that is not indicated in the approved labeling. However, the FDA policy is adequately protected if the fact the treatment involves a drug unapproved by FDA is disclosed. Even if there is arguably some conflict with the objectives of the FDA prohibition, we believe this result represents the most sensible accommodation of the above-indicated competing policies.

²⁶ The Commission may, and should, “close all roads to the prohibited goal.” *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952).

²⁷ 39 F. R. 42402, CX 6-f. The Commission’s determination that the failure to disclose that FDA had not approved HCG for weight reduction rendered respondents’ advertising deceptive and unfair under Section 5 and false under Section 12 applies perforce to a failure to disclose that FDA has actually found HCG had not been shown to be safe and effective for weight reduction. Although there has been no finding that respondents have violated Sections 5 and 12 by failing to disclose the FDA determination, see note 19 *supra*, it is well established that “the Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past.” *Ruberoid, supra*, at 473.

import of FDA's non-approval.²⁸

Office Disclosure

Like Judge Dufresne, we do not believe that a disclosure in advertising will constitute a sufficient remedy for the abuses found here; therefore, our order will also require that each customer receive a disclosure at the time the contract is signed.²⁹

[16] Several reasons support the need for disclosures during the first office visit. Many of respondents' prospective clients may have learned about respondents' services from advertising prior to the time the advertising contained the ordered disclosures. Still others may come to respondents on the advice of friends and acquaintances³⁰ who in turn learned about respondents' services from the earlier advertising. Without in-office disclosures, these prospective patients will suffer from the deception caused by the original advertisements.³¹ Moreover, when so serious a matter as the safety and efficacy of a prescription drug is concerned, every precaution must be taken that cautionary information is effectively communicated to the prospective client.³²

Other Order Changes

As requested by complaint counsel,³³ we will make two minor modifications to Judge Dufresne's order. First, since it has come to our attention that several of the respondents [17] have sold some of their clinics to parties previously affiliated with them, we will require that the details of these transactions be set forth in respondents' compliance report. Second, we will broaden the order to include acts and practices which "affect" commerce, as well as those which are "in" commerce.

We will also modify the individual reporting of change in employment requirement. While we agree with Judge Dufresne that it is unnecessary in this case to require each individual respondent to report each change of employment for the remainder of his life, we do believe that reporting is appropriate for the following changes in employment: (1) For the first ten years following the effective date of the order,

²⁸ Respondents made no specific objection on appeal to the order provision requiring disclosure in advertising that their treatments include a 500 calorie daily diet. We will, therefore, retain that provision in the order. We have, however, eliminated any reference to the drug HCG from the advertising and office disclosures. See p. 9 *supra*.

²⁹ Unlike the law judge's order, our order requires that this disclosure be made *before* the contract is signed. The purpose of the disclosure is to enable the consumer to make an informed purchase decision; only a disclosure effected before the decision is irrevocable can serve this purpose.

³⁰ Tr. 649, 663.

³¹ See *Travel King, Inc.*, Dkt. No. 8949 (Sept. 30, 1975) [86 F.T.C. 715].

³² While it may be argued that the representations made by a physician to a prospective patient are not generally "in or affecting commerce," we need not decide that question. These respondents have conducted their operations on such a scale that, even apart from their advertising, their operations are in or affect interstate commerce and promote the sale of drugs in or having an effect upon commerce.

³³ CAB 15-16.

effect upon commerce, or where said purchase would be in or affecting or having an effect upon commerce, as "commerce" is defined in the Federal Trade Commission Act) without disclosing, in a clear and conspicuous manner, that the treatments usually include adherence to a 500 calorie daily diet.

