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:

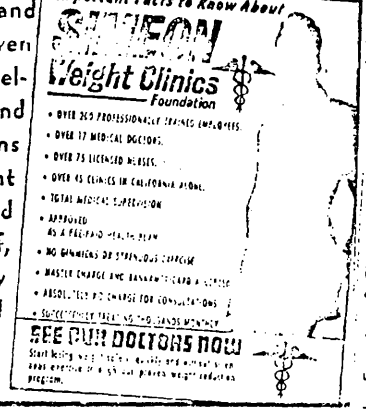
SIMEON WEIGHT CLINICS FOUNDATION

DECLARE 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.



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	928-5935	SAN JOSE	267-8000
S.F. 2065 MISSION STREET	626-5251	OAKLAND	465-5845
S.F. WEST PORTAL	665-5164	EL CERRITO	525-2312
DALY CITY	756-6525	HAYWARD	537-0622
SAN MATEO	341-6273	SAN RAFAEL	456-5930

CALL A CLINIC IN YOUR AREA

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

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

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

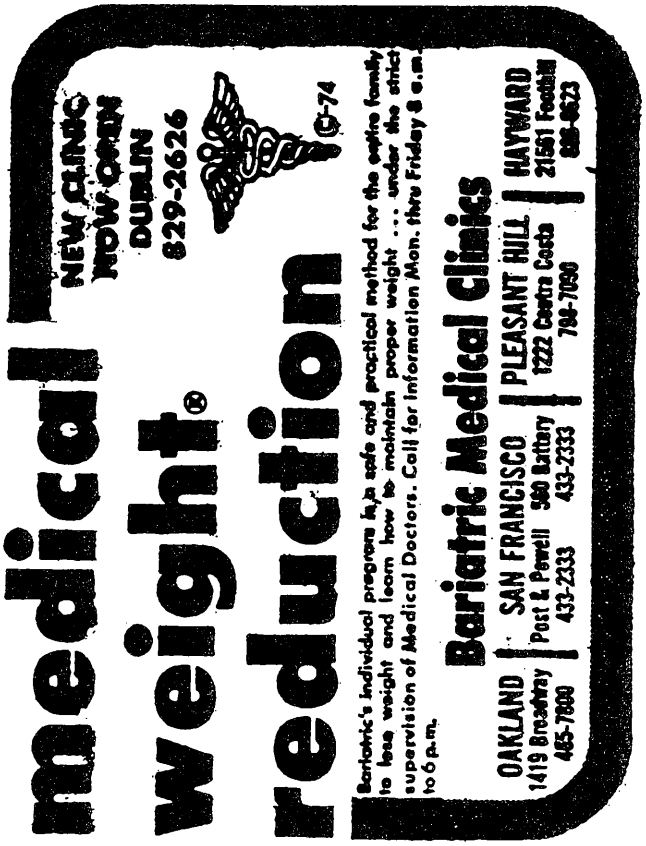
NO CONTRACTS TO SIGN...42 CLINICS OPEN IN THIS AREA

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

SO. SAN FRANCISCO 588-7117	REDWOOD CITY 369-2935	FREMONT 796-9232
DALY CITY 994-6446	MOUNTAIN VIEW 965-4308	SAN LORENZO/ HAYWARD 278-4134
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

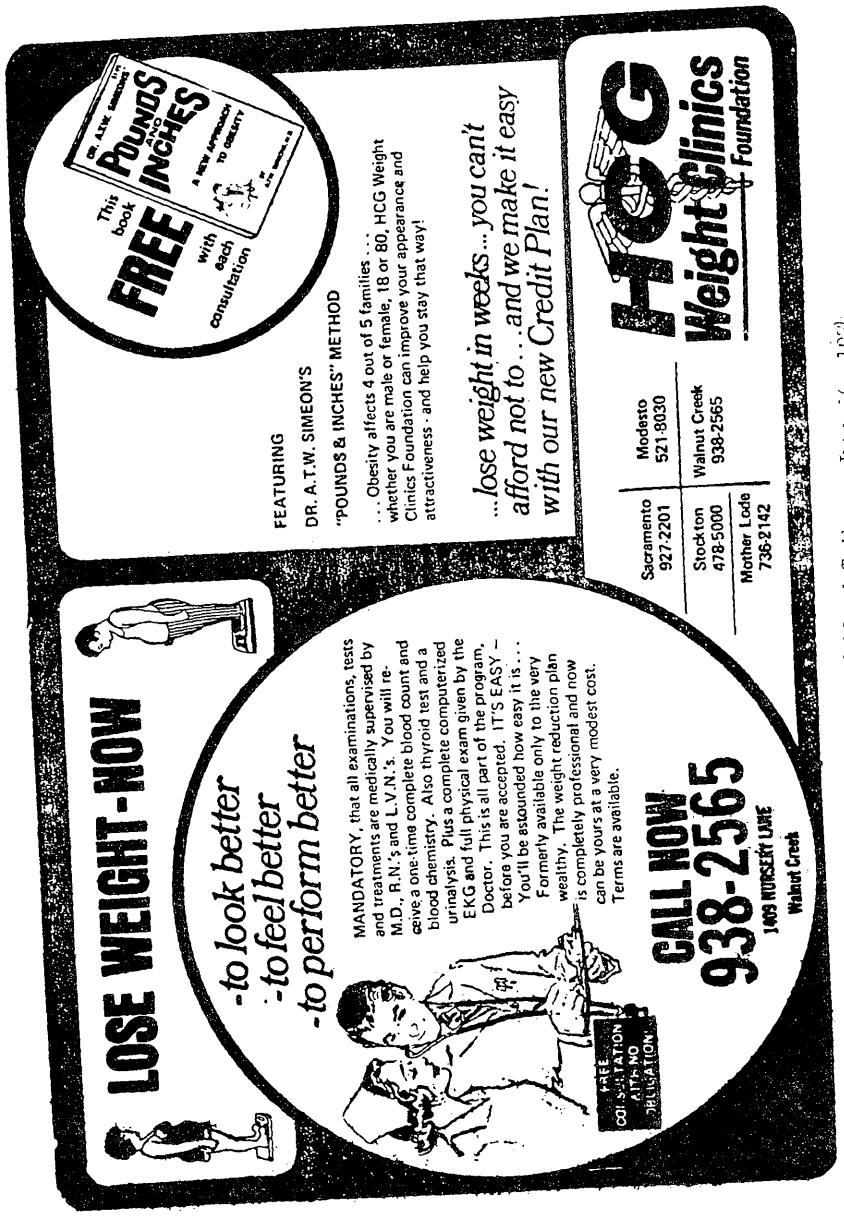
BankAmericard or Master Charge Welcome

FOR INFORMATION CALL (415) 697-0600



14 San Francisco Chronicle Mon., June 24, 1974

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



Oakland Tribune, Jun[illegible], 197[illegible]

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.

216-969 O-LT - 77 - 76

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.

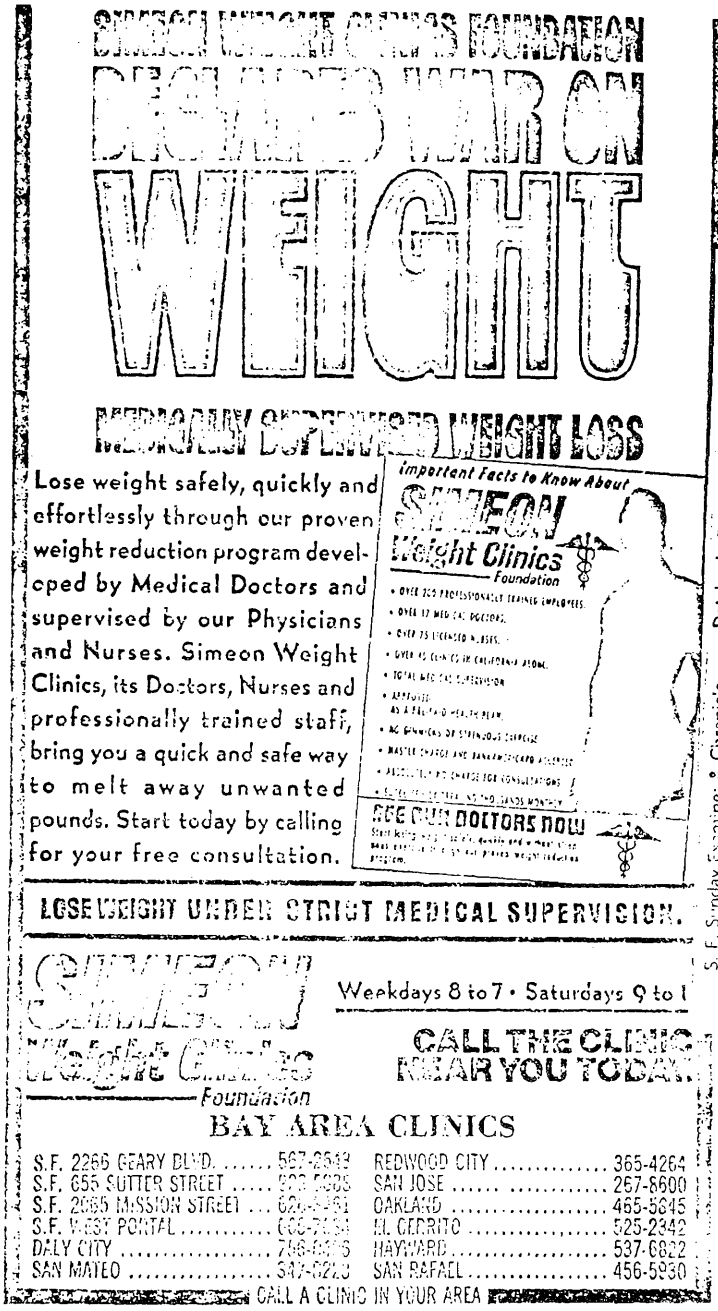
Respondent Darrel P. Simpson is an officer of Medical Weight Loss, Inc. Said individual respondent formulates, directs and controls the acts and practices of said corporate respondent, including the acts and practices hereinafter set forth. His business address is the same as that of said corporate respondent.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

