IN THE MATTER OF

PORTER & DIETSCH, INC., ET AL.

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

Docket 9047. Complaint, July 29, 1975 — Final Order, Dec. 20, 1977

This order, among other things, requires a St. Paul, Minn. distributor of non-prescription drugs, its Chicago, Ill. advertising agency, and a Seattle, Wash. drug store chain to cease making unsubstantiated claims or misrepresenting that products contain a unique ingredient, or that users of weight control products can achieve weight loss without restricting their caloric intake or limiting their choice of foods. Further, the firms are required to include prescribed disclosure statements in promotional materials for products containing certain ingredients, and to recall all advertising data disseminated during the past two years for X-11 tablets.

Appearances

For the Commission: *Dean A. Fournier* and *William H. Patton.*

For the respondents: *Albert A. Carretta,* Washington, D.C. and *Jerold W. Dorfman,* New York City for Porter & Dietsch, Inc., et al. and *Michael Rayton,* Seattle, Washington for Pay'n Save Corporation.

COMPLAINT

The Federal Trade Commission, having reason to believe that Porter & Dietsch, Inc., a corporation, and William H. Fraser, individually and as an officer of said corporation, and Kelly Ketting Furth, Inc., a corporation, and Joseph Furth, individually and as an officer of said corporation, and Pay'n Save Corporation, a corporation, hereinafter sometimes referred to as respondents, have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this complaint stating its charges as follows:

PARAGRAPH 1. Respondent Porter & Dietsch, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Minnesota, with its office and principal place of business located at 2453 University Ave., St. Paul, Minnesota. Respondent William H. Fraser is president of said corporation. He formulates, directs and controls the policies, acts and [2] practices of this corporate respondent, including the acts and practices hereinafter set forth. His address is the same as that of said corporation.

Respondent Kelly Ketting Furth, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Illinois, with its office and principal place of business located at 400 North Michigan Ave., Chicago, Illinois. Respondent Joseph Furth is an officer of said corporation and formulates, directs and controls certain acts and practices of this corporate respondent, including the acts and practices hereinafter set forth. His address is the same as that of said corporation.

Respondent Pay'n Save Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of Washington, with its office and principal place of business located at 1511 Sixth Ave., Seattle, Washington.

PAR. 2. For purposes of this complaint, the term "commerce" shall mean commerce as defined in the Federal Trade Commission Act.

PAR. 3. Respondents Porter & Dietsch, Inc. and William H. Fraser are now and have been engaged in the packaging, advertising, offering for sale and sale of various products at wholesale and retail levels. Among such products is a non-prescription preparation which comes within the classification of "drug" (as that term is defined in the Federal Trade Commission Act) and which has the following designation, directions for use and active ingredients:

Designation: "X-11 Tablets"

Dosage:

One tablet three times daily, one-half hour before each meal.

Active Ingredients:

Vitamin A	1388.0 U.S.P. units
Vitamin B	0.5 mg.
Vitamin B_2	0.5 mg.
Vitamin B_6	1.0 mg.
Vitamin C	15.0 mg.
Calcium Pantothenate	1.0 mg.
[3]Niacinamide	5.0 mg.
Vitamin E	5.0 int. units
Vitamin B_{12}	0.5 mg.
Phenylpropanolamine Hydrochloride	25.0 mg.
Methylcellulose	25.0 mg.
Caffeine	25.0 mg.

PAR. 4. Respondent Kelly Ketting Furth, Inc. is now and has been the advertising agency of Porter & Dietsch, Inc. Respondent Joseph Furth is now and has been the account executive in such agency responsible for advertising of products marketed by Porter & Dietsch, Inc. As such, these respondents have prepared and placed for publication advertising material, including but not limited to the advertising referred to herein, to promote the sale of the aforesaid preparation and other products. In the course and conduct of their business, and at all times mentioned herein, these respondents have been and are now in substantial competition, in or affecting commerce, with other corporations, firms and individuals in the advertising business.

PAR. 5. Respondent Pay'n Save Corporation operates a chain of drug and sundries stores in Washington, Oregon, Alaska, California, Hawaii, and Canada. Said respondent is now and has been engaged in the advertising, offering for sale and sale of various products including the aforesaid preparation.

PAR. 6. In the course and conduct of their business, respondents Porter & Dietsch, Inc. and William H. Fraser ship, distribute and cause to be shipped and distributed the aforesaid preparation from their place of business in the State of Minnesota to retail stores and purchasers located in various other States of the United States.

In the course and conduct of its business, respondent Pay'n Save Corporation operates retail stores and storage warehouses in several States of the United States. Said respondent causes the aforesaid preparation to be shipped from Minnesota to storage points and Pay'n Save stores located in various other states, for sale to the general public.

In the further course and conduct of their businesses, and using means and mechanisms of commerce, these respondents and respondents Kelly Ketting Furth, Inc. and Joseph Furth cause advertisements for said preparation to be published in media of interstate circulation. [4]

Respondents maintain, and at all times mentioned herein have maintained, a substantial course of trade in the aforesaid preparation and advertisements, in or affecting commerce.

PAR. 7. In the course and conduct of their businesses, respondents have disseminated, and caused the dissemination of, certain advertisements concerning said preparation by the United States mail and by various means in or having an effect upon commerce, including but not limited to advertisements inserted in newspapers, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparation; and have disseminated

and caused the dissemination of advertisements concerning said preparation by various means, including but not limited to the aforesaid media, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparation in or having an effect upon commerce.

PAR. 8. Typical of the statements and representations in said advertisements, but not all inclusive thereof, are the following:

Eat well . . . and lose that fat! – without ever missing a meal . . .

* * * * * * *

You eat 3 satisfying balanced meals a day – plus snacks. You eat what you want . . .

* * * * * * *

You do not deny yourself.

* * * * * * *

. . . Laboratory Science has perfected a Tiny Tablet for EASY REDUCING . . . clinic-tested ingredients . . .

* * * * * * *

I lost 80 pounds! When I started on the X–11 Reducing Plan, I weighed 205 pounds. Now my weight is down to 125 pounds. I enjoy wearing dresses sizes 11 or 12's, rather than size 20 1/2 . . .

* * * * * * *

Part of the secret of this method is a unique ingredient . . . which puts a "brake" on your cravings for sweets, candy, pastries, rich gravies.

USED TO WEIGH 160 LBS. NOW I'M DOWN TO 105

says Mrs. George Stowe
Canon, Georgia

"I started on the X-11 Plan and started losing weight almost right away. I am so grateful . . . I recommend the X-11 Plan to everyone I see. It's wonderful."

I LOST OVER 40 LBS.

says
Mrs. Beverly Tellier
Chula Vista,
California

"I used to weigh over 170 lbs. Now I'm less than 125 lbs. and going down. I have recommended your plan to a lot of people because they just couldn't believe the results."

Mrs. George Stowe says:
"I am 25 years old and here are my before-and-after measurements . . ."

	WAS	AM
WEIGHT	160 lbs.	105 lbs.
HEIGHT	5-2½ in.	5-2½ in.
DRESS SIZE	18	8
BUST	38 in.	34 in.
WAIST	29 in.	24 in.

...and I LOST OVER 40 LBS., TOO

says Mrs. Ken Schmidt
Norfolk, Nebraska

"When I started on the X-11 Reducing Plan, I weighed 180 lbs. Now I'm under 125. I enjoy wearing dresses sizes 11 - 12's rather than 20½. It's good to know there's a way to lose ugly fat and keep my weight at a level I dreamed of holding."

X-11 REDUCING PLAN

FROM GEORGIA TO NEBRASKA TO CALIFORNIA AMERICAN WOMEN HAVE FOUND A WAY THAT REALLY HELPS OFF THAT UGLY FAT

No Starvation Dieting - No Strenuous Exercise RESULTS ARE GUARANTEED - OR MONEY BACK

Here, at last, is that wonderful kind of plan that offers you a way to help get rid of 5, 10, 25 or more pounds of unsightly fat. Not by suffering thru starvation dieting hunger . . . not by sticking to boring reducing diets . . . not by extra-tiring exercises . . . not by any of the humdrum methods you have known and given up.

Now . . . Lose Ugly Fat . . . *and don't go to bed hungry.* The X-11 Plan is not a crash or starvation diet. That's because X-11 is the proved and sound method, used from one end of America to the other, to curb the appetite and still eat 3 satisfying, sensible meals a day.

Laboratory Science has perfected a tiny pre-meal tablet with a plan that lets you eat 3 sensible meals a day, plus "dream meal" extras.

X-11 REDUCING PLAN

42 Tablets 3.00
105 Tablets 5.00
OR MAIL COUPON!

EAT WELL ...and lose that Fat.

You will eat, satisfying meals and snacks, but you won't be the prisoner of the overeating habit. If you aren't 100% delighted, return your first package for an immediate refund — no questions asked.

PAY 'n SAVE
AVAILABLE AT ALL STORES

Mail to: PAY 'n SAVE DRUGS — Dept. AD.
1811-8th AVE., SEATTLE, WASH. 98101
Please send me ..... Packages of X-11
☐ 42 Tablets at $3.00 (Plus 15c Sales Tax)
☐ 105 Tablets at $5.00 (Plus 25c Sales Tax)
PLEASE PRINT YOUR NAME AND ADDRESS BELOW:
Name _____
Address _____
City _____ State _____ Zip _____
☐ Cash enclosed ☐ Money Order ☐ Check enclosed
GUARANTEE — You must be 100% delighted with results of your first package or your money will be refunded — no questions asked.

[6] PAR. 9. Through the use of said advertisements and others similar thereto but not specifically set out herein, respondents have represented and are now representing, directly or by implication, that:

A. Users of X-11 tablets can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice.

B. Respondents have a reasonable basis from which to conclude that substantially all users of X-11 tablets will lose a significant amount of weight.

C. The X-11 tablet contains a unique ingredient.

PAR. 10. In truth and in fact:

A. Users of X-11 tablets cannot lose weight without restricting their accustomed caloric intake nor while they continue to eat the foods of their choice. In fact, each X-11 package includes a diet highly restricted as to calories and choice of foods, which must be adhered to if weight loss is to be achieved.

B. Respondents have no reasonable basis from which to conclude that substantially all users of X-11 tablets will lose a significant amount of weight.

C. The X-11 tablet does not contain any unique ingredient.

PAR. 11. Several of the advertisements described and alluded to in Paragraph Eight hereof include testimonials reciting weight reduction and other figure improvements purportedly attained by lay users of the aforesaid preparation, when such stated results do not reflect the typical or ordinary experience of consumers with said preparation under circumstances similar to those depicted in the advertisements. These advertisements do not disclose or identify such typical or ordinary experience in any way. Thus, respondents have failed to disclose in their advertising a material fact which, if known to consumers, would be likely to affect their consideration of whether or not to purchase said preparation. [7]

PAR. 12. Respondents have marketed and advertised X-11 tablets without disclosing in the advertising thereof that persons with high blood pressure, heart disease, diabetes or thyroid disease should use said preparation only as directed by a physician. Inasmuch as a substantial number of overweight persons are suffering from one or more of said physical conditions, respondents have failed to disclose in their advertising a material fact which, if known to such persons, would be likely to affect their consideration of whether or not to purchase said preparation.

PAR. 13. Respondents have marketed and advertised the "X-11 Reducing Plan" without disclosing in the advertising thereof that a

highly restricted caloric diet is an integral part of said plan. Such fact, if known to consumers, would be likely to affect their consideration of whether or not to purchase said product. Thus, respondents have failed to disclose a material fact in their advertising.

PAR. 14. The advertisements referred to in Paragraphs Eight, Eleven, Twelve and Thirteen were and are misleading in material respects, as alleged in Paragraphs Ten, Eleven, Twelve and Thirteen, and constituted, and now constitute, "false advertisements," as that term is defined in the Federal Trade Commission Act, and the statements, representations and omissions described in Paragraphs Nine, Eleven, Twelve and Thirteen were and are misleading, deceptive and unfair acts or practices.

PAR. 15. The use by respondents of the aforesaid misleading, deceptive and unfair statements, representations, acts and practices, and the dissemination of the aforesaid "false advertisements," have had and now have the capacity and tendency to mislead members of the consuming public into the erroneous and mistaken belief that said statements and representations were and are true and complete, and into the purchase of substantial quantities of X-11 tablets by reason of said erroneous and mistaken belief.

PAR. 16. In the course and conduct of their businesses, and at all times mentioned herein, respondents Porter & Dietsch, Inc., William H. Fraser and Pay'n Save Corporation have been and now are in substantial competition, in or affecting commerce, with corporations, firms and individuals in the sale of products and services for weight reduction. [8]

PAR. 17. The aforesaid acts and practices of respondents including the dissemination of "false advertisements," as herein alleged, were and are all to the prejudice and injury of the public and of respondents' competitors and constituted, and now constitute, unfair and deceptive acts and practices in commerce and unfair methods of competition in or affecting commerce in violation of Sections 5 and 12 of the Federal Trade Commission Act.

Commissioner Thompson dissenting.

DISSENTING STATEMENT OF COMMISSIONER MAYO J. THOMPSON

JULY 29, 1975

I share the majority's view that the principal distributor of an alleged weight-reducing pill ought to be able to substantiate the claims he makes for it and that, if it is in fact dangerous for people with heart disease, diabetes, high blood pressure, and other diseases

to take it, he ought to say so in his ads. But I cannot agree with my Brethren that a *retailer* with no involvement in the preparation of the ads in question should be subjected to liability here.

The advertisements in question are prepared by the distributor of these pills, Porter & Dietsch,[1] with the actual copy being written by its president and controlling owner, Mr. William H. Fraser. Advertising mats are prepared and sent out to the major regional and local drug chains, including Pay'n Save Corporation, a Seattle-based drug retailer with some 90 stores located in five (5) states. The distributor pays for approximately 90 percent of the cost of these ads, with the cooperating retailer paying the remaining 10 percent. Since the messages are directed to the ultimate consumer and generally exhort him to buy from the drug chain, it is the latter's name rather than that of the distributor which appears in the ads.

Why pick on Pay'n Save? Other drug chains have been similarly "involved," including Fred Meyer (Portland); Western Drug (Montana); Pay Less (Tacoma); Skaggs and Grand Central Stores (Boise); Tiffany [2] Drugstores (Eugene, Oregon); Drug Fair (Washington, D.C.); and Walgreens (Chicago). The staff explains the selection of Pay'n Save by simply noting that it is the largest of the participating chains in the Pacific Northwest. (The investigation was conducted by our Seattle regional office.) In other words, Pay'n Save was the most *convenient* retailer target.

It is conceded that Pay'n Save "had a significantly lower level of involvement" in the ads than Porter & Dietsch and its president, Mr. Fraser, but the staff believes this factor is more than outweighed by the need to establish a new legal precedent. An "important aspect of this case," the staff tells us, "is the inclusion of the advertising retailer, Pay'n Save Corporation, as a named respondent." A retailer who *uses* a deceptive ad, we're told, ought to be held just as liable as the fellow who created it in the first place. Had Pay'n Save made a "thoughtful" examination of the packages in question, including the disclosures on the package insert, it would have known something was wrong.

The problem, the staff reports to us, is that the country's retailers have been getting away with murder in this area. While "major general-merchandise retailers are frequently involved and/or specifically identified as the advertiser in highly questionable ads devoted to a single product, our research has disclosed no clearcut instances of such retailers being held responsible for manifestly deceptive product claims appearing in such ads. Subjection of Pay'n Save to

[1] Porter & Dietsch is the "exclusive national distributor" of this product, the "X-11" reducing pill.

the 'cease and desist' provisions of this order will help to reestablish this responsibility principle in the context of this type of advertising."

So there we have it. The staff wants to establish a new principle of trade regulation law. *Any retailer who runs an ad prepared by a supplier is legally liable for the truthfulness of everything in it.* Never mind that he didn't participate in the preparation of the ad and that it would be economically prohibitive for [3] him to maintain a staff of scientists and lawyers to screen all the supplier ads that a substantial retailer is confronted with in the course of a business year. In short, strict "no-fault" liability. Run the ad at your peril.

I think the Commission is embarking on an unwise, dangerous, and unnecessary course of action here. It is unwise because it defies common sense. It is dangerous because it imposes an intolerable cost burden on the nation's retailers that can only be passed on to the consumer in the form of still more inflated prices than those we now labor under. And it is unnecessary because a cease and desist order that stops the development of deceptive advertisements at the headwaters clearly makes it unnecessary to seine all the downstream tributaries.

I would dismiss Pay'n Save from this complaint.

INITIAL DECISION BY DANIEL H. HANSCOM, ADMINISTRATIVE LAW JUDGE

MAY 21, 1976

I

STATEMENT OF THE CASE

ALLEGATIONS OF COMPLAINT

The complaint in this proceeding charged respondents Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., Joseph Furth and Pay'n Save Corporation with the dissemination of false advertisements and unfair, misleading and deceptive statements and representations in the advertising, promotion and sale of X-11 tablets in violation of Sections 5 and 12 of the Federal Trade Commission Act.[1] More specifically, the complaint alleged that respondents disseminated advertisements which misrepresented,

[1] Then Commissioner Thompson dissented from the naming of Pay'n Save Corporation, a large West Coast drug chain, as a respondent in this proceeding on the grounds, *inter alia*, that he could not agree that "a *retailer* with no involvement in the preparation of the ads in question should be subjected to liability here," and that Pay'n Save was being singled out among many drug store chains, as "the most *convenient* retailer target." See statement issued with the complaint.

directly or by implication, that "[u]sers of X-11 tablets can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice," that respondents had a "reasonable basis from which to conclude that substantially all users of X-11 tablets will lose a significant amount of weight," and that each "X-11 tablet contains a unique ingredient."

The complaint further alleged that some of respondents' advertisements included testimonials reciting weight reduction and other figure improvements purportedly attained by lay users of the "aforesaid preparation" which did not reflect the "typical" or "ordinary" experience of consumers "under circumstances [3] similar to those depicted in the advertisements." Failure of the advertisements to disclose or identify the typical or ordinary experience of persons using the tablets was alleged to constitute a failure to disclose a material fact which, if known, would have affected the consumer's consideration of "whether or not to purchase said preparation."

The complaint also alleged that respondents "marketed and advertised X-11 tablets without disclosing in the advertising thereof that persons with high blood pressure, heart disease, diabetes or thyroid disease should use [them] only as directed by a physician," and that in doing so respondents failed to disclose a material fact in such advertising. Finally, the complaint charged that the "X-11 Reducing Plan" was marketed and advertised without disclosing that "a highly restricted caloric diet [was] an integral part of said plan," and that such constituted a failure to disclose a material fact.

RESPONDENTS' ANSWERS

Respondents filed answers denying most of the substantive allegations of the complaint, and raising a number of affirmative defenses. Respondents Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth denied that they ever marketed a product designated "X-11 Tablets," contending that they were engaged in the sale of the "X-11 Reducing Plan" which "includes for ingestion tablets having the ingredients set forth in Paragraph Three of the Complaint." The foregoing respondents also denied representing that "users of X-11 tablets can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice," and denied representing "that substantially all users of X-11 tablets [would] lose a significant amount of weight." Respondents contended that they had advertised [4] only the "X-11 Reducing Plan," not tablets and represented only that users of the "X-11 Reducing Plan" would lose some weight, and

that they had a reasonable basis for this assertion. Lack of public interest also was urged.

Respondent Pay'n Save maintained that it received the prepared X-11 advertisements from Porter & Dietsch, Inc., and therefore "cannot be held liable for the truthfulness of representations made therein by others."

Prior to the completion of evidentiary hearings respondents Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc. and Joseph Furth filed an amended answer contending that the Federal Trade Commission is "precluded from bringing this proceeding . . . under the principles of collateral estoppel and/or stare decisis." Respondent Pay'n Save likewise filed an amended answer contending that "Complaint Counsel is precluded from bringing this proceeding under the principles of res judicata, collateral estoppel and/or stare decisis." According to respondents, three litigated decisions, *Alleghany Pharmacal Corporation,* 75 F.T.C. 990 (1969), *Hanover House* and *Romar Sales,* proceedings before the Postal Service,[2] preclude trial in this proceeding of issues relating to the "safety and efficacy of phenylpropanolamine as an appetite suppressant for weight reduction."

PROCEDURAL HISTORY

Complaint was served on the various respondents between the end of August and early September 1975. On September 10, the law judge issued an order directing counsel to attempt agreement on a timetable for completion of prehearing matters and a date and place for hearings on the merits. Thereafter, at the request of counsel for Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth, a prehearing conference was held on October 7, 1975, [5] and a timetable was issued the following day setting hearings on the merits to commence January 6, 1976.

The parties disagreed as to the location of hearings. After considering all submissions, the law judge ordered that hearings be held in Seattle, Washington, where Pay'n Save Corporation and its counsel[3] and a number of witnesses and complaint counsel were located, and in Washington, D.C., to take the testimony of East Coast witnesses. Hearings in Chicago, Illinois, to accomodate Porter &

[2] *Hanover House* and *Romar Sales Corp.*, P.S. Dkt. Nos. 2/143 and 2/149, decision of December 5, 1975.

[3] Original counsel for Pay'n Save Corporation withdrew on October 2, and Albert A. Carretta, counsel for Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth, took over as counsel for all respondents. However, on October 28, Mr. Carretta withdrew as counsel for Pay'n Save Corporation because of a possible conflict of interest between that respondent and one or more of the other respondents. Original counsel for Pay'n Save Corporation then reentered the proceeding.

Dietsch, Inc., William H. Fraser, Kelly Ketting Furth and Joseph Furth were also offered if requested by those respondents.[4]

In the meantime, Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth moved on September 24, 1975, for a "Corrective News Release" and a stay of the date for filing an answer on the ground that the Commission's News Release failed to contain the usual caveat that the Commission issues a complaint when it has "reason to believe" that the law has been violated, and that such action did not imply adjudication of the matters alleged. This motion for a "Corrective News Release" was certified to the Commission recommending that it be granted, but the request for a stay of the date for filing an answer was denied. On October 17, 1975, the Commission granted the motion for such correction. [6]

Thereafter, discovery and various other pretrial proceedings continued. The law judge issued a number of subpoenas requiring the production of documents and information by respondents, directed the production of specified Commission materials, ordered the taking of certain depositions and disposed of a variety of motions. Included among the latter were a motion and supporting memorandum of Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth to "Dismiss Complaint Before Trial For Lack Of Public Interest Sufficient To Justify Issuance Of A Cease And Desist Order" and their motion and supporting memorandum for a "Supplementary Corrective News Release." The latter motion was certified to the Commission with a recommendation pursuant to §3.22 of the rules and was denied by the Commission on December 19, 1975.

Respondent Pay'n Save Corporation also filed a motion to "Dismiss Complaint Before Trial Or, In The Alternative, For Summary Decision" which was supported by a memorandum filed by Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth. This motion was denied by the law judge on December 30, 1976.

On December 23, 1975, all respondents filed an action in the U.S. District Court for the District of Columbia seeking a declaratory judgment and restraint of further proceedings in this matter. They alleged that a cease and desist order against them would not be in the public interest, that the Commission's News Releases were improper, and that the scheduling of hearings in Seattle and Washington, D.C., rather than in one location "convenient to all parties," violated the due process clause of the Fifth Amendment,

[4] On December 29, 1975, counsel for respondents formally declined hearings in Chicago, Illinois, and evidentiary hearings were not held at this location.

the Administrative Procedure Act and the Commission's rules. On January 5, 1976, after hearing oral argument, the District Court denied respondents' motion for a preliminary injunction and thereafter dismissed the complaint. [7]

Hearings on the merits commenced in Seattle, Washington, on January 7 and concluded in Washington, D.C., on January 26, 1976, 8 actual hearing days having been utilized during that period. The record consisting of 220 exhibits, many of them multi-paged, and 1,405 pages of transcript was closed by order of the law judge on February 10. Twelve witnesses testified including the individual respondents and an official of Pay'n Save Corporation, and the testimony of three witnesses was entered in the record by stipulation. Complaint counsel called four medical or scientific experts, Drs. Margen, Drenick, Prout and Sorer, and respondents Porter & Dietsch, Inc., William H. Fraser, Kelly Ketting Furth, Inc., and Joseph Furth called three, Dr. Fineberg, a medical doctor, Dr. Silverman, a pharmacologist, and Dr. Hoebel, a specialist in physiological psychology.

At the conclusion of the case-in-chief respondents orally moved to dismiss on the ground that complaint counsel had not made out a prima facie case (Tr. 1038–97). Ruling was deferred by the law judge until decision on the entire case after all evidence had been received, and permission was granted to respondents to reduce their motion to writing supporting it with record references and legal authority. On March 29, 1976, respondents (except Pay'n Save) filed a comprehensive written motion to dismiss with a separately bound appendix in support. This motion will be referred to hereinafter as "Motion to Dismiss" and will be ruled upon in this Initial Decision in accordance with the findings, discussion and conclusions set forth.

This matter is now before the undersigned for decision based upon the allegations of the complaint, the answers, the evidence and the proposed findings of fact, conclusions and legal authority filed by all parties. All proposed findings of fact, conclusions and arguments, including those in the Motion to Dismiss, not specifically found or accepted herein, are rejected. The law judge, having considered the entire record, and all the contentions of the parties, makes the following findings and conclusions and issues the order set out at the end hereof: [8]

II

FINDINGS OF FACT

RESPONDENTS

1. Respondent Porter & Dietsch, Inc. (Porter & Dietsch), is a Minnesota corporation with its office and principal place of business in St. Paul. It is engaged in the packaging and sale of pharmaceutical products, principally by mail and through retail drug stores (Ans. P&D, ¶1; Fraser, Tr. 753-54). Porter & Dietsch has sold its X-11 tablets since 1967 (Ans. P&D, ¶3; Fraser, Tr. 769, 823) and, although a few other products are sold, the tablets are by far its largest volume item, amounting to over 80 percent of all sales (Fraser, Tr. 757-61).

2. Individual respondent William H. Fraser is the president and sole owner of Porter & Dietsch (Fraser, Tr. 753-54). As such, Mr. Fraser formulates, directs and controls the policies, acts and practices of corporate respondent Porter & Dietsch (Ans. P&D, ¶1).

3. In the course and conduct of their business, Porter & Dietsch and William H. Fraser have been and now are in substantial competition in or affecting commerce (as "commerce" is defined in the Federal Trade Commission Act) with other corporations, firms and individuals in the sale of products and services for weight reduction (Ans. P&D, ¶16).

4. Respondent Kelly Ketting Furth, Inc. (Kelly Ketting Furth) is an advertising agency incorporated in Illinois, with its office and principal place of business in Chicago (Ans. P&D, ¶1). Since its organization in 1968, Kelly Ketting Furth has been, and is, the advertising agency for Porter & Dietsch in the marketing of X-11 tablets (Ans. P&D, ¶4; Fraser, Tr. 805; Furth, Tr. 927-32). [9]

5. Individual respondent Joseph Furth is a vice-president of Kelly Ketting Furth and is the advertising account executive for respondent Porter & Dietsch (Ans. P&D, ¶4; Furth, Tr. 927-36). Mr. Furth participates in the management of Kelly Ketting Furth and is among those responsible for the formulation, direction and control of its acts and practices, including those alleged in the complaint (Ans. P&D, ¶1).

6. In the course and conduct of their business Kelly Ketting Furth and Joseph Furth are now, and have been, throughout the period that Kelly Ketting Furth has been the advertising agency for Porter & Dietsch, in substantial competition in or affecting commerce (as "commerce" is defined in the Federal Trade Commission Act) with

other corporations, firms and individuals in the advertising business (Ans. P&D, ¶4).

7. Pay'n Save Corporation is a Washington corporation with its headquarters located in Seattle. It is a major chain of retail drug and sundry stores with outlets located principally in the Northwest and in northern California with some stores in Alaska and Hawaii (Ans. P&D, ¶¶ 1 and 5). Gross sales volume for the 12-month period ending November 1, 1975, was approximately $290,000,000 (Stipulation, Tr. 435). Porter & Dietsch's X-11 tablets have been sold by Pay'n Save since 1969 (Ans. P&D, ¶5; Palmer, Tr. 507-08).

8. In the course and conduct of its business and throughout the period of its marketing and/or advertising of Porter & Dietsch's X-11 tablets, Pay'n Save has been and now is in substantial competition in or affecting commerce (as "commerce" is defined in the Federal Trade Commission Act) with other corporations, firms or individuals in the sale of various products, including products sold as aids in weight reduction (Ans. P&S, ¶¶ 2, 4, 5). [10]

X-11 TABLETS

1. *Nature and sales*

9. Porter & Dietsch purchase the X-11 tablets they market from the manufacturer in polyethylene pouches containing 21 tablets each. These pouches are then packaged in cartons of two sizes - one box containing two (2) pouches totaling 42 tablets and a larger size containing five (5) pouches totaling 105 tablets (Fraser, Tr. 769-70). The smaller box is normally sold at retail for $3.00 and the larger size for $5.00 (Adm. P&D, No. 9b; CX 36, 39, and 62). In addition to the tablets, each box contains a leaflet providing directions for the purchaser in using the tablets and some advice about obesity, a rudimentary low-calorie diet for a 5-week period, a "calorie value chart" for a limited number of foods, a weight chart and a "warning" against use by individuals with certain physical conditions unless medically supervised (CX 37 and 40). The outside of the box containing the X-11 tablets features in bold lettering "X-11 Reducing Plan" and the headline "EAT WELL!! — and LOSE THAT FAT" (CX 36, 38, 39 and 41). The ingredients, the "adult dose," and a "Caution" (warning) are also provided.

10. X-11 tablets were, and are, advertised and marketed extensively throughout the United States as a reducing aid or preparation for the obese, and for those who wish to shed what they consider to be excess body weight. Approximately 80 percent of all retail chain stores in the nation sell X-11 tablets (Fraser, Tr. 783), and annual

sales for the year ending April 30, 1975, were in the area of $1,789,000 (Fraser, Tr. 759-61). Each X-11 tablet contains 25 milligrams of phenylpropanolamine, 25 milligrams each of methylcellulose and caffeine and vitamins A (1388 U S P units), B_1 (0.5 mg), B_2 (0.5 mg), B_6 (1 mg), C (15 mg), calcium pantothenate (1 mg), niacinamide (5 mg), E (5 int. units), and B_{12} (0.5 mcg) (Ans. P&D, ¶3). The ingredients in the X-11 tablets allegedly conducive to weight loss are phenylpropanolamine and methylcellulose. The former is an [11] amphetamine-related compound, which is claimed to act as an appetite suppressant. The characteristics of phenylpropanolamine will be considered in subsequent findings dealing with the representations contained in respondents' advertising. Methylcellulose is also represented in the marketing of X-11 tablets as an aid to weight loss, and the characteristics of this substance will also be considered.

11. The promotional approach of respondents with respect to phenylpropanolamine and methylcellulose in marketing X-11 tablets is illustrated by statements in an advertisement given wide circulation in *TV Guide* for October 18 through 24, 1975, which stated under a picture of two fingers holding a pill adjacent to the headline "WHAT EACH TABLET CONTAINS" (CX 13):

> 25mg METHYLCELLULOSE A pure vegetable extract which expands and is intended to give one a feeling of being fuller.
>
> 25mg PHENYLPROPANALOMINE [sic] An appetite depressant intended to help give one the feeling of a restricted appetite.

(See also CX 69-73 and 90-91.) Other advertisements hold out the effects purportedly attributable to methylcellulose and phenylpropanolamine, i.e., a feeling of fullness and depressed appetite, without specifically identifying these substances (CX 4-8, 10, 14-15, 43, 46-47, 50, 52-56, 59, 61, 63-64, 67-68, 74, 77-80, 82-85 and 87-88).

2. *Respondents were engaged in the advertising and sale of diet tablets*

12. Respondents place great emphasis on their contention that they neither marketed nor advertised "tablets" but, rather, a "plan." Insofar as this [12] contention involves a defense that representations were not made to the public in respondents' advertisements as to the characteristics and qualities of the X-11 tablets, and the weight losses achievable from their use, it is contrary to the evidence and is rejected. Respondents' advertisements, directly and by implication, conveyed the net impression to the public that a

"wonder" preparation for easy weight reduction - the X-11 tablets - was available. The advertisement in the *Seattle Times* September 10, 1972, reprinted herein, is illustrative (CX 18). This advertisement begins with the banner headline "X-11 IS HERE!" and then tells readers who are overweight and want to reduce that they can "EAT WELL. . .AND LOSE THAT FAT! - without ever missing a meal." Weight losses of 5, 10, 25 or more pounds are represented, "GET RID OF 5, 10, 25 OR MORE POUNDS!," as achievable with X-11 tablets. A picture of an attractive and trim lady is given prominence who is quoted as saying "I LOST 80 LBS!" The advertisement announces to the overweight reader that you "satisfy your appetite while you take off pounds and inches" without "strenuous exercises" and "without starvation dieting hunger," that "[Y]ou do not deny yourself," and that "you lose weight. . .while you eat well." How is all this accomplished? The advertisement answers: "here's why" — a *tablet* which:

1. COUNTERACTS HUNGER

Take one of these tablets a half-hour or so before your regular meals. It combines a pure vegetable extract that has no calories, and quickly starts acting to provide the feeling of a fuller, satisfied, contented stomach. You eat 3 satisfying balanced meals a day - plus snacks. You eat what you want, but eat less because you don't feel so hungry throughout the day.