It is further ordered, That each respondent forthwith cease and desist from failing to furnish the following disclosure to each potential subscriber to the course of weight reduction treatments he offers (where such treatment involves the use of HCG or any drug in any manner or for any purpose, which manner or purpose would, if included in the labeling of such drug when such drug was introduced into commerce, cause such drug to be misbranded under the terms [6] of the Federal Food, Drug, and Cosmetic Act, or which the Secretary of the Department of Health, Education, and Welfare or his delegate has, under color of authority of that Act, determined would cause said drug to be so misbranded) unless at the time of sale and prior to the sale becoming final and prior to the commencement of the treatment or service or transfer to the purchaser of the product or drug, there is clearly and conspicuously disclosed to the purchaser, in writing, the following statement:

THESE WEIGHT REDUCTION TREATMENTS INVOLVE THE INJECTION OF A PRESCRIPTION DRUG WHICH HAS NOT BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION AS SAFE AND EFFECTIVE IN THE TREATMENT OF OBESITY OR WEIGHT CONTROL. THERE IS NO SUBSTANTIAL EVIDENCE THAT THIS DRUG INCREASES WEIGHT LOSS BEYOND THAT RESULTING FROM CALORIC RESTRICTION, THAT IT CAUSES A MORE ATTRACTIVE OR "NORMAL" DISTRIBUTION OF FAT, OR THAT IT DECREASES THE HUNGER AND DISCOMFORT ASSOCIATED WITH CALORIE-RESTRICTIVE DIETS.

It is hereby *provided*, that: (a) if the drug employed is not a prescription drug, respondents shall omit the word "prescription," (b) if the drug is not to be injected, respondents shall employ the word "use" instead of "injection."

[7] *It is further ordered*, That each respondent and its successor or assignee (1) deliver a copy of this order to cease and desist to all persons now engaged, or who become engaged, in the management, advertising, promotion, or marketing of weight reducing treatments as respondent's agents, salesmen, representatives, franchisees or employees, (2) secure from each of said persons a signed statement acknowledging receipt of a copy thereof and (3) continue to engage such a person only so long as such person abides by the terms of this order.

It is further ordered, That each respondent and its successor or

assignee notify the Commission at least thirty (30) days prior to any proposed change in their respective corporate respondent, successor or assignee, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, licensees, or franchisees, or any other change in the corporation which may affect compliance obligations arising out of this order.

It is further ordered, That each individual respondent named herein promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with [8] a new business or employment. In addition, for a period of ten years from the effective date of this order, the respondent shall promptly notify the Commission of each affiliation with a new business or employment whose activities include the offering of treatments or other methods for reduction of weight or in the use of drugs which are required under the Federal Food, Drug, and Cosmetic Act to be approved by the Food and Drug Administration as safe and effective for the conditions for which they are to be used and are not so approved. Such notice shall include the respondent's new business address and a statement of the nature of the business or employment in which the respondent is newly engaged as well as a description of respondent's duties and responsibilities in connection with the business or employment. The expiration of the notice provision of this paragraph shall not affect any other obligation arising under this order.

It is further ordered, That the respondents herein shall, within sixty (60) days after service upon them of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order; and the full names and addresses of any parties to whom any respondent has sold, transferred or conveyed any interest in a business subject to the complaint which led to [9] this order, since the date of service of said complaint. With respect to any such sale, transfer or conveyance, the report shall set forth in detail the date of each transaction, the nature and extent of any respondent's continuing interest in the business resulting from said transaction, the manner and form in which any purchaser was given notice of the pendency of the subject complaint, and any other information which may affect compliance obligations arising out of this order.

Chairman Collier having not participated in the oral argument in this matter, did not participate in its resolution.

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Final Order

wherever the new job involves the offering of treatments or other methods for reduction of weight or entails the use of any drug required under the FFDCA to be approved by FDA as safe and effective but which drug is not so approved; and (2) each individual respondent's first change of employment subsequent to the effective date of the order.

The findings and conclusions of the administrative law judge are adopted as the findings and conclusions of the Commission, except to the extent that they are inconsistent with this opinion. An appropriate order is appended.