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:



[illegible] WEIGHT FOUNDATION

[illegible] BEAR 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

SEE OUR DOCTORS NOW

LOSE WEIGHT UNDER STRICT MEDICAL SUPERVISION.

Weekdays 8 to 7 • Saturdays 9 to 1

CALL THE CLINIC NEAR YOU TODAY.

BAY AREA CLINICS

S.F. 2266 GEARY BLVD.	567-2642	REDWOOD CITY	365-4264
S.F. 655 SUTTER STREET	928-5825	SAN JOSE	267-8600
S.F. 2665 MISSION STREET	826-5451	OAKLAND	465-5645
S.F. WEST PORTAL	665-7654	EL CERRITO	525-2342
DALY CITY	756-6565	HAYWARD	537-6822
SAN MATEO	347-5223	SAN RAFAEL	456-5930

CALL A CLINIC IN YOUR AREA

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

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

[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,

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 PRE-PAID HEALTH PLAN.
- NO GIMMICKS OR STRENUOUS EXERCISE.
- MASTER CHARGE AND BANKAMERICARD 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.

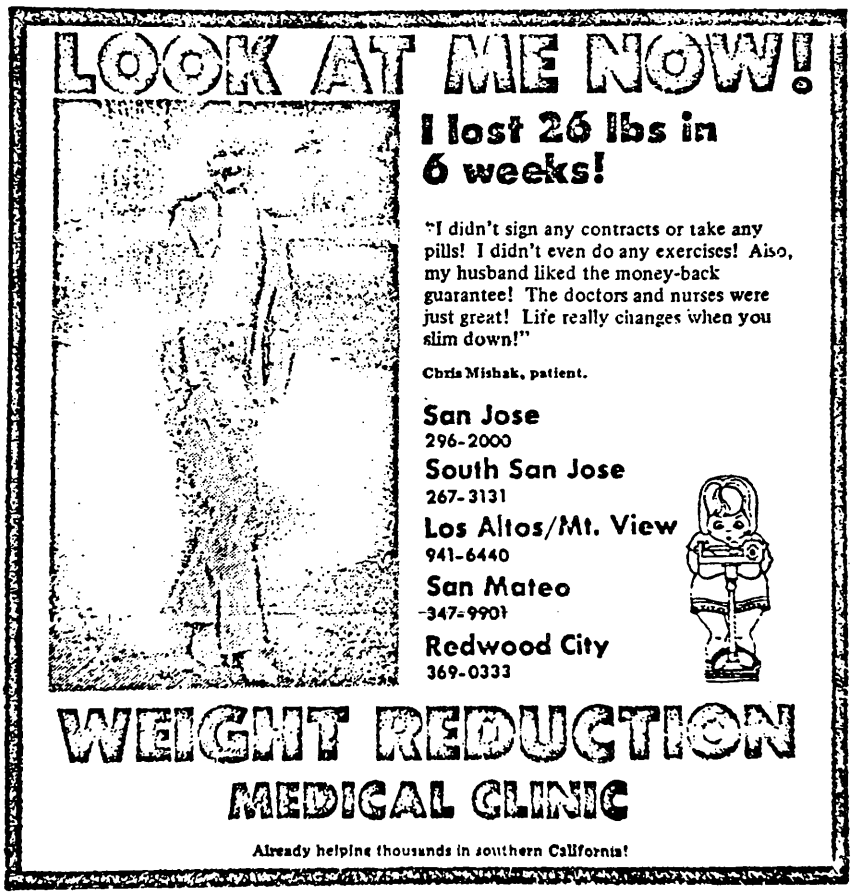
BAY AREA CLINICS

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

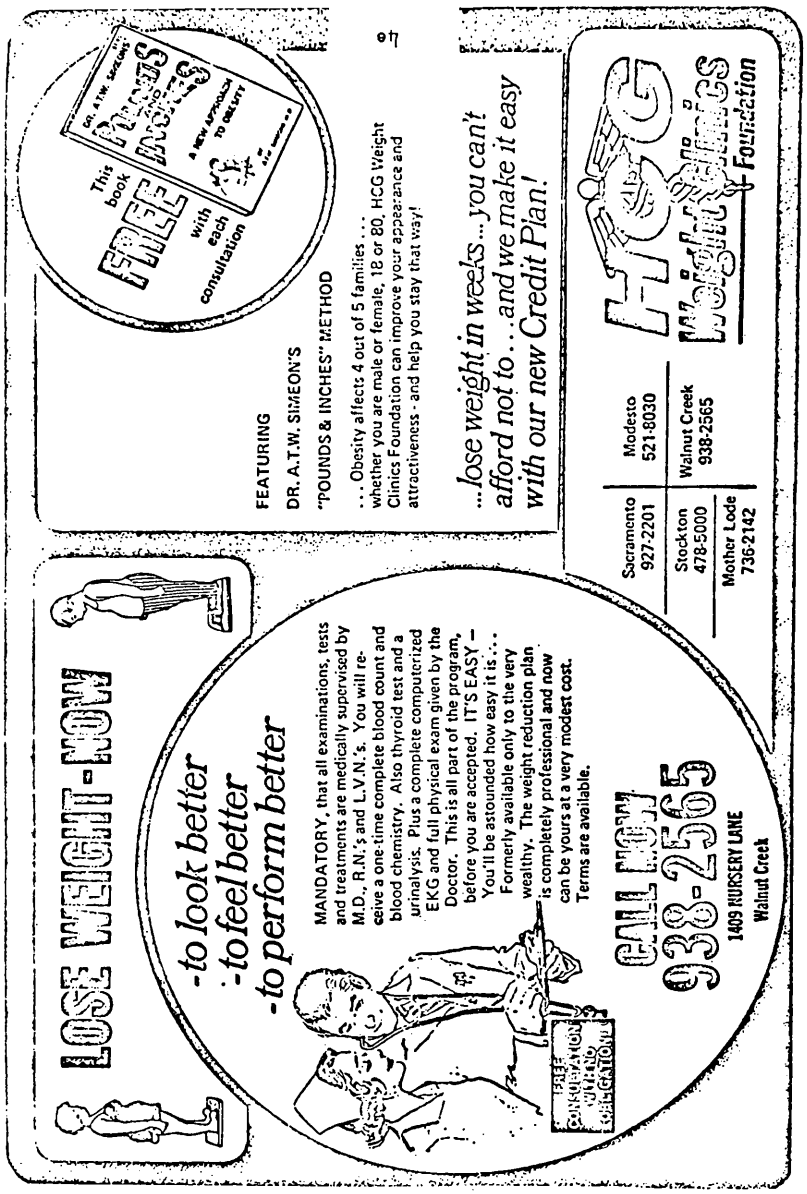
CALL A CLINIC IN YOUR AREA

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

14 San Francisco Chronicle Mon., June 24, 1974



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



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 Alberty 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 premarketing 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

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.

216-969 O-LT - 77 - 78

[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 purposes[5] 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

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[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 408, 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 no. 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 acquaintances[30] 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.

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

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.

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 & Rubicum, 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.

promulgation of a rule which might address some of the claims included in the complaint. Accordingly,

It is ordered, That the aforesaid motion be, and it hereby is, denied;

It is further ordered, That the aforesaid certification with respect to Dkts. 8917 and 8919 be, and it hereby is, rejected.

216-969 O-LT - 77 - 79

IN THE MATTER OF

SOUND ALIKE MUSIC CORPORATION, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION ACT

Docket C-2817. Complaint, May 10, 1976—Decision, May 10, 1976

Consent order requiring a Los Angeles, Calif., seller and distributor of tape products, among other things to cease using, in connection with their tape products, deceptive and misleading advertisements, labels, packages and promotional materials which misrepresent performers as original artists. The order further requires respondents to disclose in advertising and on packaging either the name of the actual recording artist or that their tape products are not original artist recordings, and to furnish, for a seven-year period, copies of the order to all retailers and distributors who purchase respondents' products.

