DECEPTION AND FRAUD IN THE DIET INDUSTRY
PART I

HEARING
BEFORE THE
SUBCOMMITTEE ON REGULATION, BUSINESS
OPPORTUNITIES, AND ENERGY
OF THE
COMMITTEE ON SMALL BUSINESS
HOUSE OF REPRESENTATIVES
ONE HUNDRED FIRST CONGRESS
SECOND SESSION

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## CONTENTS

Hearing held on March 26, 1990 ................................................................................... 1

### WITNESSES

**Monday, March 26, 1990**

<table>
<thead>
<tr>
<th>Witness</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Callaway, C. Wayne, M.D.</td>
<td>40</td>
</tr>
<tr>
<td>Householder, Carol, AZ</td>
<td>31</td>
</tr>
<tr>
<td>Johnson, Ray, assistant attorney general, State of Iowa</td>
<td>47</td>
</tr>
<tr>
<td>Pameijer, Loretta, Miami, FL</td>
<td>28</td>
</tr>
<tr>
<td>Steiger, Janet D., Chairman, Federal Trade Commission, accompanied by Barry Cutler, Director, Bureau of Consumer Protection</td>
<td>5</td>
</tr>
<tr>
<td>Steinberg, Sherri, Coral Springs, FL</td>
<td>26</td>
</tr>
<tr>
<td>Wellman, Nancy S., Ph.D., president, American Dietetic Association</td>
<td>51</td>
</tr>
</tbody>
</table>

### APPENDIX

Additional material submitted for the record:

<table>
<thead>
<tr>
<th>Source</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marketdata Enterprises, The U.S. Weight Loss &amp; Diet Control Market</td>
<td>156</td>
</tr>
<tr>
<td>National Council Against Health Fraud, Guidelines for Evaluating Commercial Weight Loss Programs</td>
<td>182</td>
</tr>
<tr>
<td>News from Congressman Ron Wyden</td>
<td>183</td>
</tr>
<tr>
<td>Subcommittee staff memo and miscellaneous brochures submitted to Chairman Wyden</td>
<td>185</td>
</tr>
<tr>
<td>Wall Street Journal, article</td>
<td>284</td>
</tr>
</tbody>
</table>

Prepared statements:

<table>
<thead>
<tr>
<th>Speaker</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Callaway, C. Wayne, M.D.</td>
<td>109</td>
</tr>
<tr>
<td>Householder, Carol</td>
<td>106</td>
</tr>
<tr>
<td>Johnson, Ray</td>
<td>132</td>
</tr>
<tr>
<td>Pameijer, Loretta</td>
<td>101</td>
</tr>
<tr>
<td>Steiger, Janet D.</td>
<td>68</td>
</tr>
<tr>
<td>Steinberg, Sherri, with attachments</td>
<td>93</td>
</tr>
<tr>
<td>Wellman, Nancy S.</td>
<td>149</td>
</tr>
<tr>
<td>Sisisky, Hon. Norman, opening statement</td>
<td>65</td>
</tr>
</tbody>
</table>
DECEPTION AND FRAUD IN THE DIET INDUSTRY—PART I

MONDAY, MARCH 26, 1990

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON REGULATION, BUSINESS
OPPORTUNITIES, AND ENERGY,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2359-A, Rayburn House Office Building, Hon. Ron Wyden (chairman of the subcommittee) presiding.

Chairman WYDEN. The subcommittee will come to order.

Today, the subcommittee continues its 3-year-long inquiry into fast-growing health care industries that have dramatically changed the $600-billion-per-year medical marketplace.

Fueling this extraordinary growth has been hard-sell advertising and Government deregulation. This subcommittee has found the medical field is riddled with hucksters who ply their dubious wares and their miracle cures, while Government regulators sit snoozing on the sidelines.

This morning, the subcommittee will inquire into the $33-billion-per-year diet industry, another largely unregulated health business which touches the lives of 65 million Americans.

While potions and weight-losing nostrums have been around for generations, our research indicates that a new mix of questionable products, untrained providers, and deceptive advertising is exposing our citizens to unexpected and unnecessary health risks.

This subcommittee is particularly concerned about commercial weight-loss clinics and physician-supervised weight-loss programs.

Many products peddled in commercial clinics are untested, with little or no scientific proof of their safety and effectiveness.

Most lay counselors and specialists in commercial diet clinics are undertrained lay people operating without any medical supervision. There are no minimum standards for their qualifications.

Most commercial clinics promise fast, safe, easy weight loss. Most experts agree that fast weight loss is dangerous in and of itself. Further, little research has been done to show what does and does not work for each individual, according to the Surgeon General's Report on Health and Nutrition.

"The recent and zealous marketing of various formula products to physicians, as well as the public's appetite for such diets could lead to yet another round of complications and fatalities," accord-
According to the American Medical Association's Council on Scientific Affairs.

Such formula products include various low-calorie liquid diets.

Sixty percent of medical school graduates don't get adequate training in nutrition, leaving them often without even a basic understanding of the complicated physiological and psychological factors in obesity, according to the Association of American Medical Colleges in 1984.

"A lot more depends on how good your marketing is than on your product," according to one industry consultant.

Armed with a new tool—the 30-minute paid TV ad called an "infomercial"—some entrepreneurs are rushing to cash in on our national preoccupation with never-too-thin role models.

The National Council on Health Fraud calls these ads that gain credibility through the use of talk show and news formats an "abuse of public airways."

Impressive so-called doctors, complete with white coats and stethoscopes, tout original clinical studies and scientific breakthroughs with dramatic testimonials from grateful former patients.

Citing the proliferation of commercial weight-reduction clinics, Dr. Antonio Gott, former president of the American Heart Association, warned of the need for a "strong caveat emptor" in choosing among these clinics.

He also cautioned that clinic programs should be preceded by "careful medical and behavioral assessments." Our research shows that few Americans get even a cursory physical.

Overall, "the unregulated multibillion dollar weight-loss industry is placing our citizens at significant health risk," according to a special task force assembled by the Michigan Health Council in 1989.

For its part, the Food and Drug Administration is supposed to stop misbranded diet gadgets, drugs, foods, or products that are actually tainted. They can claim credit for a few notable cases, including the diet patch and the starch blocker diet pills.

Their health fraud pamphlets for consumers are important efforts to educate consumers about the rising scammer evident almost continually when one opens the newspaper or turns on the TV.

Today, I am releasing an FDA proposal for a landmark survey of the weight-loss industry. Calling existing gaps a serious handicap, 5 years ago, FDA went to the Office of Management and Budget to get the go-ahead to find out which diet products and services work and which don't, who chooses what kind of products and why, and how to develop effective preventive and ongoing treatment strategies.

OMB sent the request back, and despite FDA's own conclusion that, "The consequences of not collecting the information will be delay and inefficiency in implementing," the project languishes at FDA.

That goal was "a reduction in the incidence of obesity for Americans," an objective that was a "primary nutrition goal" missed in 1990, and now has been reset for 2000.

We will be calling FDA to testify on its Weight-Loss Practices Survey, and we intend to get it dislodged. We also want to know
why the regulations on over-the-counter drugs—many of them weight-loss products—still sit in proposed form after 8 years on the shelf.

Another Federal agency, the Federal Communications Commission, has abandoned many of its environmental responsibilities over the last decade. As weight-loss products and clinics have increasingly turned to the airwaves, the FCC has turned its back on the growing abuses.

In an embarrassing disclosure to Congress last year, commission officials even asserted they did not “watch television,” to assure truth in advertising.

A January 1990, FCC ruling limiting entertainment options to cablecasters will invite more entrepreneurs to use the half-hour infomercial. Ironically, the FCC decision has put stations in a position of needing those pitchmen to keep revenues up.

That finally brings us to the Federal Trade Commission. While I agree with FDA’s Office of Consumer Affairs that “health fraud is too big and complex a problem for any one organization to combat by itself,” putting a halt to false and deceptive advertising could go a long way.