FINAL ORDER

[2] This matter having been heard by the Commission upon the separate appeals of complaint counsel and respondents from the initial decision; and

The Commission having considered the oral arguments of counsel, their briefs, and the whole record; and

The Commission, for reasons stated in the accompanying opinion, having denied in part and granted in part the appeal of complaint counsel and having denied in full the appeal of respondents' counsel; accordingly

It is ordered, That, except to the extent that it is inconsistent with the Commission's opinion, the initial decision of the administrative law judge be, and it hereby is, adopted together with the opinion accompanying this order as the Commission's final findings of fact and conclusions of law in this matter;

It is further ordered, That the following cease and desist order be, and it hereby is, entered:

ORDER

It is ordered, That respondents Simeon Management Corporation, Medical Weight Loss, Inc., Simeons Weight Clinics Foundation, Bariatric Medical Clinics Management Corporation, C. M. Norcal, Inc., and HCG Weight Clinics Foundation, corporations, their successors and assigns and their officers, and [3] Harvey J. Lobelson, individually and trading and doing business as Weight Reduction Medical Clinic, or under any other name or names, his successors and assigns, and John D. Howell, Robert Van Dine, Darrel P. Simpson, J. William Byrd, David L. Cunningham, Peter J. Marengo, III, and Joseph Costa, individually and as officers, respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the offering for sale, sale or

distribution, directly or indirectly, of the "Simeon" or "Simeons" treatment for weight reduction, of any other weight reducing service, product or treatment, or of any drug do forthwith cease and desist from disseminating or causing the dissemination of any advertisement for the purpose of inducing or which is likely to induce, directly or indirectly, the purchase of any drug or any weight control or reduction service, treatment, or product (where such advertisement is disseminated by means of the United States mail, or by any means in or affecting or having an effect upon commerce, or where said purchase would be in or affecting or having an effect upon commerce, as "commerce" is defined in the Federal Trade Commission Act) when performance of said treatment or service or use of said product or drug may involve the use of HCG or any drug in any manner or for any purpose, which manner or purpose would, if included in the [4] labeling of such drug when such drug was introduced into commerce, cause such drug to be misbranded under the terms of the Federal Food, Drug and Cosmetic Act, or which the Secretary of the Department of Health, Education, and Welfare or his delegate has, under color of authority of that Act, determined would cause said drug to be so misbranded, without making the following disclosure in a clear and conspicuous manner:

THESE WEIGHT REDUCTION TREATMENTS INVOLVE THE INJECTION OF A PRESCRIPTION DRUG WHICH HAS NOT BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION AS SAFE AND EFFECTIVE IN THE TREATMENT OF OBESITY OR WEIGHT CONTROL. THERE IS NO SUBSTANTIAL EVIDENCE THAT THIS DRUG INCREASES WEIGHT LOSS BEYOND THAT RESULTING FROM CALORIC RESTRICTION, THAT IT CAUSES A MORE ATTRACTIVE OR "NORMAL" DISTRIBUTION OF FAT, OR THAT IT DECREASES THE HUNGER AND DISCOMFORT ASSOCIATED WITH CALORIE-RESTRICTIVE DIETS.

It is hereby *provided* that: (a) if the drug employed is not a prescription drug, respondents shall omit the word "prescription," (b) if the drug is not to be injected, respondents shall employ the word "use" instead of "injection," (c) if the advertised product, service, or treatment does not [5] relate to weight reduction, respondents shall petition the Commission to request that the disclosure be reworded as is appropriate for the particular product, service, or treatment offered.

It is further ordered, That respondents cease and desist from disseminating or causing the dissemination of any advertisement for the purpose of inducing or which is likely to induce, directly or indirectly, the purchase of the "Simeon" or "Simeons" treatment for weight reduction (where such advertisement is disseminated by means of the United States mail, or by any means in or affecting or having an

Order

IN THE MATTER OF
HERTZ CORPORATION*Docket 9033. Order, April 29, 1976*

In an FOIA proceeding, members of General Counsel's staff permitted immediately to examine and copy pages 15-20 of complaint counsel's expanded statement of facts and to examine contracts upon which the statement is based.