Appearances

For the Commission: *Robert H. Wyman.*
For the respondents: *Eugene J. Weiss,* Beverly Hills, Calif.

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 Sound Alike Music Corporation, a corporation, and Richard Taxe, individually and as an officer of said corporation, hereinafter sometimes 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. For the purposes of this proceeding, the following definitions shall apply:

Original Artist: The original artist is the person who originally recorded and made popular the song(s) or album in question, or with whom the public generally identifies the song(s) in question.

Sound Alike Recording: A sound alike recording is a recording of a hit song(s) or a hit album recorded by one other than the original artist and performed in the style and manner of the original artist.

Compilation of Hits: A compilation of hits is a tape product featuring a variety of songs originally recorded and made popular by various artists.

Tape Products: Tape products include tape cartridges or tape

cassettes; or, insofar as Sound Alike Music Corporation produces or distributes them, phonograph records.

PAR. 2. Respondent Sound Alike Music Corporation is a corporation organized, existing, and doing business under and by virtue of the laws of the State of California, with its office and principal place of business located at 6330 Arizona Circle, Los Angeles, California.

Respondent Richard Taxe is an individual and an officer of the corporate respondent. He formulates, directs, and controls the acts and practices of the corporate respondent, including the acts and practices hereinafter set forth. His address is the same as that of the corporate respondent.

PAR. 3. Respondents are now, and for some time last past have been engaged in the manufacture and distribution of various tape products, including compilations of hits and sound alike recordings.

PAR. 4. In the course and conduct of their business as aforesaid, respondents now cause, and for some time last past have caused, their products when sold to be shipped from their place of business located in the State of California to purchasers thereof located in various other States of the United States, and maintain and at all times mentioned herein have maintained, a substantial course of trade in said products in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, as amended.

PAR. 5. In the course and conduct of their business, and for the purpose of inducing the purchase of their sound alike tape products, respondents have caused, and are now causing:

(A) Certain labels to be used on the aforesaid tape products employing the name of the original artist.

Typical of these labels, but not all inclusive thereof, are the following:

A Tribute to RAY PRICE

* * * * * * *

A Salute to CHICAGO

* * * * * * *

The Best of TOM JONES

* * * * * * *

CARPENTERS

* * * * * * *

(B) Certain labels to be used on the aforesaid tape products bearing the likeness of the original artist, or depicting drawings similar to those appearing on the album cover of the original recording.

(C) Certain labels to be used on the aforesaid tape products, which state that the album contains a compilation of hit songs.

Typical of these labels, but not all inclusive thereof, are the following:

A Tribute to the Early BEATLES VOL. I

* * * * * * *

Tribute to the Best of THE DECADE OF THE '40s

VOL. I

* * * * * * *

(D) Certain statements and representations to appear in promotional literature and advertisements with respect to the nature of the aforesaid tape products.

Typical of such statements and representations, but not all inclusive thereof, are the following:

* * * top hit songs made famous by artists like these (alongside illustrations of well-known recording performers)

PAR. 6. By and through the use of the aforesaid labels, catalogues, advertisements, and other promotional materials, and statements and representations of similar import and meaning, respondents have represented, and are now representing, directly or by implication, that the aforesaid tape products feature the original artists.

PAR. 7. In truth and in fact, the aforesaid tape products are not original artist recordings.

PAR. 8. By the aforesaid practices, respondents have placed, and are now placing, in the hands of distributors and retailers the means and instrumentalities by and through which the respondents may mislead and deceive the public in the manner and as to the matters herein alleged.

PAR. 9. The use by respondents of the aforesaid false, misleading, and deceptive statements, representations, acts, and practices has had, and now has, the capacity and tendency to mislead members of the purchasing public into the erroneous and mistaken belief that said statements and representations were and are true, and into the purchase of substantial quantities of respondents' products by reason of said erroneous and mistaken belief.

PAR. 10. The aforesaid acts and practices of respondents as herein alleged were and are all to the prejudice and injury of the public and

constituted, and now constitute, unfair and deceptive acts and practices in commerce within the intent and meaning of Section 5 of the Federal Trade Commission Act.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Los Angeles Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Sound Alike Music Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its office and principal place of business located at 6330 Arizona Circle, Los Angeles, California.

Respondent Richard Taxe is an officer of said corporation. He formulates, directs and controls the policies, acts and practices of said corporation, and his principal office and place of business is located at the above stated address.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

It is ordered, That respondents Sound Alike Music Corporation, a corporation, its successors and assigns, and its officers, and Richard Taxe, individually and as an officer of said corporation, and respondents' agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device in connection with the sale of tape products recorded by a person or persons other than the original artist(s), in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Using any label, package, catalogue, or any form of advertising, promotional material or point of sale material which:

(a) Contains any likeness of an original artist(s);

(b) Contains any illustration similar to that on the album cover or tape label used in any recording by the original artist(s);

(c) Implies, in any manner, that the tape product has been recorded by an original artist(s).

2. Offering for sale, selling, or distributing any tape product recorded by one other than the original artist(s), unless the tape product's package or label contains either the name(s) of the actual artist(s) or a clear and conspicuous disclosure which reads:

"THIS IS NOT AN ORIGINAL ARTIST RECORDING."

(a) If the legend "THIS IS NOT AN ORIGINAL ARTIST RECORDING" is employed, that legend shall appear on the front and spine of the tape product's label in capital letters and in boldface type set in type of at least the following sizes:

Front of the package — 12-point type
Spine of the package — 8-point type.

(b) If the name(s) of the actual artist(s) is(are) used in conjunction with the name(s) of the original artist(s), the name(s) of the actual artist(s) shall appear in capital letters and in boldface type on the same surface of the tape product as the name(s) of the original artist(s) appear(s). The name(s) of the actual artist(s) shall be printed in type which is at least the same size as the type size employed for the name(s) of the original artist(s).

(c) If the name(s) of the actual artist(s) is(are) not used in conjunction with the name(s) of the original artist(s), the disclosure shall comply with the requirements of Paragraph 2(a).

(d) The disclosure employed shall be a separate element, set in contrasting type on a solid-color background and shall not include any

part of any picture, design, illustration or other text, *provided* that if the name(s) of the original artist(s) is(are) used, the name of the actual artist(s) may be placed directly under or adjacent to the name(s) of the original artist(s).

3. Offering for sale, selling, or distributing any sound alike tape product, the title of which does not either name the actual artist or clearly disclose that the tape product is a sound alike recording, by incorporating the words, "Sounds like" or "Sound alike," or words of similar import and meaning.

4. Advertising any tape product not recorded by the original artist(s), unless respondents, in all advertisements of such tape products, either disclose clearly and conspicuously the name(s) of the actual artist(s) for each such recording, or make one clear and conspicuous disclosure which reads:

"THIS IS NOT AN ORIGINAL ARTIST RECORDING."

For the purposes of this section of the order, the term "advertisement" shall mean all advertising in newspapers, magazines, catalogues and other printed materials; and advertisements appearing on television and radio.

(a) If the name of each actual artist is not clearly and conspicuously disclosed, respondents shall set forth the disclosure, "THIS IS NOT AN ORIGINAL ARTIST RECORDING," in all printed advertisements, in capital letters and in boldface type, set in type of at least the following sizes:

Advertisements of a trim size larger than 144 square inches ..... 24-point type

Advertisements of a trim size larger than 65 square inches but not larger than 143 square inches ..... 14-point type

Advertisements of a trim size larger than 36 square inches but not larger than 64 square inches ..... 12-point type

Advertisements of a trim size not larger than 35 square inches ... 10-point type

The disclosure shall comply with the requirements of Paragraph 2(d) of this order.

(b) In all radio and television advertisements, the disclosure shall at least be made orally. There must be no less than one half-second pause both before and after the disclosure.

It is further ordered, That respondents may continue to distribute tape products presently in inventory with labels and packaging not bearing the disclosures required by this order, *provided* that respondents shall affix to each and every tape product a label which contains a clear and conspicuous disclosure which reads, "NOT AN ORIGINAL ARTIST RECORDING."

(a) The disclosure shall be in boldface capital letters, set in at least 14-point type;

(b) The disclosure shall be set in black type on a bright-red background;

(c) The disclosure shall appear as a separate element, and shall not include any part of any picture, design, illustration, or other text.

It is further ordered, That respondents shall, for a period of seven years, deliver a copy of this order to all retailers or distributors known to respondents who purchase respondents' tape products from respondents.

It is further ordered, That a copy of this order be delivered to all present and future personnel of respondents engaged in the design and creation of any packaging or labels for respondents' tape products, and that respondents shall secure from each such person a signed statement acknowledging receipt of said order.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That the individual respondent named herein 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 respondent's 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 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.