I USED TO WEIGH 160 LBS. NOW I'M DOWN TO 105
says Mrs. George S
Canon, Georgia
"I started on the X-11 Plan and started losing weight almost right away. I am so grateful . . . I recommend the X-11 Plan to everyone I see. It's wonderful."
I LOST OVER 40 LBS.
says
Mrs. Beverly Tallier
Chula Vista
California
Mrs. Stowe says:
WAS AM
WEIGHT 160 lbs. 105 lbs.
HEIGHT 5-2½ in. 5-2½ in.
DRESS SIZE 18 8
BUST 38 in. 34 in.
WAIST 29 in. 24 in.
...and I LOST OVER 40 LBS., TOO
say: Mrs. Ken Schmidt
Norfolk, Nebraska
rather than 20's. It's good to know there's a way to lose ugly fat and keep my weight at a level I dreamed of holding."
FROM GEORGIA TO NEBRASKA TO CALIFORNIA
American Women Have Found A Way That Really Helps Off
THAT UGLY FAT
No Starvation Dieting - No Strenuous Exercise
RESULTS ARE GUARANTEED - OR MONEY BACK
Here, at last, is that wonderful kind of plan that offers you a way to help get rid of 5, 10, 25 or more pounds of unsightly fat. Not by suffering thru starvation dieting hunger, not by sticking to boring reducing diets, not by extra tiring exercises, not by any of the humdrum methods you have known and given up.
Now Lose Ugly Fat . . . and don't go to bed hungry. The X-11 Plan is not a crash or starvation diet. That's because X-11 is the proved and sound method, used from one end of America to the other to curb the appetite and still eat 3 satisfying, sensible meals a day.
42 Tablets 3.00
105 Tablets 5.00
OR MAIL COUPON:
EAT WELL ...and lose that Fat.
You will eat, satisfying meals and snacks, but you won't be the prisoner of the overeating habit. If you aren't 100% delighted, return your first package for an immediate refund — no questions asked.
X-11 REDUCING PLAN
PAY 'n SAVE
AVAILABLE AT ALL STORES
Mail to: PAY 'n SAVE DRUGS—Dept. AD
1511 - 6th AVE., SEATTLE, WASH. 98101
Please send me ....Packages of X-11
PLEASE PRINT YOUR NAME AND ADDRESS BELOW
Name
Address
City State Zip
Cash enclosed Money Order Check enclosed
THE SEATTLE TIMES Sunday, July 8 1973 Pictorial 31

19

9/9

Sept. 9th, 1973 The Idaho Statesman 5

Eat Well...and Lose That Fat!

AN EFFECTIVE PLAN TO LOSE UGLY FAT

NOW...LABORATORY SCIENCE HAS PERFECTED A TINY PRE-MEAL TABLET WITH A PLAN THAT LETS YOU ENJOY FOODS YOU CHOOSE

X-11

This unique formula—now in easy-to-use tablet form—with the X-11 Reducing Plan helps lose excessive weight, reduce inches. Don't go hungry. Eat 3 sensibly square meals a day while you slim down!

So you want to lose 5, 10, 25 or more pounds of excessive weight? . . . Here now is an extraordinary easy figure-slimming Plan that offers you a way to get rid of unsightly, superfluous fat you're carrying—without strenuous exercises . . . and, most important of all, without missing a meal.

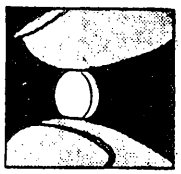
EAT AND LOSE THAT EXCESSIVE WEIGHT. You can satisfy your appetite and peel off those extra pounds, too. Now, with the X-11 Plan, you can remove pounds and inches from thighs, neck, legs, waist — all OVER — without ever going hungry — and stabilize reduced weight at a level you've always dreamed of holding as you follow the Plan. While you eat satisfying meals, no longer will you be the prisoner of the overeating habit, because with the X-11 Plan, *you eat less and want less. So you lose weight . . . while you eat well.*

NO EASIER REDUCING METHOD EVER DEVELOPED

1. COUNTERACTS HUNGER
Take one of these tablets a half-hour or so before your regular meals. It combines a pure vegetable extract *that has no calories*, and quickly starts acting to provide the feeling of a fuller, satisfied, contented stomach. You eat 3 satisfying balanced meals—*eat what you want*, but eat less.

2. ACTS AS APPETITE APPEASER
Part of the secret of this method is a unique ingredient that acts as a beneficial appetite appeaser, *which puts a "brake" on your cravings for sweets*, candy, pastries, rich gravies, High-Fat/High-Calorie foods—everything. It helps you conduct a kind of psychological warfare with yourself as you break some bad old eating habits you probably thought you were stuck with forever.

3. FORTIFIED WITH VITAMINS, MINERALS
Important to those who feel it their lot to feel jumpy, jittery, or fagged out when dieting. Your daily supply now combines a whole spectrum of vitamins and minerals, including: *Vitamin A, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin C, Niacinamide, Vitamin E, Vitamin B12* — all so important to helping prevent these nutritional deficiencies.



X-11

42 TABLETS **2.98**

105 TABLETS **4.98**

SATISFACTION GUARANTEED OR MONEY BACK

Grand Central

FAMILY SAVINGS STORE

FTC EXHIBIT 20
8-14 1974

OBTAINED BY

ATTORNEY

FILE NO. 732 3187


Advertising Supplement to Chicago Tribune
Sunday, February 11, 1973
Section 9-A
EAT WELL...and Get Rid of 5, 10, 25 or More Pounds!
lose ugly fat
with This Amazingly Easy Reducing Plan!
Eat 3 Sensible Meals a Day — and SLIM DOWN!
Today, thousands of women throughout America are discovering an extraordinary simple Plan that helps get rid of 5, 10, 25 or even more pounds and stabilize achieved weight at a level they've "dreamed of" holding as you follow this simple Plan.
Not by suffering thru starvation dieting hunger . . . not by sticking to boring reducing diets . . . not by strenuous exercising . . . not by any of the humdrum methods so many women have tried, and given up in despair.
Now you can EAT and LOSE WEIGHT! You can satisfy your appetite and remove pounds and inches . . . at thighs, neck, legs, waistline . . . all over!
So, why carry around needless, excess weight — when it's so simple to follow the X-11 Reducing Plan to lose ugly fat
Just take one of these specialized tablets ½ hour before your regular meals. Its unusual combination of ingredients helps give you the feeling of a fuller, contented stomach; appeases cravings for 'tween-meal snacks; and provides a range of vitamins and minerals to help prevent these nutritional deficiencies.
MONEY BACK GUARANTEE
Enjoy eating the foods you choose while you lose unsightly, superfluous fat. Get on the X-11 Plan now. Available at your favorite drug or department store on guarantee of satisfaction — or your money back.
GUARANTEED or MONEY BACK
Don't miss out! Take advantage of this generous offer that you must be completely satisfied after taking your first 14-day trial of the X-11 Reducing Plan — or money refunded without questions asked.
42 TABLETS $3.00
105 TABLETS $5.00
If Your Drug or Department Store has run out of stock
FOR QUICK ACTION USE THIS COUPON TO ORDER BY MAIL
Fill out coupon below — place in envelope MAIL TODAY!
If your store is out of stock — fill out and mail this coupon for your
QUICK-E-MAIL-SUPPLY
GUARANTEE
WALGREENS
Box 695
Berkeley, Ill. 60163
My store is out of stock.
Please rush supply checked below
Name
Address
City State Zip
Cash enclosed Money Order Check enclosed
Illinois residents please add 5% sales tax.

IF YOUR STORE HAS RUN OUT OF X-11 TABLETS HURRY!!!

Fill out and mail this coupon for your supply

Lose Ugly Fat – or Your Money Back

Just fill out coupon below Place in envelope MAIL TODAY!

Mail This Coupon Today for Your Supply of X-11 Tablets if your store has run out of stock

The X-11 Reducing Plan has been made available at Walgreens and other fine drug stores. If, because of the demand, your store has run out of the supply of X-11 Tablets, just tear off this card, fill in other side and mail it to us with your remittance to:

WALGREENS
Box 695
Berkeley, Ill. 60163

Please Print Your Name and Address On Other Side

GUARANTEE
You must be 100% delighted with results of your first package or your money will be refunded. No questions asked.

X-11 IS HERE!

an effective Plan to Lose Ugly Fat – without ever missing a meal!

Now you can satisfy your appetite and peel off that excessive weight

■ Here is that unique new figure slimming plan, called the X-11 Reducing Plan, which now offers you a way at last to get rid of 5, 10, 25 or even more pounds of unsightly, superfluous fat. ■ This plan helps you enjoy three appetizing, sensible meals day after day. ■ Just one of these pre-meal tablets before eating — and you'll notice the difference! It counteracts hunger — appeases your appetite — provides a whole spectrum of vitamins and minerals to help prevent these nutritional deficiencies. ■ Hence, you don't get hungry. Down goes your calorie intake — and down goes your weight. ■ So, if you're trying to lose weight, and it's difficult for you to stick to a reducing diet because, you feel hungry or deprived, the X-11 Reducing Plan can help you to be slimmer more easily than you ever dreamed possible.

Enjoy eating 3 sensible meals a day... while you take off unsightly fat.

■ The new X-11 Reducing Plan helps you control your appetite in spite of yourself. You eat less — because you don't want more. You'll find yourself saying, good-bye to second and third helpings — and your unnatural cravings for 'tween-meal snacks won't bother you. ■ The X-11 Plan is not a crash or starvation diet. You won't go to bed hungry. That's because X-11 is the PROVED and SOUND method to curb the appetite and still eat 3 good sensible meals a day.

Remove pounds and inches at thighs, neck, legs, waistline — . ALL OVER!

... with the X-11 Reducing Plan, Laboratory Science has perfected a Tiny Tablet for EASY REDUCING

SATISFIES APPETITE
APPEASES TASTE-SENSE
SUPPLEMENTS VITAMINS

Recently, laboratory science has perfected a tiny tablet that now ... clinic-tested ingredients ! act hunger, appease the desire to eat, and supplement vitamins. These ingredients, plus others, carefully blended, tested and measured ... go into X-11 Tablets.

NOW AT **Walgreens** AND OTHER FINE DRUG STORES

Don't Delay! *IF YOUR STORE HAS RUN OUT OF STOCK, MAIL ATTACHED COUPON FOR QUICK ACTION!*

CX 49

[15] 2. ACTS AS AN APPETITE APPEASER

Part of the secret of this method is a unique ingredient that acts as a beneficial appetite appeaser, which puts a "brake" on your cravings for sweets, candy, pastries, rich gravies. High-Fat/High-Calorie foods - everything. It helps you conduct a kind of psychological warfare with yourself as you break some bad old eating habits you probably thought you were stuck with forever. Thus, your appetite is appeased while you take off fat.

13. The advertisement appearing in the *Seattle Times,* July 8, 1973, also reprinted, emphasizes testimonials of ladies reporting very substantial weight losses (CX 19). It also contains a picture of two fingers holding the X-11 tablet, and advises the reader that if not 100 percent delighted, the "first package" of either 42 tablets or 105 tablets may be returned for an immediate refund.

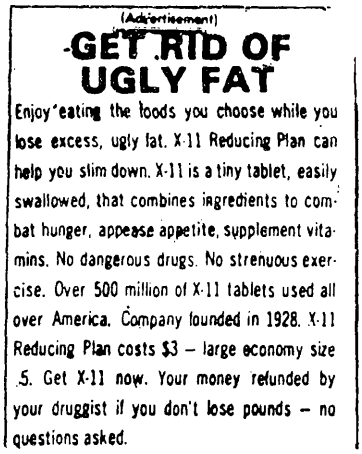
14. The advertisement in *The Idaho Statesman,* September 9, 1973, likewise reprinted, contains two pictures of the X-11 tablet (CX 48). The first features the picture of a young lady holding up an X-11 tablet and states:

> NOW. . . LABORATORY SCIENCE HAS PERFECTED A TINY PRE-MEAL TABLET WITH A PLAN THAT LETS YOU ENJOY FOODS YOU CHOOSE

The bottom half of this advertisement emphasizes the X-11 tablet by a much larger picture of two fingers holding the tablet with adjacent paragraphs entitled "COUNTERACTS HUNGER," "ACTS AS APPETITE APPEASER," containing the same text referred to in Finding 12, and "FORTIFIED WITH VITAMINS, MINERALS." The advertisement concludes by announcing "42 Tablets 2.98," "105 Tablets 4.98." [19]

15. The elaborate advertising supplement distributed in the *Chicago-Tribune,* February 11, 1973, although varying in language, is similar in its message and representations to the foregoing advertisements (CX 49). A post card for mailing to the Walgreen drug chain is printed within the advertisement with the admonition to prospective purchasers: "IF YOUR STORE HAS RUN OUT OF X-11 TABLETS HURRY!!!" "FILL OUT AND MAIL THIS COUPON FOR YOUR SUPPLY." This advertisement is headlined "X-11 IS HERE" and gives prominence to the picture of a tablet being held between two fingers, telling Chicago-area readers that ". . . Laboratory Science has perfected a Tiny Tablet for EASY REDUCING."

16. Some of respondents' smaller advertisements designed for insertion in newspaper columns, or in fractions of pages in periodicals, condense the representations contained in the larger advertisements and refer to X-11 simply as a "tiny tablet." The following is an example (CX 42):


(Advertisement)

GET RID OF UGLY FAT

Enjoy eating the foods you choose while you lose excess, ugly fat. X-11 Reducing Plan can help you slim down. X-11 is a tiny tablet, easily swallowed, that combines ingredients to combat hunger, appease appetite, supplement vitamins. No dangerous drugs. No strenuous exercise. Over 500 million of X-11 tablets used all over America. Company founded in 1928. X-11 Reducing Plan costs $3 – large economy size 5. Get X-11 now. Your money refunded by your druggist if you don't lose pounds – no questions asked.

(See also CX 5–7 and 77.)

[20] 17. Other advertisements told members of the public that they could "LOSE THAT FAT" but "EAT SUFFICIENTLY" by taking "a pre-meal X–11 Tablet before meals" (CX 51) and that "today" there is "an amazing new reducing plan with X–11 Tablets" (CX 52, 61 and 84). Still other advertisements were again specific in telling the public "WHAT EACH TABLET CONTAINS" (CX 13, 69–73, 90 and 91). Occasional advertisements stated "NO PRESCRIPTION NEEDED" (CX 12, 57 and 65), and some told the public to "[A]sk the pharmacist for a 42 tablet pack of X–11 Reducing Aid" (CX 53 and 66).

18. With few exceptions, respondents' advertisements concluded with a coupon or statement offering *tablets* to the public, usually 42 for $3.00 and 105 for $5.00 (see *e.g.,* CX 18–19 and 49 reprinted in this decision).

19. The ladies whose testimonials are prominently displayed in the *Seattle Times* advertisement (CX 19), and published in other newspapers (CX 1, 16, and 76), perceived the advertisements as promoting pills or tablets. Mrs. George Stowe in her initial letter to Porter & Dietsch refers to taking "X–11 tablets" (CX 149). Mrs. Beverly Tellier begins by stating "I am a user of your X–11 diet pills" (CX 148; see also CX 184(2)), and Mrs. Ken Schmidt states to Porter & Dietsch that "I talked with you from Walgreen Drug here in Norfolk, Nebraska, last week, about your X–11 diet pills" (CX 147). In publishing these testimonials respondents changed all such product

references to read "X-11 Plan" or "X-11 Reducing Plan," rather than "tablets" or "diet pills."

20. Other members of the public writing to Porter & Dietsch also looked upon what was marketed and advertised as "tablets," "pills" or "reducing pills." Their perceptions of the product are evidenced by the following statements: "I started on your X-11 Tablets. . ." (CX 185); "I called up Saturday for an order of 2 boxes of diet X-11 pills" (CX 186); "We are wondering if we [21] couldn't buy these pills directly from you . . ." (CX 187); ". . . I need these pills" (CX 188); "I received your letter regarding getting X-11 tablets in Sutter Creek" (CX 189); "On occasion my husband has the use of your X-11 diet pills" (CX 190); "X-11 is the only diet pill I have found that works" (CX 191); "I have tried your X-11 tablets for reducing. . ." (CX 192); "I have been taking your reducing tablet for 4 months. . ." (CX 193); "I was on vacation . . . and saw your pills (105)/(X-11) reducing pills so I bought a box. . ." (CX 194); "I used your diet pills about four years ago. . .", "P.S. The name of the diet pills are X-11 reducing plan" (CX 195); "Please send me another box of 42 X-11 Reducing pills. . ." (CX 196); "X-11 is the best reducing tablet sold" (CX 199); "Will you please let me know if there is a place . . . where I can purchase the X-11 reducing Plan pills" (CX 201); "So I tried X-11 and got down to 130 pounds on the first box of pills" (CX 202); ". . .send me some X-11 Reducing Plan Tablets. . .I try some of the other kind of Tablets, but I got sick from them . . ." (CX 203); "In past years I have taken several kinds of reducing pills (from Doctors). All they did was make me nervous . . . But on X-11 there is no after effects" (CX 204); ". . .[i] ordered $5.00 worth of diet pills from you . . ." (CX 206); and, "I would like for you to send me X-11 reducing tablets" (CX 207).

21. The purpose behind the repeated use of the word "plan" in the advertising copy for X-11 tablets, and the use of "X-11 Reducing Plan" as Porter & Dietsch's designation for its product is evident in the letter dated September 13, 1973, to Mr. Fraser, Porter & Dietsch's president, from Mr. Furth, vice-president of respondent Kelly Ketting Furth and the account executive for X-11 tablet advertising (CX 164): [22]

Dear Bill:

* * * * * * *

Appedrine is flirting with danger. It is the same kind of danger that hit us in the head in the insurance business.

Appedrine and Hungrex (even Odrinex) put emphasis on the tablets. That's murder, because the pills will not reduce weight an iota.

It is the "Plan" that will keep us out of hot water.

I've said it before. If you want me to put the same kind of "punch" into the advertising, so be it. But we've been getting along swell, without it.

Let them make their claims, we'll make ours. But I'm afraid we're all going to get into hot water because of Appedrine, Hungrex and Odrinex.

Because Hungrex won its case at one time, doesn't mean the sore cannot be reopened.

I've seen it happen in the mail order insurance business.

[23] I don't know if the new 42 line ad will work. That's what tests are for. Ads like Appedrine (from a copy standpoint) may work, but it may put us out of business faster.

* * * * * * *

Cordially,

Joseph Furth
Vice President

22. Labeling the box of tablets the "X-11 Reducing Plan" and including within the tablet box a leaflet (CX 37 and 40) containing a low-calorie diet, a calorie value chart, a table of desirable weights and advice, *inter alia,* that in most cases "obesity is caused strictly by overeating and indiscretions of diet," that "weight loss is only accomplished when a minimum of calories are consumed," that the purchaser must not "expect a miracle overnight" but "must practice a little 'self-denial' — plus, a will power to get thin," and that if the X-11 tablets are taken one-half hour before each meal *and* the "Plan, or any other low-calorie diet" is followed, he or she "should lose weight," does not transform the advertising of "diet pills" into the promotion of a reducing "Plan" so as to mean that no representations were made to the public about X-11 tablets.

23. Respondents were engaged in the advertising, marketing and sale of X-11 tablets. The representations to the public in respondents' advertisements were about X-11 tablets and their efficacy in facilitating weight loss.[5] Such representations were made for the sole purpose of promoting and inducing the sale of X-11 tablets. [24]

ADVERTISING OF X-11 TABLETS

24. Although the pictures, language and format varied, essentially similar statements and themes pervaded respondents' advertisements of X-11 tablets. Respondents agree that "from 1969 to date, the advertising of the 'X-11 Reducing Plan' had remained substantially unchanged" (*see* Memorandum In Support of Motion to

[5] All advertising slicks or mats in the record (CX 50 through 91) were published by respondents in some media (Fraser, Tr. 804 and 883).

Dismiss, etc., filed October 30, 1975, p. 11; *see also* Furth, Tr. 952, 968–69 and 978–80).

25. Porter & Dietsch's advertising expenditures for X-11 tablets were as follows (CX 179):

Year (Ending April 30)	*Dollars*
1975	$882,570
1974	1,082,396
1973	862,986
1972	781,566
1971	593,723
1970	460,902

26. The record contains a large number of advertisements published in various media, predominately newspapers, promoting the X-11 tablets. As noted earlier, five examples have been reprinted in this decision, four large ads and a small one (CX 18–19, 42, 48 and 49), and have already been discussed to some degree. Major metropolitan dailies such as the *Seattle Post-Intelligencer* (CX 1–4), the *Seattle Times* (CX 19), the *Washington Post* (CX 47), the *Baltimore Sun* (CX 46), the *Chicago Tribune* (CX 49) were utilized, as well as smaller circulation newspapers such as the *Anchorage Daily Times* (CX 33), the *Longview Daily News* (CX 21), the *Greensboro Daily News* (CX 74), and the *Peoria Journal-Star* (CX 83). Specialized publications such as *TV Guide* (CX 10–13) were also employed in the dissemination of X-11 advertisements.

27. Ads occupying a small portion of a newspaper or periodical page (CX 5–7, 9, 17, 20–34, 42–43, 51, 54, 64, 77, and 89), as well as very large and prominent advertisements, were published (CX 1–4, 8, 10, 13–16, 18, 35, 44–48, [25] 50, 52–53, 66–76, 78–88, 90–91). Some of the large advertisements were elaborate color inserts known as "free standing stuffers" in the advertising trade (Furth, Tr. 930–33). These were placed in the Sunday editions of the nation's leading newspapers. CX 46 was inserted in the *Baltimore Sun* for Sunday, April 20, 1969, CX 47 in the *Washington Post* on the same date, and CX 49 in the *Chicago Tribune* on February 11, 1973.

REPRESENTATIONS CONVEYED TO THE PUBLIC BY RESPONDENTS' ADVERTISEMENTS FOR X-11 TABLETS

1. *Representation that users of X-11 tablets can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice*

28. The advertisement published in the *Seattle Times,* September

10, 1972 (CX 18), as indicated, told prospective users that "X-11 is here" and they could "EAT WELL . . . AND LOSE THAT FAT—without ever missing a meal," that they could "satisfy [their] appetite" while taking off "pounds," that they could lose "5, 10, 25 or more pounds" without denying themselves, without dieting hunger, that they would "eat what [they] want," but would eat less because they would not "be the prisoner of the overeating habit."

29. The advertisement published in the *Seattle Times,* July 8, 1973 (CX 19), also told prospective users of the X-11 tablets that they could "EAT WELL . . . AND LOSE THAT FAT." The ad advised that "NO STARVATION DIETING" was required, that unsightly fat could be lost without "suffering through starvation dieting hunger" or following "boring reducing diets," or any of the "humdrum methods you have known and given up." The advertisement told prospective purchasers of X-11 tablets that they could eat "satisfying meals and snacks," that they would not "go to bed hungry," that the "X-11 Plan" was "not a crash or starvation diet" but a "proved and sound method" "to curb the appetite and still eat 3 satisfying, sensible meals [**26**] a day," and that laboratory science had perfected a "tiny pre-meal tablet" which "lets you eat three sensible meals a day plus 'tween meal snacks."

30. The advertisement published June 24, 1973, in the *Seattle Post-Intelligencer* TV Section (CX 2) likewise featured in black, prominent type "Eat Well . . . Lose That Fat!" The advertisement referred to the "X-11 Plan" as "an extraordinary easy figure-slimming Plan" that offered a way to "get rid of unsightly, superfluous fat" without "missing a meal," and told the prospective X-11 tablet user that she or he could "Satisfy your appetite and peel off those excess, extra pounds, too."

31. The advertisement in the same newspaper on June 25, 1974 (CX 3), was again headed in boldtype "Eat Well . . . And Lose Ugly Fat." This advertisement continued the theme of the earlier ads that X-11 tablet users could "EAT AND LOSE THAT EXCESSIVE WEIGHT," could "satisfy" their appetites and yet "peel off extra pounds" and could remove excessive weight "without ever going hungry." An identical ad was published in the *Seattle Post-Intelligencer* TV Section January 1, 1975 (CX 4).

32. The advertisement in the *Anchorage Daily Times* of March 29, 1974 (CX 8) repeated the statements "Eat Well . . . and Lose That Fat!", that laboratory science had "PERFECTED A TINY PRE-MEAL TABLET WITH A PLAN THAT LETS YOU ENJOY FOODS YOU CHOOSE," that X-11 users could "EAT AND LOSE THAT EXCESSIVE WEIGHT," and could "satisfy" their appetites and "peel off those extra pounds" "without

ever going hungry." Users were promised "you will lose weight . . . while you eat well."

33. The full page advertisement in the *Spokane Spokesman-Review* Sunday Magazine, October 22, 1972 (CX 15), similarly announced "EAT WELL . . . AND LOSE THAT FAT!" "WITHOUT EVER MISSING A MEAL," and "You do not deny yourself." [27]

34. A large advertisement in the *Seattle Times,* February 3, 1974 (CX 45), was headlined "NOW EAT WELL" and "LOSE UGLY FAT!" The text continued this theme with the statement "So enjoy eating that satisfies your appetite as you peel off those extra pounds. You lose weight . . . while you eat well."

35. The elaborate "free standing stuffer" in the Sunday *Baltimore Sun* on April 20, 1969 (CX 46) featured banner headlines which read "Lose Ugly Fat" with an "Amazingly Easy Reducing Plan." The text promised that fat would be lost without "starvation dieting hunger," "boring reducing diets" or "humdrum methods so many women have tried, and given up in despair." Readers were assured that users of X-11 tablets could "now" "EAT AND LOSE WEIGHT," could "satisfy" their appetites yet "remove pounds and inches," could "peel off that excessive weight," and could "Enjoy eating the foods" they chose while they lost "unsightly, superfluous fat." Readers were told in heavy letter type "X-11 IS HERE," and that they could "LOSE UGLY FAT . . . without ever missing a meal!" An identical "free standing stuffer" was inserted in the *Washington Post* on the same Sunday (CX 47).

36. Another advertisement disseminated by respondents announced "Are you on a diet? Or planning to go on one? WHY STARVE YOURSELF WHILE YOU REDUCE? EAT . . . AND LOSE THAT FAT!" (CX 57) Other advertisements told the public "TAKE OFF UGLY FAT WITH AN 'EAT WELL' EATING PLAN" (CX 64). Still others stated "Enjoy eating the foods you choose while you lose excess, ugly fat" (CX 77).

37. The "free standing stuffer" inserted in *The Greensboro Record,* January 26, 1969 (CX 74), featured "EAT WHAT YOU WANT - AND SLIM DOWN," as did the large insert of January 12, 1969, in the *Wisconsin State Journal* (CX 75), and the insert of July 28, 1968, in the *Peoria Journal Star* (CX 83). Other advertisements communicated similar representations, with occasional minor changes in emphasis. See CX 5-7, 9-35, 42-45, and 47-91. [28]

38. Respondents' advertising told the public that with the X-11 tablets people could "EAT WELL AND LOSE THAT UGLY FAT" (CX 2), that X-11 tablets put "enjoyment into eating" while "unsightly, superfluous fat" was lost (CX 52), that overweight persons could take off ugly fat with an "EAT WELL" eating plan (CX 50), and that people

who wanted to lose weight could "eat" and lose "pounds" without dieting hunger, or giving up meals, or by any of the "torturous 500/1000 calorie diets so many women try, and give up in despair" (CX 72).

39. Incorporation deep in the advertising copy of occasional phrases such as users will no longer be the prisoner of the "overeating habit" or that users will "want less" and therefore "eat less" does not change the overall message conveyed to the public. The overall effect of respondents' advertisements was to convey the net impression to the public that users of X-11 tablets could lose body weight without dieting or consciously or materially changing their eating habits, in the language of the complaint, "without restricting their accustomed caloric intake and while they continue to eat the foods of their choice."

2. *Representation that substantially all users of X-11 tablets would lose a significant amount of weight and that Respondents had a reasonable basis from which to conclude this*

40. Although the advertisements for X-11 varied in their format and wording, as stated, the themes remained relatively constant. Purchasers were assured they would realize significant weight losses through use of the X-11 tablets. Respondents' advertisements were of a nature to attract the attention of the seriously overweight, especially women, and to induce them to purchase X-11 tablets in the hope of losing large amounts of excess fat.

41. Representations of significant, indeed, very large, weight losses achievable through the X-11 tablets are prominent in the advertisements respondents disseminated to the public. The impact of these representations is evident by statements recurring throughout the X-11 advertisements, as follows: [29] "I Used to Weigh 160 lbs. Now I'm Down to 105," i.e., 55 pounds lost, (CX 1, 16, 19, and 76); "I lost over 40 lbs.," "And I lost over 40 lbs. too" (CX 1, 16, 19, and 76); "I Lost 80 lbs" (CX 2, 9, 18, 20, 22-24, 30-31, 33-35, 44, and 81); "Lose Ugly Fat" (CX 3, 4, 10, 14, 25-29, 32, 45, 53-56, 60-61, 63-64, 66-67, 74-75, 78-80, 82-84, and 88); "Lose That Fat" (CX 8, 11, 48, 50-51, 57-59, 69-73, 79, 87, and 90-91); "So You Want To Lose 5, 10, 25 Or More Pounds" (CX 1, 14, 48, 58-59, 63, 78-80, 82, and 87); "Get Rid of 5, 10, 25 Or More Pounds" (CX 13, 15, 18, 46-47, 49, 50, 52, 57, 65, 70-75, 83, 86, and 90-91); "Get Rid of Ugly Fat" (CX 42, 77); "Lose 5, 10, 25 Or More Pounds Of Fat" (CX 67, 88); "College Student Lost 83 lbs Of Ugly Fat" (CX 68); "Now. . .Remove Pounds And Inches From

Thighs, Neck, Legs, Waist" (CX 84-85); "I enjoy wearing dresses sizes 11-12's rather than 20 1/2" (CX 44).

42. The X-11 advertisements also conveyed the impression of slimness, and significant weight losses to be achieved through use of X-11 tablets, by pictures of trim-looking women, and silhouettes of slim female figures (CX 1-4, 8-11, 13, 29-31, 33-35, 44-49, 51-56, 58-61, 63, 66-67, 69-76, 78-83, 85, 87-88 and 90-91).

43. Testimonials reporting very large weight losses and implying that new users of X-11 tablets could anticipate like results appeared frequently and were highlighted in respondents' advertisements. These testimonials reported weight losses, as just quoted, of 55 lbs., over 40 lbs., and 83 lbs. (CX 1-2, 9, 16, 18-20, 22-24, 33-35, 44, 68, 76, and 81).

44. Respondents' advertising portrayed the X-11 tablets as a new, simple, easy, amazing, extraordinary way to lose many pounds of fat. The achievement of such weight losses was, in fact, depicted as a virtual certainty. Continual references in respondents' advertisements to "Laboratory Science" having developed a "Tiny Tablet" coupled with the words "NOW," "TODAY," or [30] "RECENTLY" conveyed the impression that the X-11 tablets were the culmination of scientific research, and reinforced the representation that substantially all users could and would lose any amount of pounds desired, up to 80 and 83 lbs. (CX 8, 14, 46-47, 52, 56, 59, 61, 74-75, 79, 83-84, and 87).

45. Significant, large weight losses, in fact, were represented, as "automatic" (CX 74-75):

> So why carry around needless, excess weight — when it's so easy to lose ugly fat *automatically* with the new X-11 Reducing Plan" (Emphasis in original).

The overweight were assured that "thousands of women throughout America are discovering an extraordinary new plan that *automatically* helps get rid of 5, 10, 25 or even more pounds. . ." (CX 74, 75). The public was promised that the X-11 plan "*automatically* keeps working at home, at work, at play — 24 hours a day." (See also CX 46, 47 and 49 which contain similar language.)

46. Significant, large weight losses were guaranteed: "RESULTS ARE GUARANTEED — OR MONEY BACK" (CX 1, 16-17, 19); "[I]f flabby fat doesn't disappear, just return the empty package for an immediate refund" (CX 2 and 81; see also 57-58, and 65-66), and "If flabby fat does not vanish 'like magic' when you follow the X-11 Reducing Plan, just return the empty package for an immediate refund" (CX 15). This theme was constantly repeated in varying language: "LOSE WEIGHT OR YOUR MONEY BACK" (CX 60); "LOSE FAT OR

MONEY BACK" (CX 43 and 77); and "TAKE WEIGHT OFF WITH VERY FIRST BOX OR MONEY BACK" (CX 90). The advertisements repeatedly assured members of the public that "You have nothing to lose but pounds and inches," and that large weight losses would be achieved (CX 24, 50, and 79). [31]

47. Respondents' advertisements for X-11 tablets represented to the public that substantially all users of X-11 tablets would lose a significant, in fact, as large an amount of weight as they desired, and that respondents had a reasonable basis from which to conclude this.

3. *Representation that the X-11 tablets contained a "unique" ingredient*

48. An examination of respondents' X-11 advertising reveals that, through the use of explicit words and phrases, these advertisements conveyed to the public the representation that X-11 tablets contained something new, different and unusual—a "unique ingredient" (CX 3-4, 10, 14-15, 18, 48, 50, 63, 68, 70-80, 82, and 87). Respondents Porter & Dietsch, William H. Fraser, Kelly Ketting Furth and Joseph Furth admitted in their answer that their advertisements represented directly or by implication that the X-11 tablet contained a "unique" ingredient (Ans. P&D, ¶9), and subsequently identified this "unique" ingredient as phenylpropanolamine (Supp. Adm. P&D, No. 41).

49. In addition to specific reference to a "unique" ingredient, many advertisements described the X-11 tablet as: "a unique formula" (CX 8, 10, 14, 48, 59, 67, 78-80, 82, and 87-88); a "unique preparation" (CX 52, 56, 61 and 84-85); a "special formula" (CX 54); a "specialized, laboratory-approved tablet" (CX 74-75); an "unusual combination of ingredients" (CX 49, 52, 56, 61, 74, and 83-85); a combination of "clinic-tested ingredients" (CX 46-47, 49, 74-75, and 83), and "one of the STRONGEST DIET AIDS available without a prescription" (CX 3-4, 10-11, 58, 63, 68, 78, 80, 82 and 88). These phrases were copiously utilized in respondents' advertisements to reinforce the claimed "uniqueness" of X-11 tablets to the purchasing public. [32]

DECEPTIONS IN THE ADVERTISING OF X-11 TABLETS

1. *Users of X-11 tablets cannot lose weight without restricting their accustomed caloric intake nor while continuing to eat the foods of their choice*

50. Excess body weight results from ingestion of more food than the body uses (Dr. Drenick, Tr. 345). A reduction in calories taken in

by the body or an increase in calories used by the body must occur for a person to lose any weight, and the weight lost is directly related to the reduction in calories consumed and/or calories utilized (Dr. Drenick, Tr. 350). However, in programs for the overweight or obese, reduction in caloric intake is emphasized. Dr. Thaddeus E. Prout, an expert in endocrinology and metabolism from Johns Hopkins University Medical School, testified (Tr. 706):

> In general, one does not attack obesity on the outgoing side for the most part, since it is not profitable to try to run off pounds, in the usual sense of the word, without caloric reduction.

For a person to lose a pound of excess fat, a calorie deficit of about 3500 must be incurred (Dr. Margen, Tr. 264).

51. The X-11 tablets do not, and cannot, in and of themselves, remove weight, fat or excess poundage from the human body (CX 164; Dr. Drenick, Tr. 411; Dr. Margen, Tr. 162; Dr. Fineberg, Tr. 1380-82, and 1392-93).