But despite the burgeoning deception and danger, the previous FTC—particularly under Chairman Daniel Oliver—has let the consumer protection program crumble, while the hucksters multiplied.

In the name of promoting competition in health care, Mr. Oliver fostered an environment that led to a buyer beware medical marketplace in which the scam artists could claim virtually anything with impunity, and did.

State medical boards told the subcommittee that their lawyers advised them that if they moved forcefully against deceptive medical advertising, they could be sued by the FTC under Chairman Oliver for restraint of trade. Several professional medical societies testified that they had the same fears.

Mr. Oliver told this subcommittee that the States and the boards were merely “confused.” But when he testified to this, he couldn’t get the majority of his fellow Commissioners to support his views on medical advertising.

In fact, his policies so warped the notion of legitimate competition that two of his fellow Commissioners filed what amounts to dissenting views on the issue with the subcommittee.

Commissioner Azcuenaga informed this subcommittee that the FTC had “undercut the ability of States to stop fraud and deception.”

Commissioner Strenio cautioned that the Commission “should not impinge upon the States' valid interest in ensuring that consumers receive high quality services from professionals.”

Commissioner Azcuenaga emphasized the importance of professional societies and peer review in determining professional competence, and while acknowledging the potential for antitrust activities, she warned that, “The Commission must take care to avoid imposing undue restrictions that will preclude these organizations from carrying out legitimate efforts to regulate the performance of health care professionals.”

Clearly, Mr. Oliver was not able to achieve a proper balance between promoting competition and stopping abuses.
So, it is hardly surprising that the hucksters have flourished, and it is no surprise that the 13 weight-loss cases the FTC has brought since 1980 focused on the gadgets and gimmicks—the Gut Buster and the Fat Magnet, to name a couple.

While we are pleased to see any action from this agency, no FTC case to date has tackled the potentially greater threats, the growing trends toward commercial weight-loss clinics and physician-supervised diet programs. Nor has the FTC acted in the diet or to police the new tin-men of television—the infomercial.

The Chair believes in competition, including competition to drive down medical costs. But our Government ought to get out of the business of encouraging competition at the expense of its citizens' health and safety.

There is a new chairwoman at the FTC, confirmed not long ago by the Senate. The Chair has met with Mrs. Steiger to discuss the Commission's future approach on these critical issues, and we are pleased to have Mrs. Steiger as a witness today.

We will also hear witnesses testify today who have suffered from injuries resulting from their weight-loss regimens, and we will hear from some others' families. We will hear from health industry experts who will raise serious questions about the safety and effectiveness of some of these diets.

We are going to welcome Mrs. Steiger. We've been looking forward to your testimony. I am very pleased that the ranking minority member, a very good friend and Member of Congress whom I particularly enjoy, a gentleman from Michigan, Mr. Broomfield, is with us today.

Mr. BROOMFIELD. Thank you very much, Mr. Chairman.

I want to compliment you on your opening statement. You certainly have outlined the importance of these hearings, and I want to also join you in welcoming Mrs. Steiger, whom I have known for a long time.

She does bring new emphasis to consumer protection, and I think the administration is very fortunate, and our Government is very fortunate to have a lady of her ability to head this important work.

I look forward to the witnesses today. This is a subject that I know concerns a lot of us. I don't take any diet pills myself, but my wife keeps telling me I should at least do more exercise. I know that many Americans are very interested in this subject.

So, with that, I would like to get on with the hearing.

Chairman WYDEN. Thank you, Mr. Broomfield.

Mrs. Steiger, before we turn to you for testimony, the subcommittee staff would like to show a brief 2- or 3-minute diet infomercial called the Diet of the Stars. It will take just a couple of minutes, and if the staff can get the lights, that would be helpful.

[Video film shown.]

Chairman WYDEN. Let us just note for the record that our colleague, Norman Sisisky from Virginia, couldn't be with us today. He has been the leader in the effort to deal with infomercials, an issue that we will be focusing on in the health context as well.

He asked that his statement be included in the record, and without any objection, that will be done.

[Mr. Sisisky's statement may be found in the appendix.]
Chairman Wyden. Mrs. Steiger, we welcome you to the subcommittee. We are very pleased that you have come as Chair to the commission. I have enjoyed meeting with you in the office, and I think this is a particularly important time for you to outline new directions at the Commission.

It has always been the practice of our subcommittee to swear all witnesses before this subcommittee. Do you have any objection to being sworn?

Mrs. Steiger. No.

Chairman Wyden. Please raise your right hand.

[Witness sworn.]

Chairman Wyden. We will make your prepared remarks a part of our hearing record in their entirety, and if you would like to proceed in any fashion that you think adequately addresses the Commission's concerns, that would be very helpful.

Let me also note, you have with you Mr. Cutler. Mr. Cutler, do you anticipate responding to any of the questions I may pose to Mrs. Steiger?

Mr. Cutler. Depending on the questions, that is always possible.

Chairman Wyden. All right. Let's swear you, as well.

[Witness sworn.]

Chairman Wyden. Mrs. Steiger, please proceed.

TESTIMONY OF JANET D. STEIGER, CHAIRMAN, FEDERAL TRADE COMMISSION, ACCOMPANIED BY BARRY CUTLER, DIRECTOR, BUREAU OF CONSUMER PROTECTION

Mrs. Steiger. Thank you, Mr. Chairman, for my welcome this morning, and a special thanks to Mr. Broomfield for his kind words.

I am pleased to be here today to discuss Commission actions.

Chairman Wyden. Mrs. Steiger, I am sorry. I think that microphone is going to be a problem all day. If you could speak right into it, that would be great.

Mrs. Steiger. I am delighted to be here to discuss Commission acts to combat deceptive claims for weight-loss products and programs.

With the chairman's permission, I will briefly summarize the prepared statement and submit the full statement for the record.

The Commission has authorized submission of that prepared text. As always, however, I want to make a disclaimer that my remarks and responses represent my views and not necessarily those of the Commission or other Commissioners.

Chairman Wyden. Let's pull that microphone down just a little bit. That will do it.

Mrs. Steiger. The commission has an important, longstanding commitment to protecting the public from the deceptive marketing of health care products and services, and, as part of this effort in the past year, FTC staff has worked closely with you and with your staff, Chairman Wyden, and we look forward to continuing this relationship.

As you have indicated, many adult Americans are overweight, raising two areas of concern. One is cosmetic, a concern for appearance, and the other is the health risk caused by extra pounds.
At any given time, more than 20,000,000 Americans are on a diet, and last year, Americans spent over $32,000,000 on products and services ranging from artificial sweeteners to weight-loss clinic programs.

Unfortunately, as anybody knows who has tried it, losing weight is not easy and thus consumers are highly receptive to aids for quick and easy ways to shed pounds.

Many people lose money, but some diet plans can also pose health risks. Since 1926, the Commission has devoted significant resources in this area, bringing more than 80 false or deceptive weight-loss claims cases.

Over the years, product names have changed and the substances are different, but the advertising claims have a common theme in their promise of effortless weight reduction.

In the 1970's, to reemphasize its commitment in this area, the Commission brought two significant enforcement actions. The first involved a weight-loss product which was falsely promoted as allowing users to lose weight without restricting their caloric intake.

The Commission's order reaffirmed in the dieter the requirements that advertisers must have a reasonable basis and adequate scientific support for their claims.

The second suit was against a chain of medically supervised clinics for their use of the "Simeon" method for weight reduction.

The Commission required the disclosure in advertising and to each respective patient that the program involved injections of a prescription drug that had not been approved by the FDA as safe and effective for the treatment of obesity.

In the last 10 years, the Commission has brought 12 actions involving the entire gamut of weight-loss products from diet pills, to dietetic foods, to a starvation binge diet plan, to various devices.

Let me highlight just a few of the cases. In the mid-1980's, the Commission successfully sued a mail order diet plan called the "The Rotation Diet." This was the starvation binge diet planned with claimed psychological underpinnings.

Dieters were told they could eat virtually unlimited quantities of any food they wished and still lose substantial weight if for the other 3 days they followed a severely restricted low-calorie diet.