IN THE MATTER OF

SOUNDTRACK CHEVELL INDUSTRIES, INC., ET AL.

Docket 8998. Order, May 11, 1976

Denial of motions to dismiss the complaint as to Lonnie Temple and Gene Temple.

Appearances

For the Commission: *Richard H. Gateley* and *John J. Hemrick.*

For the respondents: *Thompson, Knight, Simmons & Bullion,* Dallas, Tex. for Soundtrack Chevell Industries, Inc., William F. Temple and Helen Temple.

ORDER DENYING MOTIONS TO DISMISS THE COMPLAINT AS TO LONNIE TEMPLE AND GENE TEMPLE

By order of March 16, 1976, the Commission withdrew this matter from adjudication for settlement purposes as to respondents Soundtrack Chevell Industries, Inc., William F. Temple, and Helen Temple, and directed that complaint counsel file a response to the motions of respondents Lonnie Temple and Gene Temple asking that the complaint be dismissed as to them.

Respondents Lonnie Temple and Gene Temple contend, in letters they have transmitted, that the complaint should be dismissed as to them because they did not exercise control over the corporate respondent's policies, and are not personally responsible for the acts and practices alleged in the complaint. Complaint counsel respond that movants' contention runs counter to the allegations of the complaint that they, in conjunction with other respondents, formulated the policies and directed and controlled the acts and practices of the corporate respondent, raising factual issues which should most appropriately be resolved in the pending administrative hearing.

In an order of April 22, 1975, the Commission denied the motions of Lonnie Temple and certain other respondents to dismiss the complaint as to them. Lonnie Temple's motion, like the ones now before the Commission, asserted that he was not responsible for the acts and practices alleged in the complaint. The Commission stated that nothing raised in the motions before it had altered the Commission's original reason to believe a proceeding as to those respondents would be in the public interest.

Respondent Lonnie Temple has made no further showing, nor has respondent Gene Temple made any showing, sufficient to dismiss the complaint as to them. Their bare allegations, without more, that they did not exercise control over the corporate respondent's policies and are

not personally responsible for the acts and practices alleged in the complaint, simply raise issues of fact going to the merits of the complaint, to be resolved in the administrative proceeding. *Cf. Koppers Co., Inc.*, 75 F.T.C. 1065 (1969). Furthermore, as the Commission reiterated in *Freight Liquidators*, D. 8937 (Feb. 25, 1975) [85 F.T.C. 274] individuals have been held liable under the Federal Trade Commission Act when they have exercised no control over the policies of the corporate respondent itself, but were involved in implementing an illegal scheme. *See also American Chinchilla Corp.*, 76 F.T.C. 1016, 1025 (1969) (individual respondent who "cooperated in and effectuated the acts, policies and practices of the corporate respondent" held liable). The Commission expresses no opinion at this time, however, as to any liability of movants; any determinations on the merits of the complaint must be based upon the record developed at the administrative proceeding.

Accordingly, the motions to dismiss the complaint as to Lonnie Temple and Gene Temple are denied.

It is so ordered.

IN THE MATTER OF

HANG UPS SPORTSWEAR LTD., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION AND WOOL PRODUCTS LABELING ACTS

Docket C-2818. Complaint, May 13, 1976—Decision, May 13, 1976

Consent order requiring a New York City importer of fabrics and manufacturer of women's sportswear, among other things to cease violating the Wool Products Labeling Act by falsely and deceptively labeling and misbranding products; and failing to securely affix labels and/or other means of product identification. The order further requires that purchasers of the misbranded products be informed of the deceptions.

Appearances

For the Commission: *Jerry R. McDonald.*
For the respondents: *Pro se.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, and the Wool Products Labeling Act of 1939, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission, having reason to believe that Hang Ups Sportswear Ltd., a corporation, and Bernard Berkoff, Nicholas Lambo, and Robert Berkoff, individually and as officers of said corporation, and Elliot Morris, individually and as a former officer of said corporation, hereinafter sometimes referred to as respondents, have violated the provisions of said Acts and the rules and regulations promulgated under the Wool Products Labeling Act of 1939, 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. Respondent Hang Ups Sportswear Ltd. is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its office and principal place of business located at 229 West 36th St., New York, New York.

Respondents Bernard Berkoff, Nicholas Lambo, and Robert Berkoff are officers and Elliot Morris is a former officer of Hang Ups Sportswear Ltd. At all times relevant to the acts and practices hereinafter set forth they formulated, directed and controlled the acts and practices of the corporate respondent. Their business address is the same as that of the corporate respondent.

Respondents are engaged in the business of importing wool products

into the United States, manufacturing clothing from said wool products and selling such clothing to their customers in the various States.

PAR. 2. Respondents, now and for some time last past, have introduced into commerce, sold, transported, distributed, delivered for shipment, shipped and offered for sale, in commerce, as "commerce" is defined in the Wool Products Labeling Act of 1939, wool products as "wool product" is defined therein.

PAR. 3. Certain of said wool products were misbranded by the respondents within the intent and meaning of Section 4(a)(1) of the Wool Products Labeling Act of 1939 and the rules and regulations promulgated thereunder, in that they were falsely and deceptively stamped, tagged, labeled, or otherwise identified with respect to the character and amount of the constituent fibers contained therein.

Among such misbranded wool products, but not limited thereto, were certain garments stamped, tagged, labeled, or otherwise identified by respondents as "55% polyester, 45% wool" whereas, in truth and in fact, said garments contained substantially different fibers and amounts of fibers than represented.

PAR. 4. Certain of said wool products were further misbranded by respondents in that they were not stamped, tagged, labeled or otherwise identified as required under the provisions of Section 4(a)(2) of the Wool Products Labeling Act of 1939 and in the manner and form as prescribed by the rules and regulations promulgated under said Act.

Among such misbranded wool products, but not limited thereto, were wool products, namely garments with labels on or affixed thereto, which failed to disclose the percentage of the total fiber weight of the said wool products, exclusive of ornamentation not exceeding 5 per centum of said total fiber weight, of (1) wool, (2) reprocessed wool, (3) reused wool, (4) each fiber other than wool, when said percentage by weight of such fiber was 5 per centum or more, and (5) the aggregate of all other fibers.

PAR. 5. The acts and practices of respondents as set forth above were, and are, in violation of the Wool Products Labeling Act of 1939 and the rules and regulations promulgated thereunder, and constituted, and now constitute, unfair methods of competition and unfair and deceptive acts and practices, in commerce, under the Federal Trade Commission Act.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a

copy of a draft of complaint which the New York Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act, as amended, and the Wool Products Labeling Act of 1939 and;

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Acts, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Hang Ups Sportswear Ltd. is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its office and principal place of business located at 229 West 36th St., New York, New York.

Proposed respondents Bernard Berkoff, Nicholas Lambo, and Robert Berkoff are officers and Elliot Morris is a former officer of said corporation. At all times relevant to the allegations in the complaint, they formulated, directed and controlled the policies, acts and practices of said corporation, and their address was the same as that of said corporation.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

It is ordered, That respondents Hang Ups Sportswear Ltd., a corporation, its successors and assigns, and its officers, and Bernard Berkoff, Nicholas Lambo, and Robert Berkoff, individually and as officers of said corporation, and Elliot Morris, individually and as a former officer of said corporation, and respondents' representatives, agents and employees, directly or through any corporation, subsidiary,

division or any other device, in connection with the introduction, or manufacture for introduction, into commerce, or the offering for sale, sale, transportation, distribution, delivery for shipment or shipment, in commerce, of wool products as "commerce" and "wool product" are defined in the Wool Products Labeling Act of 1939, do forthwith cease and desist from misbranding such products by:

1. Falsely and deceptively stamping, tagging, labeling or otherwise identifying such products.

2. Failing to securely affix to, or place on, each such product a stamp, tag, label, or other means of identification showing in a clear and conspicuous manner each element of information required to be disclosed by Section 4(a)(2) of the Wool Products Labeling Act of 1939.

It is further ordered, That respondents notify, by delivery of a copy of this order by registered mail, each of their customers that purchased the wool products which gave rise to this complaint of the fact that such products were misbranded.

It is further ordered, That the respondent corporation forthwith distribute a copy of this order to each of its operating divisions.

It is further ordered, That each of the individual respondents named herein promptly notify the Commission of the discontinuance of his present business or employment and his affiliation with a new business or employment. Such notice shall include each individual respondent's 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 respondents notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That respondents 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 the order to cease and desist contained herein.

IN THE MATTER OF

BOVERMAN FABRICS, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION AND WOOL PRODUCTS LABELING ACTS

Docket 9036. Complaint, June 24, 1975—Decision, May 17, 1976

Consent order requiring a New York City importer and distributor of fabrics, among other things to cease misrepresenting the wool content of wool blend fabrics; and to notify its customers that the fabrics they have purchased were misbranded.