52. As set forth in prior findings, respondents' advertisements represented that X-11 tablet users could "Eat Well" and lose weight, and conveyed the net [33] impression to prospective purchasers that ingestion of X-11 tablets would result in a loss of weight without restriction of accustomed caloric intake and while they continued to eat the foods of their choice. Although this representation was made repeatedly in X-11 advertisements, respondents acknowledged in the package insert that "weight loss is only accomplished when a minimum of calories are consumed" (CX 37, 40, and 133). The leaflet admonished X-11 tablet users not to eat between meals and to follow the diet enclosed with the X-11 tablets "or any other low calorie diet." The diet enclosed with the X-11 tablets provided for a drastically restricted caloric intake. Estimates of the caloric intake permitted under this diet ranged from 650 to 1,000 calories (Dr. Margen, Tr. 169; Dr. Drenick, Tr. 404; Furth, Tr. 986 and 990), and expert witnesses characterized it as a starvation or semi-starvation diet (Dr. Margen, Tr. 169; Dr. Drenick, Tr. 406; Dr. Fineberg, Tr. 1330). Respondents' diet was also described as "ketogenic" and "unphysiologic." Such a diet causes the person following it to experience a feeling of illness and general weakness, and has other undesirable physical effects (Dr. Margen, Tr. 169-72; Dr. Drenick 415-16).

53. Counsel for respondents Porter & Dietsch, William H. Fraser, Kelly Ketting Furth and Joseph Furth admit that users of X-11 tablets "cannot lose weight without restricting their accustomed caloric intake" (Tr. 661).

54. Respondents' advertisements also represented, as described, that users of X-11 tablets could lose weight while continuing to eat the foods of their choice. Porter & Dietsch admit that in order to lose weight users of X-11 tablets must diet and not consume high-calorie foods such as gravies, nuts, candy, mayonnaise, pastries, whole milk, fried foods, rich dressings and rich desserts, and must reduce or minimize their intake of salt, butter and high-calorie foods generally (Adm. P&D, No. 28). The insert in the package of X-11 tablets admonishes X-11 users to take coffee or tea without sugar or cream, to eat no gravy, to trim the [34] fat off all meat, to cut down on cream, butter and other high-calorie foods, and to avoid all fried foods, nuts, candy and rich dressings (CX 37, 40 and 133). This extensive enumeration of dietary restrictions makes it clear that users of X-11 tablets cannot continue to eat the foods of their choice. They must restrict the foods and quantities they consume to those permitted under the X-11 diet or other low-calorie diets. The representations of respondents in their advertisements that users of X-11 tablets could lose weight without restricting their accustomed caloric intake, and while continuing to eat foods of their choice, were false, misleading and deceptive.

2. *Respondents had no reasonable basis when they introduced their X-11 tablets and now have no reasonable basis from which to conclude that substantially all users of X-11 tablets would lose a significant amount of weight*

55. As stated earlier, the X-11 tablets contain some vitamins, caffeine, methylcellulose and phenylpropanolamine. Users were to take one (1) tablet a half-hour before each meal, and then to follow the menu enclosed in the box of X-11 tablets "or any other low-calorie diet." According to respondents' advertising the X-11 tablets "counteracted hunger," "curbed," "appeased," or "depressed" the appetite, put a "brake" on cravings for high-calorie foods—"everything," and enabled users to adhere to the drastically low-calorie intake provided. The alleged appetite "depressant," "appeaser," "brake" or "diet aid" in the X-11 tablet is phenylpropanolamine, and the alleged hunger "counteracter" is methylcellulose, a vegetable extract. Respondents' advertisements represented that, because of the presence of phenylpropanolamine and methylcellulose in X-11 tablets, all users would achieve significant weight losses of virtually any amount desired. [35]

A. Respondents had conducted no tests, and were in possession of no reports, tests or studies providing a reasonable basis from which to conclude that substantially all users of X-11 tablets would lose a significant amount of weight

56. Individual respondent William H. Fraser, president of corporate respondent Porter & Dietsch, admitted that he had nothing to support the claims made in advertisements for the X-11 tablets. He testified (Tr. 822):

Q. Mr. Fraser, at the time you received that letter and in 1974 what tests or studies or reports of studies or reports of tests or other evidence of effectiveness of the X-11 product did you have in your possession?

A. I did not have any.

Q. Mr. Fraser, at the time the complaint in this matter issued in August 1975, what tests or studies or reports of tests or other evidence of effectiveness did you have in your possession?

A. I had none.

57. In 1969 and 1970 the FDA sent one of its investigators to Porter & Dietsch as a result of the advertising claims which were being published "around the country" (Tr. 904-07). The FDA investigator asked Mr. Fraser for any "information or reports on the efficacy of the product which would indicate that it [36] was effective for the claims that were being made for it" (Tr. 909-10). Mr. Fraser's response was that he had none (Tr. 910).

58. The moving force behind the formation of Porter & Dietsch, and the initiation and marketing of the X-11 tablets, was Frank Gettleman, a Chicago attorney, now deceased. In 1967 he contacted Mr. Fraser, who had just suffered a business reverse, telling him that he had something that Mr. Fraser could make a "comeback" at. At a subsequent meeting in Chicago, Mr. Gettleman told Mr. Fraser about "this diet plan," the X-11 tablets (Tr. 823-24).

59. Mr. Fraser testified that he placed complete reliance upon Mr. Gettleman for having support and authority for the advertising representations made for X-11 tablets. Mr. Fraser testified (Tr. 877):

When Mr. Gettleman sent an ad to me he marked it okay. I did not cross a T nor dot an I. He was the king. He was the man that knew the obesity field. He knew the law. He knew the regulations and I relied entirely on him.

60. Mr. Gettleman had no information, research reports, studies or competent test evidence, which provided a reasonable basis for the representations of weight loss contained in respondents' X-11

advertising. Individual respondent Joseph Furth, who handled the advertising of the X-11 tablets, testified that in 1968, when his firm, Kelly Ketting Furth, took over the X-11 account, Mr. Gettleman showed him two documents (Tr. 1001 and 1006), the 1967 Certification of Record by then Hearing Examiner Poindexter in *Alleghany Pharmacal Corp., et al.,* Dkt. 7176, 75 F.T.C. 990, and the Court of Appeals decision in [37] *Carlay Co.* v. *Federal Trade Commission,* 153 F.2d 493 (7th Cir. 1946). In 1972 when the Commission's staff contacted respondent Pay'n Save Corporation in this matter requesting substantiation of the representations in the X-11 advertisements, the Commission's letter of inquiry (CX 112) was sent by Pay'n Save to Porter & Dietsch for reply, inasmuch as "Pay'n Save had conducted no scientific studies of X-11" (Affidavit of Calvin Hendricks, Executive Vice-President of Pay'n Save Corporation, attached to Motion to Dismiss Complaint Before Trial Or, In the Alternative, For Summary Decision dated November 28, 1975, p. 3). Mr. Gettleman answered this inquiry on behalf of Porter & Dietsch and Pay'n Save, and forwarded to the Commission, as substantiation for the X-11 advertising, copies of the *Alleghany* certification, *supra,* and the *Carlay* decision, *supra* (CX 122-26).

61. In his letter Mr. Gettleman discussed the evidence introduced in the *Alleghany* proceeding, contending that it supported the claims made in respondents' advertising. A thorough reading of the *Alleghany* certification discloses that it does not substantiate respondents' advertising representations of weight losses achievable through the use of their X-11 tablets. The complaint in *Alleghany Pharmacal* did not allege that claims of specific and significant weight losses of virtually any amount from the use of diet pills or tablets were false. The issue was whether "Hungrex" tablets, the active ingredient of which was phenylpropanolamine, had any significant pharmacological value as an appetite depressant or weight-reducing agent, or were adequate or effective in the treatment, control or management of obesity. 75 F.T.C. at 997. The hearing examiner thought that the evidence was conflicting and that the allegations of the complaint had not been established by a preponderance of the evidence. 75 F.T.C. at 1034. On review, the Commission expressly disavowed any opinion "as to the accuracy of [these] findings and conclusions," but dismissed the complaint. The Commission, on the hearing examiner's recommendation, [38] however, ordered that the cease and desist order issued earlier in *Alleghany Pharmacal,* 55 F.T.C. 705 (1958), remain in effect. That order prohibited dissemination of any advertisements for "Hungrex" which represented, directly or indirectly, "that any predetermined

weight reduction can be achieved by taking or use of said preparation for a prescribed period of time." The *Alleghany Pharmacal* case does not provide a reasonable basis for the representations of weight loss contained in respondents' X-11 advertisements.

62. The *Carlay* decision, *supra,* did not provide a reasonable basis for respondents to hold out to substantially all users of the X-11 tablets the prospect of significant weight losses of virtually any amount. The product in *Carlay* was simply a candy-vitamin product, did not contain phenylpropanolamine, and has no bearing whatever on the truthfulness of respondents' advertisements for their X-11 tablets.

B. Medical texts and references provided no reasonable basis from which to conclude that substantially all users of X-11 tablets would lose a significant amount of weight

63. Excerpts from a number of authoritative medical references and texts were received in evidence. Having reviewed their individual and cumulative import, it is the finding of the law judge that they did not provide a reasonable basis from which respondents could conclude that substantially all users of X-11 tablets, containing phenylpropanolamine (25 mg) and methylcellulose (25 mg), would lose a significant amount of weight.

64. The 1962-63 Edition of *Drugs of Choice* by Drs. Walter Modell and George G. Reader (CX 92), a reliable text of widespread circulation and use in the [39] medical profession, devotes an entire chapter to anorexiants and the problem of obesity. The chapter commences by observing that the designation "anorexigenic" to a "group of drugs in common use is unfortunate because it implies a precise pharmacologic action on the central nervous system which has never been demonstrated" (CX 92, pp. 1-2). Taking up the properties of specific anorexiant drugs, Drs. Modell and Reader include phenylpropanolamine in the category of "amphetamine-like drugs" (CX 92, p. 5), note that it tends to elevate blood pressure and that this characteristic "limits its usefulness in the treatment of obesity," and state that (CX 92, p. 7):

> [a]lthough it is used in over-the-counter remedies for obesity, such as Regimen tablets, Du-Dol, and R_x 121, the amount of phenylpropanolamine which they contain is too small to exert any pharmacologic effect at all.

In their 1966-67 Edition of *Drugs of Choice,* Drs. Modell and Reader added to the remarks under phenylpropanolamine concerning "over-the-counter remedies for obesity" that (CX 93):

[t]hese nostrums have been, or are likely to be, removed from the market because of unsupportable and in some cases grossly illegal advertising claims.

An almost identical statement was repeated in the 1972–73 Edition of their text (CX 94).

65. The *Pharmacologic Basis of Therapeutics* by Drs. Goodman and Gilman, 4th Edition (1970)(CX 95), is another authoritative and reliable text used by the [40] medical profession (Dr. Margen, Tr. 219; Dr. Drenick, Tr. 471). In a section on "Obesity and Weight Reduction," Drs. Goodman and Gilman state that various "sympathomimetic and related drugs" had been used but "[t]hese appetite depressants are of no value without an accompanying stringent dietary regimen," and that "without consistent supervision no prescribed regimen of drug or diet is predictably successful" (CX 95C). Drs. Goodman and Gilman do not include phenylpropanolamine in their list of "anorectic drugs" (CX 95D). In the 5th Edition of their text (1973) (CX 96), Drs. Goodman and Gilman note that "[w]hatever the etiology of obesity, a factor common to all cases is necessarily an intake of amounts of food that supply more energy than the body uses" (CX 96, p. 6). They then repeat statements in the earlier edition that appetite depressants are of "no value" in the areas of obesity and weight reduction without a "stringent dietary regimen." Again, phenylpropanolamine is not included in their discussion of "anorectic drugs" (CX 96, pp. 6–7).

66. The *AMA Drug Evaluations,* First Edition, 1971, published by the American Medical Association (CX 97), is another authoritative and reliable reference work widely used by the medical profession and available to respondents (Dr. Margen, Tr. 219; Dr. Drenick, Tr. 471). This text states bluntly in its chapter on "Anorexiants" that phenylpropanolamine "is probably ineffective in the dose provided (25 mg)."

67. In December 1972, the FDA published and widely circulated a Drug Bulletin titled *Anorectics Have Limited Use in Treatment of Obesity* (CX 101). The FDA's findings applied "to all anorectic drugs," and informed the medical profession and other concerned persons that "all anorectic drugs including amphetamines and methamphetamines" had "limited usefulness in the treatment of obesity." The FDA based its findings on a "unique evaluation of information submitted by the manufacturers of anorectic drugs and a review of the medical literature." After a review of more than [41] 200 drug studies and the records of more than 9,000 patients, the FDA found that "the total impact of drug-induced weight loss over that of diet alone must be considered clinically small," that "patients treated with anorectic drugs lose only a fraction of a pound a week

more than those not taking drugs," and that this "weight loss appeared to be related in part to variables other than the drug, such as the physician-investigator, the population treated and the diet selected" (CX 101).

68. As prior findings disclose, respondents' advertisements communicated to the public the net impression that virtually any amount of weight could be lost through use of X-11 tablets, "5, 10, 25 or more" pounds, even 80 or 83 pounds. These are significant weight losses. They are of a magnitude to be impressive to the seriously overweight or obese, and obviously were held out to the public because of that fact, and the capacity of such representations to sell X-11 tablets. In relation to the large amounts of weight loss represented in respondents' advertising as possible through the use of X-11 tablets, the loss of a fraction of a pound a week is insignificant. As Dr. Drenick observed, it "would not be noticeable to anyone who is significantly overweight" and would be medically meaningless (Tr. 386). Further, there is no reason to believe the loss of an additional fraction of a pound would continue for more than a few weeks, even if it were attributable solely to the use of X-11 tablets, because of the development of drug tolerance and other factors (RX 2, p. 206; RX 14, p. 1; Dr. Drenick, Tr. 356; Dr. Prout, Tr. 682).

69. Respondents introduced excerpts from *Drill's Pharmacology in Medicine,* 4th Edition (1971), which referred to phenylpropanolamine as "active enough to be used for controlling the appetite" (RX 4, p. 2), from Martindale *The Extra Pharmacopoeia,* 26th Edition (1972), an English reference work published by direction of the Council of the Pharmaceutical Society of Great Britain, which concluded [42] a descriptive paragraph of phenylpropanolamine by stating it "has also been given to reduce the appetite in obesity" (RX 5, p. 3), and from *Pharmacology and Therapeutics,* 7th Edition (1970), by Drs. Grollman and Grollman who state that phenylpropanolamine "is used . . . to depress appetite in obesity" (RX 6, p. 2). Dosages for use as an anorectant were not listed in these references.

70. The medical texts and references in the prior finding do not provide support for significant weight losses of virtually any amount held out by respondents' advertising to purchasers and users of X-11 tablets. That a drug is "used" for a purpose cannot be equated with effectiveness for that purpose (Dr. Margen, Tr. 307; Dr. Drenick, Tr. 471). But even if the references in the foregoing finding were to be taken as evidence that phenylpropanolamine had some effectiveness as an appetite suppressant, it does not follow that substantially all users of X-11 tablets would lose a significant amount of weight.

C. Expert testimony disclosed no reasonable basis in medical science from which to conclude that substantially all users of X-11 tablets would lose a significant amount of weight

71. The state of medical experience, knowledge and understanding generally, and in the field of obesity and its treatment, did not provide respondents with a reasonable basis for the representations of weight loss contained in respondents' X-11 advertising. The record contains the testimony of three expert medical doctors, called by complaint counsel, who had long-term experience in the treatment of obesity. Additionally, complaint counsel called an FDA pharmacologist who [43] testified in connection with the FDA Drug Bulletin (CX 101). Respondents called three experts, a medical doctor, a professor of pharmacology, and a professor and researcher specializing in physiological psychology. The testimony of these experts viewed overall discloses no reasonable basis in medical science, in the opinion of the law judge, for respondents to conclude that substantially all users of X-11 tablets would lose a significant amount of weight.

Medical Doctors

Dr. Margen

72. Dr. Sheldon Margen, called by complaint counsel, is a Professor of Human Nutrition, and the 1970-74 Chairman of the Department of Nutritional Sciences, at the University of California at Berkeley. After majoring in zoology and receiving a Master's degree in that science and experimental embryology, he graduated from the University of California Medical School in 1943, and was licensed to practice medicine in California the same year. Dr. Margen subsequently has had a distinguished medical career involving private practice, teaching, lecturing and, in particular, extensive research. He is an authority in the field of human nutrition, metabolism, and the treatment of obesity, and has individually and jointly authored over 85 scientific papers, many in the fields of his expertise. In addition, Dr. Margen has written chapters for a number of scientific texts, and has participated in the writing of a number of others (CX 110). Currently, he is operating, with other researchers at the University of California, a controlled metabolic unit funded by the National Institutes of Health where metabolic studies in human nutrition are conducted. He is also participating in an ongoing, multi-disciplinary obesity program

conducted on an outpatient basis at the University (Dr. Margen, Tr. 129 and 141-43). [44]

73. In Dr. Margen's expert opinion drugs have "no place in the treatment of obesity" because it is not a simple problem capable of being cured by a pill (Tr. 162). If there were a "magic pill," in Dr. Margen's view, "obesity would have disappeared by now" (Tr. 162). Drugs in the treatment of obesity are "essentially placebos in their effect," and are not a helpful or proper therapeutic approach (Tr. 163). According to Dr. Margen, phenylpropanolamine is essentially a placebo, and is useless in treating obesity (Tr. 164-65, 292-95 and 299-302). Dr. Margen saw "no reason to get an individual started" on drugs such as phenylpropanolamine (Tr. 296):

> . . . when the very slight gain which may occur early can just as well be taken care of and overcome by the sympathetic working with a person instead of relying upon just handing out a drug or prescription.

Dr. Margen's opinion that drugs such as phenylpropanolamine are useless in the treatment of obesity are based upon his research and experience over a ten (10) year period, "I would say after about ten years of trial, I gave them up" (Tr. 255).

74. Dr. Margen testified that he agreed (Tr. 241) with the statements under "Obesity and Weight Reduction" in *The Pharmacologic Basis of Therapeutics* (CX 95 and 96) to the effect that appetite depressants were of "no value" in weight reduction "without an accompanying stringent dietary regimen," and that it had been regularly demonstrated that "without consistent supervision" no prescribed regimen of diet is "predictably successful." Dr. Margen also agreed with the *AMA Drug Evaluations* (CX 97) that phenylpropanolamine was "probably ineffective" as an anorexiant in the dose of 25mg provided in X-11 tablets (Tr. 242-43). Dr. Margen testified that epidemiological studies had shown the [45] "break point" between obesity having adverse effects upon health and not having adverse effects upon health was around 20 percent overweight (Tr. 150). Accordingly, Dr. Margen defined a "significant" loss of weight from an epidemiologist's viewpoint as one which returned an individual's weight to "the area of the so-called safe level" (Tr. 151).

Dr. Drenick

75. Dr. Ernst J. Drenick, called as an expert witness by complaint counsel, is a Professor of Medicine at UCLA Medical School, heads the UCLA obesity clinic, and is Chief of Internal Medicine at the Veterans Administration Hospital, West Los Angeles. He graduated

from New York University College of Medicine in 1941, and has been on the faculty of UCLA medical school since 1955. Dr. Drenick's special interest is nutrition and metabolic diseases, and his primary work has been in the field of obesity (Tr. 340-41). He has been involved in the study of obesity since 1962, and from that year to the present has studied overweight patients, admitting them to the hospital and determining how they responded to various nutritional and weight-reduction programs, their needs for vitamins and different food items, and the effect of various treatment methods. He handles an average of 60 to 70 hospitalized patients and 200 to 300 outpatients each year. Hospitalized patients are admitted for two to four months each, and are carefully observed from the standpoint of psychological responses to various methods of treatment, psychologic makeup, including the reasons for abnormal eating habits, and how such habits can best be remedied (Tr. 341-42). He is supported by several technicians, two of whom are graduate students with advanced degrees, and at times is assisted by graduate fellows who are M.D.'s or Ph.D.'s (Tr. 342). Dr. Drenick is an authority in the field of obesity and its treatment. He has written or co-authored 50 scientific papers, most of which have [46] dealt with obesity, weight reduction and associated subjects, including the various psychological processes of obese individuals (CX 114). Dr. Drenick also has prepared chapters for two medical textbooks and performs editorial services as a reviewer for the *Journal of the American Medical Association, American Journal of Clinical Nutrition,* the *Journal of Laboratory and Clinical Medicine,* the *Annals of Internal Medicine, Gastroenterology, Metabolism,* and *Obesity and Bariatric Medicine* (CX 114; Tr. 344–45).

76. Dr. Drenick has been unable to achieve permanent weight reduction and maintenance of normal weight with "any of the so-called appetite suppressants." The only way this has been accomplished has been through dietary restriction in conjunction with increased activity levels, and "prolonged educational programs to re-educate the patient to normal eating habits." Such re-education requires a close, ongoing relationship between the patient and the individual supervising his or her progress (Tr. 353). Without such supervision the results are "pitiful" (Tr. 354). Over a period of two years better than 90 percent of those treated return to their original weight or have increased beyond what they started with (Tr. 354). Without continuing "follow-up" the failure rate is "almost universal" (Tr. 354–55). In Dr. Drenick's experience the obese patient has to be taken under the care of a doctor or leader of a weight-reduction program, such doctor or leader has to make sure the patient is well

motivated, and such motivation has to be maintained to make sure the patient does not "backslide" (Tr. 355).

77. Dr. Drenick knew of no drug that had "significant results or benefits in weight reduction." Drugs in the "appetite suppressant family," such as phenylpropanolamine, "have a very limited span of effectiveness even if a mild effectiveness were present" (Tr. 356). In Dr. Drenick's professional experience (Tr. 356): [47]

> The weight loss usually is very, very minor and at the end of five or six weeks the patient realizes that the drug isn't doing any good. He becomes disappointed and is no better off and perhaps worse off.

78. Dr. Drenick agreed with statements in the medical literature that phenylpropanolamine was "ineffective" in achieving weight loss, and shared the opinion that "it should not be used in the treatment of obesity" (Tr. 368-69). Dr. Drenick also agreed with *Drugs of Choice* (CX 92, 93 and 94) testifying that phenylpropanolamine was "of questionable value or of no value" (Tr. 369). He further agreed with *AMA Drug Evaluations* (CX 97) that phenylpropanolamine was "probably ineffective in the dose provided (25 mg)" (Tr. 372).

79. Dr. Drenick testified that a "significant" weight loss must be a weight loss which was meaningful to the patient and significant from a clinical point of view (Tr. 356). To illustrate, Dr. Drenick cited the case of a 350-pound patient who lost 5 or 6 pounds. Such a weight loss was measurable on the scales, but "for the patient medically, it is totally insignificant" (Tr. 357). Dr. Drenick testified (Tr. 357):

> You can say, well, I have given him amphetamines, he has lost seven pounds in weight. Therefore, that is a great result. It is totally insignificant medically but statistically you can say there was a significant weight los[s]. [48]

Dr. Prout

80. Dr. Thaddeus Prout, the third medical expert called by complaint counsel, graduated from Harvard Medical School in 1948. After training in general internal medicine, he studied for three additional years as a fellow in the fields of endocrinology and metabolism. He is currently Chief of Medicine, Greater Baltimore Medical Center, and Associate Professor of Medicine at Johns Hopkins University School of Medicine. Dr. Prout has taught at Johns Hopkins for many years, and for a period was a full-time faculty member. He is currently Director, Metabolic Division, Moore Clinic, The Johns Hopkins Hospital; Consultant in Endocrinology, Veterans Administration Hospital, Perry Point, Maryland; Consultant in Endocrinology, Veterans Administration Hospital, Baltimore, Maryland; Consultant, Department of Health, Education and

Welfare; Consultant, Food & Drug Administration, National Institutes of Health; and has served as a consultant for the Bureau of Dangerous Drugs and Narcotics (CX 119; Tr. 670). Dr. Prout is an authority in the fields of endocrinology and metabolism, and is Chairman of the FDA's Committee on Endocrine and Metabolic Drugs (Tr. 668–72; CX 119).

81. In 1972 Dr. Prout headed a panel of experts established to advise the FDA on the safety and efficacy of anorectic drugs (CX 120; Tr. 680). This panel, "Consultants on Anorectic Drugs," reported to the FDA in the Fall of 1972 (CX 120). The report of Dr. Prout's panel resulted in the "FDA Drug Bulletin" being circulated to the medical profession, and to other interested groups and organizations in December 1972 (CX 101; Tr. 687).

82. The advisory panel of experts chaired by Dr. Prout reviewed the "best evidence available" on anorectic drugs and all the information submitted to [49] the FDA, including studies, tests, and histories of individuals involving "something in excess of 10,000 patients" (Tr. 723–27). The drugs studied by the panel included amphetamine-related drugs, known also as sympathomimetic amines. Phenylpropanolamine is of the same class although it was not specifically a subject of the panel's study (Tr. 676). The amphetamine-type drugs studied were stronger than phenylpropanolamine in their effects on the human body. According to Dr. Prout "[a]ll the evidence that we have suggests that it is less potent as an anorectic agent than is the parent compound" (Tr. 708). The panel's findings applied to "all anorectic drugs" including phenylpropanolamine (CX 101).

83. Although there were some members "who would have preferred to make the statements stronger than we made them" (Tr. 727), Dr. Prout's panel of experts were in agreement that anorexiants had a "clinically trivial" effect on weight loss (CX 120). The "increased weight loss of drug treated patients over placebo treated patients was only a fraction of a pound a week," and the panel concluded that ". . .the total impact of drug-induced weight loss over that of diet alone must be considered clinically trivial" (CX 120). Dr. Prout testified that the panel, after reviewing the massive amount of data available to it, found (Tr. 681–82):

. . .that in general, one would see somewhere between 0.3 to 0.4 pounds per week on the average for these short term studies. Considering the fact that many of these patients were 100 percent over body weight, that was, in fact, a trivial reduction in their total body overload.

Losses of 0.3 or 0.4 of a pound a week applied for short periods and would tend to decrease for greater time periods (Tr. 682). [50]

84. The final report to the FDA by the "Consultants on Anorectic Drugs" stated that the possible origins of the small weight loss described in the preceding finding were not established and that (CX 120):

> . . .The increased weight loss appears to be related to variables other than the drug prescribed, such as the physician-investigator, the population treated, and the diet prescribed. Studies do not permit conclusions as to the relative importance of the drug and non-drug factors on weight loss.

85. Dr. Prout considered that a weight loss due to the action of an anorexiant or other drug, that is, the "additional effectiveness of an anorectic agent over that of a placebo or diet plus placebo" of a pound a week would be "clinically useful and quite significant," but such a drug or agent "is certainly not known at the present time" (Tr. 690–91). He had used anorectic drugs in treating overweight persons in the course of his medical practice, but "without any success" so he had discontinued them "having found no usefulness for them" (Tr. 722–23).

Dr. Fineberg

86. Dr. Seymour K. Fineberg, an expert medical doctor called by respondents, is a physician practicing in New York City and specializing in internal medicine with particular emphasis in the fields of diabetes, obesity or metabolic disease, and cardiology. He graduated from the University of Arkansas in 1936 and obtained his M.D. in 1940. After receiving his M.D. he spent two years in a general rotating internship, followed by a two-year residency in internal medicine, [51] and then graduate study in basic sciences at New York University School of Postgraduate Medicine (Tr. 1313). He is currently Clinical Associate Professor of Medicine at New York Medical College. Dr. Fineberg has served as a consultant in the field of anorexigenic drugs, and has advised pharmaceutical manufacturers who were evaluating anorexigenic drugs presently on the market (Tr. 1314). He has been a consultant for the AMA Council on Drugs and worked on the chapter on anorexigenic agents in the 1973 Edition of *AMA Drug Evaluations.* Dr. Fineberg has published about 40 medical papers, the bulk of them being in the fields of obesity, diabetes and nutrition (RX 44; Tr. 1314). He has a private practice, some of which relates to obesity, which takes about 25 percent of his time (Tr. 1315).

87. Dr. Fineberg became interested in appetite suppressants in

the treatment of diabetes in 1958. He wrote an article, "Obesity-Diabetes and Anorexigenics," published in the *Journal of the American Medical Association* in February 1961 in which he reported that phenmetrazine hydrochloride and diethylpropion were "significantly anorexigenic" (RX 43). Although Dr. Fineberg believed that anorexiants relieved the symptoms of hunger and produced weight loss (Tr. 1325-26, 1328-29, 1344), phenylpropanolamine has not been among the drugs used or studied by him (Tr. 1323, 1336). Dr. Fineberg's knowledge of phenylpropanolamine is based on its molecular structure and the fact that it is a member of the phenethylamine group (Tr. 1342).

88. In another article, "Anorexiant Drugs In Perspective," published in 1967 in the *Journal of the American Geriatrics Society* (RX 46), Dr. Fineberg sought "to teach the medical profession where they have been making mistakes in the treatment of obesity and in their use of appetite suppressants," that those drugs were widely used "despite what all has been said about them," and that "if they do have a small but definite role to play" they "should be used properly" [52] in order to "obtain the right effect in the overall treatment of obesity" (Tr. 1348-49). In this article Dr. Fineberg stated that anorexigenic drugs were useful "only during the initial, relatively short weight-reduction period in the course of lifetime control," and that the "sole purpose" of the drug was "to provide symptomatic relief" (RX 46, p. 3). In concluding his article Dr. Fineberg states (RX 46, p. 7):

> The anorexigenic drug plays a relatively short, minor, though often integral, role in the treatment of obesity, a disorder which requires lifetime control and cannot be cured. The foundation for permanent weight control is an education in calories, dietetics and nutrition and in the acceptance of a new way of life. Appetite suppression by drugs is used only to relieve the discomfort of caloric restriction during the early stages of education and mental adjustment.

Dr. Fineberg did not mention phenylpropanolamine in his discussion of "anorexiant" drugs, although many others are described or mentioned including dextro-amphetamine, methylamphetamine, phenmetrazine, and diethylpropion.

89. In an article in *Drug Therapy* in March 1973, cast in a question and answer format, Dr. Fineberg wrote that the only purpose of appetite suppressing drugs was to "relieve the symptoms of physiologic hunger," and they were only a "crutch" to help an obese patient beyond the initial phase of treatment (RX 45). He stated that obesity should be thought of as a condition "which requires continuous treatment," and that anorexigenic drugs are not useful in helping a patient maintain an initial weight loss, but are

only useful "to relieve [53] the discomfort associated with dieting." All in all, Dr. Fineberg felt that the medical profession did not have a great deal to offer the obese patient (RX 45). Dr. Fineberg also testified that he believed appetite suppressants had an effect, and if properly used and properly presented to an obese patient, often meant "the difference between success and failure in the treatment of a patient's obesity" (Tr. 1329). The appetite suppressants do not take off weight but, in Dr. Fineberg's opinion, the "symptoms are relieved that are produced by hunger" (Tr. 1322).

90. Dr. Fineberg used prescription drugs such as phenmetrazine, dextroamphetamine, and diethylpropion as appetite suppressants (Tr. 1382). He had never been impressed by anything he read about phenylpropanolamine as an anorexiant, and had never used it, explaining that he wanted to use a drug "most likely to succeed and do the job that I am asking it to do" (Tr. 1384; see also Tr. 1336, 1341 and 1383). He "had no interest in going to an older member of this family which had never been thought to be a very strong or potent member of that family" — "Why should I go back and use something which I feel is not as efficacious as the one I had in hand" (Tr. 1383). Dr. Fineberg could not say whether phenylpropanolamine was effective in a 25 mg dosage tablet for the "normal run of people" (Tr. 1384). However, based on its molecular structure and upon medical references, Dr. Fineberg believed it to "have some anorexigenic properties" (Tr. 1342). Nevertheless, Dr. Fineberg testified that it would be "impossible" for him to predict what effect the ingestion of a tablet containing phenylpropanolamine prior to a meal would have on the food eaten by a person at such meal (Tr. 1352 and 1384). The dosage of an appetite suppressant of any type, in Dr. Fineberg's experience, is a "widely variable thing individually" and must be "tailored to the individual" (Tr. 1345, 1352 and 1388). [54]

Other Experts

Dr. Silverman

91. Dr. Harold I. Silverman, a Professor of Pharmacology at Massachusetts College of Pharmacy, the Massachusetts College of Optometry, and Boston University Medical School, was called as an expert witness by respondents Porter & Dietsch, William H. Fraser, Kelly Ketting Furth and Joseph Furth. He has published approximately 75 articles and a text on pharmacology. Dr. Silverman graduated from the Philadelphia College of Pharmacy in 1952 where he also received his Ph.D. in 1956 (RX 35; Tr. 1101-04). He is not an M.D. and does not treat patients for overweight or obesity.

92. Among Dr. Silverman's publications is an article published in the *American Journal of Pharmacy* in 1963 entitled "Phenylpropanolamine–Misused? Or Simply Abused?" (RX 36). Dr. Silverman testified that his main purpose in writing this article was to criticize the "Fazekas" report, published in 1959, which had concluded that phenylpropanolamine was ineffectual as an appetite suppressant (Tr. 1148). Dr. Silverman reviewed the literature, both national and international (Tr. 1105), and wrote that of all the anorexiants, amphetamine and its analogs are the most effective (RX 36, p. 3). Reviewing the literature, Dr. Silverman found favorable, as well as unfavorable, comments regarding the appetite-suppressant qualities of phenylpropanolamine, noting in the process that the FDA had "gone on record" in stating that phenylpropanolamine was "worthless as an appetite depressant" (RX 36, p. 8). One of the references listed by Dr. Silverman (RX 36, p. 11, note 15) was a 1939 article which he quoted as reporting that phenylpropanolamine was "[e]ffective in controlling the appetite of patients on an obesity diet." The author of this article, Dr. Hirsh, had later testified publicly before a Subcommittee of the House Committee on Government Operations investigating advertising of weight reducing [55] products in 1957, six years before Dr. Silverman's article was published, and had changed his opinion. See *False and Misleading Advertising* (Weight Reducing Preparations), *Hearings before a Subcommittee of the Committee on Government Operations,* House of Representatives, 85th Cong., 1st Session, August 2, 6, 7 and 8, 1957, pp. 56–63. Dr. Hirsh stated to the House Subcommittee that firms marketing reducing pills "endeavor to exploit phenylpropanolamine," and that a dose of 25 mg of phenylpropanolamine taken three times daily "would exercise no appetite depressant effect of significance for the great vast majority of persons." Although Dr. Silverman's article referenced (RX 36, p. 11, note 7) the Committee hearings, the disparity between the foregoing statement of Dr. Hirsh before the House Committee in 1957, and the 1939 article quoted by Dr. Silverman, was not noted. In concluding his article, Dr. Silverman made a number of points critical of the "Fazekas" study, questioning whether that study warranted condemnation of phenylpropanolamine, but making no claims of specific amounts of weight loss associated with that drug.