Most people, however, did not lose weight. More significant, such diets are considered potentially harmful. The Commission prohibited the company from making such claims, and, in fact, it is no longer in business.

In 1988, the Commission charged a nationwide chain of more than 1,100 health food retail outlets with making deceptive claims that users of its amino acid and growth hormone food supplements would lose weight, retard aging, or build muscle.

The company was prohibited from making deceptive claims in the future and agreed to pay $600,000 for research in nutrition, obesity, or physical fitness.

In the last several years, the Commission has increased the severity of its enforcement efforts by filing injunctive actions in Federal court and seeking refunds for consumers or other remedies requiring discouragement of funds.

This approach was successfully used against Dream Away diet pills which claimed that by taking a pill upon going to bed, the
consumer would wake up slimmer in the morning. The company was required to send refunds to over 50,000 consumers, amounting to over $1.1 million.

In January, the Commission went into Federal court seeking to halt the claims that a diet pill trapped fat particles before they could become ugly, bulging fat.

We also challenged claims that no special diet or exercise was necessary and that the pills were "100 percent safe." The U.S. Postal Service, the FDA, and nine States' attorneys general assisted the Commission in developing this case.

Three other matters are in litigation before FTC administrative law judges involving an anticellulite body cream, a diet pill promoted as an appetite suppressant and high fiber supplement, and an exercise device call the Gut Buster.

There are other recent trends in the weight-loss services market. For example, some weight-loss plans involve very-low-calorie liquid diets that are dispensed to the public through hospitals that purchase the programs under licensing or franchising agreements from national distributors.

Others involve predetermined caloric intake goals that may also be combined with counseling and/or requirements that the diet food products be purchased as an integral part of the plan.

Because the liquid diet plans and other hospital-based plans are described as medically supervised, some consumers may view them as safer and more effective than other weight-loss products or plans.

We are aware, however, of the concerns that these liquid diet plans should be available only to persons who are severely overweight and require strict and frequent medical supervision by trained medical personnel.

We are also aware of studies that indicate that weight loss achieved by reducing caloric intake without an increase in the level of physical activity is rarely permanent.

Finally, it seems that obesity, weight loss, and their attendant health risks, present many complex scientific issues that need to be carefully evaluated.

We plan to continue to work closely with other Federal and State agencies and to seek expert advice to guide us in this important area.

As the record demonstrates, the commission is committed to combating deception about weight-loss products and services, but in the 1980's, the Commission's resources and staff were cut nearly in half, requiring the commission to divide its scarce resources into literally dozens of important law enforcement areas.

Within these constraints, the FTC's Bureau of Consumer Protection will continue to challenge deception by marketers of health care products and services, and we will be especially vigilant about deception involving the safety or efficacy of these products or programs.

As part of our health care initiative, headquarters and regional office staff will examine advertising claims made by the major diet clinic chains, as well as hospital- and physician-based weight-loss programs and recommend appropriate action.
We plan to work closely with the FDA, with whom we share jurisdiction in this important area, and we also share responsibility with the States' attorneys general in regulating in the advertising and promotion of products and services and with the State medical boards in regulating deceptive promotional claims by physicians.

In recognition of these shared responsibilities, the FTC working group of the National Association of Attorneys General recently established a staff level joint committee to discuss ways to improve enforcement against health fraud and deception.

In conclusion, Mr. Chairman, I wish to express again my support for your efforts to bring national attention to the problems presented by the deceptive promotion of health care services.

I also want to assure you that we will continue to work with you, with your staff, and the staff of the full committee, to eliminate fraud and deception in these areas.

Thank you, Mr. Chairman.

[Mrs. Steiger's statement may be found in the appendix.]

Chairman Wyden. Mrs. Steiger, thank you very much.

Mr. Cutler, did you want to make an opening statement?

Mr. Cutler. I have no opening statement. I would just observe that I am a veteran myself in the battle against the bulge, and since I am on the road, I would have to say that I have had many purple hearts.

Chairman Wyden. We thank you, and we appreciate your cooperation, as well.

Why don't we begin with questions. Mrs. Steiger, the gentleman from Michigan would like to begin.

Mr. Broomfield. First of all, I would like to compliment you, Janet, for your statement. I think you put a different perspective on the situation, the fact that the administration is concerned about what is happening.

I think the question I have is what more can we do? In other words, what do you have in mind that could improve the situation where we can get a better handle, particularly on the advertising aspect of this?

Mrs. Steiger. Well, the FTC staff is examining advertising claims in the whole weight-loss market, including, as I mentioned, the hospital-based clinic plans.

We understand the chairman has kindly offered to make some significant data available to us that the staff has collected, and we will be happy to analyze those and to continue.

I do think there are many arrows to this particular quiver. First of all, consumer education cannot be ignored. It's terribly important. One of the things we are attempting to do is catch as quickly as we can, what we feel to be possibly deceptive advertisements in this area, so that we can inform the public.

We are working very closely with the Alliance Against Telemarketing Fraud, a 60-member group, to attempt to get at the root of some of the telemarketing scams.

We have proceeded already with four formal cases in the commercial area, and we have others that are nonpublic that we think will come very quickly to fruition within the next month to 90 days, and this may have a deterrent effect as well. So, we are moving on as many fronts as our resources will allow.
Mr. BROOMFIELD. What about the State effort? I understood you to say 17 States are working in this area.

Mrs. STEIGER. I think I would say there are more States than that, but certainly the FTC working task force, the small subcommittee that NAAG has begun, is a start at attempting to see if there are joint areas of concern; if there are areas in which we can most effectively share our resources.

Mr. BROOMFIELD. That would be a good start; getting all of the States working together to come up with their own recommendations.

While I am not opposed to having the Federal Government getting involved, I think you must have some guidance in this area. I come from the old school where the best enforcement is done by the States and local communities, where they can keep on top of things more effectively than the Federal Government.

Is any thought being given to this aspect of enforcement?

Mrs. STEIGER. I think its very clear, and I have said many times since coming to the FTC, that at the critical front line in the consumer protection fight are the States' attorneys general, and the State consumer protection boards, and the local consumer protection boards.

I think you will hear from a representative of the States' attorneys general this morning that they share this very deep concern for consumer welfare across the board, but I would assume in this area, too.

So, yes; we want to do all that we can do to work cooperatively with the States and to assist the States. Many of these deceptive advertisements, particularly in the health care field, are local. That is why it's critical that local medical boards and local law enforcement agencies are active in it.

I agree with that.

Mr. BROOMFIELD. Do you have any new regulations in mind that should be formulated in view of this problem?

Mrs. STEIGER. We have worked with other committee staffs and continued to pursue some more authority in the area of telemarketing.

We have out for notice and comment, a provision that would extend our mail order rule to telemarketing, and we would like to see the ability of the agency to get physical CID's authority, which is often important in these kinds of cases. I believe I mentioned that to the chairman when we first talked, and there is also the question of venue, where we could coalesce cases into one jurisdiction.

It's often the case, particularly when products are advertised that are real scams, you may have multi-State involvement and defendants scatter very quickly. We have asked for some more authority in the telemarketing area, and I think we are getting a sympathetic hearing.

Mr. BROOMFIELD. Mrs. Steiger, how about penalties? Are you satisfied with the type of penalties we have on the books today for people who are found to use deceptive or unsubstantiated advertising?

Mrs. STEIGER. I think the levels of those penalties should be looked at again. The Commission has said that in the past, has
asked whether they are adequate for deterrent purposes. The question of clarifying whether disgorgement is or is not an appropriate remedy is also useful, I believe.

It has been some time since those penalty levels were set. I think they could be reviewed.

Mr. BROOMFIELD. Mr. Cutler.

Mr. Cutler. I am a former prosecutor, and while the FTC doesn’t have criminal jurisdiction, to the extent that we are talking about mail fraud and wire fraud, it would be nice to see other Federal and State agencies involved in these types of cases.

Unfortunately, as you know from S&L problems and drug problems, other agencies are as swamped as we are. But it’s an area for criminal enforcement as well as what we can add.