Appearances

For the Commission: *Jerry R. McDonald* and *Herbert S. Forsmith.*
For the respondents: *Pro se.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, and the Wool Products Labeling Act of 1939, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission, having reason to believe that Boverman Fabrics, Inc., a corporation, and Milton Boverman, individually and as an officer of said corporation, hereinafter sometimes referred to as respondents, have violated the provisions of said Acts and the rules and regulations promulgated under the Wool Products Labeling Act of 1939, 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. Respondent Boverman Fabrics, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its principal office and place of business located at 252 West 38th St., New York, New York.

Respondent Milton Boverman is an officer of the corporate respondent. He formulates, directs, and controls the acts and practices of the corporate respondent including the acts and practices hereinafter set forth. His address is the same as that of the corporate respondent.

Respondents are now, and for some time last past, have been engaged in the importation and sale of fabrics including but not limited to wool products.

PAR. 2. Respondents, now and for some time last past, have imported for introduction into commerce, introduced into commerce, transported, distributed, delivered for shipment, shipped, offered for sale, and

sold in commerce as "commerce" is defined in the Wool Products Labeling Act of 1939, wool products as "wool product" is defined therein.

PAR. 3. Certain of said wool products were misbranded by the respondents within the intent and meaning of Section 4(a)(1) of the Wool Products Labeling Act of 1939 and the rules and regulations promulgated thereunder, in that they were falsely and deceptively stamped, tagged, labeled, or otherwise identified with respect to the character and amount of the constituent fibers contained therein.

Among such misbranded wool products, but not limited thereto, were certain wool fabrics stamped, tagged, labeled, or otherwise identified by respondents as "55% polyester, 45% wool", whereas, in truth and in fact, said products contained substantially different fibers and amounts of fibers than represented.

PAR. 4. Certain of said wool products were further misbranded by respondents in that they were not stamped, tagged, labeled or otherwise identified as required under the provisions of Section 4(a)(2) of the Wool Products Labeling Act of 1939 and in the manner and form as prescribed by the rules and regulations promulgated under said Act.

Among such misbranded wool products, but not limited thereto, were wool products, namely wool fabrics, with labels on or affixed thereto, which failed to disclose the percentage of the total fiber weight of the said wool products, exclusive of ornamentation not exceeding 5 per centum of said total fiber weight, of (1) wool, (2) reprocessed wool, (3) reused wool, (4) each fiber other than wool, when said percentage by weight of such fiber was 5 per centum or more, and (5) the aggregate of all other fibers.

PAR. 5. The acts and practices of respondents as set forth above were, and are, in violation of the Wool Products Labeling Act of 1939 and the rules and regulations promulgated thereunder, and constituted, and now constitute, unfair methods of competition and unfair and deceptive acts and practices, in or affecting commerce, under the Federal Trade Commission Act, as amended.

PAR. 6. Respondents are now and for some time last past have been engaged in the importation, offering for sale, sale, and distribution of certain products, namely fabrics. In the course and conduct of their business as aforesaid, respondents now cause and for some time last past, have caused their said products, when sold, to be shipped from their place of business in the State of New York to purchasers located in various other States of the United States, and maintain and at all times mentioned herein have maintained, a substantial course of trade in said products in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, as amended.

PAR. 7. Respondents in the course and conduct of their business have made statements on invoices to their customers, misrepresenting the fiber content of certain of their products.

Among such misrepresentations, but not limited thereto, were statements setting forth the fiber content thereof as "55% polyester, 45% wool" whereas, in truth and in fact, said products contained substantially different fibers and amounts of fibers than represented.

PAR. 8. The acts and practices set out in Paragraph Seven have the tendency and capacity to mislead and deceive the purchasers of said products as to the true content thereof.

PAR. 9. The aforesaid acts and practices of the respondents as herein alleged in Paragraph Seven were, and are, all to the prejudice and injury of the public, and constituted, and now constitute, unfair and deceptive acts or practices in or affecting commerce, within the intent and meaning of the Federal Trade Commission Act, as amended.

DECISION AND ORDER

The Commission having heretofore issued its complaint charging the respondents named in the caption hereof with violation of Section 5 of the Federal Trade Commission Act, as amended, and the Wool Products Labeling Act of 1939, and the respondents having been served with a copy of that complaint; and

The Commission having withdrawn the matter from adjudication for the purpose of considering settlement by the entry of a consent order; and

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as set forth in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having considered the agreement and having provisionally accepted same, and the agreement containing consent order having thereupon been placed on the public record for a period of sixty (60) days, now in further conformity with the procedures prescribed in Section 3.25(d) of its Rules, the Commission hereby makes the following jurisdictional findings, and enters the following order.

1. Respondent Boverman Fabrics, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its principal office and place of business located at 221 West 36th St., New York, New York.

216-969 O-LT - 77 - 80

Respondent Milton Boverman is an officer of the corporate respondent. He formulates, directs, and controls the acts and practices of the corporate respondent including the acts and practices hereinafter set forth. His address is the same as that of the corporate respondent.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

It is ordered, That respondents Boverman Fabrics, Inc., a corporation, its successors and assigns, and its officers, and Milton Boverman, individually and as an officer of said corporation, and respondents' representatives, agents, and employees, directly or through any corporation, subsidiary, division, or any other device, in connection with the introduction, or importing for introduction, into commerce, or the offering for sale, sale, transportation, distribution, delivery for shipment or shipment, in commerce, of wool products, as "commerce" and "wool product" are defined in the Wool Products Labeling Act of 1939, do forthwith cease and desist from misbranding such products by:

1. Falsely and deceptively stamping, tagging, labeling, or otherwise identifying such products.

2. Failing to securely affix to or place on, each such product a stamp, tag, label, or other means of identification showing in a clear and conspicuous manner each element of information required to be disclosed by Section 4(a)(2) of the Wool Products Labeling Act of 1939.

It is further ordered, That respondents Boverman Fabrics, Inc., a corporation, its successors and assigns, and its officers and Milton Boverman, individually and as an officer of said corporation, and respondents' representatives, agents, and employees, directly or through any corporate or other device, in connection with the importing, advertising, offering for sale, sale or distribution of fabrics in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, as amended, do forthwith cease and desist from misrepresenting such products on invoices or shipping memoranda applicable thereto, or in any other manner.

It is further ordered, That respondents mail a copy of this order by registered mail to each of their customers that purchased the wool products which gave rise to this complaint.

It is further ordered, That the individual respondent named herein promptly notify the Commission of each change in business or employment status, which includes discontinuance of his present

business or employment and each affiliation with a new business or employment, for ten (10) years following the effective date of this order. Such notice shall include respondent's current business address and a description of the business or employment in which he is engaged as well as a description of his duties and responsibilities. The expiration of the notice provision of this paragraph shall not affect any other obligations arising under this order.

It is further ordered, That the respondent corporation shall forthwith distribute a copy of this order to each of its operating divisions.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That respondents 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 the order to cease and desist contained herein.

IN THE MATTER OF

HAIR REPLACEMENT CENTERS OF BOSTON, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION ACT

Docket C-2819. Complaint, May 17, 1976—Decision, May 17, 1976

Consent order requiring a Newton, Mass., hair replacement firm, among other things to cease making false and misleading claims with respect to their hair implant process, and failing to disclose that their implant process involves surgical implantation of sutures which can cause pain, infection, scarring, and other disorders. Further, respondents are required to advise prospective customers to consult with a physician prior to contracting to undergo the process, and to provide customers a three-day cooling off period during which they may cancel their contract with full refund of all payments. In addition, respondents are required to devote 15 percent of their advertisements to warning prospective purchasers of the inherent dangers associated with the system of hair implant replacement.

Appearances

For the Commission: *Harold F. Moody.*
For the respondents: *Pro se.*

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 Hair Replacement Centers of Boston, Inc., a corporation, doing business as Hair Replacement Centers and Bruce S. Davis, individually and as an officer of said corporation, 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. Respondent Hair Replacement Centers of Boston, Inc. is a corporation, organized, existing and doing business under and by virtue of the laws of the Commonwealth of Massachusetts, with its principal office and place of business located at 850 Boylston St., Newton, Massachusetts.

Respondent Bruce S. Davis is an individual and an officer of corporate respondent Hair Replacement Centers of Boston, Inc. He formulates, directs and controls the acts and practices hereinafter set

forth. His business address is the same as that of the corporate respondent.

PAR. 2. Respondents are now, and for some time last past have been engaged in the operation of the Hair Replacement Centers and promote on their own behalf, among others, a medical implant hair replacement system, (hereinafter sometimes referred to as the "system"). The system involves a surgical procedure whereby a prolene thread is used to stitch six to eight hollow metal cylinders or clips on to the scalp of respondents' customers. A net type base, to which wefts of hair have been attached, is then affixed to the cylinders or clips. Hair Replacement Centers (hereinafter sometimes referred to as Centers) sells and maintains the system, except that the surgical procedure itself is performed by a medical doctor.