93. Dr. Silverman testified that, in his opinion, phenylpropanolamine is effective as an appetite depressant in 75 mg daily dosages (three X-11 tablets), and that use in conjunction with a dietary program of 1,200 calories per day would bring about a significant decrease in weight with time (Tr. 1107). He also testified that he had

no question that anorectic preparations were very useful in helping individuals lose weight (Tr. 1111). Dr. Silverman regarded statements questioning the value of anorectic drugs or describing them as placebos as "frequently made unfortunately because of certain intimidation that has occurred in the field of drug therapy" and because there is "unfortunately a small group of persons who try to develop their opinions and unfortunately sometimes manage to get their opinions published in the literature" (Tr. 1110). [56]

94. Dr. Silverman had conducted a study evaluating phenylpropanolamine and a placebo over a several week period (RX 3). He concluded that phenylpropanolamine was effective as an anti-obesity agent when used as it was in his study (Tr. 1120). Dr. Silverman's study was received in evidence, and will be considered in the following section of this decision along with studies of Dr. Hoebel.

95. Dr. Silverman agreed with the statements in *Drill's Pharmacology in Medicine* (RX 4), *The Extra Pharmacopoeia* (RX 5), and *Pharmacology and Therapeutics* (RX 6), that phenylpropanolamine is used in the treatment of obesity (Tr. 1108–09). Referring to the *FDA Drug Bulletin* (CX 101), Dr. Silverman testified that he was familiar with this publication and its conclusions. He testified that the FDA had concluded "that anorectic drugs are acceptable and useful agents for the reduction of appetite and useful as a proven measure for those people who are obese" (Tr. 1111). In fact, the *FDA Drug Bulletin,* as earlier described, concluded that anorectic drugs were of "limited usefulness" in the treatment of obesity, that their effects "must be considered clinically small," that patients treated with such drugs lost "only a fraction of a pound a week more than those not taking drugs," that the fraction of a pound weight loss of those taking drugs "appeared to be related in part to variables other than the drug," and that the weight loss "declines in succeeding weeks" (CX 101).

Dr. Hoebel

96. Dr. Bartley G. Hoebel is a physiological psychologist, and a Professor in the Department of Psychology at Princeton University. His field of specialization involves the study of the relationship between brain and behavior. He obtained his Ph.D. at the University of Pennsylvania in 1962, and taught at [57] that institution briefly before moving to Princeton in 1963 where he became a full professor in 1970 (RX 37; Tr. 1176–77). He has authored or co-authored about 35 publications (RX 37).

97. Dr. Hoebel testified it was his opinion, based on his studies, that "people interested in weight loss and knowing that a pill might

be involved in suppressing appetite is being [sic] under test" will eat less (Tr. 1195), and that "people taking this pill [containing phenylpropanolamine] will lose some [weight], on the average, and that individuals, some individuals will lose a lot" (Tr. 1296). People following a restricted diet would be happier, according to Dr. Hoebel, if they used an appetite suppressant, but the effects of the diet and the appetite suppressant have not been scientifically demonstrated to be additive (Tr. 1199–1200). Dr. Hoebel emphasized, however, that his studies demonstrated the effectiveness of phenylpropanolamine to bring about weight loss only under the conditions of his experiments and for short time periods (Tr. 1241).

98. Contrary to his earlier statement, published as recently as 1975, that phenylpropanolamine "has never adequately been proven effective" (RX 41, p. 7–8), Dr. Hoebel in this proceeding stated that such proof existed. Recent studies by himself, Dr. Silverman and a Dr. Palmer, according to Dr. Hoebel, support the view that phenylpropanolamine is an effective anorexiant (Tr. 1205).

99. Dr. Hoebel disagreed with statements made in *Drugs of Choice* that phenylpropanolamine is ineffective in 25 mg dosages, that obesity is a "singularly human trait," and could be of psychiatric origin and therefore not amenable to treatment with drugs. He also disagreed with the statement that no anorectics are effective without simultaneous control of food intake (Tr. 1223–24). Dr. Hoebel testified that these and [58] other statements of Dr. Modell's were "based on old, inadequate studies which have led him to false conclusions, numerous false statements and a basic bias" (Tr. 1220). Dr. Hoebel also testified that the other medical references referred to during his questioning suffer the same defects as *Drugs of Choice* since they rely on this major work for the accuracy of their statements. Dr. Hoebel testified that medical textbooks lead people to conclude that phenylpropanolamine is not effective because they were written (Tr. 1225):

> . . .without access to the current or the latest data and in some cases, by people who had very strong prejudices about the nature of obesity in humans and the fact that in their minds, it is something that is psychic and not amenable to drug treatment.

Dr. Hoebel's studies (RX 1 and 2) will be considered in detail in the following section of this discussion.

Dr. Sorer

100. Dr. Heinz Sorer, called as an expert by complaint counsel, is a pharmacologist on the drug abuse staff of the FDA, Division of Neuropharmacological Drug Products (Tr. 616). Dr. Sorer's work

entails safety evaluations of drugs, including appetite suppressants, which affect the central nervous system (Tr. 617). Between 1966 and 1972, Dr. Sorer was concerned with an evaluation of sympathomimetic amines undertaken by the FDA to gather information regarding potential abuse of these drugs, and to formulate an FDA policy regarding evaluation of their efficacy (Tr. 618–19). The culmination of this FDA effort was CX 101, the *FDA Drug Bulletin,* discussed in detail earlier herein by Dr. Prout who headed the expert panel evaluating these drugs. Dr. Sorer testified that the effects of the sympathomimetic amine drug group, of which phenylpropanolamine is a member, varied "from individual to individual" (Tr. 630). **[59]**

D. Studies by experts called by respondents did not provide a reasonable basis from which to conclude that substantially all users of X-11 tablets would lose a significant amount of weight

The studies of phenylpropanolamine by respondents' expert witnesses, Drs. Silverman and Hoebel, were received in evidence, being offered by respondents as substantiation for the weight-loss claims made in X–11 advertisements (RX 1, 2 and 3)

(a) *Dr. Silverman's Study*

101. "A Double-Blind Clinical Evaluation of a Phenylpropanolamine-Caffeine-Vitamin Combination And A Placebo In The Treatment of Exogenous Obesity" (RX 3), published in *Current Therapeutic Research,* Vol. 17, No. 6, June 1975, is a study which Dr. Silverman conducted in collaboration with two medical doctors. Inasmuch as this study was published in June 1975, it obviously could not have provided a reasonable basis for claims for X–11 tablets in advertisements of respondents disseminated in 1968 and subsequent years prior to its publication. Nevertheless, such a study would bear upon the propriety of an order in this proceeding if, in fact, it provided a reasonable basis for the advertising claims. This was not the case, however, for Dr. Silverman's "double-blind" study had some dubious aspects, raising questions as to the reliability of its conclusions. Furthermore, even if this were not the case, the study did not provide a reasonable basis for the representations in respondents' advertisements that users of X–11 tablets could lose significant, large amounts of excess weight of virtually any amount. **[60]**

102. Two allegedly parallel groups of exogenously obese adults

were employed in the study. One group was given a test preparation containing phenylpropanolamine (25 mg), caffeine and multi-vitamins while the other group received a placebo tablet. Both groups were also given a 1,200 calorie diet plan and instructions on its use. Dr. Silverman reported that over a "four-week period" while on the test preparation the "median" weight loss of males was 3 1/2 pounds greater than males on the placebo. The "median" weight loss of females on phenylpropanolamine was 2 pounds greater than the median weight loss of females on the placebo. Dr. Silverman concluded that the results produced a "statistically significant difference at the $<$ 0.05 probability level in the weight loss of females using the test preparation compared to those using the placebo," but "no significant difference in the case of males" (RX 3, pp. 538–39).

103. Both Dr. Margen and Dr. Drenick analyzed the study of Dr. Silverman (Dr. Margen, Tr. 209–17; Dr. Drenick, Tr. 390–98). Dr. Margen found that the combined treatment group had a difference of 1 1/2 pounds in 4 weeks which comes out at a .05 probability, the lowest possible range of significance, "you can't have anything worse than that in terms of probability" (Tr. 213). Dr. Margen further found that the greatest weight loss of anyone in the study occurred in a female who was on the placebo (Tr. 213). Among the males in the study "there was no significant weight loss between the placebo and the PPA [phenylpropanolamine]" (Tr. 214). Dr. Margen testified (Tr. 214):

> What is even more important is that, in the case of the males, there was no significant weight loss between the placebo and the PPA. In the case of the females, again, it was at the 10 to 20 probability range and certainly statistically in one case absolutely nothing happened. Clinically you have a weight difference which is of [61] absolutely no significance and, lastly, and I think what was sort of curious, the tremendous variability which you see in patients losing weight, and if one wants to make a joking point one can say that the greatest weight loss was with the female on the placebo."

104. Dr. Silverman reported his results in terms of a "median." In Dr. Drenick's professional judgment, use of a median to assess weight changes in such a study is unacceptable as it is not a proper scientific method for evaluating the test results (Tr. 390 and 398). This is a serious defect in the study because, as Dr. Drenick testified (Tr. 392–93):

> Another reason why this study is uninterpretable to me is that the authors used a way of assessing weight changes that are really not acceptable. They talk about median weights and median weight losses.

* * * * * * *

A median weight loss of eight pounds means absolutely nothing because I don't know what the other people on this side or on this side of the man in the middle lost. Since all of the weight losses are given as median weight loss I really don't know what he is talking about and I cannot say what his conclusions are or have any meaning at all.

(See also, Dr. Margen, Tr. 212). [62]

105. The characteristics of the subjects who participated in Dr. Silverman's study were so varied in their body builds and weights as to render meaningless the fractions of a pound of weight loss per week Dr. Silverman attributed to phenylpropanolamine (Dr. Drenick, Tr. 391-92). The females in the group on the test preparation had a median starting weight 12 pounds heavier than the median starting weight of females in the placebo group. Dr. Drenick testified that heavier individuals tend to lose more weight when following a diet simply because their caloric deficit is greater (Tr. 391). Dr. Drenick found that almost half (46 percent) of the females on the placebo were small framed, compared with one-quarter (24 percent) of those on the test preparation. Only 17 percent of the placebo group females were heavy framed contrasted with 32 percent of the group on the test preparation (Tr. 390-92). This is significant since "a small framed individual who is overweight carries a lot more fat" than a heavy framed individual (Tr. 391). The test groups were so dissimilar in significant characteristics as to render the study meaningless. Dr. Drenick testified (Tr. 392):

This may be an accident in their selection but it certainly is not true that these are comparable groups and for this reason any assessment of differences in weight loss is meaningless because you are not judging identical groups. They are totally dissimilar.

106. The small weight losses reported by Dr. Silverman of those on the test preparation over those on the placebo may even have been due to a diuretic effect (Dr. Drenick, Tr. 393-94).

107. Dr. Silverman's study further assumed that the crucial period in any reducing regimen was "usually during the initial part of the program" (RX 3, p. 541). [63] This is contrary to the prolonged and extensive experience of both Drs. Margen and Drenick in treating obese and overweight persons. Dr. Drenick testified (Tr. 397):

Everyone knows that obese individuals go on diets time after time after time and usually they lose a few pounds in the first few days. But the extended period, the long haul, this is where they fail.

Dr. Margen testified that to say the initial period of a dietary

regimen was the most crucial period was wrong "because the most crucial period is the long-term period" (Tr. 214). According to Drs. Drenick and Margen, Dr. Silverman thus tested phenylpropanolamine in the period where it is easiest to lose weight, and did not follow his test subjects over a more extended period of time.

108. Additional and thoroughly complete professional evaluation of the results published in this study were made impossible by Dr. Silverman's refusal to allow complaint counsel an opportunity to examine the study's underlying data (Tr. 1131).

109. Dr. Silverman's study, in any event, provided no basis for respondents' representations of weight loss from use of their X-11 tablets. Loss of one-half, or less than one-half a pound a week, over a 4 or 5-week period for an obese person is "clinically trivial" (see CX 101, 120), particularly in the absence of evidence that such loss can be continued.

(b) *Dr. Hoebel's Studies*

110. Dr. Hoebel, whose testimony has already been discussed to some extent, conducted experiments involving phenylpropanolamine with both animal and human [64] subjects. Before conducting studies with human subjects Dr. Hoebel experimented with phenylpropanolamine on rats. Four of his studies with rats were offered by respondents and received in evidence (RX 38-42). Dr. Hoebel's experiments with rats involved doses of phenylpropanolamine 100 to 1,000 times greater, on a relative basis, than the standard 25 mg dosage used with human subjects, and in many of the animal experiments the drug was injected directly into the brain (Dr. Margen, Tr. 186). Under these circumstances, loss of appetite or weight loss obtained by Dr. Hoebel in rats does not imply similar results in humans from oral ingestion of far smaller amounts of phenylpropanolamine. Moreover, overweight or obesity in humans derives from a variety of causes to which rats are not subject. As Dr. Drenick testified (Tr. 396):

> . . .making a rat lose weight does not mean that you are going to have a human losing weight because obviously humans overeat for reasons that are totally different from a rat.

111. Dr. Hoebel has published two papers dealing with human subjects, "Appetite Suppression By Phenylpropanolamine In Humans" (RX 1) and "Body Weight Decreased In Humans By Phenylpropanolamine Taken Before Meals" (RX 2), both in *Obesity/Bariatric Medicine,* Vol. 4, No. 5, 1975. From the foregoing date it is clear that these are recent studies and could not have provided a

reasonable basis for X-11 advertising claims made prior to their publication. However, like the Silverman study, Dr. Hoebel's work would bear upon the propriety of an order in this proceeding if it did, in fact, support respondents' advertising claims.

112. Both of Dr. Hoebel's studies were published "under the auspices of the Brain Research Instruments Company," Dr. Hoebel's private consulting firm (RX 1, p. 192, note 2 and RX 2, p. 200, note 2). The University of Princeton had no connection with either of them and they were not submitted to or reviewed by [65] any of Princeton's faculty committees (Dr. Drenick, Tr. 387-88; Dr. Hoebel, Tr. 1262). In this connection, Dr. Drenick testified (Tr. 387-88):

. . .I have never before seen a publication in medical literature where the author under his credit lines has to state or states that this study was not performed under the auspices of the Investigators [sic] Institution. Dr. Hoebel is a member of the faculty of the Department of Psychology of Princeton University and he prints a statement on Page 192 which says,"This study was performed under the auspices of the Brain Research Instruments Company, 207 Hartley Avenue, Princeton, with support from the Alleghany Pharmacal Corp. of New York, New York, and not Princeton University nor the Medical Center at Princeton,"which indicates to me that his institution and the Medical Center associated with Princeton University did not sanction or approve of this article.

113. Alleghany Pharmacal Company and respondent Porter & Dietsch have provided financial support for Dr. Hoebel's work with phenylpropanolamine. Dr. Hoebel had contacted each of these firms and sought financial support. Alleghany Pharmacal, as already noted, markets "Hungrex," a diet pill containing phenylpropanolamine in the same dosage as X-11 tablets (Tr. 1293; see also, CX 123). After Dr. Hoebel had been doing research with phenylpropanolamine on rats for several years, he saw "Hungrex" pills on sale in a drug store and testified that he (Tr. 1179): [66]

. . .got the name of the company off the books [boxes], called them up and suggested they should be supporting our research and, in fact, they did. This was the Alleghany Pharmacal Company. They gave a grant to Princeton University to continue this work with animals.

They also contacted me later and asked if I would be interested in running a study to test the efficacy of this drug in human beings.

On February 10, 1974, Dr. Hoebel wrote to Alleghany over the letterhead of his company, Brain Research Instruments Co., seeking additional funds stating that (CX 209):

Considering that Alleghany's future all hinges on F.D.A. decisions, my publication of the Brain Research Instruments Co. and Princeton University reports is the best buy in advertising you have.

Dr. Hoebel's study results on phenylpropanolamine have been used by "Alleghany Pharmacal in their advertising" (Tr. 1299).

114. Dr. Hoebel's research has also been supported by respondents in this proceeding, Porter & Dietsch. After the complaint issued in this matter, Dr. Hoebel was introduced to individual respondent William H. Fraser, president of Porter & Dietsch. Dr. Hoebel later contacted Porter & Dietsch and suggested that that firm support his research. Dr. Hoebel testified (Tr. 1288): [67]

Q. When did you begin conducting a study for Porter and Dietsch, or when were arrangements made for you to conduct such a study?

A. This fall [1975]. Well, more specifically, when this case came up, and I was introduced to Mr. Fraser of Porter and Dietsch.

My parents live in Minnesota, in St. Paul, so when I visited them, I went to visit him and asked him if he would like to support research at Princeton University, and he said yes. He has.

With respect to his letter to Alleghany Pharmacal Company, Dr. Hoebel testified (Tr. 1291):

It is my opinion that anyone that is selling a drug for human use has a responsibility to support research on that product.

The grant from Porter & Dietsch or Mr. Fraser, although in name to Princeton University, is specifically earmarked for Dr. Hoebel's research (Dr. Hoebel, Tr. 1290).

115. The first study of Dr. Hoebel, "Appetite Suppression By Phenylpropanolamine In Humans" (RX 1), involved a "double-blind" experiment in which test subjects were given either a placebo or a pill containing phenylpropanolamine 30 minutes before being instructed to begin a lunch of Metrecal. The amount of Metrecal ingested at each lunchtime session was measured. In the initial phase of the experiment the test subjects were told by Dr. Hoebel that the purpose [68] was to test the effect of a drug on food intake, and that the subjects would be paid. After a number of procedural refinements were introduced, a difference of 38 cubic centimeters was found between the mean noontime intake of 669 cc's Metrecal for subjects on phenylpropanolamine and 707 cc's for those on the placebo (RX 1, p. 195). Dr. Hoebel reported that "phenylpropanolamine can decrease meal size in a selected population such as we sampled when they are instructed to use the drug according to the instructions given when sold over the counter" (RX 1, p. 196).

116. In evaluating this study, Dr. Margen testified that he disagreed with the statistical methodology employed in reporting

test results. He wrote on the paper when studying it that the statistical methodology was "rigged," and testified (Tr. 179):

. . .as far as the paper is concerned I cannot utilize the data and find that I can come up with any of the conclusions which the author did . . .

Use of a "mean" without any mention of individual variability of food intake was, in Dr. Margen's opinion, a serious defect since any individual differences in a test of this type would be highly significant (Tr. 180–81). Additionally, when further refinements were made in the experimental design by Dr. Hoebel, absolutely no difference in Metrecal consumption was reported and Dr. Margen therefore concluded that "in this paper I cannot find that there is any significant demonstration of the effectiveness of PPA" (Tr. 184). Dr. Margen concluded (Tr. 184): [69]

So here you have a paper which is published without any consideration to variability, and I don't see that the variability was handled in the entire matter of statistics or statistical analyses, and you come up with a very inconclusive thing.

See generally, Dr. Margen (Tr. 174–85).

117. Dr. Drenick also analyzed Dr. Hoebel's first study (RX 1). When asked if this study indicated that phenylpropanolamine is an effective appetite suppressant in humans, Dr. Drenick testified (Tr. 374–75):

I don't think that this article proves that at all, and the reason for my opinion is as follows: Dr. Hoebel treated three groups of subjects. To one group he gave phenylpropanolamine. To another group he gave a placebo but told them that they were going to test the effect of a drug on food intake and weight reduction and he also promised them $15 for participating to be paid at the end of the testing. Therefore, for these two groups he introduced the bias which I have explained to you before. One must not provide that if one wants to have an objective assessment.

In the third group of 32 subjects he stated that he was giving this medication which was a nasal decongestant and to his surprise, when he did that, the [70] patients did not lose any weight and did not reduce their food intake. To my interpretation and assessment this is the only valid group because they did not know that they were supposed to have a weight loss.

Therefore, his conclusion that it was effective in reducing food intake I think is totally in error. The only objective assessment is in the group which did not know what they were getting and there, in fact, he found no effect. So my conclusions differ from his, and I think his are wrong.

118. Dr. Hoebel's second paper, "Body Weight Decreased In Humans By Phenylpropanolamine Taken Before Meals" (RX 2), reported the results of a double-blind, subject-crossover study also designed to investigate the effectiveness of phenylpropanolamine in

appetite suppression and weight control. A weight loss associated with phenylpropanolamine of a fraction of a pound per week during the 4-week period of the study was reported (RX 2, p. 203), and the paper concluded that "phenylpropanolamine was effective in producing a short-term weight loss in the population sampled" (RX 2, p. 206).

119. After analyzing this study Dr. Margen stated that the fractions of a pound of weight loss Dr. Hoebel reported to be associated with phenylpropanolamine may, in fact, have been the result of entirely different stimuli. Dr. Margen testified (Tr. 189–90): [71]

. . .if you look at the percent weight change in two weeks, in the case of the drug it is minus 1.2 percent and in the PPA a difference of 5 percent, and we know the body weight can vary without any treatment over two weeks by that amount.

But I want to point out that even more interesting, and I think this is really a very fascinating part, before the subjects entered the study they were weighed and then they entered the study and in both cases, in the PPA and in the placebo group, there was a significant weight loss in the few days before the study was undertaken, before anything was given. In fact, the weight loss in the patients who were then given the PPA was greater than the weight loss of the people given the placebo and, in fact, the weight loss in the few days in the group given the PPA was, as I calculated it here, about 1.3 pounds, which was as great as the change in over two weeks of the placebo week, so just in anticipation of the experiment the patients lost almost the same amount of weight. It had nothing to do with the administration of anything.

Dr. Margen also noted that, again, only the "means" were reported and no mention was made of the individual variability of test subjects. The potential effect of this omission was explained by Dr. Margen (Tr. 189): [72]

Now, what are the differences? First of all, Dr. Hoebel, if you look at the chart [RX 2, p. 203], the differences look as if they might be rather impressive. For instance, if you look at the PPA [phenylpropanolamine] versus the placebo on the first two weeks, it looks like the people on the PPA went down more than they did on the placebo and it is true they did go down more. The change in body weight during the first two weeks on the drug was minus 2 pounds, on the placebo minus 1.23 pounds, and we are not told the variability.

Now, one individual, mind you, in that group having, let's say, a weight loss of approximately 10 pounds could completely distort the entire group and tell you absolutely nothing and give you an entirely erroneous impression, so unless you have some idea of the variability or some idea of what the individual weight losses were in there, this is absolutely valueless.

In commenting on the study's reported weight losses, Dr. Margen testified (Tr. 191):

. . . [W]e don't have evidence from this paper that this weight loss was even

statistically significant and certainly, from a clinical point of view, this is totally insignificant.

120. Dr. Drenick likewise questioned whether Dr. Hoebel's test results were valid or had medical significance. He testified (Tr. 385-86): [73]

To decide whether or not it [phenylpropanolamine] is effective one has to answer the question whether or not it has a significant effect from a medical point of view or is significant from the point of view of the patient who wants to lose weight. And, in fact, if one analyzes this article more closely, one can see that the greatest weight loss, regardless of whether any drug or placebo was given, occurred before either of these items was administered. The patients lost either 2-1/2—no, 1-1/2 or 1 pound of weight before they received any kind of treatment. Then, over a two-week period the patients who were given the drug lost less than 2 pounds or less than 1-1/2 pounds.

The difference between the phenylpropanolamine treated group and the placebo treated group, the difference in weight loss was less than 1 pound. If you want to express this in a per cent weight change and the difference between the two groups it is 1/2 of 1 per cent difference in weight change.

* * * * * * *

When you, however, ask yourself does a difference of less than one pound between treatment groups mean anything to the patient or to a physician, the answer would be obviously not. This much of a difference would not be noticeable in anyone who is significantly overweight.

[74] Of basic importance, moreover, Dr. Drenick pointed out that Dr. Hoebel had no reason to believe the fraction of a pound a week weight loss he attributed to ingestion of a tablet containing phenylpropanolamine would continue, and that Dr. Hoebel himself recognized this (Tr. 386) when he wrote (RX 2, p. 206):

One should also be aware that our evidence for a statistically significant weight loss in a two-week period does not mean that this rate of loss would be continued over longer periods. Drug tolerance and a myriad of other physiological and social factors could affect longer term results.

121. Neither of Dr. Hoebel's studies constitutes a reasonable basis for the representations of weight losses held out to the public in respondents' advertisements. Weight losses of a fraction of a pound a week do not support or substantiate advertising of respondents conveying the net impression that prospective purchasers and users of the X-11 tablets would lose large poundages of "ugly fat" amounting to virtually any amount, "5, 10, 25 or more pounds," "83 lbs.," "80 lbs.," "40 lbs.," etc. For the obese or overweight, weight losses of a fraction of a pound a week were clinically trivial and insignificant. Further, as already pointed out, Dr. Hoebel himself concluded that a weight loss in a two-week period did not mean that

this rate of loss would be continued over a longer period because of drug tolerance and other factors (RX 2, p. 206).

122. Little of the evidence introduced in this proceeding related to methylcellulose, the second ingredient in X-11 tablets which allegedly is conducive to weight loss. Methylcellulose, as noted, is a "bulk producer," a non-digestible but harmless bulky material [75] no more effective for the treatment of obesity than the "high-residue, low-calorie diet itself" (CX 92, p. 9). "Bulk producers of the methylcellulose family have no proved anorectic effect" (CX 115). Tests by Dr. Drenick, established that within minutes after ingestion of one-half to one gram of methylcellulose, (which is twenty to forty times the 25 mg in an X-11 tablet), the methylcellulose had passed out of the stomach well into the small intestines with no effect on the appetite (CX 115; Dr. Drenick, Tr. 367).

3. *The X-11 tablet does not contain any "unique" ingredient*

123. Respondents have admitted that phenylpropanolamine is the allegedly "unique" ingredient which they identified or alluded to in their X-11 advertisements (Ans. P&D, ¶9, p. 10; Supp. Adm. P&D, No. 41). They also concede that phenylpropanolamine is not unique to X-11 tablets (Motion to Dismiss, p. 84), but contend that the representation made by them was that phenylpropanolamine is a "unique" pharmacological substance. Respondents' advertisements, however, have the capacity to convey the net impression to members of the public reading them the representation that X-11 tablets were the only preparation available without prescription containing phenylpropanolamine. This conclusion is reinforced by the frequent use of terms such as "Now . . . LABORATORY SCIENCE HAS PERFECTED A TINY TABLET" (CX 8, 14 and 15), "RECENTLY, Laboratory Science has perfected. . ." (CX 46-47 and 49), "Here, at last. . ." (CX 19), which convey the impression that scientific research has developed a new, heretofore unknown, aid to those seeking to lose weight.

124. As hitherto made clear, phenylpropanolamine "is a member of the sympathomimetic amine family," a group of agents related pharmacologically and in their chemical structure (Supp. Adm. P&D, No. 35; CX 92, pp. 5-6; RX 1 and 2; Dr. Prout, Tr. 676). Although there are [76] quantitiative differences, phenylpropanolamine being a weak member of this group, all these amphetamine-like drugs produce the same types of responses, *i.e.,* central stimulant effects, wakefulness and increased mental and physical activity (CX 92, p. 6; RX 14, p. 1; Sorer, Tr. 622). Phenylpropanolamine being considerably less potent than amphetamine, its parent

compound (Dr. Prout, Tr. 708), has fewer side effects than other members of the amphetamine family. Because it produces less central nervous stimulation and is the only drug of this class available without prescription, phenylpropanolamine was described as "unique" (Palmer, Tr. 562; Hoebel, Tr. 1201-02). However, considering the representation of "uniqueness" in respondents' advertisements, it is unlikely that the public would interpret this representation to mean only that phenylpropanolamine is unique with reference to other sympathomimetic amines or other pharmacological substances. On the contrary, the representation that respondents' advertisements had the capacity to convey is that, when compared to other dietary aids available without prescription, X-11 tablets contain a totally different or "unique" chemical, in other words, that phenylpropanolamine is unique to X-11 tablets. Since phenylpropanolamine is in many over-the-counter preparations (Dr. Sorer, Tr. 641-42; Supp. Adm. P&D, Nos. 42 and 43; Adm. P&S, No. 42), this representation is false. Respondents have therefore misrepresented in their advertisements that X-11 tablets contain a unique ingredient.

RESPONDENTS' FAILURE TO DISCLOSE MATERIAL FACTS IN ADVERTISING X-11 TABLETS

1. *Respondents failed to disclose that testimonials reciting weight losses of great magnitude did not reflect the typical or ordinary experience of x-11 users*

125. Respondents' advertisements contain a number of testimonials reciting great weight losses achieved by users of X-11 tablets. For example, in CX 19, as [77] discussed in earlier findings, Mrs. George Stowe, Canon, Georgia, is quoted "I USED TO WEIGH 160 LBS. NOW I'M DOWN TO 105", Mrs. Ken Schmidt, Norfolk, Nebraska, is pictured stating "I LOST OVER 40 LBS., TOO," and Mrs. Beverly Tellier, Chula Vista, California, likewise is shown stating "I LOST OVER 40 LBS." In another ad Mrs. Ken Schmidt is quoted "I LOST 80 LBS!" (CX 18). The record is replete with similar testimonials (see, *e.g.*, CX 1, 2, 15, 22, 24, 44, 49 and 68).

126. Through the use of such testimonials respondents represented that the results obtained by those giving testimonials reflected the typical or ordinary experience of persons purchasing and using X-11 tablets. In the testimonials the least amount of weight loss claimed is 40 pounds (CX 19), and the claims range as high as 83 pounds (CX 68). Multiple testimonials were often used in the same advertisement adding to the implication that it is typical for users of

X-11 tablets to experience weight losses of such magnitudes. Statements such as "FROM GEORGIA TO NEBRASKA TO CALIFORNIA American Women Have Found A Way That Really Helps Off THAT UGLY FAT" (CX 1 and 19) also reinforced the implication that the stated weight losses were typical for all users of X-11 tablets.

127. The weight losses cited in the testimonials in respondents' advertisements, however, are not representative of the typical or ordinary experience of purchasers and users of X-11 tablets. The tablets themselves produce no weight loss and medical experience establishes that even with a stringent dietary regime, and professional supervision, weight losses of the magnitudes portrayed by respondents' testimonials are highly unusual and extraordinary for overweight or obese individuals.

128. Dr. Prout testified that only one in twenty patients instructed in a weight-reducing regimen would achieve weight losses of twenty to thirty pounds within [78] a period of approximately twenty weeks (Tr. 717). Dr. Drenick testified that "[o]nly ten percent of obese individuals will ever lose more than 40 pounds in a single dietary regimen" (Tr. 412). In *Drugs of Choice* (CX 92), Drs. Modell and Reader stated that "most obese patients will not stay in treatment," and "of those who do, most will not lose weight" (CX 92, p. 2).

129. Based on the above statements, it is apparent that a weight loss of 40 to 83 pounds for an obese individual would be extremely rare. Respondents have failed to disclose to potential users of X-11 tablets the fact that, contrary to the results achieved by those whose testimonials are published, weight losses of great magnitude are not representative of the typical or ordinary experience of X-11 users.

2. *Respondents failed to disclose in their advertisements for X-11 tablets that persons with high blood pressure, heart disease, diabetes or thyroid disease should use X-11 tablets only under the direction of a physician*

130. Respondents Porter & Dietsch, William H. Fraser, Kelly Ketting Furth and Joseph Furth admitted that phenylpropanolamine, because of its pressor effect, should not be ingested by persons with high blood pressure, heart disease, diabetes or thyroid disease except under the advice and supervision of a physician (Adm. P&D, No. 59). The package insert accompanying X-11 tablets contains an FDA-required warning that persons with those diseases or conditions should use X-11 tablets only as directed by a physician (Adm. P&D, Nos. 60-61; Adm. P&S, Nos. 60-61). [79] The package containing X-11 tablets also has "CAUTION: Individuals with high blood pressure,

heart disease, diabetes or thyroid disease should use only as directed by a physician. . ." printed on the back (CX 36 and 39). Despite respondents' awareness that X-11 tablets should not be used by such members of the public, they made no mention of this fact in any of the X-11 advertisements.

131. Phenylpropanolamine is an active vasoconstrictor which tends to constrict blood vessels and thereby elevate blood pressure (CX 94; RX 5; Dr. Drenick, Tr. 369-70; Dr. Prout, Tr. 695). For a person already afflicted with high blood pressure, ingestion of phenylpropanolamine could elevate blood pressure to even higher, and possibly dangerous, levels (Dr. Margen, Tr. 238-39); Dr. Drenick, Tr. 417; Dr. Sorer, Tr. 627-28). According to Dr. Sorer, giving a product containing a sympathomimetic amine to an individual with high blood pressure "would be like dousing a fire with gasoline" (Tr. 627).

132. Phenylpropanolamine can also be dangerous to a person with heart disease by putting an extra strain on his or her heart, with potentially serious consequences (Dr. Drenick, Tr. 417-18); Dr. Sorer, Tr. 629-30). Dr. Sorer testified (Tr. 629):

> We are talking about people with low cardiac reserve where an extra weight placed on the heart or its organism could prove fatal or adverse.

Such danger would be greater for a person on a nutritionally deficient diet such as that contained in the X-11 package, because this makes a person's nervous system even more susceptible to the irritant effects of phenylpropanolamine (Dr. Drenick, Tr. 417). [80]

133. Large numbers of the nation's public have high blood pressure or heart disease. Data of the National Center for Health Statistics of the U.S. Public Health Service, reported by the American Heart Association, show that, as of 1972, an estimated 28,410,000 Americans have either high blood pressure or some form of heart disease. Of these, some 22,950,000 — or one of every six adults — have high blood pressure (CX 109, pp. 13, 29). Although half of the people with high blood pressure are not aware that they have this condition (CX 109, pp. 13, 29), an admonition in advertisements against use of X-11 tablets by individuals with high blood pressure or heart disease would serve to notify a large number of potential purchasers that they should not use, or purchase, X-11 tablets.