Appearances

For the Commission: *Thomas F. McNerney.*

For the respondent: *Schnader, Harrison, Segal & Lewis*, Philadelphia, Pa.

ORDER

The General Counsel has represented to the Commission that a suit has been filed by Patricia Kennedy pursuant to the Freedom of Information Act to enjoin the Commission from withholding pages 15-20 of the Complaint Counsel's Expanded Statement of Facts in this matter, which pages have been removed from the public record pursuant to a protective order dated November 7, 1975, issued by Administrative Law Judge Miles J. Brown. The General Counsel's Office requires access to this Expanded Statement of Facts and to the contracts upon which it is based in order to adequately describe the Statement to the District Court, to defend the action, and to respond, if necessary, to interrogatories issued by plaintiffs. The General Counsel's Office also needs to copy the Statement in the event the District Court requires its *in camera* submission.

It is ordered, That members of the General Counsel's staff be immediately permitted to examine and copy pages 15-20 of the Complaint Counsel's Expanded Statement of Facts in Dkt. No. 9033 and to examine the contracts upon which this statement is based.

Order

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IN THE MATTERS OF

BRISTOL-MYERS COMPANY, ET AL. — DOCKET 8917
AMERICAN HOME PRODUCTS CORPORATION, ET AL. —
DOCKET 8918
STERLING DRUG INC., ET AL. — DOCKET 8919

Order, May 4, 1976.

Denial of motion by American Home Products to dismiss complaint or suspend proceeding; and rejection of administrative law judge's certification with respect to Dockets 8917 and 8919 as to whether continued proceedings are in the public interest.

Appearances

For the Commission: *H. Robert Field, Thomas J. Donegan, Jr., Lynne C. McCoy, David O. Bickart and Leroy M. Yarnoff.*

For the respondents: *Weil, Guttman & Davis*, New York City for Bristol-Myers. *Cahill, Gordon, Sonnett, Reindel & Ohl*, Washington, D.C. for Ted Bates & Company, Inc. *Donovan, Leisure, Newton & Irvine*, Washington, D.C. for American Home Products. *Paul, Weiss, Rifkind, Wharton & Garrison*, New York City for Young & Rubicam, Inc. *Bergson, Borkland, Margolis & Adler*, Washington, D.C.

ORDER DENYING RESPONDENT AMERICAN HOME PRODUCTS
CORPORATION'S MOTION TO DISMISS COMPLAINT OR SUSPEND
PROCEEDING

The administrative law judge has certified to the Commission respondent American Home Products Corporation's motion to dismiss the complaint, due to changed circumstances, or, in the alternative, to suspend the proceeding pending the publication of a Food and Drug Administration ("FDA") monograph covering internal analgesics. Respondent argues that this proceeding is no longer in the public interest in view of the Commission's proposal of a trade regulation rule for over-the-counter drug advertising that would prohibit claims in advertising which FDA does not permit in labeling. 40 F. R. 52631 (Nov. 11, 1975).¹

The Commission, however, does not believe that it would be in the public interest to terminate this proceeding or suspend it pending final

¹ The administrative law judge, *sua sponte*, has certified the question whether continued proceedings in two companion cases, Dkts. 8917 and 8919, are in the public interest. Since respondent Bristol-Myers (Dkt. 8917) has stated that it neither supports nor opposes the instant motion, (see Respondent Bristol-Myers' Statement Regarding Certification of Motion of American Home Products Corporation to Dismiss the Complaint or in the Alternative Suspend the Proceeding Due to Changed Circumstances, and of Similar Questions in the Two Companion Analgesic Proceedings 2), and none of the other respondents in Dkts. 8917 and 8919 have responded to the law judge's certification, the Commission will confine its decision to the motion filed in Dkt. 8918.