I have one other thought on the subject of these hearings; that is, the FTC does have expertise in advertising. In some of the programs that the chairman has referenced where we are talking about hospital-based or physician-based diet programs, it’s very easy to look, for instance, in the Tuesday Washington Post Health Section and see very, very simple, straightforward ads for one product or another, under the guidance of a hospital or physician.

Frankly, there is nothing on the face that is deceptive about those ads. It requires looking at the program itself, at the credentials of the doctors.

I understand that there is very little by way of credentialing, and that this panel will be hearing more about that.

While we intend to be very active in the enforcement of ads, to a very real extent, some of this involves medical practice where the public and, perhaps, even some physicians don’t have the background that they should for the kinds of diet products and services we are talking about.

Mr. BROOMFIELD. Mr. Chairman, that is all the questions I have at the moment.

Chairman WYDEN. All right. I thank the gentleman.

Mrs. Steiger, you and I had a chance to visit a little bit before your appearance here, and one of the reasons that I was so anxious to discuss with you where you were headed is that we had very profound disagreements with your predecessor.

My sense was that in the name of health care competition, he simply warped the doctrines that we would like to see and really permitted claiming any kind of advertising.

It was best symbolized by the fact that the majority of the Commission didn’t even go along with his views, and Commissioners were filing differing views, and what amounted to an unprecedented role for the FTC was developing with respect to health care advertising where the Commission couldn’t even agree among itself where it was headed.

I really would like to spend a few minutes talking to you about where we are headed.

My colleague from Michigan asked you about the penalty question. I am very pleased to hear you say that you wish to reevaluate the nature of the penalties.

That certainly is one way to send a strong message, and if we could, let’s spend a few minutes using the question of the diet pro-
grams and diet advertising as a way to look at where the Commission will be headed in the future.

It seems to me that every few years, almost on a cyclical basis, we see a boom in diet programs and diet advertising.

Do you share my view that we are right in the middle of a new boom in this field that is going to generate a great deal more revenue for entrepreneurs and those who try to tap it?

Mrs. Steiger. Well, certainly the evidence that has been brought before this committee of national concern with weight, with health in general, and the number of Americans who are dieting on a regular basis at any given time, would indicate this is a matter of substantial national interest.

Apparently, a boom like that has been going on for several years, but I think, certainly, public notice of it has increased, no doubt in part, sir, because of your focus on health concerns.

In the area of advertising in general, I would like to simply reinforce first, what Barry Cutler has just said. We do know that in many areas of hard core fraud, we are not the answer. Criminal enforcement is the answer, sir.

But given the scarce resources that all of us seem to share in the enforcement area, we are certainly going to continue to press here, because we can at least shut them down.

Even though we are not the best answer, we would certainly want to encourage more State and more Federal criminal enforcement where it's appropriate.

I consider the State medical boards to be a front line of defense against deceptive advertising. As I have mentioned, it's frequently a local issue, and they are the people best able to handle it.

To the extent that there remains any perception that the antitrust laws prevent the medical authorities from moving against false and deceptive advertising, we must again clarify that.

Our top staff of both the Bureau of Competition and the Bureau of Consumer Protection will be taking that message to the annual meeting of the Federation of State Medical Boards.

Further dialog will assist us in ensuring that, first of all, we work with the States where they have a question, and we can be advisory in these areas, and that we do believe that these local experts are truly the front line of defense against much of this deceptive and localized advertisement.

We can do our best job on national multi-State problems, and so we want to encourage this kind of interaction.

Chairman Wyden. We will have some questions on the role of the State boards in just a moment.

We are in agreement that we are in the middle of a new diet boom. My research indicates that the $33 billion in diets and diet products is likely to shoot up to about a $50-billion market over the next few years.

Do you have any research on that point?

Mrs. Steiger. I am not aware of it.

Mr. Cutler. We see what has been in the literature, but, of course, we also have the phenomenon that millions of Americans are on their own diets at any particular time, and they are largely unsupervised, and this isn't an area that requires medical treatment.
I suspect that the number of people who are dieting at any particular time is much higher than any reported figures.

Chairman Wyden. We will share with you the research we have. Market Data Enterprises indicates that there will be a 10.6-percent annual growth to $50.7 billion by 1995, is the information that we have.

The third concern that we have about the future of the market is that it seems that major national companies are the ones that are going to dominate in this field in the days ahead, and because that relates to the question of States and local jurisdictions to take on this oversight and this field, I wonder if you share that observation, that it’s going to be major national firms that are going to be the ones that aggressively go out and generate that growth up to $50 billion by 1996?

Mrs. Steiger. I would note that there are clearly some large national firms in existence now, and to the extent that your research would predict growth, it would be logical to presume that they will be in the forefront of the growth curve.

As I noted, we are examining advertising claims, including claims for the nationwide hospital-based clinics, and we are looking at that.

Chairman Wyden. Do you also share our view that the trend is toward the commercial diet clinics and these liquid diets that are supervised by physicians, Mrs. Steiger?

Mrs. Steiger. That seems to be the trend; yes. It does seem to be in the forefront from what we read in the literature and in the latest press.

Chairman Wyden. Both in hospitals and outside the hospitals, I gather?

Mrs. Steiger. Yes.

Chairman Wyden. We also have found that many of the products that are peddled in commercial clinics are untested, and there is little proof of their safety and effectiveness.

Do you all share that view?

Mrs. Steiger. I don’t know. On the question of the efficacy of a particular product, of course, it would be the FDA with the expertise. I know they have been struggling with the diet monograph for some 8 years now, as you noted.

We would certainly be in close touch on this question with the FDA. We have an ongoing liaison relationship. We have just met with Acting Commissioner Benson to make sure that it’s in place.

But on the analysis of the particular product, that would be a medical and an FDA determination.

Chairman Wyden. Do you think that there is widespread misrepresentation by individuals holding themselves out as experts, people who call themselves counselors and specialists.

For example, in commercial diet clinics, we have found indications that this really amounts to misrepresentation, and that citizens believe that these kinds of individuals are experts, and they really have no expertise, no minimum standard for qualifications.

Do you feel that there is misrepresentation by some of these so-called experts?

Mrs. Steiger. Well, to the extent that a company or an entity is using suggestive promotional materials that misrepresent experi-
ence or qualifications, we would want to look at it on a case-by-case basis to see if this does exist.

But it's a standard area of concern for our monitoring of advertising and promotion.

Chairman Wyden. Is the Commission looking at that now, because that seems to me not to be a question of regulating a product like the FDA? That is a question of misrepresentation, and our subcommittee has found that it's widespread.

Mr. Cutler.

Mr. Cutler. Well, that involves a variety of products and services. Of course, the most blatant services, where you could wear a patch, or lose while you snooze, or follow a number of other claims are obvious enough that my seventh or eighth grade daughters can see them on television and say, Daddy, why aren't you doing something about that? We say that we are.

But when you get into clinics or some of the other services that you are referring to, we get back to the credentialing process that we are talking about.

We have brought a case against a doctor on the Rotation Diet, binge for a few days and starve for a few days.

But to a large extent, we are talking about physicians, some of whom are working with the national companies that the chairman talked about, some of whom are just working alone in their offices. It's much harder for an agency like the FTC to determine the credentials of doctors who are making claims.

As I think you will hear from other witnesses, even among experts in nutrition and specialties in medicine, there is still a lot of disagreement about what programs work, and what doesn't, and why some people can lose weight and some cannot.

So, we are caught up, as the committee is, with a lot of medical expertise that is in disagreement.

Chairman Wyden. Mr. Cutler, we are not talking about subtle questions of credentialing among physicians. We are talking about people in these clinics who hold themselves out as experts with virtually no training at all. They may just have a handful of days worth of training.

Is the Commission concerned about this problem, and, if so, what is the Commission doing about it?

Mr. Cutler. We are very concerned about that, and in the diet center cases that we have pending, including a team effort involving some of our regional offices, we will be looking at that issue.