134. For persons with diabetes, phenylpropanolamine carries the risk of elevating the blood glucose level, thus aggravating a situation already potentially hazardous. Dr. Sorer testified (Tr. 630):

> On pharmacological grounds, again these agents do elevate blood glucose. Diabetics

have already elevated blood glucose very simplistically so this could again make a potentially bad situation worse. It is possible.

135. According to the official Report of the National Commission on Diabetes, dated December 1975, diabetes is increasing by 6 percent each year, and now affects one out of every 20 Americans (CX 108, p. 1). Dr. Prout, whose expertise includes diabetes treatment, feels that these figures are conservative and that the true rates of increase are even higher (Tr. 701-02). Dr. Fineberg characterizes the increase in diabetes as "exploding" (Tr. 1360-61). The likelihood of being diabetic doubles with every decade of life, and more than doubles with every 20 percent of excess weight (CX 108, pp. 2, 47; Dr. Prout, Tr. 703), and 70 to 85 percent of all adult diabetics are over-weight [81] (CX 108, p. 15; Dr. Prout, Tr. 703). These figures establish the need for a warning in respondents' advertisements against use of X-11 tablets by a substantial portion of the purchasing public who should not ingest any product containing phenylpropanolamine.

136. High blood pressure, heart disease and diabetes occur more frequently and with greater severity among the obese and overweight than in the population generally (Adm. P&D, No. 53; Dr. Prout, Tr. 702; Dr. Margen, Tr. 151).

137. Persons with overactive thyroid also subject themselves to increased health hazards by ingesting phenylpropanolamine. Dr. Drenick testified (Tr. 418):

Q. If a person with thyroid disease took X-11 tablets together with the instructions [sic] for their use, would that result in a danger for that person?

A. If the thyroid were overactive, I think it would. . . .

Q. Should . . . persons with . . . thyroid disease use such a preparation as X-11 only as directed by a physician?

A. Yes.

138. First-time purchasers of X-11 tablets through the mails plainly have no way of knowing, and obviously are unaware at the time of purchase, of the warning on the package of X-11 tablets. (Adm. P&D, No. 62; Adm. P&S, No. 62). Also, the public may rely [82] entirely on the affirmative representations in respondents' advertisements and fail to notice the limitation as to use printed on the back of the X-11 package prior to purchase.

139. The potentially hazardous consequences to the health of overweight or obese persons who have high blood pressure, heart disease, diabetes or thyroid disease from ingestion of X-11 tablets,

are material facts of the greatest importance, and plainly had the capacity to affect the consideration by such persons of whether or not to purchase respondents' tablets.

3. *Respondents failed to disclose in advertising that a highly restricted caloric diet is an integral adjunct to the use of X-11 tablets*

140. As is clear from what has already been said, for users of X-11 tablets to lose weight, a "diet" must be followed and caloric intake must be restricted (Dr. Drenick, Tr. 350; Carretta, Tr. 661). The package of X-11 tablets, as noted, contains instructions and a diet providing for a drastic reduction of caloric intake (CX 37, 40 and 133), and expert testimony described this as a "starvation" or "semi-starvation" diet (Dr. Margen, Tr. 169; Dr. Drenick, Tr. 406; Dr. Fineberg, Tr. 1330). Respondents' advertisements, however, failed to disclose that, in conjunction with the use of X-11 tablets, a severely restricted diet had to be followed. On the contrary, the public was told that they could continue to "EAT" and "EAT WELL" while losing "ugly fat." Failure to disclose that a highly restricted, low-caloric diet had to be followed for purchasers and users of X-11 tablets to lose weight constituted a failure to disclose a material fact likely to affect the decision of members of the public whether or not to purchase X-11 tablets. [83]

RESPONSIBILITY OF WILLIAM H. FRASER FOR DECEPTIVE ADVERTISING OF X-11 TABLETS

141. As stated at the beginning of this decision, individual respondent William H. Fraser is the president and sole owner of Porter & Dietsch (Fraser, Tr. 753-54). Admittedly, he formulates, directs and controls the acts and practices of Porter & Dietsch (Ans. P&D, ¶1).

142. Mr. Fraser's responsibility for the deceptive advertising of X-11 tablets does not, however, derive solely from his role as the chief executive officer and owner of respondent Porter & Dietsch. He was an active participant in the formulation and dissemination of the advertising here in issue. Although stating he relied entirely on Mr. Gettleman for the X-11 tablet advertising content (Tr. 798 and 878-80), Mr. Fraser, in fact, originated the use of testimonials (Furth, Tr. 962-63), and made other contributions to the advertising content (Furth, Tr. 977-78). He discussed X-11 advertising with Mr. Furth, who subsequently met with Mr. Gettleman to complete the ad copy (Fraser, Tr. 797; Furth, Tr. 959). Mr. Fraser, furthermore, had

the power to reject advertisement ideas developed by Mr. Furth and Mr. Gettleman (Fraser, Tr. 798). When advertisements were completed in final form, Mr. Fraser handled their preparation for dissemination (Fraser, Tr. 796), and thereafter placed them directly or sent authorizations to retailers for ad placement (Fraser, Tr. 795 and 799). Mr. Fraser is responsible for the X-11 advertisements as chief executive officer and sole owner of Porter & Dietsch, and as an active participant in their creation and dissemination.

RESPONSIBILITY OF KELLY KETTING FURTH AND JOSEPH FURTH FOR DECEPTIVE ADVERTISING OF X-11 TABLETS

143. Respondent advertising agency Kelly Ketting Furth and individual respondent Joseph Furth played an active role in the misleading and deceptive advertisements [84] disseminated by respondents Porter & Dietsch and William H. Fraser. Mr. Furth began work on the advertising of X-11 tablets for Porter & Dietsch in June 1968, two or three weeks before the formation of Kelly Ketting Furth (Furth, Tr. 928-35; CX 83). After Kelly Ketting Furth commenced business, Mr. Furth summarizes the firm's role as the advertising agency for Porter & Dietsch as follows (Tr. 927):

> An advertising agency functions with an advertiser in the liaison preparation of, development of, placing of advertising.

Joseph Furth was the account executive in Kelly Ketting Furth responsible for the Porter & Dietsch account, and prepared advertising copy for products marketed by Porter & Dietsch (Ans. P&D, ¶4). His function as account executive was ". . . to handle it in a normal way in which an advertising agency might handle the advertising for an advertising client" (Tr. 937). During the time he has been Kelly Ketting Furth's account executive for Porter & Dietsch, Joseph Furth has implemented and prepared all advertising copy for the X-11 tablets (Fraser, Tr. 794-98; Furth, Tr. 944-46; Adm. P&D, No. 10 b and 3).

144. In addition to implementing and preparing advertising copy, Mr. Furth originated the theme which pervaded respondents' X-11 advertising in one form or another: "Eat Well and Lose [That] Fat." Mr. Furth testified that his suggestion to Mr. Gettleman developed into this advertising concept and was used in the "first original conventional newspaper advertisement" (Tr. 981-82). This slogan appeared in an X-11 advertisement as early as 1969 (CX 87). Mr. Furth and Mr. Gettleman worked together in creating and developing subsequent X-11 advertising (Tr. 951 and 956). [85]

145. Kelly Ketting Furth and Mr. Furth put the ideas and

suggestions of Mr. Gettleman into finished advertisements, establishing emphasis, headlines and layout (Tr. 940-41, 958-61 and 964-65). In short, they played an active role. A letter to Mr. Fraser from Kelly Ketting Furth by Mr. Furth, vice-president, dated September 13, 1968, reads (CX 151): "Enclosed is suggested copy and layout for ad you requested for newspaper weeklies." On November 1, 1968, Mr. Furth wrote to Mr. Fraser (CX 152):

About two months ago, on your request, I prepared a 35-line ad on X-11, and sent it to you.

* * * * * * *

This could be an effective way to get a steady bleed on Free Standing Stuffer markets.

Again on December 4, 1968, Mr. Furth wrote to Mr. Fraser (CX 153):

I am enclosing layout for a revised format for the Free Standing Stuffer.

I believe that it has a "nicer feel," yet retains the power of the previous insert.

On the Imprint side we have used a more meaningful illustration of a slim doll, who appears to be anticipating the food she has ordered. It graphically gets over the point, "Eat what you want and slim down." [86]

On this side, I would like to use the copy we used previously.

We have reversed the panel on the flap from red to blue — and I think it looks stronger.

On the back side I wanted to retain the "power" of our previous insert, but have changed the headline to that of our 16" dealer ad which seems to be perking. Here, I would intermix copy from the dealer ad with some of the copy now in the stuffer. I would like to keep the copy as is in the pink panel.

We have made provision for the weight chart in the lower panel.

What do you think? Should we switch over perhaps in February?

146. Mr. Furth kept Mr. Fraser up to date on X-11 advertising developments (CX 154-55). In a letter of January 28, 1971, Kelly Ketting Furth and Mr. Furth advised Mr. Fraser of Mr. Gettleman's "approval on copy" for an X-11 advertisement, Mr. Furth stating that he would work Mr. Gettleman's idea in "as follows" providing Mr. Fraser with proposed copy (CX 156). In another letter dated July 14, 1971, Mr. Furth wrote Mr. Fraser "I am returning the Odrinex copy, and copy I have prepared patterned on the small ad all type format" (CX 157). "Odrinex" is a "diet pill" competing with X-11 tablets (CX 157, p. 3). In letters of August 29 and December 4, 1972, Mr. Furth made suggestions to Porter & Dietsch relating to the

testimonials in the X-11 advertisements of Mrs. Stowe, Mrs. Tellier and Mrs. Schmidt, and the layout of other features (CX 159 and 160). On June 18, 1973, Mr. Furth sent Mr. Fraser a "second 2-column newspaper ad" noting that it was [87] "virtually resized from the page Roto ad which ran over Drug Guild's name in the New York News and did so splendidly," and that "it basically is our original ad, done a little differently, and the ad that Thompson 'swiped' for Appedrine" (CX 162). The advertisement featured "Eat Well. . .And Lose That Fat" picturing an X-11 tablet and a silhouette of a slim lady (CX 162, p. 2). On July 13, 1973, Mr. Furth sent Mr. Fraser an X-11 advertisement cast in the "Standard [R]oto size" suitable for the "Minneapolis Sunday Roto" (CX 163). This advertisement contained handwritten revisions on the Kelly Ketting Furth letterhead. On October 31, 1973, Mr. Furth wrote Mr. Fraser (CX 165):

> You've asked for "new" ads. I've been holding out for the old.
>
> Here is a compromise that has some new elements the competition is not yet using.
>
> First, Appedrine and now Odrinex have adopted our silhouette figure. I don't want to drop ours. But I have added a reduced "pot-bellied" man to indicate how much "gut" he has taken off. This may give us the man-and-woman appeal, which the others aren't using.

(See also CX 166 through CX 173).

147. On March 14, 1974, Mr. Furth advised Porter & Dietsch against a suggestion for affixing "a pressure sensitive sticker on the X-11 package stating 'Does not contain amphetamines' ", a proposal advanced to counter newspaper publicity linking Hodgkin's disease with the use of diet pills containing "amphetamines or related drugs" (CX 168). He commented to Mr. Fraser that the idea "should be viewed cautiously" because phenylpropanolamine "is a 'cousin' related structurally and pharmacologically" to amphetamine, and that since [88] "[w]e are dealing with 'Label' as differentiated from advertising. . .we would be a 'sucker' for possible FDA misbranding, hence seizure" (CX 168).

148. Kelly Ketting Furth and Joseph Furth handled the placing of Porter & Dietsch's X-11 advertising in publications throughout the country (Stipulations, Tr. 378-83; Fraser, Tr. 881; and Furth, Tr. 942-43). Advertisements in media which recognize "national" advertisers as a rate class, such as *TV Guide,* were placed for Porter & Dietsch by Kelly Ketting Furth by forwarding them directly to the publication. Kelly Ketting Furth was then billed for such space (Furth, Tr. 942-43; Stipulation, Tr. 381-83). "National" advertising

accounted for about half of all advertising of X-11 tablets (Fraser, Tr. 868).

149(a). Kelly Ketting Furth, and individual respondent Joseph Furth, played an active role in the creation and dissemination of Porter & Dietsch's advertising for X-11 tablets, and knew or should have known that the representations contained in such advertising were false, misleading and deceptive. That this is true is not only revealed by the facts set out in the foregoing findings, but is dramatically shown by the letter from Mr. Furth to Mr. Fraser (CX 164), quoted earlier in this decision, in which he answered Mr. Fraser's criticism that an advertisement for the X-11 tablets lacked "punch." Mr. Furth displayed his keen knowledge of the X-11 tablet advertising, both content and strategy, and his active role in creating and disseminating it, by commenting to Mr. Fraser on the dangers of "put[ting] emphasis on the tablets" in making weight loss claims—"That's murder, because the pills will not reduce weight an iota" (CX 164). Mr. Furth continued in his letter warning Mr. Fraser against putting in the advertisements for X-11 tablets the same kind of "punch" used in the competing "diet" pill advertising of Appedrine, Hungrex and Odrinex, [89] noting frankly that he was afraid "we're all going to get into hot water because of Appedrine, Hungrex and Odrinex" (CX 164, p. 2).

RESPONSIBILITY OF PAY'N SAVE CORPORATION FOR THE DECEPTIVE ADVERTISING OF X-11 TABLETS

149(b). Pursuant to arrangements with Porter & Dietsch, many advertisements for X-11 tablets were placed for publication by officials of Pay'n Save Corporation over the Pay'n Save corporate name. Pay'n Save lent its name, prestige and corporate identity to the advertisements for X-11 tablets, and the claims and representations made for them in such advertisements thus became those of Pay'n Save Corporation.

150. The working arrangement between Porter & Dietsch and Pay'n Save Corporation originated around 1969 or 1970. A representative of Porter & Dietsch persuaded the manager of the Everett, Washington, store of Pay'n Save to put in a stock of X-11 tablets and to run an advertisement (Palmer, Tr. 507-08; Affidavit of Calvin Hendricks attached to Motion to Dismiss of Pay'n Save dated November 28, and filed December 1, 1975). The promotion was successful and the Pay'n Save buying committee decided to advertise X-11 tablets throughout the Seattle area. Thereafter, Pay'n Save drug stores generally carried and advertised the X-11 tablets (Tr. 508-13). The criteria used by the Pay'n Save buying committee in

deciding to carry and advertise X-11 tablets, according to Pay'n Save's pharmacy supervisor, was that (Palmer, Tr. 513): [90]

> They [Everett Pay'n Save store] had sold a hundred-plus units of product in a three-day ad, which is considered very good return on a brand new item, and so, based on this, they [the buying committee] were looking for something that might be successful in all stores. If we could sell a hundred of everything brand new the first time we advertised it, we would be very happy.

The decision of the buying committee was based entirely on the successful sales generated in the Everett store, and the claims and representations contained in the advertisements to which Pay'n Save lent its name were not scrutinized (Palmer, Tr. 510-14).

151. Under the arrangement between Pay'n Save and Porter & Dietsch, the dates and media in which X-11 advertisements were published were selected by Porter & Dietsch, and insertion orders were sent by that respondent to Pay'n Save. The latter paid the publication for carrying the advertisements and was later reimbursed for between 75 and 90 percent of the cost by Porter & Dietsch upon transmittal of a tear sheet. In such instances, the X-11 tablets were advertised, and all the claims and representations described and set out in earlier findings, were made over the name of Pay'n Save Corporation (see Stipulations Tr. 115-17, 377-80, 428-35; Affidavit of Calvin Hendricks, *supra;* RX 8 through 13; Palmer, Tr. 518-26). Readers and prospective purchasers were told that the X-11 tablets were available at all Pay'n Save stores. A coupon was also attached to many of the advertisements for prospective purchasers to fill out and mail to Pay'n Save Corporation to receive a supply of X-11 tablets by mail (CX 1-2, 14-20, 29, 31-33, and 35). In other words, respondent Pay'n Save Corporation advertised the X-11 tablets as if the tablets were its own product. [91]

152. Wherever advertisements for X-11 tablets appeared over the Pay'n Save corporate name, it was with the approval and by the direction of Pay'n Save (Tr. 525). At all times, Pay'n Save Corporation had the option of accepting or rejecting the X-11 advertisements submitted to it by Porter & Dietsch (Fraser, Tr. 807). However, as indicated, such advertisements were neither analyzed nor evaluated by Pay'n Save prior to its decision to publish them (Palmer, Tr. 510-14).

153. Porter & Dietsch was never contacted by Pay'n Save Corporation for material substantiating the claims and representations for the X-11 tablets made in the advertisements, nor to determine if Porter & Dietsch had such material, and Pay'n Save had no information whatever as to whether there was any reasonable basis for such claims and representations (Palmer, Tr.

547-50, 471-72). Nor did Pay'n Save officials, or its pharmacy supervisor, make any inquiry of their own. In sum, Pay'n Save depended totally upon Porter & Dietsch, as follows (Tr. 547):

> I think we were depending totally upon the manufacturer to present a product that had been sold and advertised to other people for a number of years and that upon that basis we felt that apparently the product did have merit.

Pay'n Save Corporation thus published advertisements over its own name making affirmative claims and representations to the public for the X-11 tablets without knowing whether or not those claims and representations were true or false, without having made any inquiry to determine whether they were true or false, and without knowing or having made any inquiry to determine whether there was even a reasonable basis for such claims and representations. [92]

154. Under the circumstances, Pay'n Save Corporation is, and must be, responsible for the deceptive representations made to the public. Pay'n Save is not relieved from such responsibility because the content and copy of the advertisements were prepared and created by the other respondents in this proceeding.

III

BASIC CONSIDERATIONS

1. Tablets

Respondents Porter & Dietsch, William H. Fraser, Kelly Ketting Furth and Joseph Furth place great emphasis upon the contention that they advertised and marketed a "plan," not tablets and therefore made no representations as to the X-11 tablets alone. As the findings disclose, this argument is unsubstantiated by the facts and is rejected. An examination of respondents' many advertisements, in the opinion of the law judge, demonstrates beyond question that respondents were promoting and selling X-11 diet tablets, and that the representations made to the public in respondents' advertisements related to the efficacy of the tablets and the results to be achieved from their use.

Labeling the box of tablets the "X-11 Reducing Plan," coupled with the liberal use in advertising copy of the word "plan," does not and cannot change the realities of respondents' product. Repeated use of the word "plan" in the advertisements and on the box of X-11 tablets was, in the view of the law judge, a transparent attempt to avoid what respondents accurately perceived to be dangers in [93] making significant, large weight reducing claims of virtually any amount for the tablets. As reiterated herein, Porter & Dietsch's

advertising account executive, individual respondent Joseph Furth, revealed the true reason for respondents' effort to transform the advertising and sale of X-11 tablets into the promotion of a reducing "plan" (CX 164):

> Appedrine and Hungrex (even Odrinex) put emphasis on the tablets. That's murder, because the pills will not reduce weight an iota.
>
> It is the "Plan" that will keep us out of hot water.

The genesis of respondents' claim to be marketing a "plan" undoubtedly lies in *Carlay Co.* v. *Federal Trade Commission,* 153 F.2d 493 (7th Cir. 1946), where a Commission order against a candy product presented as a reducing aid was overturned, and the court accepted the argument that a "plan" was involved. But *Carlay* does not decide the factual issue of what respondents were, and are, marketing in this proceeding.

The Commission has had occasion in recent years to deal with cases where contentions were made that a "plan" rather than an individual product was being advertised and sold.

In *Stauffer Laboratories, Inc.,* 64 F.T.C. 629 (1964), a "Magic Couch" was marketed as part of a home reducing "plan" to "lose unwanted pounds." Respondents in that proceeding contended that their couch was sold only as an "inextricable integral [94] component" of the Stauffer "plan," and that it was erroneous to construe representations in their advertising as applicable only to the "Magic Couch." Many of the advertising claims in *Stauffer* resemble those of respondents here. (See 64 F.T.C. at 646.) The Commission concluded that, notwithstanding repeated references to "plan," claims were made for the "Magic Couch" independent of the "plan." The Commission concluded (64 F.T.C. at 648):

> We fail to see merit in respondents' urging that a "plan" is involved. As stated above, the device was represented as being effective of itself, and the challenge is made to that claim. Moreover, the "plan" is in reality nothing more than the device served with a little garnish of advice and handholding.

On appeal, *Stauffer Laboratories, Inc.* v. *Federal Trade Commission,* 343 F.2d 75 (9th Cir. 1965), respondent *Stauffer* relied on the *Carlay* case and charged the Commission with error in finding that members of the public were misled into believing that claims made for the "plan" related solely to the couch. *Stauffer* argued to the Court of Appeals that (343 F.2d at 78):

> . . .Petitioner advertises and sells a "Stauffer Home Plan," a "Stauffer Home Reducing Plan," a "Figure-Beautifying Plan," and a "Stauffer Principle" of "sensible"

weight reduction and muscle toning. All of these terms are constantly used in Petitioner's advertising and booklets.

[95] The Ninth Circuit rejected this argument and affirmed the Commission's decision, without even citing *Carlay,* noting that in working out its selling program *Stauffer* undertook to tie the couch in with a "plan" consisting of a diet and couch, because the device was the money making part of the operation whereas (343 F.2d at 78):

> Low calorie diets can be readily procured in small, inexpensive booklets or pamphlets; they can be procured without charge or for a nominal sum from the Government Printing Office, and they may be found in almost any ladies' magazine.

In the present proceeding respondents' claim to be promoting a "plan" is likewise grounded on the insertion in the box of X-11 tablets of a single-page leaflet containing a low-calorie diet (CX 37 and 40).

In *Damar Products, Inc.,* 59 F.T.C. 1263 (1961), respondents marketed a "Salon Vibrator Plan" for helping "to achieve the slimmer figure you have often admired." The Commission adopted the then hearing examiner's decision finding that respondents' advertisements had the effect of causing members of the public to believe that the claims of "body-weight reduction" related to the "vibrator" alone even though the *Damar* advertisements referred to a "plan." The Court of Appeals affirmed. *Damar Products, Inc.* v. *Federal Trade Commission,* 309 F.2d 323 (3rd Cir. 1962).

As it was in the foregoing cases, so it is here. Respondents' use of "plan" in marketing their diet tablets was simply a "gimmick" used in an effort to escape liability for deceptive claims and representations for X-11 tablets. [96]

2. *Representation that users could lose weight without dieting*

Respondents contend that their advertising did not represent that users of X-11 tablets could lose weight without restriction of their caloric intake stating that the ads "speak loudly" that the X-11 tablets will "control your appetite," "counteract hunger," and further contain language such as "you eat less, want less." Respondents, however, ignore the predominant theme of the X-11 advertisements.

Respondents' advertisements, as described in the findings, are replete with emphatic statements and bold-type representations implying that no dieting was required, that users of X-11 tablets could "EAT WELL . . . AND LOSE THAT FAT," "WITHOUT EVER MISSING A

MEAL," could "ENJOY FOODS [THEY] CHOOSE," that users could "SATISFY [THEIR] APPETITE" "WITHOUT EVER GOING HUNGRY," that users could lose weight without "STICKING TO BORING REDUCING DIETS," without "STARVATION DIETING HUNGER," without "HUMDRUM METHODS SO MANY WOMEN HAVE TRIED AND GIVEN UP IN DESPAIR," and many other like promises and representations. The net impression conveyed to the public by respondents' advertisements is what counts. *Charles of the Ritz* v. *Federal Trade Commission,* 143 F.2d 676, 679 (2nd Cir. 1944); *U.S. Retail Credit Ass'n, Inc.* v. *Federal Trade Commission,* 300 F.2d 212, 219 (4th Cir. 1962); *J. B. Williams Co. Inc.,* v. *Federal Trade Commission,* 381 F.2d 884, 889-90 (6th Cir. 1967). Advertisements are to be judged by their effect on the average member of the public who will be influenced by the impression gleaned from a quick glance at the most legible words. *Ward Laboratories, Inc.* v. *Federal Trade Commission,* 276 F.2d 952, 954 (2nd Cir. 1960), *cert. denied,* 364 U.S. 827; see also, Commission decisions of November 26, 1974, in *Standard Oil of California,* CCH Trade Reg. Rep., ¶20,789, page 20,655, and in *Crown Central Petroleum Corp.,* CCH Trade Reg. Rep. ¶26,790, page 20,669. The net impression of [97] respondents' advertisements, as previous findings set out, is that users of X-11 tablets could lose "ugly fat" "without restricting their accustomed caloric intake—in short, without dieting."

3. *Representation of reasonable basis for advertising that substantially all users of X-11 tablets would lose a significant amount of weight*

Respondents insist that even if they are held to have marketed and made representations about tablets rather than a reducing "plan," they did not represent to the public that *substantially all* users of X-11 tablets would lose a significant amount of weight. Respondents' advertisements were directed to the public at large, particularly to the overweight and obese. They held out and represented to the public that significant, large amounts of body weight of virtually any amount, could and would be lost by anyone who purchased and used the X-11 tablets. Such representation was not made to any limited portion of the public, but to every reader of X-11 advertisements. The advertisements contained no limitations, but told all readers "YOU" are offered "a way to get rid of unsightly, superfluous fat you're carrying," a way "to lose 5, 10, 25 or more pounds of unsightly fat," and the like. Results were guaranteed to every reader or "money back." Considering respondents' advertisements in their entirety, such advertisements had the capacity and tendency to lead

members of the public to believe that respondents had a reasonable basis from which to conclude that substantially all X-11 users would lose virtually any amount of weight desired. See *National Dynamics Corp.*, 82 F.T.C. 488, 564 (1973), *aff'd* but remanded as to Paragraphs 1 and 2 of the order, *National Dynamics* v. *Federal Trade Commission,* 492 F.2d 1333 (2nd Cir. 1974), *cert. denied,* 419 U.S. 993. [98]

4. *Failure to have a reasonable basis for representations of a significant weight loss*

Respondents did not have a reasonable basis for their representations of weight loss, either when X-11 tablets were first put on the market and advertised in 1967, during subsequent years, or as a result of more recent studies by respondents' experts, Drs. Silverman and Hoebel.

In support of their claim that they had a reasonable basis for their representations of weight loss respondents rely on the *Alleghany Pharmacal* proceeding, 75 F.T.C. 990 (1969). The evidence in that proceeding most favorable to respondents, however, only supports the proposition that a preponderance of the evidence did not establish that phenylpropanolamine was without "significant pharmacological value as an appetite suppressant or weight reducing agent."

There is, in fact, substantial evidence in this record that phenylpropanolamine is ineffective as an appetite suppressant in the 25 mg dosage contained in each X-11 tablet. But whatever the truth may be in this respect, neither the evidence here nor in *Alleghany Pharmacal* establishes that respondents had a reasonable basis for representing that 25 mg of phenylpropanolamine ingested one-half hour before each meal will bring about the significant, large weight losses of virtually any amount held out to the public in respondents' advertising. As the Commission remarked in *Crown Central Petroleum, supra,* CCH Trade Reg. Rep. at page 20,665:

> respondents' advertising claims greatly exceed even the most favorable interpretation of [the] evidence.

[99] And as the Commission said in *National Dynamics, supra,* 82 F.T.C. at 549:

> A performance claim is not a technique which can be used with impunity for ascribing specific attributes to a product based on nothing more than a guess that it will perform as represented.

In the opinion of the law judge, before respondents could lawfully

hold out to the public in their advertising that users of X-11 tablets would lose virtually any amount of weight—83 lbs., 80 lbs., 55 lbs., 40 lbs., "5, 10, 25 or more" lbs.—respondents were obligated to have available adequate and well-controlled scientific studies or tests providing a valid scientific or medical basis for such claims. The Commission made clear in *Pfizer, Inc.*, 81 F.T.C. 23 (1972), that the type of substantiation required to satisfy the reasonable basis standard would depend on the facts of each case. In this proceeding, respondents were advertising a drug to be taken internally for the treatment of overweight and obesity, which conditions pose serious and real dangers to the health. Under such circumstances, the foregoing standard of substantiation was required. Respondents did not, and do not now, have such substantiation. Indeed, respondents did not even meet a lesser standard. Neither medical literature, clinical experience, nor general medical knowledge provided in 1967, when X-11 tablets were first placed on the market, or now provide, a reasonable basis for the representations of weight loss in respondents' advertising.

5. *Advertising X-11 tablets as containing a unique ingredient was deceptive*

Respondents contend that X-11 tablets contain a "unique" ingredient because phenylpropanolamine differs from other pharmacological substances, and because [100] phenylpropanolamine is the only member of the phenethylamine family sold without a prescription. Respondents' advertisements, however, do not convey this limited meaning for "unique" to the public. It has long been established that in evaluating advertising claims, a technical interpretation of each phrase is not the standard applied to determine deceptiveness. Rather, evaluation of the over-all impression advertisements are likely to make on the buying public determines whether or not such advertisements are deceptive. *Murray Space Shoe Corp.* v. *Federal Trade Commission,* 304 F.2d 270, 272 (2nd Cir. 1962). Purchasers of X-11 tablets could reasonably have concluded that the "unique" claims in respondents' advertisements meant that X-11 tablets were the only dietary aid available over the counter containing phenylpropanolamine.

In finding that respondents' advertising of a "unique" ingredient is deceptive, it is not necessary that a conscious intent to deceive be shown. *Federal Trade Commission* v. *Algoma Lumber Co.*, 291 U.S. 67, 79 (1934); *Koch* v. *Federal Trade Commission,* 206 F.2d 311, 317 (6th Cir. 1953); *Ford Motor Company* v. *Federal Trade Commission,* 120 F. 2d 175, 181 (6th Cir. 1941); *Gimbel Bros., Inc.* v. *Federal Trade*

Commission, 116 F.2d 578 (2nd Cir. 1941). Even if respondents intended to convey only the limited meaning which they now ascribe to "unique," where an advertising claim has dual or multiple meanings, one of which is false, such advertisements are misleading. *Giant Food Inc.* v. *Federal Trade Commission,* 322 F.2d 977, 981 (D.C. Cir. 1963); *cert. dismissed,* 376 U.S. 967 (1964); *Rhodes Pharmacal Co., Inc.* v. *Federal Trade Commission,* 208 F.2d 382, 387 (7th Cir. 1954), *rev'd* in part reinstating Commission decision, 348 U.S. 940 (1955). **[101]**

6. *Testimonials were deceptive*

Respondents assert that testimonials included in their advertisements were not deceptive since these testimonials "relate specifically to the 'plan' and do not relate to the tablets at all" (Motion to Dismiss, p. 89). The contention relating to the "plan" has been discussed in detail and rejected. It is worth noting again, nevertheless, that as their original letters disclose (CX 147-49), persons whose testimonials were used looked upon respondents' product as tablets, not a "plan." In publishing the testimonials, the endorsements of "tablets" or "diet pills" in the original letters from X-11 users were changed to refer to the "X-11 Plan" or "X-11 Reducing Plan."

When an advertisement contains a testimonial reflecting the experience of an individual with a product, there is an implicit representation that such experience reflects the typical or ordinary results anyone may anticipate from use of the product. *National Dynamics Corp., supra* at 564. The weight losses publicized in testimonials in respondents' advertisements do not reflect the typical or ordinary experience of users of X-11 tablets, or the results overweight or obese persons can typically anticipate from their use. Following a low-calorie diet is very difficult, especially for the seriously obese and overweight and is seldom successful (see, for example, CX 92-93, 96 and Dr. Drenick, Tr. 406), although on occasion, of course, someone will persevere and lose a large amount of weight.

The argument of respondents' (Motion to Dismiss, p. 91) that a testimonial to a weight loss of 83 lbs. is only relevant to someone who is 83 lbs. or more overweight is fallacious. As complaint counsel correctly point out, someone who is 25 pounds overweight will reason that if X-11 tablets will cause a person 83 lbs. overweight to lose that amount of excess fat, they will surely be effective to cause a 25 pound weight loss. **[102]**

As previously discussed, X-11 tablets in and of themselves will not cause any weight loss. A stringent diet, faithfully followed over a

prolonged period, will undoubtedly result in weight loss. However, the testimonials do not reflect the typical or ordinary experience of X-11 users, and their use without noting this fact is deceptive.

7. *Failure of advertisements to contain a health warning*

Brief comment is appropriate with respect to Paragraph Twelve of the complaint. The record establishes that phenylpropanolamine is a "vasoconstrictor" which tends to constrict the blood vessels and to raise blood pressure. It should not be ingested by persons with high blood pressure, heart disease, diabetes or thyroid disease except as directed by a physician. Failure to disclose this in respondents' advertising for X-11 tablets constitutes a failure to disclose a material fact. The "Caution" on the box of X-11 tablets warning that persons with these conditions should use X-11 tablets only as directed by a physician does not, in the view of the law judge, render it proper and nondeceptive for the advertisements to omit such a "Caution."

Members of the public who have high blood pressure, heart disease, diabetes or thyroid disease, and such persons are very numerous, have a right to the warning before making a trip to a store to buy respondents' X-11 tablets.

Respondents also market their X-11 tablets by mail order. Many of their advertisements contained a coupon for the prospective purchaser to fill out and mail to a retail store, or to Porter & Dietsch, to obtain a supply of tablets (for example, CX 18, 19 and 49, reprinted herein). Mail order purchasers, obviously, will not know about the "Caution" on the [103] box until they receive their X-11 tablets. The law is violated if the first contact with a prospective purchaser is deceptive. *Carter Products, Inc.* v. *Federal Trade Commission,* 186 F.2d 821, 824 (7th Cir. 1951); *Montgomery Ward & Co., Inc.* v. *Federal Trade Commission,* 379 F.2d 666 (7th Cir. 1967).

Nor does the fact that large numbers of the public do not know they have high blood pressure, heart disease, diabetes or thyroid disease render, as respondents urge, a warning in the advertisements "meaningless" (see Motion to Dismiss, p. 87). Significant numbers of the public with high blood pressure, heart disease, diabetes or thyroid disease do know of their condition, and a warning in X-11 advertisements would serve to dissuade them from using X-11 tablets without the guidance of a physician. It is significant that a disproportionate number of individuals with these conditions are overweight or obese and, absent such warning, a greater percent than that in the population at large would be attracted by respondents' advertisements. Additionally, a warning in the adver-

tisements might well cause prospective purchasers of X-11 tablets who have the proscribed conditions, but who are ignorant of that fact, to check with a doctor before purchasing the tablets.