PAR. 3. In the course and conduct of their business, respondents have disseminated and caused the dissemination of, advertisements concerning their said system by the United States mail and by various other means in or having an effect upon commerce, as "commerce" is defined in the Federal Trade Commission Act, including but not limited to advertisements inserted in newspapers of general circulation, brochures and in oral sales presentations to prospective purchasers and purchasers, for the purpose of inducing, and which are likely to induce, directly or indirectly, the purchase of said system, and respondents have also disseminated, and caused the dissemination of, advertisements concerning their system by the aforesaid means for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of their said system in or having an effect upon commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 4. In the course and conduct of their business, and for the purpose of inducing the purchase of the system, respondents have made numerous statements and representations in advertisements inserted in newspapers of general circulation and in other promotional literature. Typical of the statements and representations contained in said advertisements and promotional literature, but not all inclusive, are the following:

> Men, wouldn't you really like to have your own full head of hair once more? — now you can. Quickly, simply, permanently.

* * * * * * *

> If you're bald or balding — you can look and feel ten years younger with a full head of your own permanent hair in just two hours. Our revolutionary medical hair implant process is painless.

* * * * * * *

It is a simple cosmetic surgical technique which fastens a full head of replacement hair to your scalp — making it part of you.

* * * * * * *

Not hair weaving, not a transplant, not a toupee.

* * * * * * *

Do everything. Dive, stand on your head, walk through a jet stream.

* * * * * * *

Your present barber will be able to handle the maintenance of your hair without any problem, so long as he is aware of the fact that you are wearing surgically attached replacement hair.

* * * * * * *

Once the replacement hair is applied it becomes a full time solution to baldness. It goes with you everywhere you go — swimming, skiing, sailing, even into the shower and to bed.

PAR. 5. Through the use of the above statements and representations, and others of similar import and meaning, but not expressly set out herein, respondents have represented, directly or by implication, that:

1. The system does not involve wearing a hairpiece or toupee.

2. The hair applied becomes a permanent part of the anatomy like natural hair and has characteristics of natural hair, including the following:

(a) The same appearance as natural hair upon normal observation and upon extreme closeup examination.

(b) It may be cared for like natural hair, particularly in that actions such as washing, combing, brushing and shampooing may be performed on it in the same manner as a person might with natural hair.

(c) The wearer may engage in physical activities with as much disregard for his applied hair as a person might with natural hair.

3. After the system has been applied, the wearer can care for it himself and will not have to seek professional or skilled assistance in maintaining the system, and that the customer will not incur charges over and above the charge for installing the system.

PAR. 6. In truth and in fact:

1. The system does involve the wearing of a hairpiece or toupee, inasmuch as the affixing of the wefts of hair to the net type base creates what is essentially a hairpiece or toupee.

2. The hair applied does not become a permanent part of the anatomy like natural hair. The system involves prolene sutures which

are stitched into the scalp by a surgical procedure and which may be rejected by the body. The hair applied differs from natural hair in many respects, including the following:

(a) It does not have the same appearance as natural hair in a substantial number of instances. It is often discernible as a hairpiece or toupee upon normal observation, and upon extreme closeup examination.

(b) It cannot be cared for like natural hair, but requires special care and handling. Strong pulling on the applied hair, such as may be expected to occur in washing, combing, brushing, and shampooing, can cause pain because of the pressure exerted on the sutures in the scalp, may cause bleeding, and may cause the sutures to pull out. As a consequence, washing the applied hair and scalp requires extra care. Unless extra care is taken while washing the hair and scalp, foreign particles and dead skin tissue tend to accumulate beneath the base and become a significant source of irritation. The hair styles into which the applied hair may be combed or brushed without professional treatments are limited.

(c) The wearer may not engage in physical activities with as much disregard for his applied hair as might a person with natural hair. The wearer must at all times be careful that the applied hair does not pull or get pulled, or become tangled, or strained. Discomfort and pain may be caused by common actions, such as rolling the head on a pillow during sleep.

3. The wearer cannot in most instances care for the applied hair himself; he must seek professional or skilled assistance on many occasions. Medical problems associated with the surgical procedure or the continuing presence of prolene thread in the scalp may require subsequent visits to a medical doctor. Wearers having some natural hair under the hair applied by respondents would have to have a haircut at regular intervals and such hair would be difficult to cut without skilled assistance and a substantial additional charge for such service would be incurred. Respondents' applied hair is subject to bleaching in sunlight and other discoloration normally associated with hairpieces, and where the hair applied has been color-dyed, loss of dye through washing and normal wear; thus, replacement wefts of hair or hairpieces are required at intervals in order to maintain a color match with any natural hair the wearer may have. Because of the difficulty in washing the hair and scalp described previously in Paragraph Six, assistance is often required to wash the hair.

Therefore, respondents' statements, representations, acts and practices as set forth in Paragraph Four and Paragraph Five were and are false, misleading, unfair or deceptive acts and practices.

PAR. 7. In the course and conduct of their business respondents have represented in advertisements, brochures and by oral representations the asserted advantages of their system, as hereinbefore described. Respondents have represented their system to be painless, and in no case have respondents in their advertisements, brochures and oral representations disclosed:

(a) That clients may experience discomfort and pain as a result of the surgical procedure, from the prolene sutures themselves, and from pulling normally incident to wearing the hairpiece;

(b) That clients will be subject to the risk of irritation, infection, and skin diseases as a result of the surgical procedure and as a result of the prolene thread remaining in the scalp; and

(c) That permanent scarring to the scalp may result from the required surgical procedures, and as a result of the prolene thread remaining in the scalp.

The consequences described in this paragraph have in fact occurred, and to a reasonable medical certainty can be expected to occur, and respondents knew, and had reason to know, that they could be expected to occur.

Therefore, the respondents' non-disclosure of material facts, as set forth in Paragraph Seven, was and is false, misleading, unfair and deceptive.

PAR. 8. For the purpose of inducing the purchase of their hair replacement system, respondents entice members of the purchasing public to their Center with advertisements such as "NEW COSMETIC SURGICAL TECHNIQUE CREATES NATURAL NEW HAIR IN JUST A FEW HOURS," and like advertisements designed to attract members of the purchasing public concerned about their hair loss, and with offers of free information without any obligations.

In most cases respondents do not disclose details of their system unless and until a prospect visits the Center. When members of the purchasing public have visited the Center, they have been subjected to sales pressure, for the purpose of persuading them to sign a contract for the application of the system, and to make a substantial downpayment, without being afforded a reasonable opportunity to consider and comprehend the scope and extent of the contractual obligations involved, the seriousness of the surgical procedure and the possibilities of discomfort, pain, disease, or disfigurement related to the continued presence of the prolene thread in the scalp. Persons are urged to sign such contracts and make such downpayments, through the use of sales presentations employing the following practice, among others:

A. Inducing prospects to sign contracts and/or make downpay-

ments before they have consulted a medical doctor and freely and openly discussed with such doctor the medical risks and consequences of the surgical procedure, and of the prolene thread being embedded in their scalp. Such consultations typically occur immediately before the commencement of surgery by which time the client is likely to feel pressured to go through with the application.

Therefore, respondents' statements, representations, acts and practices as set forth in Paragraph Eight, were and are false, misleading, unfair or deceptive acts or practices.

PAR. 9. In the course and conduct of their business, and at all times mentioned herein, respondents have been and are in substantial competition in or affecting commerce with corporations, firms, and individuals, in the sale of cosmetics, devices and treatments for the concealment of baldness.

PAR. 10. The use by respondents of the above unfair or deceptive statements, representations, acts, and practices and their failure to disclose material facts has had, and now has, the capacity and tendency to mislead consumers, and to unfairly induce consumers to hurriedly and precipitately sign contracts for the application of the system, and to make partial or full payment therefor, without affording them reasonable opportunity to consider and comprehend the scope and extent of the contractual obligations involved, or the seriousness of the surgical procedure, and the possibilities of discomfort, pain, disease and disfigurement related thereto, and related to the continual presence of the prolene thread in the scalp, or to compare prices, techniques, and devices available from competing corporations, firms, and individuals selling baldness concealment cosmetics, devices, and treatments to the purchasing public.

PAR. 11. The aforesaid acts and practices of respondents, including the dissemination of "false advertisements" as herein alleged, were and are to the prejudice and injury of the purchasing public, and of respondents' competitors and constituted and now constitute unfair methods of competition in or affecting commerce, and unfair and deceptive acts and practices in or affecting commerce in violation of Sections 5 and 12 of the Federal Trade Commission Act, as amended.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Boston Regional Office proposed to present to the Commission for its consideration and which,

if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Hair Replacement Centers of Boston, Inc. is a corporation, organized, existing and doing business under and by virtue of the laws of the Commonwealth of Massachusetts, with its office and principal place of business located at 850 Boylston St., Newton, Massachusetts.