I understand just from background investigations that there are some of the national companies that will make it appear that the doctors are running the programs, and I have a concern that where the public—and this reflects the chairman's testimony—where the public believes that a qualified physician is running their program, they probably have a lower guard than if they are buying an over-the-counter product or just doing something on their own.

So, we would agree that when there is the appearance of a qualified expert doing a diet program or selling a diet product, it's particularly important for the public to have confidence that the individual is qualified.

Yes; we are concerned about that.
Chairman Wyden. How about claims with respect to success rates? You have said you are looking at the question of unqualified experts, and I am pleased about that.

Are you also concerned about exaggerated claims and misrepresentation about success rates?

Mrs. Steiger. The Commission has acted in the past in the area of success rates for infertility clinics, as you know. Where success rates can be material to the consumer, we are looking at whether there is substantiation, as we always do, through our ad substantiation program.

Success rates can be an important part of an examination of promotional and advertising materials.

Chairman Wyden. Is that part of the pending examination, Mr. Cutler?

Mr. Cutler. It will be with the ones that we are going into, as we discussed in your office. There are two questions. There is a safety question and the success question.

As you know, below 900, certainly below 400 calories a day, there will be medical experts who talk about the actual safety dangers in some of these programs.

From a commercial standpoint, success is a question that we need to look at, and I think you will hear testimony from other witnesses today that when a celebrity, television celebrity, or sports celebrity is able to talk about all the weight they have lost, the literature says that there is a rapid increase in the amount of interest that generates.

When the same celebrity puts the weight back on, we tend to blame it on lack of will power. I think it's only very recently in the literature, that we are learning that the problem may not be with will power but in the programs.

There hasn't been enough knowledge to get that perspective in the past, but I think it's developing now.

Chairman Wyden. I think that is helpful, as well. What we found is that most diet programs loudly proclaim these natural success rates, and fail to mention that few customers keep their weight off for even 1 year.

In both of those areas, it seems to me that we have to break new ground. Misrepresentation of success rates, and the questions of so-called experts, nonphysicians calling themselves counselors and the like, holding themselves out as having particular abilities that they clearly don't have.

I will have some more questions in a moment. But let me recognize my colleague from Michigan again.

Mr. Broomfield. Mr. Chairman, I have just one question. Mrs. Steiger, you indicated that staff and budgetary constraints make regulating very difficult. How many individuals at the FTC are involved in monitoring false and deceptive advertising now?

Mrs. Steiger. Well, our whole Bureau of Consumer Protection is involved in it in one way or another, and when there are questions that may raise antitrust concerns, then you will have additional help from the Bureau of Competition staff.

So, there are around 350, I would say, in the Bureau of Consumer Protection, and then our regional offices play an important role, and there are roughly 125 people in the region.
That is still half of where this Commission was about 8 years ago.

Mr. Broomfield. I see.

Mrs. Steiger. Resources remain a serious concern.

Mr. Broomfield. Do you feel that these should be increased substantially?

Mrs. Steiger. We had hoped that the budgetary mark given us by the Appropriations Committee this year would, in fact, offer us a modest increase.

However, part of that budgetary action was to institute a filing fee, filings in the merger area. We are, therefore, some 25 percent dependent upon those filing fees for funding.

Filings have dropped this time a year ago by some 11 percent, and we are very concerned that if this trend continues, we could see serious budget shortfalls.

So, I remain very concerned about our resource level for 1990 and for 1991, given the newness of our experience with the filing fees.

Mr. Broomfield. Again, back to the States. Are there any States that are out doing more in the field of investigating deceptive advertising?

Mrs. Steiger. The States have been very active, and I think they remain keenly interested in it.

We have established two working groups, one in the antitrust area and one in the general consumer protection area with the States.

We are very heartened by their response and by our increased mutual respect.

We are working now, for example, with about nine States' attorneys general under the leadership of General Humphrey in Minnesota, who is very concerned about another whole range of consumer issues, environmental claims.

So, we think there is very good movement back toward a more cooperative working relationship with the States. We are very pleased with it.

Mr. Broomfield. Mr. Cutler.

Mr. Cutler. I really don't have much to add, except as a note that in our preliminary discussions with the States, and this was not based on their taking a careful look but an informal discussion that we had, I have the sense that neither States nor the FTC have gotten as many complaints from consumers in this area as in others.

I suspect that is because of the phenomenon that we have seen that people don't blame companies and products for their failure.

I hope that hearings such as this, and efforts that we and others will make, will raise the public's understanding enough so that there will be more complaints. But in the past, this has not been an area that has generated the number of complaints that we have had about many other areas.

Mrs. Steiger. An informal survey of the States asking whether they are inundated with these kinds of complaints does not turn up a pattern that this has been a front and center consumer issue. It may be now.
Mr. BROOMFIELD. I think that one of the most important things this committee can do, is to bring this issue to the public's attention. Hopefully, people will recognize false and deceptive advertising, file complaints, and we will begin to have a better idea of where the problems are.

Chairman WYDEN. I thank my colleague from Michigan.

One last point on this success rate question and the misrepresentation of success rates, Mr. Cutler.

If a company program, for example, says that they are working where others don't work, for example, we succeed, others don't, what proof is there for that claim? Who has done the research? Where in Government do we have any information that is an accurate claim?

Mr. CUTLER. In that area, as in any other area for a performance claim or a product attribute, a company would be responsible for having substantiation for the claim, and we would check it.

I think that a review of ads would show that most companies don't talk about success rates. They are smart enough to stay away from it.

What you see is lose weight quickly, and, of course, people do lose weight quickly, and they put it back on quickly.

But the ads are often carefully framed, and the whole issue of success, whether it's a hospital-based program or an over-the-counter program is something where the success rates need to be examined.

I would guess that companies often will not have good data on success rates. People drop out, they are out of touch, there isn't a continuing relationship, and we don't have data.

I hesitate to talk about data that we would have, but obviously, success rate claims are very important but also much more difficult to gather statistics on.

Chairman WYDEN. Has the Commission, in fact, looked to the substantiation of some of these company claims in the diet clinic area up to this point? We can talk about the actions you want to bring in the future, but as of this point, has the Commission looked at the substantiation of company success rate?

Mr. CUTLER. Not that I am aware of, but I have only been back at the Commission since last month.

In a number of the cases that we have brought, and there have been six diet product cases since 1988, of course, as we get into Fat Magnet and some of the other products that you talked about, substantiation isn't a serious question because it's clear that there isn't.

As we look more at the programs as we are now, that will be a more difficult area, but one that we will look at.

Chairman WYDEN. This is one area I am very interested in. Will the Commission in the future look more at the substantiation of diet clinic claims success rates?

Mr. CUTLER. I would certainly suspect that we would; yes.

Mrs. STEIGER. That is part of the whole promotional effort.

I would like to make one correction, if need be. I understood Mr. Broomfield's question to be, how many people did the agency have looking at deception in advertisement overall?
Was your question, how many are working in the health field? Because clearly, not everyone is working in the health field.

Mr. BROOMFIELD. Basically.

Mrs. STEIGER. Well, then, the whole bureau is working on that. If you want specific numbers on how many actually work in the health care field, it would be substantially lower than that. But I would be happy to provide it.

Mr. BROOMFIELD. That would be fine.

Chairman Wyden. I am pleased with that answer, Mr. Cutler, because that is one of the things that concerned us in our research.

As of today, we cannot find a Commission action that involves substantiation of a diet clinic's success rates, and yet every time you turn around, one of these clinics or one of these programs—we succeed where others fail. We work. We are the only one that will get you to the Promised Land. I am really pleased to hear from you and Mrs. Steiger that you are going to go back and look at some of these claims, because I think we have to challenge some of them and determine if there is a factual basis for them.

On this question of resources that my colleague asked about, Mrs. Steiger, is it your intention to devote more of your resources to health fraud and the kind of abuses that we are talking about, given how fast this market is growing?

Mrs. STEIGER. Again, as I noted, we have an enormous range of enforcement responsibility. We certainly want to give it adequate attention.