8. *Failure of advertisements to disclose that a highly restricted diet was integral to the X-11 "Plan"*

Paragraph Thirteen of the complaint alleges that respondents did not disclose in their advertising that a "highly restricted caloric diet was an integral part" of respondents' X-11 Reducing Plan. Examination of respondents' advertisements fully supports this allegation. Not only was there no disclosure that users of the X-11 tablets would have to follow a diet providing for a drastically reduced food intake to achieve significant weight losses, but the complete contrary [**104**] was represented. As has been described, and as the advertisements reprinted reveal, respondents affirmatively told the public that large poundages of body fat could be lost without "sticking to boring reducing diets," without "starvation dieting hunger," etc. Failure of respondents' X-11 advertisements to disclose that users were required to follow a low-calorie diet constituted a failure to disclose a material fact "likely to affect [the public's] consideration of whether or not to purchase said product."

9. *Collateral estoppel, stare decisis and res judicata*

As noted, respondents Porter & Dietsch, William H. Fraser, Kelly Ketting Furth and Joseph Furth filed amended answers pleading an affirmative defense that the "Commission is precluded from bringing this proceeding . . . under principles of collateral estoppel and/or stare decisis." Respondent Pay'n Save Corporation likewise filed an amended answer raising these affirmative defenses, and added "res judicata."

The basis for these defenses is the contention that the Commission and the Postal Service have already litigated the issue or issues in this proceeding, and have resolved them in favor of respondents. The cases respondents refer to are *Alleghany Pharmacal, supra,* and *Hanover House* and *Romar Sales, supra,* (see Appendix to Motion to Dismiss, p. 60).

The doctrines of res judicata and collateral estoppel are applicable to bar a second suit based on the same cause of action, or to bar relitigation of an issue or issues previously litigated. *Lawlor* v. *National Screen Service,* 349 U.S. 322, 326 (1955). The issues in *Alleghany Pharmacal, Hanover House* and *Romar* are not the same as the issues in this proceeding. [**105**]

The issue in this proceeding *inter alia* is whether X-11 tablets, containing phenylpropanolamine, will bring about the significant, large weight losses of virtually any amount held out to the public in respondents' advertising, not whether, for example, phenylpropanolamine has any significant pharmacological value as an appetite suppressant or weight-reducing agent. See *Alleghany Pharmacal,* 75 F.T.C. 996-97, *Hanover House* and *Romar Sales,* (Appendix in Support of Motion to Dismiss, pp. 6-7).

Where the issues are different, even if similar the Commission plainly cannot be estopped. *J. C. Martin Corp.* decision of the Commission of July 6, 1964, CCH Trade Reg. Rep., 1963-65 Transfer Binder, ¶16, 976, p. 22,054, *aff'd, J. C. Martin Corp.* v. *Federal Trade Commission,* 346 F.2d 147, 148 (3rd Cir. 1965), *Federal Trade Commission* v. *Raladam Co.,* 316 U.S. 149 (1942).

With respect to the defense of "stare decisis," that doctrine applies to principles of law, not to matters of fact. There were no principles of law enumerated in *Alleghany Pharmacal,* or in *Hanover House* and *Romar Sales,* binding on the Commission in this matter. Those proceedings do not preclude the Commission from litigating this matter.

10. *Responsibility of William H. Fraser*

As prior findings disclose, the responsibility of individual respondent William H. Fraser is clear, and it is essential that he be covered by the order in his individual capacity. *Standard Educators, Inc.,* 79 F.T.C. 858, 892-99 (1971), *aff'd, Standard Educators, Inc.* v. *Federal Trade Commission,* 475 F.2d 401 (D.C. Cir. 1973), *cert. denied,* 414 U.S. 828 (1973); *Coran Bros. Corp.,* 72 F.T.C. 1, 24-25 (1967); *Fred Meyer, Inc.* v. *Federal Trade Commission,* 359 F.2d 351, 367-68 (9th Cir. 1966), modified on another point, 390 U.S. 341 (1968). [106]

11. *Responsibility of Kelly Ketting Furth and Joseph Furth*

There is no warrant for relieving either Kelly Ketting Furth or Joseph Furth of responsibility for the deceptive advertising of X-11 tablets. Both were active participants in the preparation and dissemination of the advertisements, and knew or should have known of the deceptions involved. *Carter Products, Inc.* v. *Federal Trade Commission,* 323 F.2d 523, 533-34 (5th Cir. 1963); *Doherty, Clifford, Steers & Shenfield, Inc.* v. *Federal Trade Commission,* 392 F.2d 921, 928 (6th Cir. 1968); *ITT Continental Baking Co., Inc.,* CCH Trade Reg. Rep. ¶20,464, pages 20,383-85 (Order of October 19, 1973),

modified and aff'd *ITT Continental Baking Co.* v. *Federal Trade Commission,* 532 F.2d 207 (2nd Cir. 1976).

12. *Responsibility of Pay'n Save*

There is no dispute that Pay'n Save Corporation did not originate any of the claims or representations disseminated to the public in the advertisements for X-11 tablets. In the opinion of the law judge, however, this fact does not relieve Pay'n Save of responsibility. As the findings describe, Pay'n Save either received the mats or other materials from Porter & Dietsch and placed these advertisements in various media, or the advertising material was sent directly to the news media and held by them until Pay'n Save authorized publication. The fact is, however, that major newspaper advertisements were published over Pay'n Save's corporate name which made claims and representations to the public for X-11 tablets which were false, misleading and deceptive.

It would be unreasonable to permit Pay'n Save now to avoid responsibility for disseminating deceptive advertising on the ground that Porter & Dietsch furnished the advertisements. Such an outcome would [107] allow Pay'n Save to disseminate false advertising over its name with impunity, so long as it obtained the advertisements from a supplier. There is no foundation for such a position in reason or logic and, in the view of the undersigned it is contrary to the public interest.

Holding Pay'n Save responsible for false, misleading and deceptive representations disseminated over its own corporate name is not unfair, and does not place an unreasonable burden on Pay'n Save. In the case of supplier furnished advertisements Pay'n Save, or any other retail chain similarly situated, may simply elect not to publish the advertisements if it does not know whether or not the claims and representations contained in them are true. Nothing compelled Pay'n Save to publish the Porter & Dietsch advertisements here involved, and nothing in this ruling requires Pay'n Save to "maintain a staff of scientists and lawyers" to screen such advertisements. However, since Pay'n Save determined to publish advertisements furnished by Porter & Dietsch, and in effect to disseminate the claims and representations therein as its own, it must, in the view of the undersigned, as any other advertiser, assume responsibility for the claims and representations communicated to the public.

There is nothing extraordinary in imposing such a standard upon Pay'n Save. The rationale of *Pfizer, Inc., supra,* applies to any firm making claims and representations for products to the public. As the

Commission remarked over 15 years ago in the case of an advertising agency, the argument of Pay'n Save "is merely another variation of the oft-repeated effort to avoid responsibility for a violation of a statute by shifting it to another." *Colgate-Palmolive Co.,* 59 F.T.C. 1452, 1471 (1961), final order aff'd, *Federal Trade Commission* v. *Colgate-Palmolive Co.,* 380 U.S. 374 (1965). Nothing in this ruling prevents Pay'n Save from advertising suppliers' products for [108] resale. The ruling is only that, where Pay'n Save elects to publish advertisements making affirmative claims and representations for products, Pay'n Save assumes responsibility for the truthfulness of the claims and representations made.

MOTION TO DISMISS

The motion to dismiss filed by respondents (except Pay'n Save Corporation) on March 29, 1976, is hereby denied in accordance with what has been said in this initial decision.

IV

CONCLUSIONS

1. The Federal Trade Commission has jurisdiction over the corporate and individual respondents in this proceeding, and over their acts and practices in the advertising, promotion, marketing and sale of X-11 tablets.

2. The X-11 tablets, contained in packages marked "X-11 Reducing Plan," are "drugs" within the meaning and intent of Section 15(c) of the Federal Trade Commission Act.

3. Respondents have disseminated unfair, false, misleading and deceptive advertisements, statements and representations in the promotion, marketing and sale of X-11 tablets, and respondents' advertisements constitute "false advertisements" as that term is defined in the Federal Trade Commission Act.

4. The dissemination by respondents of unfair, false, misleading and deceptive advertisements, statements and representations in the promotion, marketing and sale of X-11 tablets has had, and now [109] has, the capacity and tendency to mislead members of the public into the erroneous and mistaken belief that such advertisements, statements and representations were, and are, true and free of material omissions, and into the purchase of substantial quantities of X-11 tablets by reason of such erroneous and mistaken belief.

5. The dissemination by respondents of unfair and false, misleading and deceptive advertisements, statements and representations in the promotion, marketing and sale of X-11 tablets, were, and are, to

the prejudice and injury of the public, and of respondents' competitors, and constituted, and now constitute, unfair and deceptive acts and practices in or affecting commerce, and unfair methods of competition in or affecting commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

6. This proceeding is in the public interest.

V

REMEDY

Brief comment respecting the order should be made. Broad product coverage with respect to respondents Porter & Dietsch and William H. Fraser is essential to ensure that violations similiar to those reflected in this record do not occur in the future. *Federal Trade Commission* v. *Ruberoid,* 343 U.S. 470, 473 (1952); *Federal Trade Commission* v. *National Lead,* 352 U.S. 419, 428-30 (1957). The authority of the Commission to issue an order extending to all products to prevent future violations is well established. *Consumer Sales Corp.* v. *Federal Trade Commission,* 198 F.2d 404 (2nd Cir. 1952); *Niresk Industries, Inc.* v. *Federal Trade Commission,* 278 F.2d 337, 342-343 (7th Cir. 1960), rehearing denied June 8, 1960, *cert. denied,* 364 U.S. 883. *Carter Products, Inc.* v. *Federal Trade Commission,* [110] 323 F.2d 523, 532-33 (5th Cir. 1963); *Western Radio Corp.* v. *Federal Trade Commission,* 339 F.2d 937, 940 (7th Cir. 1964), *cert. denied,* 381 U.S. 938; *Benrus Watch Company* v. *Federal Trade Commission,* 352 F.2d 313, 324 (8th Cir. 1965), *cert. denied,* 384 U.S. 939 (1966); *Firestone Tire & Rubber Company,* 481 F.2d 246 (6th Cir. 1973). Where required the order applicable to the foregoing respondents extends to "X-11 tablets or any other product." Where inappropriate the provisions have been narrowed.

As stated earlier, where human health is at stake, and other factors of a serious nature to the public are involved, *Pfizer, Inc., supra,* 81 F.T.C. at 64, respondents must, in the opinion of the undersigned, have adequate, well-controlled scientific tests to support product claims and representations disseminated. Further, to prevent evasion of this standard, and to make certain that claims and representations disseminated requiring support by adequate, well-controlled scientific tests are in truth so supported, the order requires respondents, prior to disseminating such claims and representations, to have submitted such tests to the Commission for acceptance as fully substantiating the claims and representations being made.

Respondents, however, are not limited with respect to those who

may conduct such tests, inasmuch as it is the nature and validity of the tests which is important, not who conducts them.

A provision has also been inserted requiring disclosure of the details and circumstances associated with a result publicized in a testimonial. As shown herein, testimonials were disseminated by respondents in which women were quoted as having lost significant, large amounts of body weight, for example, 40 lbs., 80 lbs. For advertisements to be fully truthful, the [111] full facts and circumstances surrounding such weight losses should be disclosed. The public should be told whether such women adhered to drastic low-calorie diets while using respondents' X-11 tablets, or engaged in strenuous reducing exercises, how long it took to achieve the weight loss, and the like. Such are material facts relevant to product claims and representations for diet or reducing pills.

Further, in the view of the undersigned, respondents must be prevented from representing that body weight may be lost through the use of X-11 tablets, or any similar preparation, without disclosing the amount of such weight loss attributable to the X-11 tablets, or similar preparation, which is substantiated by adequate, well-controlled scientific tests. If tests substantiate only a weight loss of a fraction of a pound a week, attributable to X-11 tablets or similar preparation, for a few weeks before drug tolerance or other factors end such weekly loss, it would be misleading to hold out to the public a generalized claim without disclosing that it amounted to only a fraction of a pound per week, and was limited in duration.

Finally, the order prohibits respondents from attempting to mislead or misleading the public that a reducing "plan," "regimen," or "program" is being offered when in reality respondents are simply marketing pills or tablets.

VI

ORDER

It is ordered, That respondents Porter & Dietsch, Inc., a corporation, its successors and assigns, and its officers, and William H. Fraser, individually and as an officer of said corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other [112] device, in connection with the advertising, offering for sale, sale or distribution of X-11 tablets, or of any other preparation of similar composition or of similar properties, or dietary aid containing phenylpropanolamine, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease

and desist from representing orally, in writing, or in any manner, directly or by implication, that users of X-11 tablets, or of any of the foregoing preparations, products or aids, can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice (or words of similar import or meaning).

It is further ordered, That respondents Porter & Dietsch, Inc., a corporation, its successors and assigns, and its officers, and William H. Fraser, 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 X-11 tablets, or any other product potentially affecting human health or safety, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing orally, in writing, or in any manner, directly or by implication, that X-11 tablets, or any other product potentially affecting human health or safety, will be effective in producing any type of result, unless at the time such representation is made:

1. The representation is fully substantiated by adequate, well-controlled scientific tests accepted as such by the Federal Trade Commission,

2. the results, and methodology of such tests, together with with original data collected, [113] have been furnished to the Federal Trade Commission as documents available for public inspection,

3. copies of a brief but comprehensive written summary of the test results and methodology, in terms which are understandable to the average member of the public and which disclose the nearest place or places at which the complete test results, data and methodology may be inspected, are available to the public by mail upon request, and

4. any advertisement in which the representation is made shall clearly and conspicuously disclose that such summary may be obtained by mail upon request, and shall include the address to which such requests should be directed.

It is further ordered, That respondents Porter & Dietsch, Inc., a corporation, its successors and assigns, and its officers, and William H. Fraser, 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 X-11 tablets, or any other product, in or affecting commerce, as

"commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from: [114]

1. Using any testimonial for X-11 tablets or any other product which reports a result unless the testimonial or a related disclosure in close conjunction therewith reveals clearly and conspicuously the typical or ordinary experience of members of the public with such product.

2. Using any testimonial for X-11 tablets or any other product which reports a result unless the testimonial or a related disclosure in close conjunction therewith reveals clearly and conspicuously the full details and circumstances associated with the result.

3. Representing orally, in writing, or in any manner, directly or by implication, that X-11 tablets or any other product contain one or more unique ingredients or components, unless respondents can establish that said ingredient(s) or component(s) are unique to such product.

It is further ordered, That respondents Porter & Dietsch, Inc., a corporation, its successors and assigns, and its officers, and William H. Fraser, 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 X-11 tablets, or of any other preparation of similar composition or of similar properties, or dietary aid containing phenylpropanolamine, or any other dietary aid or purported weight-reducing product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from: [115]

1. Representing orally, in writing, or in any manner, directly or by implication, that users of X-11 tablets, or of any of the foregoing preparations, products or aids, will lose body weight without disclosing clearly and conspicuously the amount of such weight loss, on a per-week basis, attributable to X-11 tablets, or to any of the foregoing preparations, products, or aids, which is supported by adequate, well-controlled scientific tests.

2. Attempting to mislead or misleading the public that a "plan," "regimen" or "program" is being offered when in truth respondents are simply marketing X-11 tablets, or one of the foregoing preparations, products or aids.

It is further ordered, That respondents Porter & Dietsch, Inc., a corporation, it successors and assigns, and its officers, and William H. Fraser, individually and as an officer of said corporation and respondents' agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, do

forthwith cease and desist from disseminating or causing to be disseminated by United States mail or by any means in or having an effect upon commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement for X-11 tablets, or for any preparation of similar properties, or for any dietary aid containing phenylpropanolamine, unless respondents clearly and conspicuously disclose the following statements, as applicable, with nothing to the contrary or in mitigation thereof:

This product requires users to "diet," that is, to restrict their caloric intake. Users cannot lose weight without restricting their accustomed caloric intake. [116]

It has not been established that this product is effective in promoting any significant or lasting weight loss.

WARNING: This product can cause a temporary increase in blood pressure. Persons with high blood pressure, heart disease, diabetes or thyroid disease should use this product only as directed by a physician. Overweight individuals are more likely to have such conditions than other persons, and often do not know it. See your doctor before taking this product.

It is further ordered, That respondents Pay'n Save Corporation and Kelly Ketting Furth, Inc., corporations, their successors and assigns, and their officers, and Joseph Furth, individually and as an officer of Kelly Ketting Furth, Inc., 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 X-11 tablets, or any other diet aid or purported weight-reducing food, drug or device, as "food," "drug," and "device" are defined in the Federal Trade Commission Act, do forthwith cease and desist from disseminating or causing to be disseminated by United States mail or by any means in or having an effect upon commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which contains a representation or testimonial for such product prohibited by this order, or which omits a disclosure for such product required by this order. [117]

It is further ordered, That all respondents forthwith deliver a copy of this order to each operating division and subsidiary, to all present and future personnel of respondents engaged in the preparation, creation or placing of advertising of foods, drugs or devices on behalf of respondents, and to all present and future agencies engaged in the preparation, creation or placing of such advertising for respondents,

and that respondents secure from each such person and agency a signed statement acknowledging receipt of said order.

It is further ordered, That respondents immediately recall and retrieve, from all persons and entities that have engaged in the advertising or promotion of X-11 tablets within the past two years, all advertising mats and promotional material which contain a representation or testimonial prohibited by this order or which omit a disclosure required by this order. Respondents Porter & Dietsch, Inc., and William H. Fraser shall also deliver written notice of the requirements of this order to all distributors and retailers of products marketed by said respondents, and shall institute a program of continuing surveillance adequate to reveal whether they are complying with said requirements including the above recall provision. In the event that nonconformity with any such requirements is discovered, said respondents shall immediately cease supplying all products to said distributors or retailers until adequate, reliable assurance of conformity is obtained.

It is further ordered, That all respondents shall maintain complete business records relative to the manner and form of their compliance with this order. Respondents shall retain each such record for at least three years, and shall retain substantiation and other documentation at least two years beyond the last dissemination of any representation or testimonial contingent thereon under the provisions of this order. [118] Upon reasonable notice, respondents shall make any and all such records available for inspection and photocopying by authorized representatives of the Federal Trade Commission at respondents' place of business or other properly designated location. For respondents Porter & Dietsch, Inc., and William H. Fraser, such records shall include (but not be limited to) all advertising, sales memoranda, policy directives, the basis for all applicable advertising claims, correspondence with persons who place advertising, and other pertinent documents.

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

It is further ordered, That each individual respondent named herein for a period of five (5) years from the effective date of this order promptly notify the Commission of the discontinuance of his present business or employment and/or of his affiliation with a new

business or employment. If applicable each such notice shall include the respondent's new business address and a statement of the nature of the business or employment in which he is newly engaged as well as a description of his 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. [119]

It is further ordered, That the respondents herein shall, within sixty (60) days after service of this order, file with the Commission a written report setting forth in detail the manner and form of their compliance with this order.

OPINION OF THE COMMISSION

BY COLLIER, *Commissioner:*

This proceeding challenges the lawfulness of advertising claims made for "X-11" tablets, a non-prescription drug sold as a weight reduction product.[1] In their appeal from the [2] Administrative Law Judge's ("ALJ's") proposed findings, conclusions, and recommended order, respondents[2] make numerous assertions of error on a broad range of factual [3] and legal issues. Contesting the initial decision page by page, respondents object to the ALJ's treatment of the meaning of the advertisements, the falsity of the claims, procedural

[1] The complaint invoked Sections 5 and 12 of the Federal Trade Commission Act. In pertinent part, Section 5 prohibits "unfair or deceptive acts or practices" and Section 12 prohibits the dissemination of "false advertisements" of food, drug, (medical) device and cosmetic products. "False advertisements" are those that are "misleading in a material respect," in light of (among other things)

> not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in light of such representations, or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in such advertisement or under such conditions as are customary and usual. [§15, 15 U.S.C. 55 (1914)]

[2] The respondents in this proceeding are Porter & Dietsch, Inc., which packages X-11 tablets and sells them through the mail and through retail drug stores (I.D. 1); Kelly Ketting Furth, Inc., an advertising agency, which works with Porter & Dietsch to prepare advertising for X-11 tablets (I.D. 4, 143-145); Pay'n Save Corporation, a chain of retail drug and sundry stores which sells X-11 tablets and disseminates X-11 advertising which has been prepared by Porter & Dietsch and Kelly Ketting Furth (I.D. 7, 149(b)-154); William H. Fraser, president and sole stockholder of Porter & Dietsch (I.D. 2, 141-142); and Joseph Furth, a vice-president of Kelly Ketting Furth, Inc., and an account executive for that concern in charge of Porter & Dietsch X-11 advertising (I.D. 5, 143-149(a)). The following abbreviations are used in this opinion:

I.D. — Initial Decision, Finding No.
I.D. p. — Initial Decision, Page No.
CX — Complaint Counsel's Exhibit No.
RX — Respondent's Exhibit No.
Tr. — Transcript of Testimony, Page No.
RB — Respondents' Appeal Brief to the Commission, Page No.
RRB — Respondents' Reply Brief to the Commission, Page No.

Respondent Pay'n Save has filed its own briefs in this appeal, while "adopting" the arguments of the other respondents as to the truth or falsity of the advertising in question. References to Pay'n Save's separate briefs will either be apparent in context or more specifically identified.

rulings, allegedly erroneous legal rulings, and the separate liability of certain respondents.

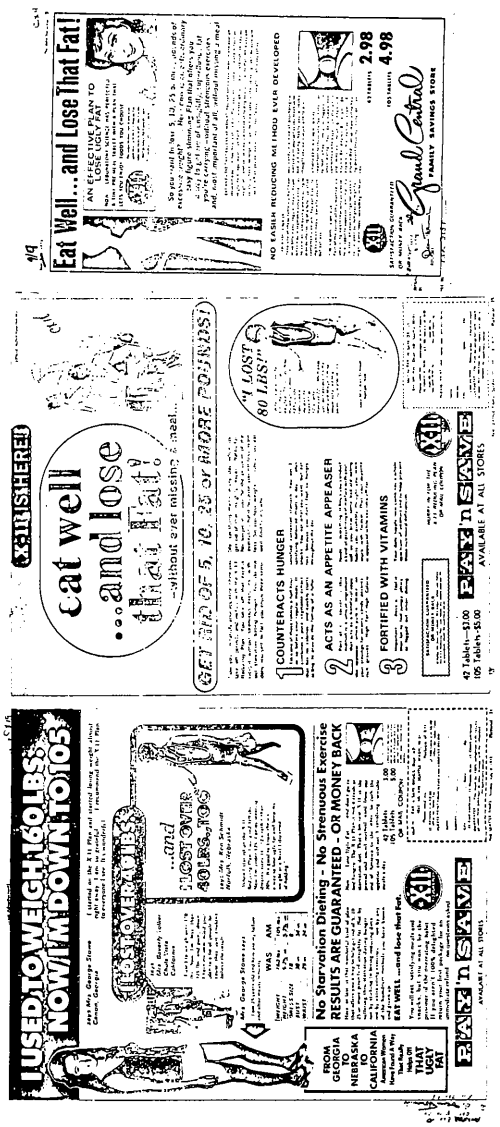
Meaning of the Advertisements

The complaint alleges, and the ALJ found, that respondents' advertisements represent:

— that users of X-11 tablets can lose weight without restricting their accustomed caloric intake and while they continue to eat the foods of their choice (Complaint, ¶ 9; I.D. 39);

— that respondents have a reasonable basis from which to conclude that substantially all users of X-11 tablets will lose a significant amount of weight (Complaint, ¶ 9; I.D. 47); and

— that the X-11 tablet contains a unique ingredient (Complaint, ¶ 9; I.D. 48).


I USED TO WEIGH 60 LBS.
NOW I'M DOWN TO 105
...and LOST OVER 40 LBS., TOO
No Starvation Dieting — No Strenuous Exercise
RESULTS ARE GUARANTEED - OR MONEY BACK
FROM GEORGIA TO NEBRASKA TO CALIFORNIA
Take 'em THAT UGLY FAT
EAST 'n SAVE
AVAILABLE AT ALL STORES
eat well ...and lose that fat!
without ever missing a meal...
GET RID OF 5, 10, 25 or MORE POUNDS!
"I LOST 80 LBS!"
1 COUNTERACTS HUNGER
2 ACTS AS AN APPETITE APPEASER
3 FORTIFIED WITH VITAMINS
42 Tablets—$3.00
105 Tablets—$5.00
EAST 'n SAVE
AVAILABLE AT ALL STORES
Eat Well...and Lose That Fat!
AN EFFECTIVE PLAN TO LOSE WEIGHT
NO EASILY REDUCING METHOD EVER DEVELOPED
42 TABLETS 2.98
105 TABLETS 4.98
Grand Central
FAMILY SAVINGS STORE

Advertising Supplement to **Chicago Tribune** Sunday, February 11, 1973 Section 9-A

EAT WELL...and Get Rid of 5, 10, 25 or More Pounds!

lose ugly fat with This Amazingly Easy Reducing Plan!

Eat 3 Sensible Meals a Day – and SLIM DOWN!

■ Today, thousands of women throughout America are discovering an extraordinary simple Plan that helps get rid of 5, 10, 25 or even more pounds and stabilize achieved weight at a level they've "dreamed of" holding as you follow this simple Plan.

■ Not by suffering thru starvation dieting hunger . . . not by sticking to boring reducing diets . . . not by strenuous exercising . . . not by any of the humdrum methods so many women have tried, and given up in despair.

Now you can EAT and LOSE WEIGHT! You can satisfy your appetite and remove pounds and inches . . . at thighs, neck, legs, waistline . . . all over!

■ So, why carry around needless, excess weight when it's so simple to follow the X-11 Reducing Plan to lose ugly fat.

■ Just take one of these specialized tablets ½ hour before your regular meals. Its unusual combination of ingredients helps give you the feeling of a fuller, contented stomach; appeases cravings for 'tween-meal snacks; and provides a range of vitamins and minerals to help prevent these nutritional deficiencies.

MONEY BACK GUARANTEE

Enjoy eating the foods you choose while you lose unsightly, superfluous fat. Get on the X-11 Plan now. Available at your favorite drug or department store on guarantee of satisfaction — or your money back.

GUARANTEED or MONEY BACK

Don't miss out! Take advantage of this generous offer that you must be completely satisfied after taking your first 14-day trial of the X-11 Reducing Plan — or money refunded without questions asked.

42 TABLETS $3.00
105 TABLETS $5.00

If Your Drug or Department Store has run out of stock

FOR QUICK ACTION USE THIS COUPON TO ORDER BY MAIL

Fill out coupon below – place in envelope MAIL TODAY!

If your store is out of stock — fill out and mail this coupon for your

QUICK-BY-MAIL-SUPPLY

Just place this coupon in an envelope and enclose your remittance on guarantee of satisfaction — or money back. Your order will be shipped same day it is received.

GUARANTEE. You must be 100% delighted with results of your first package or your money will be refunded — no questions asked.

PLEASE PRINT YOUR NAME AND ADDRESS BELOW

Mail to: WALGREENS
Box 695
Berkeley, Ill 60163

My store is out of stock
Please rush supply checked below

☐ 42 tablets @ $3.00 ☐ 105 tablets @ $5.00

Name

Address

City State Zip

☐ Cash enclosed ☐ Money Order ☐ Check enclosed

Illinois residents please add 5% sales tax

[5] Although respondents do not contest that the advertisements are theirs, they deny that the ads conveyed any of these alleged claims.

We approach the task of reviewing the ALJ's findings on the meaning of the ads with utmost care. In particular, we are acutely aware that there is a strong public interest in avoiding constraints on truthful advertising. *See Bates* v. *Arizona,* 97 S. Ct. 2691 (1977); *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748 (1976); and *Bigelow* v. *Virginia,* 421 U.S. 809 (1975). In *Virginia State Board* the Supreme Court observed:

> [the] consumer's interest in the free flow of information of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate . . . So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of commercial information is indispensable. 425 U.S. at 763–65.

The public interest in the free flow of truthful information makes the task of interpreting advertisements a delicate one. However, commercial speech is not entitled to the same unfettered constitutional protection afforded political speech. Deceptive commercial speech has no constitutional protection. *See Virginia State Board,* 425 U.S. n. 24 at 773–74 and *Bates,* 97 S. Ct. at 2708–09. Deceptive commercial speech does not aid consumers in making their purchasing decisions and may cause economic injury to those consumers who purchase the advertised product because of the deception. It also reduces the effectiveness of all advertising by casting doubt on its reliability. Therefore, although sensitive to the public interest in the free flow of commercial speech, we serve the same public goals when we meet our statutory obligations by prohibiting deceptive advertising. [6]

The ALJ applied common sense and expertise in setting forth the overall effects and net impressions that the advertisements conveyed,[3] and he supported his interpretations with references to the words used, the pictorial displays, and the layouts employed.

Respondents complain that use of these well-accepted techniques

[3] Such an approach is not merely permissible, but is required in order to assess whether advertising is "false" under Section 15 of the FTC Act, *supra* n. 1 at 1, and the Commission has long been upheld in reading advertising for its total or general impression on the consuming public. *See FTC* v. *Colgate-Palmolive Co.,* 380 U.S. 374, 385 (1965) ("the finding of a Section 5 violation in this field rests . . . heavily on inference and pragmatic judgment"); *Murray Space Shoe Corp.* v. *FTC,* 304 F.2d 270, 272 (2d Cir. 1962); *Charles of the Ritz Distribs. Corp.* v. *FTC,* 143 F.2d 676 (2d Cir. 1944); *Exposition Press, Inc.,* v. *FTC,* 295 F. 2d 869, 872 (2d Cir. 1961), *cert. denied,* 370 U.S. 917 (1962).

for discerning the meaning of advertisements distorted them and wrenched various words and phrases from their context.[4] We have carefully reviewed each of these alleged examples of gerrymandering of the advertisements and we find that respondents' arguments are without merit. [7]

The Advertising and Sale of X-11 Tablets The ALJ found that respondents marketed "X-11 tablets"; respondents argue that they marketed the "X-11 Reducing Plan." The difference is significant, we are told, because the "plan" consisted of ingestion of the tablets plus adherence to a restricted diet. Respondents virtually concede that consumption of X-11 tablets alone, without dieting, will not produce any of the weight reduction results that the advertisements proclaim (RB 31; I.D. 53).[5] The tablets contain phenylpropanolamine hydrochloride ("PPA"); and respondents argue that PPA is an appetite suppressant that helps people stay on restricted diets. They contend, in short, that the tablets are part of the plan and not the plan itself.

Respondents emphasize the number of times that the word "plan" is used in the advertisements and the care with which the advertisements were designed to assure that express claims of weight loss were credited to the "plan." The ALJ considered that argument but chose instead to ascertain the net impression conveyed by the advertisements. His choice of approach was correct and we affirm his findings. [8]

Although the word "plan" was often used in the advertisements, it was not described as a rigorous program of reduced caloric intake. On the contrary, express claims for the plan stressed its capacity to allow consumers to "eat well," to avoid "starvation dieting hunger" and "boring reducing diets," and to have "3 sensible meals a day plus 'tween meal snacks."[6] These claims were coupled with and overshadowed by ubiquitous references to X-11 tablets which were described as the key to attaining these objectives.

Respondents also object to the ALJ's reference to consumer testimonials in Findings 19 and 20. These letters show that some consumers, even satisfied ones, perceived that respondents were selling tablets or pills rather than a plan. We reject the argument

[4] Respondents' zeal in pursuing this line of attack exceeds reasonable bounds when on several occasions they argue that the ALJ's findings display bias and prejudice (RB 35, 37, 55, 57).

[5] In addition, respondents' package insert candidly admonishes that "weight loss is only accomplished when a minimum of calories are consumed" (I.D. 52), and individual respondent Joseph Furth, the advertising account executive for Porter & Dietsch, cautioned the company to avoid emphasizing "tablets" in the advertising because "the pills will not reduce weight an iota. . . . [i]t is the 'Plan' that will keep us out of hot water" (CX 164).

[6] The diet which respondents assert was part of the "plan" was set forth in the package insert. In stark contrast to the advertising claims, the insert detailed an extremely strict program of dieting which the ALJ correctly found did not permit between meal snacks and did constitute a starvation or near starvation diet.

that this evidence is not probative and the further argument that customers' perceptions are not relevant to the allegation that respondents sold X-11 tablets. At the very least, the letters show that respondents' advertisements did not so indelibly implant [9] the "X-11 plan" in consumers' minds that they refrained from referring to the product as "tablets" or "pills."[7]

In a related sally, respondents attack a phrase in one of the several relevant findings (I.D. 12) that is not to be found in the advertising itself (RB 36). But the ALJ never found to the contrary and he made it clear that the words were his and not the advertiser's by the customary technique of placing quotation marks around some words and not others. Respondents create and then flog a strawman. The advertisement itself was made a part of the partially disputed finding and we conclude that the ALJ's interpretation of it was correct.

Claims of Weight Losses Without Dieting Based on a thorough review of the challenged advertisements, the ALJ found that respondents' advertising conveyed the impression that "users of X-11 tablets could lose body weight without dieting or consciously or materially changing their eating habits, . . . 'without restricting their accustomed caloric intake and while they continue to eat the foods of their choice.' " (I.D. 39) Respondents complain that this and other relevant findings (I.D. 28-38) rest on the erroneous repetition of selective excerpts from the advertisements. In adopting the contested findings, we note that the phrases which the ALJ highlighted were prominently featured in the advertising and formed the themes which the advertisements themselves constantly repeated. [10]

The ALJ's findings on this question are entirely consistent in our view with Commission experience in dealing with advertising claims for weight reduction products[8] [11] and with common sense. It is

[7] Another objection to the testimonial letters is based on a stipulation among the parties that consumer witnesses would not be called during the proceeding. Even if, by some stretch of the imagination, the stipulation were construed to cover documentary materials, respondents waived any objections on these grounds, first, by introducing similar letters of their own and, second, by failing to object to the introduction of complaint counsel's exhibits into evidence.