Respondent Bruce S. Davis is an officer of said corporation. He formulates, directs and controls the policies, acts and practices of said corporation and his address is the same as that of said corporation.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

It is ordered, That respondents Hair Replacement Centers of Boston, Inc., a corporation, doing business as Hair Replacement Centers or any name or names, its successors and assigns, and its officers, and Bruce S. Davis, individually and as an officer of said corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale, or distribution of an implant hair replacement system (hereinafter sometimes referred to as the "system"), or other hair replacement product or process involving surgery, (hereinafter sometimes referred to as the "system") 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 or having an effect upon commerce as "commerce" is defined in the Federal Trade Commission Act, as amended, which advertisement represents, directly or indirectly:

(a) That the system does not involve wearing a device or cosmetic which is like a hairpiece or toupee;

(b) That after the system has been applied, the hair applied will become a permanent part of the anatomy like natural hair, or will have the following characteristics of natural hair:

(i) The same appearance in all applications as natural hair, upon normal observation, and upon extreme closeup examination;

(ii) It may be cared for like natural hair, particularly in that actions such as washing, combing, brushing and mussing might be performed on it in the same manner as a person might with natural hair.

(iii) The wearer may engage in physical activity and movement with the same disregard for his applied hair as he would if he had natural hair.

(c) That after the system has been applied, the customer can care for it himself, and will not have to seek professional or skilled assistance in maintaining the system, or that the customer will not incur maintenance costs over and above the cost of applying the system.

2. Communicating orally or in writing, or in any other manner, directly or by implication, any of the representations prohibited in Paragraph 1 hereof.

3. Failing to disclose, clearly and conspicuously, in all advertising, brochures and promotional materials, and in all oral sales presentations, in offering for sale, selling or distributing the system, that:

(a) The system involves a surgical procedure resulting in the implantation of sutures in the scalp, to which hair is affixed.

(b) By virtue of the surgical procedure involving implantation of sutures in the scalp, and by virtue of the sutures remaining in the scalp, there is a risk of discomfort and pain, and some risk of infection, scarring and other skin disorders.

(c) Continuing special care of the system is necessary to minimize the risks referred to in subparagraph (b) of this paragraph, and such care may involve additional costs for medications and assistance.

(d) The purchaser is advised to consult with his personal physician about the system before deciding whether to purchase it.

Respondents shall set forth the above disclosures separately and conspicuously from the balance of each advertisement or presentation used in connection with the advertising, offering for sale, sale, or distribution of the system, and shall devote no less than 15 percent of

each advertisement or presentation to such disclosures. *Provided, however*, that in advertisements which consist of less than ten column inches in newspapers or periodicals, and in radio or television advertisements with a running time of one minute or less, respondents may substitute the following statement, in lieu of the above requirements:

> Warning: This application involves surgery whereby sutures are placed in the scalp. Discomfort, pain, and medical problems may occur. Continuing care is necessary. Consult your own physician.

No less than 15 percent of such advertisements shall be devoted to this disclosure, such disclosure shall be set forth clearly and conspicuously from the balance of each of such advertisements, and if such disclosure is in a newspaper or periodical, it shall be in at least ten point type.

4. Disseminating, or causing the dissemination of any advertisement by any means, for the purpose of inducing or which is likely to induce, directly or indirectly, the purchase of said system, in or having an effect upon commerce, as "commerce" is defined in the Federal Trade Commission Act, as amended, which advertisements contain any of the representations prohibited in Paragraph 1 hereof, or which fail to make any of the disclosures required by Paragraph 3 herein.

It is further ordered, That respondents provide prospective purchasers with a separate disclosure sheet containing the information required in Paragraph 3 of this order, subparagraphs (a) through (d), thereof, and that respondents advise such prospective purchasers, subsequent to receipt of such disclosure sheet, to consult with a duly licensed physician who is not associated, directly or indirectly, financially or otherwise, with the respondents regarding the nature of the surgery to be done, the risks of discomfort and pain, and possible risks of infection, scarring, and other skin disorders.

It is further ordered, That no contract for application of respondents' system shall become binding on the purchaser prior to midnight of the third day, excluding Sundays and legal holidays, after the day on which said contract for application of the system was executed, and that:

1. Respondents shall clearly and conspicuously disclose orally prior to the time of sale, and in writing on any contract, promissory note or other instrument executed by the purchaser in connection with the sale of the system, that the purchaser may rescind or cancel any obligation incurred, by mailing or delivering a notice of cancellation to the office responsible for the sale prior to midnight of the third day, excluding

Sundays and legal holidays, after the day on which said contract for application of the system was executed.

2. Respondents shall provide a separate and clearly understandable form which the purchaser may use as a notice of cancellation.

3. Respondents shall not fail or refuse to honor any valid notice of cancellation by a purchaser and within 10 business days after receipt of such notice, to refund all payments made under the contract or sale and to cancel and return any negotiable instrument executed by the purchaser in connection with the contract or sale and take any action necessary or appropriate to terminate promptly any security interest created in the transaction.

4. Respondents shall not negotiate any contract, promissory note, or other instrument of indebtedness to a finance company or other third party prior to midnight of the fifth day, excluding Sundays and legal holidays, after the day on which said contract for application of the system was executed.

It is further ordered, That whenever respondents perform the application of the system on a customer within 48 hours from the time of that customer's initial contact with respondents, said customer may rescind or cancel any contract or agreement executed and any obligation incurred, by mailing or delivering a notice of cancellation to the office responsible for the sale prior to midnight of the third day, excluding Sundays and legal holidays, after the day on which the system was applied.

In the event of such cancellation, respondents shall refund all payments made within 10 business days after receipt of notice of such cancellation, *provided,* that said customer shall assume any cost incurred for the removal of the system.

It is further ordered, That respondents serve a copy of this order upon each physician participating in application of respondents' system, and obtain written acknowledgement of the receipt thereof. Respondents shall retain such acknowledgements for so long as such persons continue to participate in the application of respondents' system.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in any corporate respondent, 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 the order.

It is further ordered, That in the event that the corporate respondent merges with another corporation or transfers all or a substantial part

of its business or assets to any other corporation or to any other person, said respondent shall require such successor or transferee to file promptly with the Commission a written agreement to be bound by the terms of this order; *provided*, that if said respondent wishes to present to the Commission any reasons why said order should not apply in its present form to said successor or transferee, it shall submit to the Commission a written statement setting forth said reasons prior to the consummation of said succession or transfer.

It is further ordered, That respondents forthwith distribute a copy of this order to each of their operating divisions, offices, departments or affiliated corporations.

It is further ordered, That respondents shall forthwith deliver a copy of this order to cease and desist to all present and future personnel of respondents engaged in the offering for sale, sale or distribution of respondents' system or in any aspect of preparation, creation or placing of advertising, and that respondents secure a signed statement acknowledging the receipt of said order from each such person.

It is further ordered, That the individual respondent named herein 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 respondent's 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.

IN THE MATTER OF

PAY LESS DRUG STORES NORTHWEST, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION ACT

Docket C-2820. Complaint, May 17, 1976—Decision, May 17, 1976

Consent order requiring a Maryland corporation with its principal place of business in Beaverton, Oreg., operating a chain of retail drug and general merchandise stores in Washington, Oregon, California and other States, to make advertised items readily available; to use shelf signs to indicate the location of items advertised below the regular shelf price; to mark customarily price-marked items with their advertised prices; to sell advertised merchandise at or below the advertised price; and to post in its stores copies of advertisements and notices of the availability of rain-checks for unavailable items or a substituted product of equal or better quality at the advertised price of the unavailable advertised item.

Appearances

For the Commission: *W. Lee Buck.*

For the respondent: *H. Stewart Tremaine, Black, Kendall, Tremaine, Boothe & Higgins,* Portland, Oreg.

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 Pay Less Drug Stores Northwest, Inc., a corporation, hereinafter sometimes referred to as respondent, has violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereto would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent Pay Less Drug Stores Northwest, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Maryland, with its principal office and place of business located at 10605 S.W. Allen Boulevard, Beaverton, Oregon.

PAR. 2. All allegations made in the present tense include the past tense.

PAR. 3. Respondent is engaged in the operation of retail drug and general merchandise stores in Washington, Oregon, California, and other States. Its volume of business is substantial. In the operation of its retail stores, respondent offers and sells to its customers an extensive line of products, including drugs, photographic equipment, groceries, fabrics, sporting goods, household articles, tools, and other

general merchandise, all of which are referred to hereafter as "items." Many of said items are purchased from numerous suppliers located throughout the United States.

PAR. 4. In the course and conduct of its business, respondent causes, directly or indirectly, the aforesaid items to be shipped and distributed from manufacturing plants, warehouses, or from other sources of supply to its warehouses, distribution centers, or retail stores located in various States other than the State of origination, distribution or storage of said items. Respondent maintains a substantial course of trade in the distribution, advertising, offering for sale and sale of the aforesaid items in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, as amended.