We certainly hope to be able to convince the States—I shouldn't say convince, I don't think they need convincing—to pursue their concerns on a local area and hopefully, again, increase our cooperation with the State medical boards.

I think a combination of those things means we can probably do a decent job with the resources we have, but I must say with a caveat that if we get into a budgetary crunch, everything is going to suffer, Mr. Chairman.

Chairman Wyden. Now, I understand as a result of last year's appropriation bill, a significant part of your budget is dependent on merger filing fees.

We are almost halfway through the fiscal year. How are those collections going?

Mrs. STEIGER. I am concerned. We estimate that merger filings are down about 11 percent, as I said, from the same period a year ago.

Straight lining that out and allowing for seasonal adjustments, and there are some in the merger filing area, we could face a shortfall in that the fees may bring in only $14 million rather than a projected $20 million.

It would leave us with a shortfall should this occur, and there is, of course, no way that I can predict that to you, other than to look at it by a daily basis and attempt a rather crude straight line.

We could see a position of loss in excess of $4 million. That would be very serious for us.

Chairman Wyden. Have you requested a supplemental, Mrs. Steiger?

Mrs. STEIGER. The commission has authorized me to request a supplemental. It has not been agreed to, and we will continue to
talk with the Commissioners about appropriate other steps to see if we can ensure that this shortfall does not, not only stop our initiatives, but even cut us back to below the budget level of a year ago.

Chairman Wyden. You will certainly have our support in the battle for more resources, and we can go the supplemental route or another. That shortfall seems to be particularly serious, given this explosion in health fraud problems that we have seen.

I appreciate your moving vigorously on this question of resources.

Let me ask you a couple of questions about the relationship of the FTC and the FDA on these issues. You point out that FTC has primary responsibility for regulating the advertising of the diet product, while FDA has the primary role in regulating labeling.

What we have found is that part of the problem is that the label very often is accurate or substantially accurate but tends to be in fairly small print or obscure.

Then along comes the blitz of advertising, this explosion of radio and TV and this hard sell kind of approach through the electronic media.

Would you share my view that those kinds of warning labels or efforts to inform consumers on the products, basically get drowned out by the tidal wave of the electronic media, and that is contributing to the problem?

Mrs. Steiger. Well, there again, that is a sort of a case-by-case look at advertising in this area, and that is what we are doing.

The question of substantiation and the question of accuracy in the presentation of the value of these particular products, we rely on our liaison with the FDA. If we get a question on something of this nature, they are the first people we call.

As you know, they are embarking on an ambitious program to relook at the whole area of labelings, which I certainly think they ought to be commended for. It would appear that there are items on a label that don't serve the consumer's informational needs or that there may be missing items, that they may not be clear enough for really aiding the consumer.

I certainly support their attempt to do what is a very difficult job.

In the meantime, we do piggy-back on their expertise about products and contents in our own review of advertising for deception and for fruitfulness.

So, we do work with them.

Chairman Wyden. But on this question of whether or not the warning on the label gets drowned out by this wave of electronic advertising, thereby skewing consumer protection, do you and Mr. Cutler share my view that is part of the problem, because I think that there is a real gap now between what you see in these fairly small or obscure kind of warning labels and then this wave of aggressive advertising which basically drowns it all out?

Mr. Cutler.

Mr. Cutler. I understand that there is some area of overlap, and that to the extent that advertising contradicts or makes claims that go beyond the label, that while the FDA may not have jurisdiction over the advertising, they can look at the advertising to de-
termine that the label is misleading and thereby treat the product as misbranded.

So, there is not a perfect overlap, but there is some overlap that gives FDA and FTC a chance to coordinate where there is that gap between the ad and the label, and that is an important area.

Another example in the labeling is in the low-calorie diet products that you discussed. The FDA standard warning is that very-low-calorie protein diets under 400 calories a day may cause serious illness or death, and it suggests that you not try them without medical supervision.

Of course, there you could make the leap from the label to the advertising, and ask about the relationship of the label to the physicians' program. So, labeling plays an important function, but so does the provider of medical service and the advertising.

We agree that they need to be coordinated.

Chairman Wyden. Do you think that there ought to be an effort to apply the same standards to the warning on the label and the requirement for advertising? That would be one way to ensure that we were sending the same message.

That is what I am concerned about. I think we are sending mixed messages out there.

Mr. Cutler. It's clear that a truthful label will not overcome deceptive advertising. There are also, as in the area of prescription drugs, areas where the amount of disclosure would just be inappropriate for TV and print media.

I think that if the two aren't coextensive, at least the FTC and FDA have an important job to make sure that they are not inconsistent.

I don't think that there will ever be the full amount of disclosures, for instance, in a TV or radio ad that there would be on a label.

But we do share your concern that the ads be consistent, and that people not get an incorrect message from an advertisement simply because there is a technologically correct label.

Chairman Wyden. Do you anticipate meeting with the FDA on this point, to try to set in place new standards so that the same claim is made on the warning that there are in ads?

Mr. Cutler. We have had, for many years, and continue to have, a very active liaison with FDA on a broad number of points. We met with Acting Commissioner Bensen recently and even more important, the staffs of FDA and FTC have a close telephone and meeting relationship.

Chairman Wyden. I really hope that we will look at the same sort of standards in this area, because I think this is a very serious problem.

You have described it as an overlap or problems of inconsistency, and I think that certainly is a step in the right direction.

But if we are, in effect, having the small, fairly obscure warnings on products and then this tidal wave of hard sell advertising, that label is going to be missed. We lose the value of trying to make it accurate.

Mr. Cutler. Again, bear in mind that for many of the diet center programs that we are talking about, we don't even have the hard
sell advertising. We have the simple advertising and the possibility that they simply don’t work.

Chairman Wyden. Let me ask you about another area. We heard testimony, very distressing testimony last year from the State medical boards and the State medical societies, and what they said is, look, it’s one thing if the Federal Trade Commission is going to adopt these warped views with respect to health advertising. What we are really unhappy about is that they are getting in our way, as well.

We had several State societies and several professional boards just say point blank that their attorneys general, their lawyers had advised them, don’t move in this area because you are going to end up getting sued by the FTC.

If you would, Mrs. Steiger, elaborate a bit on what steps you plan to take in the future to send that message to the States’ attorneys general and the medical boards that that climate no longer exists, that they have your full support in going forward with fighting consumer deception.

You mentioned something about a meeting coming up, and there may be some other steps that you would like to outline.

Mrs. Steiger. I think, Mr. Chairman, that every consent and enforcement action for years has made it clear that nothing in the consent order is to bar appropriate medical boards from moving against deceptive and false advertisement.

If we haven’t gotten that message out, we are going to have to get it out better.

I would note that the American Medical Association recently filed a petition with the Commission in which it stated that it intends to implement a program to encourage its State and local medical societies to adopt and to enforce reasonable, ethical guidelines concerning false and deceptive advertising practices.

We will continue to try and get the message out. As I noted, our staff from both the Bureau of Competition, which handles antitrust enforcement, and the Bureau of Consumer Protection, will attend a meeting of the Federation of State Medical Boards, and we will certainly be hoping that they carry that message and that the message is heard.

We stand ready to assist the States when they have questions in areas of this nature. We are just going to have to keep getting the message out, Mr. Chairman, that nothing prevents them from regulation of deceptive advertising, and that they are the front line of defense.

Chairman Wyden. I really feel strongly about this, and you have a tremendous amount of work to do because when we talk to the State authorities again and again, and we had sworn testimony last year that they really felt that they had been pretty much intimidated by the FTC against moving in this area.

We are going to support you all the way in this effort to step up State action.

I know that when we had Mr. Oliver before us, it was always a question, I think, of he thought I wanted to federalize everything and was not supportive of State action.

Quite the contrary. We felt like you do, that there is a big role for the States, but there is no question in my mind as well that in
the past, the FTC has impeded the States. I am really pleased that you want to break some new ground in this area and move aggressively.

Now, we had some other questions with respect to the marketing, and we would be interested in knowing whether the Commission has looked at manufacturers of liquid diets who market them to doctors and hospitals.