[8] *See, e.g., McGowan Laboratories, Inc.*, 11 F.T.C. 125 (1927); *Dispensary Supply Co.*, 20 F.T.C. 346 (1935); *Dispensary Supply Co.*, 22 F.T.C. 735 (1936); *Raladam Co.*, 24 F.T.C. 475 (1937), *aff'd* 316 U.S. 149 (1942); *Germania Tea Co.*, 25 F.T.C. 150 (1937); *Glenn Laboratories, Inc.*, 25 F.T.C. 302 (1937); *Wolf Drug Co.*, 25 F.T.C. 966 (1937); *Korjena Medicine Co.*, 26 F.T.C. 1013 (1938); *Helena Rubinstein, Inc.*, 27 F.T.C. 1 (1936); *Reliable Specialty Corp.*, 27 F.T.C. 627 (1938); *Gates Medicine Co., Inc.*, 27 F.T.C. 1040 (1938); *Isabella Laboratories*, 28 F.T.C. 38 (1939); *Alberty*, 29 F.T.C. 210 (1939), *aff'd as modified*, 118 F.2d 669 (9th Cir. 1941); *American Clinical Laboratories, Inc.*, 29 F.T.C. 1389 (1939); *Jean Ferrell, Inc.*, 30 F.T.C. 647 (1940); *Le Flor Co.*, 30 F.T.C. 1086 (1940); *Chapman Health Products Co.*, 30 F.T.C. 1199 (1940); *Sekov Corp.*, 31 F.T.C. 898 (1940); *Progressive Medical Co.*, 31 F.T.C. 1111 (1940); *Thyrole Products Co.*, 31 F.T.C. 1399 (1940); *American Medicinal Products, Inc.*, 32 F.T.C. 1376 (1941), *aff'd*, 136 F.2d 426 (9th Cir. 1943); *Miller Drug Co.*, 32 F.T.C. 122 (1940); *Burtley Co.*, 33 F.T.C. 455 (1941); *Clara Stanton, Druggist to Women*, 34 F.T.C. 153 (1941), *aff'd*, 131 F.2d 105 (10th Cir. 1942); *Bentley Co., Mail Order Division*, 34 F.T.C. 410 (1941); *Battle Creek Drugs, Inc.*, 34 F.T.C. 651 (1942); *Montgomery Ward & Co.*, 34 F.T.C. 1471 (1942); *Gene Hughes Drug*

(Continued)

obvious that dieting is the conventional method of losing weight. But it is equally obvious that many people who need or want to lose weight regard dieting as bitter medicine. To these corpulent consumers the promises of weight loss without dieting are the Siren's call, and advertising that heralds unrestrained consumption while muting the inevitable need for temperance if not abstinence simply does not pass muster. Where dieting is required, there is simply no substitute for clear and conspicuous disclosure that dieting is required.

Claims that Respondents Possessed Substantiation for Claims of Significant Weight Losses by Substantially All Users Respondents concede the "partial correctness"[9] of the ALJ's finding that the advertising represents that "substantially all users of X-11 tablets would lose a significant, in fact, as large an amount of weight as they desired" (I.D. 47; RB 39). They object, however, to that portion of Finding 47 which construes the advertising as containing affirmative representations that they possessed a reasonable basis for the "significant-weight-losses-by-substantially-all-users" claim (RB 39). Respondents complain that the ALJ "cites no language" in Finding 47 representing that they had a reasonable basis for such a claim. The ALJ properly drew his conclusion from the evidence reviewed in I.D. 40-46, on which Finding 47 rests.

As the ALJ found, (I.D. 40-47) the extravagance of the weight-loss claims implies that substantiation exists, and respondents have included statements in their advertising such as: "Laboratory Science has perfected a tiny pre-meal tablet . . ." (I.D. 44) (CX 1, 2, 11, 35, 46-48, 50, 52, 56, 58, 61-62 ["X-11 is the PROVEN and SOUND method . . ."], 74, 79); "clinic tested ingredients" (CX 47, 49, 74); and "The X-11 Reducing Plan is medically recognized as an effective plan to lose ugly fat." (CX 74)[10] *See also* I.D. 123. These statements not only implied the existence of substantiation but they also represented that this substantiation consisted of competent scientific proof. [12]

Stores, Inc., 35 F.T.C. 20 (1942); *Peggie Moran Co.*, 35 F.T.C. 27 (1942); *E. Griffiths Hughes, Inc.*, 40 F.T.C. 448 (1945); *Zo-Lon Co.*, 41 F.T.C. 38 (1945); *Langendorf United Bakeries, Inc.*, 43 F.T.C. 132 (1946); *Mid-West Drug Co., Inc.*, 43 F.T.C. 349 (1947); *Natural Foods Institute*, 50 F.T.C. 434 (1953); *Marlene's, Inc.*, 50 F.T.C. 460 (1953), *aff'd*, 216 F.2d 556 (7th Cir. 1954); *Renor Co., Inc.*, 53 F.T.C. 1222 (1957); *Rennel Products*, 54 F.T.C. 719 (1957); *Rennel Sales*, 54 F.T.C. 725 (1957); *Bakers Franchise Corp.*, 59 F.T.C. 70 (1961), *aff'd*, 302 F.2d 258 (3d Cir. 1962); *Damar Products, Inc.*, 59 F.T.C. 1263 (1961), *aff'd*, 309 F.2d 323 (3d Cir. 1962); *Consumer Laboratories, Inc.*, 61 F.T.C. 910 (1962); *National Bakers Services, Inc.*, 62 F.T.C. 1115 (1963), *aff'd*, 329 F.2d 365 (7th Cir. 1964); *Stauffer Laboratories, Inc.*, 64 F.T.C. 629 (1964), *aff'd* 343 F.2d 75 (9th Cir. 1965); *Farrar, Straus and Co., Inc.*, 65 F.T.C. 253 (1964); and *Simeon Management Corp.*, 87 F.T.C. 1184 (1976), *appeal pending*, No. 76-2543 (9th Cir.). We omit consent agreements and stipulations. Falsely advertised weight reduction products have run the gamut from food and drugs to devices and cosmetics.

[9] Respondents repeat their argument that they advertised the virtues of the "X-11 Reducing Plan" rather than "X-11 Tablets." See pages 7-8 above.

[10] We amend I.D. 44 to include the latter statements. *See* Appendix.

Moreover, it is now well-established that in the absence of a contrary disclosure, a product claim necessarily carries with it a representation that "the party making it possesses a reasonable basis for so doing, and that the assertion does not constitute mere surmise or wishful thinking on the advertiser's part." *National Commission on Egg Nutrition,* 88 F.T.C. 89, 191 (1976), *modified*——F.2d——(7th Cir. November 29, 1977). *See National Dynamics Corp.,* 82 F.T.C. 488 (1973), *modified,* 492 F.2d 1333 (2d Cir.) *cert. denied,* 419 U.S. 993 (1974); *Pfizer, Inc.,* 81 F.T.C. 23, 64 (1972).[11]

Respondents further argue that, by offering a "money back guarantee" (*e.g.,* CX 1), they qualified their claims and conveyed the message that X-11 would not cause substantially all users to lose a significant amount of weight. In our view, this argument stands common sense on its head. If anything, a money back quarantee reinforces in consumers' minds the sincerity of the advertisers' assertions, including those that are false and exaggerated.[12]

[13] *Unique Ingredient Claims* According to respondents, the ALJ "correctly found that which respondents admit - they advertised that their product contained a unique ingredient and that they intended phenylpropanolomine" [sic] (RB 40).[13]

The Falsity of the Claims

Because respondents have vigorously disputed the meaning that the ALJ ascribed to their advertisements, it is sometimes difficult to discern whether they also object to the findings that these claims were false.[14]

Claims of Weight Losses without Dieting Thus, the ALJ found, and we agree, that "[t]he representations of respondents in their

[11] In *Pfizer* we suggested that the failure to possess a reasonable basis is unfair within the meaning of Section 5. The complaint here alleged that the product claims were deceptive. Whether an advertisement is analyzed from the standpoint of deception or unfairness the result is the same and so is the standard for evaluating the substantiating material. *National Dynamics Corp., supra,* 82 F.T.C. at 550 n. 10.

[12] *See* I.D. 46; FTC Guides Against Deceptive Advertising of Guarantees, 16 C.F.R. 239.7; *All State Industries of North Carolina, Inc.,* 75 F.T.C. 465, 488–489 (1969), *aff'd,* 423 F.2d 423 (4th Cir.), *cert. denied,* 400 U.S. 828 (1970). In our view, *Jeffries* v. *Olesen,* 121 F. Supp. 463 (S.D. Calif. 1954); *Pinkus* v. *Walker,* 61 F. Supp. 610 (D. N.J. 1945) (injunction granted), 71 F. Supp. 993 (D. N.J. 1947) (final order, *sub nom. Pinkus* v. *Reilly*), *aff'd,* 170 F.2d 786 (3d Cir. 1948), *aff'd, sub nom. Reilly* v. *Pinkus,* 338 U.S. 269 (1949); and *Jarvis* v. *Shackelton Inhaler Co.,* 136 F.2d 116, 121 (6th Cir. 1943), are not to the contrary. These cases involved a statute unlike the FTC Act requiring proof of "actual intent to deceive" or "actual fraud in fact" and it was found that the money-back guarantee negated that intent. *See Pinkus* v. *Walker,* 61 F. Supp. at 613–14, and *Jeffries* v. *Olesen,* 121 F. Supp. at 473.

[13] We have some difficulty, however, fathoming the remainder of respondents' argument. They object to the ALJ's finding that the advertisements represented that X-11 *tablets* were unique. We are at a loss to discover how respondents' product could contain a unique ingredient (PPA) without X-11 tablets (which were admittedly the product containing PPA) being unique to the very same extent. It also escapes us how consumers could draw any other inference.

[14] For example, to support their argument that the ads are literally truthful, respondents assert that they recommended a "balanced diet." They go on to assert that one who has a balanced diet "eats well" (RB 39). The syllogism is interesting but misses the point. Respondents' advertising conveys more than the restricted meaning to which respondents must cling in their defense.

advertisements that users of X-11 tablets could lose weight without restricting their accustomed caloric intake, and while continuing to eat foods of their choice, were false, misleading and deceptive." (I.D. 54. *See* I.D. 50-53.) Respondents seem to concede as much when they argue that "it is impossible for the user of an appetite suppressant . . . to consume the foods of their [14] choice. . . ." (RB 40)[15] Neither do they deny that the advertising represents that consumers using X-11 can lose weight while continuing to eat foods of their choice; instead, they contend that the "choices" represented "can fairly be construed to relate to" the restricted diet which is inserted into each X-11 box (RB 31). In fact, as the ALJ found, weight losses require a highly restrictive "starvation or near-starvation" diet and total abstinence from such foods as gravies, nuts, candy, mayonnaise, pastries, whole milk, fried foods, rich dressings, and rich desserts.[16] These are often the very foods that overweight consumers hope least to abandon along with their unwanted inches.

Unique Ingredient Claims Respondents raise no objections to Findings 123 or 124, which conclude that the advertisements falsely claim that X-11 tablets contain a unique ingredient (RB 53).

Claims of Substantiation for the Significant Weight-Loss-by-Substantially-All-Users Claim The major controversy surrounding the alleged falsity of the advertisements centers on the charge that respondents implicitly promised, but did not possess a reasonable basis for the claim that substantially all users of X-11 tablets can lose significant amounts of weight. The primary question thereby put in issue by the complaint is not whether the claims of weight loss are false but instead whether, at the time they were made, respondents possessed reasonable substantiation for them. [15]

In the course of the hearing, the scope of this inquiry was expanded. Rather than scrutinizing only the material that respondents possessed and relied upon in making their claims (including the claims that they had such material), the parties produced numerous experts and documents bearing upon the pharmacological properties of PPA. The initial decision sifts this evidence in painstaking detail, and we affirm the numerous findings of the ALJ on these matters. At the same time, this evidence is of limited utility to the extent that it strays from the narrower issue of the type and

[15] The full text of respondents' argument is, "In Findings 50-54 the Law Judge does not address the issue of why it is impossible for the user of an appetite suppressant such as phenylpropanolomine, to consume the foods of their choice, while consuming less, thus losing weight consistent with the findings in *Carlay, supra* and *Alleghany, supra;* and the testimony of complaint counsel's witnesses, Drs. Margan and Drenick, Tr. 308, 452."

[16] In lieu of these foods, respondents' "eat-well," open "choice" diet consisted of such breakfasts as a half grapefruit and black coffee or a glass of orange juice and black coffee; such lunches as tuna chunks, celery and carrot sticks, and a slice of bread or string beans, beets and spinach and a slice of bread; or such dinners as broiled chicken, tossed salad and a fresh fruit cup, or baked fish, raw cabbage salad and a cup of soup (CX 40).

quality of the substantiation material possessed and relied upon by respondents at the time they made their claims.

The ALJ concluded that only "adequate and well-controlled scientific studies or tests" would provide adequate substantiation for claims made for a drug product like X-11, sold for the treatment of overweight and obesity, because these conditions pose dangers to health (I.D. p. 99). We see no need to reach the question whether consumers expect this type and quality of substantiation simply because the advertised product is a drug. In the context of this advertising, consumers were led to understand that respondents had competent scientific tests to substantiate their claims.

During the investigation of this matter and during the hearing, respondents conceded that they had no tests, studies, scientific reports or other similar information to support their implied claim that they had a reasonable basis for their weight-loss representations (I.D. 56-60).

Instead, respondents contend that they relied on a recommended decision of a Commission hearing examiner (which was never adopted as a final agency decision), *Alleghany Pharmacal Corp., et al.,* 75 F.T.C. 990 (1969), the decision in *Carlay Co.* v. *FTC,* 153 F.2d 493 (7th Cir. 1946), some materials on the general properties of methylcellulose,[17] [16] and copies of two 1957 letters from the Food and Drug Administration to other companies (RB 21, 41).[18] These materials, according to the record, were not reviewed by Porter & Dietsch, William H. Fraser, or Pay'n Save, although Joseph Furth was shown the *Alleghany* and *Carlay* decisions, but were in the possession of Mr. Frank Gettleman, an attorney for Porter & Dietsch. Mr. Gettleman supplied these materials during the investigation of this matter to the Commission's staff in response to their request for substantiation for X-11 advertising claims (I.D. 56-62).

In addition, respondents refer us to a decision of the United States Postal Service which was rendered after issuance of the complaint in this proceeding,[19] materials mentioned in *Alleghany,* and testimony and documents on the efficacy or degree of use of PPA introduced into evidence in this proceeding, including reports of studies concerning PPA which were also published after the complaint

[17] Respondents do not appeal the ALJ's finding that respondents had no reasonable substantiation as to the methylcellulose contained in X-11 and that methylcellulose itself does not suppress the appetite. (I.D. 122)

[18] Respondents object that the ALJ overlooked the FDA letters and the methylcellulose materials. Accordingly, we add an appropriate finding in the Appendix.

[19] In re Hanover House, P.S. Dkt. No. 2/143; and Romar Sales Corp., P.S. Dkt. No. 2/149 (Dec. 5, 1975) (consolidated; not reported). The Postal Service decision found, at most, that expert opinion was divided on the efficacy of PPA and that the complainant had not carried its burden of proving that PPA is ineffective. Like the hearing examiner's recommended decision in the *Alleghany* case, there was no finding that "substantially all users [of PPA] will lose a significant amount of weight."

issued. As we have indicated, such evidence is irrelevant to the question whether the respondents have, as alleged in the complaint, misrepresented that they had substantiation for their advertising claims at the time that the claims were made. In any event, none of these materials supports the claim that "substantially all users of X-11 tablets will lose a significant amount of weight." [17]

Carlay involved a different product altogether, a candy which, when ingested before meals, presumably spoiled the consumer's appetite. The Commission found that the advertising was deceptive but the court held that the Commission's conclusion was not supported by substantial evidence.[20] Recognizing the factual dissimilarity between the candy in *Carlay* and their own X-11 tablets, respondents argue that the *Carlay* case gives them a license to make unlimited efficacy claims ("substantial weight losses") for any product that is an "effective" appetite suppressant sold in conjunction with a restrictive diet "plan" (revealed in full only in a package insert) (RB 42). Later cases render this alleged defense untenable. See *Stauffer Laboratories, Inc.* v. *FTC,* 343 F.2d 75 (9th Cir. 1965); *Damar Prods., Inc.* v. *FTC,* 309 F.2d 323 (3d Cir. 1962). Moreover, *Carlay* did not address the question whether substantial amounts of weight could be lost by eating candy before each meal. Even if PPA were an "effective" appetite suppressant in the dosages provided in X-11, it would not follow that "substantially all users of X-11 tablets will lose a significant amount of weight."

Alleghany involved a challenge to advertising claims for "Hungrex," a weight reduction product which also contained PPA. Respondents argue that the *Alleghany* case, or at least some of the evidence recited in the hearing examiner's recommended decision in that case, provides substantiation for the proposition that "substantially all users of X-11 tablets will lose a significant amount of weight." [18]

The hearing examiner in *Alleghany* concluded that the allegations of the Commission's revised complaint on reopening had not been established by a preponderance of the evidence, 75 F.T.C. at 1034. "[W]ithout expressing any opinion as to the accuracy of the findings and conclusions in the [hearing examiner's] Certification of Record," the Commission concluded that "it would not be in the public interest to pursue this matter further" and dismissed the complaint without prejudice, while leaving an earlier consent order against

[20] We reject the implication of respondents' argument that years after a court decision finding a failure of the government to establish the falsity of advertising claims, an advertiser can rely on the decision notwithstanding the present state of medical or scientific knowledge. We do not understand that to be the law, *see FTC* v. *Raladam Co.,* 316 U.S. 149, 150-151 (1942); *Hastings Mfg. Co.* v. *FTC,* 153 F.2d 253, 254, 258 (6th Cir. 1946), nor would we consider it to be defensible public policy.

Alleghany Pharmacal in effect, *Id.* at 1036. Moreover, the hearing examiner's unadopted, recommended decision in *Alleghany* found, at most, that PPA is an "effective appetite depressant in the treatment of obesity," *Id.* at 1033.[21] This conclusion falls far short of a finding of significant weight losses by substantially all users.

Respondents also contend that they relied on evidence discussed in the *Alleghany* decision (RB 21). However, respondents did not possess anything more than the discussion of these materials contained in *Alleghany* itself and, as the ALJ found (I.D. 61), the discussion, putting aside the inconclusive disposition of the case, does not support X-11 advertising claims.

The first example cited is a test done by Dr. Edward Settel, who testified in *Alleghany* that he had done a study of 30 persons who were 10 percent or more overweight. The entire group was on a 900 calorie a day diet. No further details of the study are provided. Dr. Settel concluded that PPA is a "more effective anorexiant agent" than a placebo. He did not testify as to the extent of weight [19] loss, if any, of the persons tested. 75 F.T.C. at 1016-1017. Dr. Frederick B. Bohensky testified that he had treated several thousand patients for obesity in his practice in Brooklyn, was familiar with PPA, used it in his practice, had tested it on dogs, and concluded that it was an "effective anorexigenic and weight reducing agency" in dosages of 75 mg. per day. *Id.* at 1019-1020. Dr. Theodore Feinblatt testified that, on the basis of a study he had done, a 75 mg. dose of PPA "effective as an anorexiant agent for the treatment of obesity." No details of the study are mentioned *Id.* at 1023. Dr. Raymond W. Healy, a general practitioner primarily interested in obesity, had been giving his patients amphetamine to reduce their appetites while they were on low calorie diets. He gave 30 patients PPA instead, and concluded that PPA was "effective in reducing the appetite in about 80 percent of his patients involved in the test." *Id.* at 1022. Dr. Harold Silverman criticized a study relied upon in an FDA proceeding against a similar product,[22] which was done by Dr. Joseph F. Fazekas. *Id.* at 1027. Dr. Fazekas had concluded that PPA "does not possess significant anorexigenic potency," *60 28-Capsule Bottles,* 211 F. Supp. at 209. Dr. Silverman's article made no claims of specific amounts of weight losses associated with PPA (I.D. 92).

The hearing examiner in *Alleghany* also discussed excerpts from medical literature which stated that: PPA is "useful to kill the appetite" [Hirsh] [Hirsh had actually repudiated that statement by

[21] *But see United States* v. *60 28-Capsule Bottles, More or Less, Etc.*, 211 F. Supp. 207 (D. N.J. 1962), *aff'd*, 325 F.2d 513 (3d Cir. 1963).

[22] *Id.*, n. 20.

the time of the Alleghany trial, see I.D. 92], 75 F.T.C. at 1009; "used . . . to depress appetite" [Grollman], *id.;* "employed . . . as an anorexiant" [Merck Index], *id.,* at 1010; listed with amphetamines as an appetite depressant [Leake], *id.;* less effective than amphetamines in the control of obesity [Sollmann], [20] *id.;* used in controlling appetite [Drill], *id.,* at 1011; "sometimes used to reduce appetite" [Laurence], *id.,* or is used for obesity [Remington's], *id.* No dosages are mentioned, no statements as to the effectiveness of PPA in appetite suppression are made (other than "useful"), no tests of the product in obesity control are mentioned; and no mention of weight losses of any degree appear in the discussion of this literature. *See* I.D. 70. Respondents also mention literature by "Kalb." We find no reference to Kalb in *Alleghany.*

None of this discussion supports the conclusion that "substantially all users of X-11 tablets will lose a significant amount of weight," since no weight losses are quantified and it is not clear whether weight losses of any quantity might be achieved by "substantially all" users of PPA in the dosages provided in X-11 tablets.

These various suggestions of PPA efficacy were placed in proper perspective by the testimony of several experts, including those of respondents. For example, Dr. Fineberg had never used PPA in his practice and could not say whether PPA would be effective in a 25 mg. dosage for the "normal run of people" (I.D. 90). Dr. Silverman made no claims "of specific amounts of weight loss associated with" PPA (I.D. 92). He did say that 75 mg. of PPA per day used in conjunction with a 1,200 calorie per day diet would bring about a significant decrease in weight in time (I.D. 93), but in a four-week study he performed with two groups on such diets, one using PPA and the other a placebo, the difference was a loss of only one-half or less than one-half pound per week, which, according to other testimony, is "clinically trivial" in obese persons, and, as the law judge found, "particularly in the absence of evidence that such loss can be continued" (I.D. 101-109). Dr. Hoebel, who also testified for respondents, also did a four-week study of the effectiveness of PPA, and also found a loss of a fraction of a pound per week associated with PPA (I.D. 118). That study was also criticized by complaint counsel's expert witnesses (I.D. 119-122), and Dr. Hoebel himself wrote that his "evidence for a statistically significant weight loss in a two-week period does not mean that this rate of loss would be continued over longer periods" (I.D. 120). [21]

The two 1957 FDA letters suggest that FDA permitted an "indications for use" labeling on a PPA product to read "useful as an appetite suppressant in the *dietary* management of obesity" (empha-

sis added). Like the other information in respondents' possession, these letters do not establish that significant weight losses may be achieved with PPA, with or without dieting.

Like Porter & Dietsch, Pay'n Save did not test X-11 and has done no research in medical literature as to its effectiveness. Pay'n Save "looked at, but did not critically examine" X-11 advertising, read the "plan," noted that the product was similar to others on the market, and assumed that the product must perform as advertised (RB 5-6).[23] We find that Pay'n Save, like Porter & Dietsch, had no substantiation whatever for the claim that "substantially all users of X-11 tablets will lose a significant amount of weight" at the time Pay'n Save disseminated X-11 advertising.

We conclude that respondents' advertising is false and misleading, because it implicitly represents that "substantially all users of X-11 tablets will lose a significant amount of weight" and that respondents possess competent scientific evidence supporting that claim, even though respondents did not have a reasonable basis for making such a claim at the time the advertising was disseminated. [22]

Failures to Disclose Material Facts

The complaint also alleges that respondents' advertisements were false because, in the words of the relevant statute, they "failed to reveal facts material in the light of [the] representations [made] or material with respect to consequences which may result from the use of the commodity to which the advertisement related under the conditions prescribed in said advertisement, or under such conditions as are customary or usual." The three alleged non-disclosures are: that the typical and ordinary experiences of consumers do not parallel the experiences reported in testimonials appearing in the advertisements (¶11); that a highly restricted caloric diet is a part of the X-11 plan (¶13); and that persons with high blood pressure, heart disease, diabetes or thyroid disease should only use X-11 tablets as directed by a physician (¶12). The ALJ found that all three of these non-disclosures violate the FTC Act. (I.D. 125-140)

We affirm all three of these conclusions.

Testimonials Respondents are charged with having failed to disclose material facts concerning testimonials used in their advertising, namely, the "typical or ordinary experience" of users of X-11 (¶11), making the advertising misleading (¶14). The ALJ found that respondents advertised testimonials proclaiming "I LOST OVER

[23] Pay'n Save also relied on the reputation of a manufacturer's representative, the fact that others advertised X-11, a Pharmacy Supervisor's recollection that he had been told in pharmacy school that PPA has been used as an appetite suppressant, and the fact that no consumer complaints were received (RB 16-17).

40 LBS.," "I LOST 80 LBS!" and others (I.D. 125). The smallest weight loss advertised is 40 pounds; the highest, 83 pounds (I.D. 126). He found that, by such representations, and other statements in the advertising, respondents left the impression that such large weight losses are typical with X-11 use. Testimonials of ordinary consumers were presented accompanied by statements such as "from Georgia to Nebraska to California American women have found a way that really helps off that ugly fat" (I.D. 126); "amazingly easy," "extraordinary simple" [sic], "more easily than you ever dreamed possible" (I.D. 12); and "RESULTS ARE GUARANTEED" (I.D. 12). [23]

The challenged testimonials did not appear in isolation and we have not read them that way. They were part and parcel of advertisements which, as we have found, claimed by implication that substantially all users of X-11 tablets would lose a significant amount of weight. The testimonials both fed this claim and drew sustenance from it. The net impression, as the ALJ found, is that the testimonials conveyed the message that extraordinarily large weight losses were typical or ordinary.

In fact, it is extremely rare for obese individuals to lose as much weight as depicted in the ads. (I.D. 126-129)

Restricted Diet For reasons that are apparent and that have already been mentioned (pages 8-9 above), we affirm the ALJ's findings and conclusions that respondents violated the FTC Act by failing to disclose that a highly restricted caloric diet is part of the X-11 regimen. Indeed, respondents concede that if their advertising is construed to promise weight reduction without dieting, as we find it did, then such a representation is false.

Safety of X-11 The final failure-to-disclose allegation concerns the safety of using X-11 tablets. An insert accompanying each package of X-11 tablets contains the following advice: "CAUTION: Individuals with high blood pressure, heart disease, diabetes or thyroid disease should use only as directed by a physician. . . ." The veracity of this warning is not disputed but the complaint challenged its sufficiency. The ALJ found that the failure of respondents to disclose these potentially hazardous consequences in their advertisements constituted false advertising (I.D. 139).

A majority of the Commission[24] agrees and adopts the ALJ's findings on this issue (I.D. 130-139). Respondents made strong, affirmative claims for their product. By failing to disclose in advertising that potentially serious health risks are associated with the use of X-11 they deprive consumers of an important and

[24] Commissioners Collier and Clanton dissent from the Commission's decision on this issue for the reasons set forth in Commissioner Collier's separate views.

material fact. The Commission finds this failure violates the letter and spirit of Section 12, and thereby Section 5. [24]

Defenses

Liability of Joseph Furth and Pay'n Save Two of the respondents, Joseph Furth and Pay'n Save object to their liability for the false advertising.

Mr. Furth objects to one of the ALJ's findings that he formulated, directed, and controlled the practices we find unlawful (RB 35). Paragraph 1 of the complaint charged that Furth "formulates, directs and controls certain acts and practices of [Kelly Ketting Furth, Inc.], *including the acts and practices hereinafter set forth*" (emphasis added). Furth's answer admits that he "formulates, directs and controls certain of its acts and practices." The Commission's Rules of Practice and Procedure provide that:

> An answer in which the allegations of a complaint are contested shall contain . . . specific admission, denial, or explanation of each fact alleged in the complaint or, if the respondent is without knowledge thereof, a statement to that effect. *Allegations of a complaint not thus answered shall be deemed to have been admitted.*

(Emphasis added.) 16 C.F.R. 3.12(b)(1)(ii). In view of the complaint's allegation, Furth's answer, and by operation of the rule, the ALJ was clearly correct in relying on the pleadings in his finding that Furth "is among those responsible for the formulation, direction and control of its acts and practices, including those alleged in the complaint." While the respondents as a group denied most of the allegations of unlawful conduct, Furth, by his answer, admitted his personal involvement for his principal, Kelly Ketting Furth, Inc., in the conduct that was subject to challenge.

Moreover, Furth does not contest Finding 143 which points to the same conclusion as the finding he challenges.[25] Furth's active role in formulating the advertising is not diminished, as respondents imply (RB 35–36), because he was "merely an employee" (a vice-president) of Kelly Ketting Furth or had to clear the initial acceptance of the Porter & Dietsch account with someone else. [25]

There is no dispute that Pay'n Save had no role in preparing X–11 advertising, but it did disseminate, in its own name, advertisements provided by Porter & Dietsch, either directly, or by paying for the placement of ads sent to news media by Porter & Dietsch (I.D. p. 106). Pay'n Save contends that it should not be held to an order because,

[25] *See also* respondents' "Answers to Request for Admissions," November 8, 1975, at 6, responding to complaint counsel's request for admissions of October 21, 1975, at 4.

as a retailer disseminating advertising prepared by another, it had no way of verifying the claims it was disseminating.

We find that Pay'n Save has violated Section 12 of the FTC Act, as alleged in the complaint. Section 12 provides that it is "unlawful for any person, partnership, or corporation to *disseminate, or cause to be disseminated,* any false advertisement . . . for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices or cosmetics . . ." (emphasis added).

We find that X-11 advertisements are "false advertisements" under Section 15,[26] and there can be no dispute that, by placing X-11 advertising, Pay'n Save "disseminated" it.[27] Section 12 does not provide any exemption for retailers who receive the advertisements they disseminate from others.[28]

It would appear to be no accident that Section 12 does not contain such an exemption. In Section 14, Congress attempted to deter the false advertising of food, drugs, devices, and cosmetics hazardous to consumer health (a subset of advertising prohibited by Section 12) by making it a misdemeanor to [26] disseminate such advertising with the intent to defraud or mislead. That section does not apply to any "publisher," radio-broadcast licensee, or agency or medium for the dissemination of advertising," in order to "avoid unwarranted hardship on the person who has conducted his business with proper prudence," H.R. Rep. No. 1613, 75th Cong., 1st Sess. 7 (1937). In hearings on predecessor legislation, Congress heard testimony to the effect that the media (like retailers, in the view of Pay'n Save) could not realistically test the veracity of claims they disseminated.[29] However, the "manufacturer, packer, distributor, or seller of the commodity to which the false advertisement relates" is expressly denied the exemption. The unmistakable implication is that such

[26] Although the ALJ did not find that Pay'n Save either disseminated the advertising in commerce or disseminated advertising for the purpose of, or which was likely to, induce purchases in commerce, with minor modifications we adopt complaint counsel's proposed finding 32, that Pay'n Save has caused X-11 advertising to be published in media of interstate circulation (and has therefore disseminated the advertising "in commerce"), which is supported by admissions and stipulations in the record and is uncontested. *See* Appendix.

[27] Counsel for Pay'n Save conceded as much at oral argument (Tr. of oral argument, p. 29).

[28] *Id.*, at 30.

[29] *See To Amend the Federal Trade Commission Act: Hearings on S. 3744 Before the Sen. Comm. on Interstate Commerce,* 74th Cong., 2d Sess. 68-69 (1936) (statement of C. B. Larrabee, representing the Legislative Committee of the National Publishers' Assn.); *Federal Trade Commission Act Amendments: Hearing on S. 3744 Before the House Comm. on Interstate and Foreign Commerce,* 74th Cong., 2d Sess. 68 (1936) (statement of William L. Daley, Washington Manager, National Editorial Assn.). Falsely advertised diet remedies were a specific concern. *See* 83 Cong. Rec. 415 (1938). A major impetus to the legislation was the Supreme Court's holding in *FTC* v. *Raladam Co.*, 283 U.S. 643 (1931), that the Commission had no jurisdiction to prevent, without a showing of injury to competition, the false advertising of a thyroid extract sold as a diet remedy. The predecessor legislation, S. 3744, 74th Cong., 2d Sess., did not incorporate language similar to that found in Sections 12-15; however, like Section 3 of the Wheeler-Lea Amendments (S. 1077, 75th Cong., 1st Sess., enacted as Pub. Law No. 447), the bill would have amended Section 5 to make it clear that false and misleading advertising ("unfair or deceptive acts or practices") is within the Commission's jurisdiction regardless of its effect on competition.

persons are subject to §12 as well as to Section 14. There can be no question that Pay'n Save is a "distributor" or "seller" of X-11. [27]

In light of the plain language of Section 12, we decline to adopt Pay'n Save's "flexible standard" of Section 12 liability, which would require us to except all but those who were "principals" in the preparation of advertising copy.[30] As Pay'n Save admits, nothing in the legislative history of Section 12 supports such an exception.[31] Moreover, we think it is not unreasonable for Congress to impose higher obligations on disseminator-distributors of advertising for food, drugs, (medical) devices, and cosmetics (items which may carry a potential for injury to health and safety).[32]

Nor do we consider this result harsh in the circumstances. Pay'n Save is a substantial company operating 140 retail stores, 92 of which are drug stores (RB 2). It runs only 30 or 40 advertisements prepared by its suppliers (Tr. 514, 566). Pay'n Save "looked at, but did not critically examine" X-11 advertising and reviewed the package insert revealing the "plan" (Tr. 531, 561). If Pay'n Save had critically examined the advertising in light of the package insert, it should have been obvious that the advertising at least did not coincide with the plan.

Collateral Estoppel As we have noted above in discussing the falsity of respondents' advertising, this is not the first occasion on which the Federal Government has challenged conduct of sellers of products containing PPA sold as a weight reduction preparation. *See Alleghany, supra,* at 15; *Hanover House, supra,* n. 19 at 16; and *60 28-Capsule Bottles* ("Unitrol"), *supra,* n. 21 at 18. In addition to asserting that these cases (except the Unitrol decision) support the truth of their advertising claims, respondents argue that they collaterally estop the Commission from a finding of liability in this case as to ¶¶9A and B, 10A and B, and 12 of the complaint. [28]

We reject this argument for several reasons. First, the truth of these respondents' advertising claims were simply not litigated in those proceedings. Moreover, the Commission decision to which we are referred was not a final adjudication but was, instead, dismissed without prejudice after the ALJ concluded that other challenges to other advertisements had not been established by a preponderance of the evidence. There can be no bar of collateral estoppel on these facts.[33]

---

[30] We intimate no view on the question whether or under what conditions such an approach would be appropriate under Section 5 of the FTC Act.