PAR. 5. In the course and conduct of its business, as aforesaid, respondent disseminates and causes to be disseminated certain advertisements concerning the aforesaid items by various means, including but not limited to advertisements in newspapers of general and interstate circulation and other advertising media, for the purpose of inducing and which are likely to induce, directly or indirectly, the attempted or actual purchase from respondent of said items in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, as amended. Many of the said advertisements list, describe or depict various items and also contain statements and representations concerning the price or terms at which said items would be offered for sale and sold to the public. Many of said advertisements contain further direct and express statements and representations concerning the time periods during which the offers would be in effect and the locations of respondent's stores at which the offers would be made.

PAR. 6. Through the use of such advertisements disseminated in various areas of the United States served by respondent's retail stores, respondent represents directly or by implication that in those stores covered by such advertisements, throughout the effective periods of the advertised offers, the items listed or depicted in such advertisements would be or are:

A. Readily available for sale to customers;

B. Readily available for sale at or below the advertised prices; and

C. Sold to customers at or below the advertised price.

PAR. 7. In truth and in fact, in a number of respondent's retail stores located in the Seattle, Washington, and Portland, Oregon, metropolitan areas in which the aforesaid advertisements are disseminated, in stores covered by such advertisements, during the effective periods of the advertised offers, a substantial number of the items listed or depicted in the said advertisements are:

A. Not readily available for sale;

B. Not readily available for sale at or below the advertised prices; or

C. Sold to customers at prices higher than the advertised prices.

Therefore, the statements and representations as referred to herein are false, misleading and deceptive.

PAR. 8. By disseminating or causing the dissemination of advertisements which offer or present for sale items as aforesaid, and by failing to have in each of its stores covered by such advertisements, throughout the effective periods of the advertised offers, in quantities sufficient to meet reasonably anticipated demands, the advertised items:

A. Readily available for sale to customers; or

B. Readily available for sale at or below the advertised prices; respondent is engaged in unfair acts and practices.

PAR. 9. By disseminating or causing the dissemination of advertisements which offer or present for sale items at specific prices, as aforesaid, and during the effective periods of such advertised offers at certain stores covered by said advertisements, by selling said items or other merchandise to customers at prices higher than the advertised prices, respondent is engaged in unfair acts and practices.

PAR. 10. The use by respondent of the aforesaid unfair and false, misleading and deceptive statements, representations, acts and practices has the capacity and tendency to mislead members of the purchasing public into the erroneous and mistaken belief that the said statements and representations are true, and to induce such persons to go to respondent's stores and to purchase from respondent substantial quantities of the advertised items at prices in excess of the advertised prices.

PAR. 11. In the course and conduct of its business, and at all times referred to herein, respondent is in substantial competition in commerce with corporations, partnerships, firms and individuals in the retail drug and general merchandise businesses.

PAR. 12. The acts and practices of respondent, as herein alleged, are all to the prejudice and injury of the public and of respondent's competitors, and constitute unfair methods of competition and unfair and deceptive acts and practices in or affecting commerce, in violation of Section 5 of the Federal Trade Commission Act, as amended.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a

copy of a draft of complaint which the Seattle Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

A. Pay Less Drug Stores Northwest, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Maryland with its office and principal place of business located at 10605 S.W. Allen Boulevard, Beaverton, Oregon.

B. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

I

It is ordered, That respondent Pay Less Drug Stores Northwest, Inc., a corporation, its successors or assigns, its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of drugs or other merchandise, hereinafter sometimes referred to as items, offered or sold in its retail stores, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from, directly or indirectly:

A. Disseminating, or causing the dissemination of any advertisement by any means which offers or presents any items for sale, unless

throughout the effective period of the advertised offer at each retail store covered by the advertisement:

(1) Each advertised item is readily available for sale to customers in the public area of the store, or if not readily available there, a clear and conspicuous notice is posted where the item is regularly displayed which states that the item is in stock and may be obtained upon request, and said item is furnished on request:

(2) There is a sign or other conspicuous marking at the place where an item advertised below regular shelf price is displayed for sale clearly disclosing that the item is "as advertised" or "on sale" or words of similar import as appropriate, and disclosing on such sign or marking, the advertised price;

(3) Each unit of each advertised item, which is usually and customarily individually marked with a price, is individually, clearly, and conspicuously marked with a price no higher than the advertised price;

(4) Each unit of each advertised item is sold to customers at or below the advertised price;

Provided, it shall constitute a defense to a charge of unavailability under subparagraph (1) if respondent maintains and furnishes or makes available for inspection and copying upon the request of the Federal Trade Commission, such records as will show that (a) the advertised items were delivered to its stores in quantities sufficient to meet reasonably anticipated demand but were "sold out," or (b) the advertised items were ordered but not delivered due to circumstances beyond respondent's control, and that respondent, upon notice or knowledge of such nondelivery acted immediately to contact the media to correct the advertisement or proposed advertisement to reflect the limited availability or unavailability of each advertised item, and (c) respondent immediately offered to customers on inquiry a "raincheck" for each unavailable item which entitled the holder to purchase the item in the near future at or below the advertised price, or a similar product of equal or better quality at or below the advertised price of the unavailable product.

Provided, further, that a coupon or book of coupons offered, presented, sold or distributed only at respondent's retail stores shall not be deemed an advertisement.

Provided, further, that in the case of advertised items the ultimate prices of whose units are determined by the use of a coupon, or other similar conditional price arrangement, the prices at which the units are sold, and not the prices marked on the units, shall govern.

Provided, further, that in stores equipped with optical scanning devices which electronically "read" the identification numbers marked

on the packaging of such units, and which transmit the number to a computer which then transmits the correct price of the items to an electronic cash register where the price is displayed and printed on the cash register tape, the units need not be price-marked in any additional manner.

Provided, further, that if an advertised item is placed for sale in a large stack, pyramid or other display containing a great number of such items, all of the items need not be individually remarked at or below the advertised price, if the items not marked individually at or below the advertised price are so situated that it would be difficult or impossible for a customer to select such item.

Provided, further, that it shall not be deemed a violation of the above subparagraphs (1) through (4) if respondent is complying with a specific exemption, limitation or restriction with respect to store, item or price which is clearly and conspicuously disclosed in all advertisements for the product in question.

II

It is further ordered, That throughout each advertised sale period in each of its retail stores covered by an advertisement, respondent shall post conspicuously (1) at or near each doorway affording entrance to the public, and (2) at or near the place where customers pay for merchandise, notices which contain the following:

A. A copy of the advertisement. Copies shall be posted at or near every checkstand where customers pay for merchandise and shall be posted in such a fashion that all customers purchasing merchandise can easily read them while standing at the checkstand.

B. The following statement:

All items advertised are required by law to be readily available for sale at or below the advertised prices in each Pay Less store except as specifically noted in this ad.

If an advertised item you wish to purchase is unavailable, you may obtain a raincheck that will enable you to purchase this item at the advertised price in the near future. Or, you will be allowed to purchase, immediately, a similar product of equal or better quality at the advertised price of the unavailable advertised item.

If you have any questions, the store manager will be glad to assist you.

III

It is further ordered, That respondent shall cause the following statement to be clearly and conspicuously set forth in each advertise-

ment which represents that items are available for sale at a stated price at any of its stores: "Each of these advertised items is required to be readily available for sale at or below the advertised price in each Pay Less store, except as specifically noted in this ad." Additionally, said statement may identify the stores, the city or the geographical area covered by the advertisement.

IV

It is further ordered, That:

A. Respondent shall forthwith deliver a copy of this order to each of its operating divisions and to each of its present and future officers and other personnel in its organization down to the level of and including assistant store managers and any other store level personnel who, directly or indirectly, have any responsibilities relating in any way to pricing and charging out of advertised items in any of the individual retail stores of respondent, or who are engaged in any aspect of preparation, creation, or placing of advertising, and that respondent shall secure a signed statement acknowledging receipt of said order from each such person;

B. Respondent shall institute and maintain a program of continuing surveillance adequate to reveal whether the business practices of each of its retail stores conform to this order, and shall confer with any duly authorized representative of the Commission pertaining to such program when requested to do so by a duly authorized representative of the Commission;

C. Respondent shall, for a period of three (3) years subsequent to the date of this order:

1. Maintain business records which show the efforts taken to ensure continuing compliance with the terms and provisions of this order and any evidence of the results of such efforts;

2. Furnish to the Federal Trade Commission copies of such records which are requested by any of its duly authorized representatives;

D. Respondent shall, all other provisions of this order notwithstanding, every six months for a period of three years from the date this order becomes final, file with the Commission a report, in writing demonstrating the effectiveness of the steps or actions taken by respondent with regard to the aforesaid surveillance program, and setting forth in detail the manner and form in which it has complied with this order in the preceding year.

V

It is further ordered, That respondent shall notify the Commission at

least thirty days prior to any proposed change in the corporate respondent, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the respondent which may affect compliance obligations arising out of this order.