Is that something that the Commission has looked at to date? We have a couple of examples that staff is supplying to you about the competitive advantage of the product and the chance to make substantial sums.

Is the commission looking at this issue of how manufacturers are marketing?

Mrs. STEIGER. That will be part of the review of promotional materials and advertisement for this type of product.

We have no case to date, sir, nor have we brought any action in this area to date.

Chairman WYDEN. But it's one that you plan to look at now, given this boom that we are discussing; is that correct, Mr. Cutler?

Mr. CUTLER. We certainly will, and I note from the handout that I just received that this type of promotion is not unique to diet programs.

But if one were to look at continuing medical education, and we are familiar with continuing health education, I think in general, physicians are very dependent on the manufacturers and marketers of drugs and services for information, and this may be one further example of that.

Chairman WYDEN. In this one that was given to you, you take a hundred patients yearly with this particular program and make $70,000 plus dollars in the process.

Do you think, given the fact that the Association of Medical Colleges has found that most physicians don't get training in nutrition and adding to that these ads that basically say, easy money is headed your way if you take these programs, that this combination is likely to produce individuals, physicians, and others, going into this area without the qualifications?

Mrs. STEIGER. Here is where we have to be very careful if we're looking at any specific promotional materials to avoid any prejudgment.

These are matters that could, of course, come before us. I would feel safer not to comment on the possible effect or outcome of any particular program with your permission, Mr. Chairman.

Chairman WYDEN. I appreciate that, Mrs. Steiger, and that is always a hard and fast rule here, but let us talk about it apart from this material.

Let us just talk about it in the diet area in the abstract.

The Association of Medical Colleges says that most physicians aren't getting nutrition training and basic information about obesity. That's not Ron Wyden, not a Member of Congress. That is the Association of Medical Colleges.

We know, apart from any material that has been used here, that there are pitches being made to physicians and to providers to go into these liquid diets.
Do you think, Mr. Cutler, that combination represents a concern that we ought to be focusing on, because unqualified people may be part of these packages and offering them to consumers?

Mr. Cutler. Well, given the underlying premises, obviously that is an issue that should be looked at.

Mrs. Steiger. Again, I think, Mr. Chairman, that if the question is of medical competence, we would want to make sure that we state that this, of course, the determination of that level of competence, is not within our purview.

But to the extent that promotional materials are misrepresenting the experience or qualifications for the performance of some sort of service, then we would want to follow up on that.

But the competence of the provider would rest with——

Chairman Wyden. I think that is a fair comment.

I just want to make sure again that we look at that promotional material, which is telling practitioners that they can make easy money, given the fact that the medical profession is telling us of their own accord that many of their practitioners are not trained in this area.

That is the reason for our concern. Tell us, if you would, how the FTC has picked its cases in the past? Up to this point, there have not been cases in what we think are the biggest threats, the commercial diet clinics and these liquid weight-loss programs, and have been more, I guess I would term it, along the lines of these sort of bizarre cases, Fat Magnets and the like.

Could you tell us how the Commission has selected its cases in the past, and how that might change in the future?

Mrs. Steiger. Part of that depends upon resources, of course, Mr. Chairman. We have had a very dramatic decline in resources.

I think I would characterize the Commission's activity as going after the truly fraudulent, trying to shut it down in areas where there was the possibility of severe consumer injury, either monetarily or physically, and in some of the really rather outrageous scams, where there was really danger to either public health, or safety, or to a loss of public income.

So, I think they really did try to concentrate on the clearest, most fraudulent cases in the interest of consumer welfare.

We are now, as we have noted, trying to take a broader look at the whole area of diet claims, and there may be others. Indeed, environmental claims are of great interest as well, where we will attempt to, with the assistance of a variety of other parties, be of some value here.

But again, resources are a question, as always, and we will have to continue to focus on what we think are areas that have the most significant potential for consumer harm.

That is the basic line of where we have to start.

Chairman Wyden. Do you think that manufacturers of diet products and advertisers of diet products are more concerned today than they were 10 years ago, for example, that their claims be accurate and verifying them?

Mrs. Steiger. I would not know, but I hope that advertisers in general are aware that the Commission does insist upon substantiation for the level of claim implied and that substantiation gets a
bit tougher, depending on a product's potential harm to the consumer.

I would hope that message is getting out there, both from the States and from the FTC.

Chairman Wyden. Mr. Cutler, on that point, do you think manufacturers are more concerned now than they were 10 years ago?

Mr. Cutler. I really don't have a great basis to testify to that from the FTC perspective.

I have been in private practice for a number of years, and I know how we counseled clients. I certainly hope that whatever has happened in the last 10 years, that the new administration at the FTC will cause manufacturers to be much more concerned, and that is certainly our goal.

Chairman Wyden. Three cheers for you, because you have read my mind. I will tell you again, I think your predecessors gave the green light to people in this field, to con men, and the rip-off artists to claim just about anything, and I am really pleased to hear you say and describe it as the new FTC because that is exactly what we are looking for.

We are looking for you all in a partnership with us on a bipartisan basis to break some new ground, and I have to tell you that I certainly don't think manufacturers and advertisers are more concerned today than they were 10 years ago.

I think that they are less concerned, and that is one of the reasons that we wanted to work with you and pursue these issues.

A question about one of the cases in particular, this matter of the Fat Magnet. Again, this was all largely before you came on, Mrs. Steiger.

So, I want to make that clear. This was a case the FTC opened in early 1988. The FTC filed its case in January 1990 after determining that the Fat Magnet posed a substantial health risk, so it took 2 years to bring this case involving an item that posed a substantial health risk.

Are you all concerned that, at least in the past, let us say, that it took too long to move on what was determined to be a substantial health risk?

Mrs. Steiger. Regrettably, that case is in litigation, and so I am not able to comment on it.

I would like to comment in a general way, if I may. There are cases that seem to move very rapidly, and there are types that Mr. Cutler referred to where his seventh- and eighth-grade daughters understand a potential fraud exists.

But in other cases, when you get into verification of claims that involve possibly getting direction from third parties, possibly entering into consent negotiations with third parties, depending upon the cooperation level that you get, and sometimes it's true we have to use compulsory process, this does seem to be a longer process.

Having said that, I think Barry Cutler and his staff are committed to moving as rapidly as we can.

We are looking at a variety of levels of case investigation, including the way in which we review what is brought to us, often very valuable materials from our regions.

So, we are, as a first priority, looking at streamlining within a judicious and rational system of case management, but we clearly
do care about the amount of time it takes, and we are committed to streamlining where we can.

Chairman Wyden. Mr. Cutler, do you, too, think that we can speed up these cases where the Commission feels there is a substantial health risk?

Mr. Cutler. Yes; I think that the problems that you noted in one case are probably true in litigation generally, not only where there are health claims, but also where there is private litigation between parties.

The adversary process is said to be good for getting at the truth, but unfortunately, it doesn't get at the truth as quickly as we would sometimes like.

But the Bureau of Consumer Protection is committed, through procedures and otherwise, to move every case as quickly as we can, particularly where there are health and safety concerns.

Chairman Wyden. I think that is a fair comment. Just so you understand what our concerns are, with respect to the Fat Magnet, both the FDA and the Postal Service moved against the Fat Magnet in 1988.

Now, that was 2 years before the FTC acted. So, we had a situation, at least from my standpoint, that the one agency clearly assigned the responsibility to monitoring advertisings and protecting the public from deception was essentially the last one to the party.

That is why we are concerned, and you all have said that you want to speed up the timetable, and I appreciate that because that is something that is important to this Member.

Mr. Cutler. Mr. Chairman, I would like to point out that we have been successful recently, and it will be a continuing effort to cooperate with other agencies.

There was a case very recently that is still in litigation where we worked with the Postal Service, with the U.S. attorney, and with a State attorney general to have what I would call a remedy mix where we would get a TRO and an asset freeze. The postal inspector would execute a search warrant and get a mail stop.