[31] Tr. of oral argument, at 29-31. *See also Mueller* v. *United States,* 262 F.2d 443, 446 (5th Cir. 1958) ("The term 'cause' is in the statute without any qualification relating to the advertiser's state of mind.").

[32] *See* Prosser, *Torts* 653-654 (4th Ed. 1971).

[33] Because the doctrine of collateral estoppel does not apply where different issues are tried, where different legal standards are applied, or where a dismissal without prejudice terminates the earlier litigation [*see George H.*

(Continued)

Location and Scheduling of Hearings The hearings were held in Seattle and Washington, D.C. on eight days between January 7, and January 26, 1976 (I.D. p. 7). In orders of December 3, 19, and 30, 1975, the law judge established the hearing sites and the hearing schedule. He noted that no one place was wholly satisfactory, because the witnesses to be called were dispersed into a number of locations, including Anchorage; Seattle; the San Francisco area; Los Angeles; Radnor, Pennsylvania; Minneapolis; Chicago; Miami; Boston; Baltimore; New York; and Princeton, New Jersey. The two individual respondents were located in St. Paul and Chicago, and all counsel in the proceeding were located in either Washington, D.C. or Seattle.[34]

[29] Respondents do not contend that their defense was impaired by the location or scheduling of the hearings, nor would the record support that claim.[35] Instead, they refer to the inconvenience encountered by the individual respondents in traveling to Washington, D.C. to testify (RB 2; RRB 9). However, in response to complaint counsel's motion to designate Seattle and Washington, D.C. as hearing sites, respondents' counsel expressed a willingness to designate "Chicago, Illinois, or, in the alternative, Washington, D.C."[36] Respondents cannot now contend that Washington, D.C. was an "inconvenient" location.[37]

[30] Respondents also argue that the complaint must be dismissed because complaint counsel did not prove that the hearing schedule was expeditious before the hearings took place, whether or not, in hindsight, the hearings were in fact expeditious (RRB 6), relying on *Universe Chemicals, Inc.*, 75 F.T.C. 1069 (1969). *Universe Chemicals* was decided when Section 3.41(b) of the Commission's Rules allowed the designation of multiple hearing sites only "in unusual and exceptional circumstances for good cause stated on the record."

Lee Co. v. *FTC*, 113 F.2d 583, 585 (8th Cir. 1940); *United States* v. *Willard Tablet Co.*, 141 F.2d 141, 143 (7th Cir. 1944); *Hastings Mfg. Co.* v. *FTC*, 153 F.2d 253, 255 (6th Cir. 1946)], we need not delve the legal question of the extent to which an administrative agency in pursuit of the public interest such as the Commission is bound by that doctrine, or whether an earlier finding that rests on then-current technical and scientific knowledge, once made, is insulated from later challenges based on new evidence or later developments and discoveries.

[34] "Order Directing Hearings in Seattle and Washington, D.C.," December 3, 1975, at 2.

[35] For that reason, *Jeffries* v. *Olesen*, 121 F. Supp. 463 (S.D. Calif. 1954) is inapposite. There a respondent in a Post Office proceeding had no funds to appear at a hearing in Washington, D.C. and was unable to present his defense.

[36] "Answer to Complaint Counsels' Motion to Designate Seattle and Washington, D.C. as the Locations for Hearings," November 18, 1975, at 10. Counsel for Pay'n Save Corporation concurred in that pleading, "Revised Statement of Pay'n Save Corporation with Respect to Location of Hearings," November 26, 1975, at 1.

[37] In choosing a hearing site, the ALJ was obligated to consider the convenience of the agency in addition to the convenience of respondents, because the term "parties" in the Administrative Procedure Act, 5 U.S.C. 554(b), 555(b), includes agency parties, *Maremont Corp.* v. *FTC*, 431 F.2d 124 (7th Cir. 1970); *Burnham Trucking Co.* v. *United States*, 216 F. Supp. 561 (D. Mass. 1963); Sen. Rep. No. 752, 79th Cong., 1st Sess. 17 (1945). Respondents also offer us a chart which purports to show that the total air miles traveled by all participants in the hearings were 22 percent greater than they would have been if all hearings had been held in Chicago or Washington, D.C. (RB, "Appendix A-1"). We do not see the relevance of this calculation to either the expeditiousness of the hearings or to the convenience of respondents.

Under the current rule, promulgated well before this proceeding began, 37 F.R. 5609 (1972), there is no longer any such requirement. In this case, the hearings were expeditious, consuming only 8 days over a three-week period.

We conclude that the ALJ did not abuse his discretion, and respondents have not been prejudiced in any cognizable way by the location or scheduling of the hearings.

Miscellaneous Objections Respondents also contend that they were misled by the ALJ and by complaint counsel's "shifting position" on the relevance of the efficacy of PPA (RB 29–30; RRB 30–32). We find it hard to believe that respondents were unfairly confused by the discussions among counsel and the ALJ which are cited to us. As the ALJ pointed out, it was not the efficacy of PPA *per se* that was put in issue by the Commission's complaint, but rather the veracity of X–11 advertising claims. The efficacy of PPA was deemed relevant only insofar as it is an ingredient of the product for which claims are made.

Moreover, the alleged prejudice is that, after respondents' counsel understood the issue "it was . . . too late to cross-examine Drs. Margen and Drenick on the 'degree of effectiveness' [of PPA]" (RB 29). But respondents did in fact cross-examine Dr. Margen extensively as to his views on the effectiveness of PPA (see Tr. 294–326), including cross-examination as to his interpretation of a study by Dr. Hoebel, on which respondents rely to establish the effectiveness of PPA. Respondents also cross-examined Dr. Drenick as to the sufficiency of studies and medical literature concerning the efficacy of PPA (Tr. 466–476). Respondents [31] had ample opportunity to present evidence and testimony concerning the efficacy of PPA insofar as it related to their advertising claims, and they did so. Indeed the purported efficacy of PPA in suppressing appetite was the cornerstone of their defense. There has been no error. *Murray Space Shoe Corp.,* 59 F.T.C. 803, 828–829 (1961), *aff'd,* 304 F.2d 270 (2d Cir. 1962); *Trade Union Courier Publishing Corp.,* 51 F.T.C. 1275, 1295 (1955). Finally, since respondents failed to request that Drs. Margen or Drenick be recalled once the scope of the inquiry was clarified in their minds, they waived any claim of error.

Respondents next argue that the proceedings against them are not in the public interest since others are engaged in similar practices. We are told that consumers with a proclivity for purchasing deceptively advertised weight reduction preparations will still be able to satisfy their demand.

We reject this variation on the old theme of selective enforcement. Official proceedings against law violators could seldom, if ever, be

brought were such a theory to be approved. Rules of conduct adopted by governments are seldom self enforcing and seldom obeyed universally. Detection and apprehension of all violators simply cannot be a precondition to the prosecution of each violator. Moreover, proceeding against all violators would be an illusory solution to this perennial dilemma since someone not currently a violator might become one tomorrow.[38]

[32] In addition to these objections, respondents argue that the delays encountered in investigating and challenging their advertising claims demonstrate a lack of public interest in these proceedings. In our opinion, this contention is without legal force.[39] It is directed basically at the wisdom of expending limited public resources to correct particular law violations, a decision that is committed to the Commission's discretion. That bridge was crossed for the last time over two years ago when the Commission issued the complaint in this case.[40]

At oral argument, respondents raised a number of additional objections: that the Commission had no "reason to believe" that Kelly Ketting Furth and Joseph Furth had violated the FTC Act at the time the complaint issued (Tr. 5-6)[41]; that a news release announcing issuance of the complaint caused some Porter & Dietsch customers to cancel orders (Tr. 6, 14); that respondents had an inadequate opportunity to negotiate a consent settlement (Tr. 6, 10); and that the law judge was biased (Tr. 6, 19). None of these objections has any merit. [33]

The complaint itself set forth the basis for the Commission's reason to believe that a law violation had occurred and that a proceeding would be in the public interest. The complaint was clearly adequate in all respects and the allegations were fully and fairly adjudicated. There was no need to try the issuance of the complaint itself or to adjudicate the investigation that preceded it.

At least some incidental individual loss is unavoidable when public rights are adjudicated, as they must be, in public forums. *FTC* v. *Cinderella Career and Finishing Schools, Inc.*, 404 F.2d 1308, 1312-1316 (D.C. Cir. 1968). There is no suggestion that the press releases announcing the initiation of this action were factually incorrect or

[38] Under 15 U.S.C. 45(m), the Commission is free to hold other concerns to the same standards we are imposing on these respondents, when the order we will enter becomes final.

[39] The existence of prior investigations which were not pursued is no bar to this action. *See Parke, Austin & Lipscomb* v. *FTC*, 142 F.2d 437, 441 (2d Cir. 1944).

[40] For the same reason, we decline to dismiss this proceeding simply because X-11 tablets are relatively inexpensive, selling for $3.00 or $5.00 a box, and because consumers may be able to discern the efficacy of the product by using it. (*See*, RRB 16-17).

[41] No facts are cited in support of the allegation, although at oral argument counsel did mention that he had refused to respond to questions concerning Kelly Ketting Furth and Joseph Furth before the complaint issued (Tr. 11).

that they evidenced prejudgment or bias on the part of the Commission. We therefore decline to disturb our earlier rulings on respondents' interlocutory motions regarding the press releases, 86 F.T.C. 896, 1570 (1975).

Respondents concede that the Commission's staff engaged in consent negotiations with them before the complaint issued, but, after "about 14 telephone calls,"[42] the parties could not agree. Of course, respondents could have engaged in consent negotiations after the complaint issued if they had wished, and under the Commission's Rules of Practice, 16 C.F.R. 3.25, could have unilaterally offered the Commission a consent order which would present a "likelihood of settlement." Respondents simply have not been denied the opportunity to settle this matter.

The evidence presented to demonstrate the ALJ's alleged "bias" is one passage of the initial decision, at 94, where he read *Stauffer Laboratories, Inc.* v. *FTC,* 343 F.2d 75 (9th Cir. 1965) as indicating that Stauffer had relied on *Carlay* on appeal. Respondents point out that there is no mention of *Carlay* in the court's decision.[43] The finding will be [34] modified to correct the ALJ's error, *infra.* However, we fail to see how his mistake evidences "bias," nor do respondents provide any authority in support of their contention.[44]

Relief

The ALJ has proposed a cease and desist order substantially similar to the detailed notice order attached to the Commission's complaint. We will revise the order in conformity with this opinion and to prevent problems of enforcement which reside in the wording of some of its provisions.

We first consider the product coverage as to the various respondents. We believe the proposed order as to Porter & Dietsch and William H. Fraser is too narrow in scope. The first paragraph of the order would only apply to the advertising of X-11 tablets, preparations of "similar composition or similar properties," or dietary aids "containing phenylpropanolamine." Although X-11 represents the bulk of Porter & Dietsch sales (I.D. 1), we find that Porter & Dietsch is "continuously trying new products" (Tr. 765), and has marketed a

[42] Tr. of oral argument at 10.

[43] The opinion does indicate that Stauffer argued that the Commission had to consider a vibrating couch an inextricable part of the Stauffer reducing "plan" as a matter of law, 343 F.2d at 78.

[44] We also reject respondents' contentions, at RB 35-58, that the ALJ's findings in any way bespeak "bias" or "prejudice." The only "bias" cited is his rejection of respondents' position. Finally, we reject respondents' contention (RB 58) that they have been denied adequate time and appeal brief pages (in excess of the limits imposed by the Commission's Rules of Practice). Respondents were given an extension of 20 days to file their appeal briefs and together filed a total of 163 pages of argument and other materials.

number over the years (Tr. 754-766, 817-819), including another diet "plan" (Tr. 758).[45] Porter & Dietsch, as a wholesale operation securing its products from others (I.D. 1, 9; Tr. 766), is not faced with the expense of modifying manufacturing facilities as new products are added to its line. Porter & Dietsch and William H. Fraser have been marketing X-11 for years, first disseminating X-11 "plan" advertising in July, 1968 (Tr. 932-939). [35]

The practice of deceptively advertising a diet remedy, with or without a "plan," is not uniquely suited to products containing PPA or ingredients of "similar composition or similar properties." As we have seen, deceptions involving diet remedies have related to a wide variety of foods, drugs, devices, and cosmetics, the common thread being that human vanity and concern for health, and the inability to cope with the self-discipline of dieting, are preyed upon by making promises which cannot be kept.[46] Finally, we note that Mr. Fraser and wholly-owned subsidiaries of Porter & Dietsch have run afoul of our statute before.[47] For these reasons, we will enter an order as to Porter & Dietsch and William H. Fraser covering any "food," "drug," "cosmetic" or "device," as these terms are defined by the Federal Trade Commission Act.

For similar reasons, the product coverage of those provisions of the order pertaining to Kelly Ketting Furth or Joseph Furth should not be limited to X-11 or dietary aids containing PPA. Kelly Ketting Furth and Joseph Furth have handled X-11 advertising since its inception, and played an active role in its development and dissemination. Advertising agencies are even less restricted in their ability to use similar deceptive practices in connection with other products than wholesale and retail distributors. Particularly mindful of Mr. Furth's open acknowledgement that "the pills will not reduce weight an iota" (CX 164), we find that an order applicable to all diet remedies should be entered against Mr. Furth and Kelly Ketting Furth. [36]

Finally, we reject Pay'n Save's contention that the order as to it should be confined to the advertising of X-11 tablets alone, and "should recite that Pay'n Save's lack of knowledge of, or reason to know of, the falsity or deception of any future ad will be a defense to

[45] It is not clear whether this product would be covered by the ALJ's proposed order or not, because the record does not reveal the product's composition.

[46] *See* n. 8, *supra* at 10.

[47] *Udga, Inc., and William Fraser and Mary Fraser,* F.T.C. Dkt. 2830, 24 F.T.C. 1245 (1937) (antacid deceptively advertised as a cure for ulcers) (Tr. 754). Mr. Fraser is also subject to a Commission consent order, *Ru-Ex, Inc.*, F.T.C. Dkt. C-1, 59 F.T.C. 839 (1961), which we do not consider in "aggravation," *ITT Continental Baking Co., Inc.* v. *FTC,* 532 F.2d 207, 223 (2d Cir. 1976), but in possible "mitigation" of the need for a broad order in this instance. We find that that order would not apply to diet remedies, since it is limited to products similar to the one sold as an arthritis or rheumatism remedy in that case.

any future charge" (RB 26). There is no such defense to Section 12 of the FTC Act and it would therefore be inappropriate to write such a defense into the order. Moreover, we believe that the order coverage should be expanded to include any food, drug, cosmetic, or device held out as a diet remedy As we have noted, X-11 is not a product uniquely suited to the dissemination of false advertisements promising weight loss. Pay'n Save has carried "several similar products" for many years (Tr. 507), and as a chain store retailer, Pay'n Save can easily shift its product lines.[48] Pay'n Save could as easily decline to examine "critically" the advertising copy of other distributors of diet remedies.[49] Finally, we note that Pay'n Save has been advertising X-11 since 1969 or 1970 (Tr. 508). We are not dealing with an isolated incident. These factors, and the apparent attraction in deceptively advertising diet remedies, exhibited by the Commission's experience of over 50 years in finding innumerable variations of this deception, *supra,* n. 8 at 10, justify a comprehensive order.

In short, we conclude that the order should not be limited to X-11, products of similar composition, or those containing PPA. We will enter an order as to Kelly Ketting Furth, Mr. Furth and Pay'n Save, applying to the advertising of any food, drug, cosmetic or device held out as a diet remedy. As to Porter & Dietsch and William H. Fraser, the order will apply to any food, drug, cosmetic or device.

These changes in product coverage will also apply to the constraints on the use of testimonials or claims of unique ingredients. We have further modified the order provision concerning testimonials so as simply to prohibit [37] respondents from representing directly or by implication that the testimonial reflects the typical experience of users of the product unless, in fact, it does. In addition we would observe that even where respondents do not represent that a testimonial reflects the typical experience of users, respondents may not employ testimonials which reflect the unusual experience of a tiny minority to suggest that a product is generally efficacious, when in fact it is not. To underscore this point, we have expressly noted in order paragraphs I A. and I B. that testimonials, among other devices, may not be used to effect the misrepresentations prohibited by those paragraphs.

We think the proposed order provision, however, is unnecessarily broad. To prevent further deception as to the need to adhere to a

[48] Pay'n Save sells "literally thousands of products" (RRB 15), and disseminates 30 or 40 advertisements prepared by its suppliers (Tr. 514, 566). The record does not reveal how many of these 30 or 40 products are foods, drugs, cosmetics or devices sold as diet remedies.

[49] *See generally* Tr. 501-577. *See also Kraftco Corp.,* F.T.C. Dkt. 9035, 89 F.T.C. 46 (1977), 3 CCH Trade Reg. Rep. ¶21,263 at p. 21,170 n. 6, *appeal pending,* No. 77-4078 (2d Cir.); *Tashof* v. *FTC,* 437 F.2d 707, 715 (D.C. Cir. 1970).

restricted diet we will prohibit respondents from representing directly or by implication that the testimonial is the typical experience of users of the product unless, in fact, the testimonial is the typical experience of the users of the product.

Finally, we find four order provisions to be unnecessary or somewhat misdirected. First, the ALJ proposes to prohibit further unsubstantiated diet remedy advertising with an order provision applying to X-11 or "any other product potentially affecting human health or safety" and requiring "adequate, well-controlled scientific tests accepted as such by the Federal Trade Commission" as substantiation for efficacy claims. The substantiation, including the "original data" supporting any tests, would have to be furnished to the Commission in advance "as documents available for public inspection," and copies of summaries of the test results and methodologies employed would have to be made available through the mail on request. The availability of the summaries would have to be disclosed clearly and conspicuously in advertising (I.D. p. 112–113).

We have eliminated the requirements that respondents pre-clear their substantiation materials with the Commission before disseminating them to the public and that they prepare and distribute summaries of such materials. Although respondents have made little effort to substantiate their claims, we doubt that a pre-clearance procedure for their future advertising copy is needed or desirable, and we doubt that most consumers would care to see the details of respondents' substantiation. More probably, consumers would prefer to be in a position to rely on the advertising claims without the trouble and expense of investigating the substantiation for themselves. Therefore, we believe that it would [38] be sufficient to require adequate substantiation for advertising claims and to require respondents to submit compliance reports for five years, so that the Commission can assure itself, in light of respondents' past disregard for the requirements of our statute, that the order is being obeyed. The order will be modified accordingly.

Second, the proposed order would also require respondents to reveal the amount of weight loss, on a "per-week basis" that might be expected from the use of X-11 or similar products, based upon "adequate, well-controlled scientific tests" if weight loss is advertised as a result of use of the products (I.D. pp. 114–115). As the record indicates, "per-week" weight losses may be deceptive because initial weight losses in the course of a dietary regimen generally are not sustained for an extended period (I.D. 68, 76–77, 83, 95, 107, 120). In addition, we believe that a requirement that respondents possess

adequate substantiation for their advertising claims including general claims will suffice to correct the deceptions we have found. We will therefore omit this provision from the order.

Third, the ALJ proposes that the Commission require an affirmative disclosure of the need to diet, the lack of evidence that significant or lasting weight losses will be assisted, and the FDA-mandated label warning in all advertising of X-11 or similar products. We agree that, to prevent further deception, consumers should be told that X-11, products of similar composition, and products containing PPA (or methylcellulose) will not assist in weight loss without adherence to a restricted diet, and may not in any way promote significant or lasting weight losses. Any advertising of such products as diet remedies without affirmative disclosure of these facts would be misleading to consumers, who, as we have found, may be expected to purchase diet remedies to avoid the self-discipline of low-[39]calorie diets. The mere holding out of such products as diet remedies without these disclosures would therefore be misleading.[50] A majority of the Commission[51] also agrees that future advertising for X-11 or similar products should warn of the health risks associated with its use. However, it believes a disclosure less lengthy than the FDA-mandated warning will provide consumers with adequate notice. The order provision is accordingly modified.

Fourth, the ALJ would also prohibit respondents from "attempting to mislead or misleading the public that a 'plan,' 'regimen' or 'program' is being offered when in truth respondents are simply marketing X-11 tablets, or one of the foregoing preparations, products, or aids" (I.D. p. 115). The deception is not in the offering of a "plan," but in the failure to disclose that the "plan" involves a stringent diet. We will enter an order requiring disclosure of the need to diet and will omit the ALJ's proposed order provision.

We find that the other provisions of the order that the ALJ recommends are necessary and appropriate to insure that false and deceptive advertising is recalled and ceased.

An appropriate order is appended.

FINAL ORDER

This matter having been heard by the Commission upon the appeal of respondents from the initial decision, and upon briefs and

[50] Should the state of medical knowledge change and provide support for the efficacy of such products, respondents will, of course, be free to petition the Commission for a modification of the order under Section 3.72 of our Rules.

[51] Commissioners Collier and Clanton dissent from the Commission's decision on this issue for the reasons set forth in Commissioner Collier's separate views.

oral argument in support thereof and opposition thereto, and the Commission for the reasons stated in the accompanying Opinion having determined to sustain the initial decision with certain modifications:

It is ordered, That the initial decision of the administrative law judge, pages 1-111, be adopted as the Findings of Fact and Conclusions of Law of the Commission, except to the extent modified or otherwise indicated in the accompanying Opinion. [2]

Other Findings of Fact and Conclusions of Law of the Commission are contained in the accompanying Opinion.

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

ORDER

I

It is ordered, That respondents Porter & Dietsch, Inc., a corporation, its successors and assigns, and its officers, and William H. Fraser, individually and as an officer of said corporation; and the agents, representatives and employees of the foregoing respondents, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale, or distribution of any "food," "drug," "cosmetic" or "device" (as these terms are defined in the Federal Trade Commission Act) in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, shall forthwith cease and desist from:

A. Representing orally, in writing, or in any manner, directly or by implication, including through the use of testimonials that a user of such a product can lose weight without restricting his or her accustomed caloric intake or while he or she continues to eat the foods of his or her choice (or words or depictions of similar import or meaning);

B. Representing orally, in writing, or in any manner, directly or by implication, including through the use of testimonials that a user of such a product can achieve any result, unless at the time such representation is made it is fully and completely substantiated by competent scientific or medical tests or studies, with the results of the tests or studies, the original data collected in the course of the test or study (if performed by or at the request of or with financial assistance from any respondent), and a detailed description of how the test or study was performed available in written form for inspection by the Federal Trade Commission for at least three years following the final use of the representation; [3]

C. Representing orally, in writing, or in any manner, directly or by implication, that any testimonial for any such product represents the typical or ordinary experience of members of the public who use the product unless this is the case.

D. Representing orally, in writing, or in any manner, directly or by implication, that any such product contains one or more unique ingredients or components, unless respondents can establish that any such ingredients or components are unavailable in products sold by others.

E. Disseminating or causing to be disseminated by United States mail or by any means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement for any such product containing phenylpropanolamine hydrochloride or similar ingredients with similar properties, or methylcellulose (whether or not such products contain other ingredients as well) or any product held out as a diet remedy or other remedy for the reduction of human body weight unless such advertising "clearly and conspicuously" (in print at least as large as the largest print appearing in the advertising or, in an oral presentation, in speech as clear and distinct as that delivered in the rest of the presentation) discloses the following statements, with nothing to the contrary or in mitigation of these statements:

DIETING IS REQUIRED
and
WARNING: THIS PRODUCT POSES A SERIOUS HEALTH RISK FOR SOME USERS. READ THE LABEL CAREFULLY BEFORE USING.

[4] II

It is further ordered, That respondents Kelly Ketting Furth, Inc., a corporation, its successors and assigns, and its officers, and Joseph Furth, individually and as an officer of said corporation; and Pay'n Save Corporation, a corporation, its successors and assigns, and its officers, agents, representatives; and employees of the foregoing respondents, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, of any "food," "drug," "cosmetic," or "device" (as these terms are defined in the Federal Trade Commission Act) held out as a diet remedy or other remedy for the reduction of human body weight, shall forthwith cease and desist from disseminating or causing to be disseminated by United States mail or by any means in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, any advertisement which contains a representation or testimonial for such product prohibited by Paragraph I of this order,

or which omits a disclosure for such product required by Paragraph I of this order.

III

It is further ordered, That each respondent forthwith deliver a copy of this order to each of its own operating divisions and subsidiaries, to all present and future personnel of respondents engaged in the preparation, creation or placing of advertising of foods, drugs or devices on behalf of respondents, and to all present and future agencies engaged in the preparation, creation or placing of such advertising for respondents, and that respondents secure from each such person and agency a signed statement acknowledging receipt of said order. [5]

IV

It is further ordered, That respondents immediately recall and retrieve, from all persons and entities that have engaged in the advertising or promotion of X-11 tablets within the past two years, all advertising mats and promotional material which contain a representation or testimonial prohibited by this order or which omit a disclosure required by this order. Respondents Porter & Dietsch, Inc., and William H. Fraser shall also deliver written notice of the requirements of this order to all distributors and retailers of products marketed by said respondents, and shall institute a program of continuing surveillance adequate to reveal whether they are complying with said requirements including the above recall provision. In the event that nonconformity with any such requirements is discovered, said respondents shall immediately cease supplying all products to said distributors or retailers until adequate, reliable assurance of conformity is obtained.

V

It is further ordered, That all respondents, their successors and assigns, shall maintain complete business records relative to the manner and form of their compliance with this order. Respondents shall retain each such record for at least three years, and shall retain for at least two years beyond the last dissemination of any representation or testimonial the documentation in support of and on which respondents relied in making such representation or testimonial. Upon reasonable notice, respondents shall make any and all such records available for inspection and photocopying by authorized representatives of the Federal Trade Commission at

respondents' place of business. For respondents Porter & Dietsch, Inc., and William H. Fraser, such records shall include (but not be limited to) all advertising, sales memoranda, the substantiation for all applicable advertising claims, correspondence with persons who place advertising, and other pertinent documents. [6]

VI

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

VII

It is further ordered, That each individual respondent named herein for a period of five (5) years from the effective date of this order promptly notify the Commission of the discontinuance of his present business or employment and/or of his affiliation with a new business or employment. If applicable each such notice shall include the respondent's new business address and a statement of the nature of the business or employment in which he is newly engaged as well as a description of his 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.

VIII

It is further ordered, That the respondents herein shall, within sixty (60) days after service of this order, and annually for five years thereafter, file with the Commission a written report setting forth in detail the manner and form of their compliance with this order. The expiration of the obligation to file such reports shall not affect any other obligation arising under this order.

Separate Statement of Commissioner Calvin J. Collier in which Commissioner David A. Clanton Concurs

There are certain specific portions of the majority decision from which I dissent. They are footnoted in the decision. My reasons follow.

Safety of X-11 The majority affirms the ALJ's decision that

respondents' failure to include FDA's required label warning message in their advertising violated duties imposed by sections 5 and 12 of our statute.

There is little evidence in this record to distinguish this case from all others in which health warnings are required to be or are voluntarily placed on packaging but are absent from advertising. The ALJ found that certain of the contraindicated medical conditions for PPA occur more frequently and with greater severity among the obese and overweight than in the population generally (I.D. 136). However, the correlations were not quantified, and nothing else is revealed about the conduct or behavior patterns of this population in relation to OTC drug use in general or weight reduction preparations in particular.

In other contexts, we have recently determined to deal with the relationships between mandatory labeling and advertising disclosures through rulemaking.[1] In the absence of other circumstances, this approach has several important advantages. For example, it permits interested persons to comment on such issues as the comprehensibility of labeling requirements communicated through other media and the net incremental health benefits of advertising disclosures. Finally, PPA, the ingredient of X-11 which precipitated the package insert warning, is found in a variety of over-the-counter drugs including other weight reduction preparations [2] and common decongestants.[2] In sum, I do not believe this case provides a sound factual or jurisprudential foundation for the majority's holding.

APPENDIX

The Findings of Fact and Conclusions of Law set out in the Initial Decision of the administrative law judge are adopted by the Commission except to the extent they are qualified or supplemented in the Commission's Opinion and in the Appendix.

The following Findings in the Initial Decision are modified as indicated:

I.D. 44: After "Tiny Tablet" in the seventh line of the finding, add:

(CX 1, 2, 11, 35, 46-48, 50, 52, 56, 58, 61-62 ["X-11 is the PROVEN and SOUND method . . ."], 74, 79)

At the end of the finding, add:

Some advertisements referred to "clinic tested ingredients" (CX 47, 49, 74); or stated that "The X-11 Reducing Plan is medically recognized as an effective plan to lose ugly fat" (CX 74).

---

[1] *See* Advertising for Over-the-Counter Drugs, 40 F.R. 52, 631 (1975); and Advertising for Over-the-Counter Antacids, 41 F.R. 14,534 (1976).

[2] Tr. of oral argument 46 (September 29, 1976). FDA is considering a monograph recognizing the drug as an effective nasal decongestant, 41 F.R. 38,400 (1976).

I.D. 60: Add, after "*supra*" in the last line, "and the following additional materials." Strike "(CX 122-26)" and substitute "(CX 122-130)." Substitute a colon for the period concluding the finding and add:

"(1) a hand-written statement that a Dr. Necheles believed that methylcellulose expands in the stomach (CX 125);
(2) a biographical sketch of Dr. Necheles (CX 126);
(3) a photocopy of a two-page statement edited by a Dr. Cyril Mitchell MacBryde, to the effect that obesity leads to increased mortality rates (CX 127);
(4) a photocopy of a two-page "product information" sheet from the Dow Chemical company describing its methylcellulose product, specifically how aqueous solutions of the product might be prepared, and describing the properties of such solutions (and mentioning that the product swells with hydration) (CX 128);
(5) a photocopy of two pages, one of which has been labeled, by hand, "U.S. Dispensatory," which indicates, among other things, that methylcellulose is "used as a laxative in chronic constipation," "imparts a sense of fullness in the patient," and "is sometimes employed in preparations intended to curb appetite in obese persons" (CX 129); and
(6) a photocopy of a letter dated February 24, 1969, from a "Butterfield Laboratories" which concluded that "methylcellulose when wetted does swell like a sponge" and that the 1967 edition of *Drugs of Choice,* edited by Walter Modell, indicated that "methylcellulose has been suggested as an appetite satiator for the treatment of obesity" (CX 130)."

Finally, add: "In addition, in his letter Mr. Gettleman mentioned two letters which FDA had written to other companies in 1957 concerning the labeling of products containing PPA, copies of which have been introduced into evidence as RX 16 and RX 17."

I.D. p. 94: Strike "relied on the *Carlay* case and" in the third line of the first full paragraph.

We make the following additional findings of fact:

In the course and conduct of its business, Pay'n Save has caused X-11 advertisements to be published in media of interstate circulation and has used means and mechanisms of interstate commerce in doing so (Admissions of Pay'n Save, Nos. 15 and 16b; Stipulations, Tr. 115-116, 377-380, 428-434; Answer of Pay'n Save, ¶6).

In the course and conduct of their business, Porter & Dietsch, Inc. and William H. Fraser cause advertisements for X-11 to be published in media of interstate circulation (Answer, ¶6, p. 7). They have used and continue to use means and mechanisms of interstate commerce in doing so (Admission No. 16a).

In the course and conduct of their business, Kelly Ketting Furth and Joseph Furth cause advertisements for X-11 to be published in media of interstate circulation (Answer, ¶6, p. 7). In doing so, they have used and continue to use means and mechanisms of interstate commerce (Admission No. 16c).

IN THE MATTER OF

FRUEHAUF CORPORATION

Docket 8972. Interlocutory Order, Dec. 21, 1977

Order requiring filing of memoranda pertaining to the issue of appropriate relief.

ORDER REQUIRING MEMORANDA ON ISSUE OF RELIEF

The Commission has taken this matter under advisement upon the appeal of respondent's counsel from the initial decision of the administrative law judge. The Commission has as yet made no determination as to liability. The Commission notes, however, that respondent has suggested in its brief that assuming *arguendo* that a violation of law is found, the Commission should consider requiring less than total divestiture of the acquired company, Kelsey-Hayes.

The question of appropriate relief in a matter is one which should ordinarily be addressed as part of the trial on the merits, so as to minimize the delay in obtaining such relief if a violation should be found. This is especially so where the extent of any violation which may ultimately be found is clear in advance of a finding of such violation. In this matter, for example, any violation found must be predicated upon Fruehauf's acquisition of Kelsey-Hayes' manufacturing capacity in one or two markets, heavy-duty wheels and/or antiskid braking devices. Accordingly the parties should be able to specify in advance of any ultimate finding of liability the contours of a remedy involving partial divestiture. [*Compare Warner-Lambert Co.*, 88 F.T.C. 503 (1976) wherein the ultimate finding of violation was predicated upon only a small fraction of the submarkets in which violations were initially alleged.]

In order to consider respondent's contention that partial divestiture would be appropriate assuming a violation is found, without, however, prolonging the time necessary for resolution of this matter, the Commission will order the parties to file supplemental memoranda on the question of an appropriate partial divestiture. The memoranda should not introduce new evidence but should cite relevant evidence already of record. They should discuss, *inter alia,* (1) the percentage of Kelsey-Hayes' assets and sales accounted for by its manufacturing capacity in the relevant markets and (2) the divisibility and independent viability of the assets which would be subject to any order of partial divestiture. Both parties shall also submit a proposed form of order which they believe suitable to effect a partial divestiture if such should be ordered. Submission of such an order, is, of course, without prejudice to the contention of respondent

that no violation has occurred and of complaint counsel that full divestiture is the appropriate remedy.[1]

Each side shall have 30 days from the date of receipt of service to submit its initial memorandum, and thereafter shall have 15 days from the date of receipt of the other side's memorandum within which to submit a reply.

Therefore, *it is ordered,* That within 30 days from the date of service of this order, each party shall file with the Commission a memorandum pertaining to the issue of appropriate relief in this matter, as described hereinabove. Thereafter, each party, within fifteen days after receipt of the memorandum of the other may file with the Commission a reply thereto.

[1] In issuing this order we have taken into account the contention of complaint counsel that a presumption should favor total divestiture in merger cases, because the acquired entity is more likely to prove viable upon divestiture (having proven viable before its acquisition) than some arbitrarily created sub-entity with no prior market history. We believe this argument is correct, and that the burden rests with respondent to demonstrate that a remedy other than full divestiture would adequately redress any violation which is found. However, complaint counsel when preparing their memorandum should assume, *arguendo,* that some partial divestiture may be deemed appropriate, and discuss what form it should take.