By coordinating, we can bring remedies that we have in conjunction with remedies that others have. So, coordination really can help in that area, as well.

Chairman Wyden. Mrs. Steiger, you heard me talk about the FDA proposal 5 years ago to do a major survey in this area. It's the first really of its kind with respect to diet.

It seems stuck at the FDA. The States have been very critical of this study not being done. In fact, the Iowa attorney general, who will be testifying—their State has been out in front on diet issues—has felt very strongly that this survey be done.

Is it your view that this information could really be critical to you, the information to be gained in the FDA survey as you try to assess the advertising and promotional claims in this field?

Mrs. Steiger. I wouldn't know—I should say, it depends on what kind of information we are going to be able to share and what we have from others, as to whether we can proceed in the advertising claims area without the finished FDA monograph.

As a general rule, obviously, any expert information that we get from one of our sister agencies is always a value to us.
But I am hoping that we can at least bring some light to this area, notwithstanding the fact the study is not yet completed.

Chairman Wyden. We will give you a copy of the study, and just so we are all talking about apples and apples, rather than oranges, what we are talking about is not the monograph.

We are talking about the survey, and it seems to me that we have to get that survey out of the bowels of FDA and OMB to really assess the diet industry, which is going to allow you to really monitor these claims and promotional techniques.

Would you agree, Mr. Cutler?

Mr. Cutler. I am not familiar with the FDA study, and I hear that you would like to use this occasion to get action from FDA.

So, I am sure that any expert information would be helpful.

I would like to add the note that even though there is not scientific agreement about environmental claims, just as there may not yet be scientific agreement about medical claims, that doesn't stop the FTC from enforcing its mandate as to truthful advertising.

While I am sure that you are anxious to have FDA produce materials, that will not stop the FTC staff from looking at advertising to make sure that the claims that are made can be substantiated.

I wish I could be more helpful, and I will be happy to look into it.

Chairman Wyden. We don't quarrel with that at all. You are still going to have an important and aggressive job, whether or not that survey gets done.

Mr. Cutler. It's certainly true that if FDA can help us with that product and service work, that will certainly make our job a lot easier, because we are lawyers, for the most part, and economists. We are not physicians.

Chairman Wyden. That is why the survey is so important. The heart of the survey is to find out what influences the type of weight-loss methods a consumer chooses, and that seems to me to be right at the heart of trying to follow up and look at these questions of deception.

I realize you are not the FDA, but because, as you have said, this is going to have to be a coordinated intra-agency kind of effort, I want to make sure that, at least up here on this side of the dais, the case is made for why that survey is so important.

I think that, unless my colleague has any other questions, we will excuse you at this time.

Mrs. Steiger, let me ask you maybe one last question. When do you think it would be possible to get back to us with an assessment of these newest concerns, the liquid diets?

Would it be possible for your staff to have at least an assessment of the problems out there within those two areas, say, within 60 days?

Mrs. Steiger. We will certainly give that a try, Mr. Chairman, and again, we do thank you for the offer of information that you have already garnered here, because, given our limited resources, it will be very valuable to us, and we appreciate that cooperation.

Chairman Wyden. I will tell you, Mrs. Steiger, that this is a very different set of discussions than we had with Mr. Oliver, and I have to tell you that this is exactly what I think we need to do, to address these issues on a bipartisan basis.
It seems to me it's a two-part equation. One, you absolutely have to have the resources to do the job, and you all have not had them in the past.

But also it's a question of will, and it's a question of whether or not there is a determination and a drive to go after what I think are state-of-the-art ripoffs in the fastest growing segment of our economy, which is the $6 billion medical marketplace.

So, we are anxious to work with you and pleased that we are looking at some new approaches.

My colleague from Michigan may want to ask another question or make an additional comment. Otherwise, we will excuse you.

Mr. BROOMFIELD. Mr. Chairman, I want to thank both Mrs. Steiger and Mr. Cutler for their appearance here today. I think the information they have given us has been very useful.

Chairman WYDEN. We thank you both.

We will leave the record open, as well, if the Commission would like to add additional materials, you may supplement your views. [The information was not received.]

Chairman WYDEN. Our next panel, Sherri Steinberg, Coral Springs, Florida; Loretta Pameijer, Miami, Florida; and Carol Householder of Flagstaff, Arizona. If you three will come forward, we will welcome and swear you in.

We are happy to have all three of you.

Mrs. Householder, Mrs. Pameijer, and Mrs. Steinberg, we welcome all three of you.

It's the practice of our subcommittee to swear all the witnesses. Do you three have any objection to being sworn?

[Witnesses sworn.]

Chairman WYDEN. We welcome all of you to our Subcommittee on Regulation. We very much appreciate your speaking out.

I know that these are not subjects that are overly easy for someone to speak about in a personal way, and I just want you to know I appreciate your being with us to share your views and your assessment.

We will make a copy of those prepared remarks that you have a part of the hearing record in their entirety. If you would like to take 5 minutes or so to just highlight some of your principal concerns, that would help.

The one thing we have to do, Mrs. Steinberg, is get that microphone right in front of you if we can because it's awfully hard to hear, and you might want to move it just a little bit to your center.

Let's begin with you.

TESTIMONY OF SHERRI STEINBERG, CORAL SPRINGS, FL

Mrs. STEINBERG. My name is Sherri Steinberg, and I live in Coral Springs, which is in Broward County, Florida.

I am married to Steven Steinberg and have a son named Jason who is 6 years old.

Like many people, I wanted to lose weight, and I didn't know where to turn. All of the different diet companies and weight-loss programs claim how safe and effective they are, and it was confusing.
But one diet company stood out among the others to me. I had always seen and heard so much about the Nutri/System Diet Program in various advertisements that I believed it had to be a safe program.

I thought they would take care of me. I was overweight, and I had high blood pressure, so it was important for me to go to people I could trust.

I went to my local Nutri/System center on about June 17, 1989. I met with the Nutri/System representative and told her that I wanted to lose weight but was concerned for my safety because of my high blood pressure.

She specifically told me I had nothing to worry about because I would be watched closely by Nutri/System's professional staff of nurses and nutritional specialists while I was on the diet. I was accepted into the program and given the standard meal plan.

She never had me fill out a questionnaire about my health history, and she never told me to see my doctor to get approval first. They never did anything but weigh me and take my blood pressure and measurements.

I asked her how much weight I should lose. She told me that I should lose 34 pounds by August 24 and wrote it down on my "Service Guarantee."

I left that first meeting feeling confident that I could lose an average of over 3½ pounds a week like they told me.

Somehow the guarantee gave me confidence that they were sure I could really do it, or they wouldn't have actually signed that guarantee with me.

Just as Nutri/System promised, I began to lose weight very fast. I lost almost 10 pounds in the very first week, one-quarter of a pound in the second and 7 pounds in the third week. I'd lost 17 pounds after only 3 weeks, and I was really pleased. I lost another 11 pounds.

But then after just a couple of months into the program, in early September, I found myself doubled over in excruciating pain. I had never felt anything like that pain before.

I thought I was having a heart attack it hurt so much. It was in the middle of the night, and I was really scared. I woke up my husband, and he immediately called 911 and called my mother.

The police came to my house and gave me oxygen. When the paramedics arrived, they gave me an EKG test. They told us that it wasn't my heart. But they said they didn't know what was causing the pain.

My husband took me to the emergency room. After they had looked at me, they told me that it was my gallbladder. They removed my gallbladder several days later, and I was in pain the whole time.

After my surgery, I told Nutri/System how upset I was about what had happened to me and demanded a full refund of my money. The lady from Nutri/System told me that I should come back on the program and go on a special low salt diet. I refused, and they sent me a refund check for half what I had paid them.

I couldn't possibly go back on their diet because I was convinced that their diet program was what caused me to lose my gallblad-
der. I was afraid what else might happen to me if I went back to them. I didn’t trust them any more.

This has been a nightmare for me and my family. I have gone through enormous pain as a result of having major surgery. The tests were painful and humiliating. Recovering from the surgery has been slow, and I have still never fully recovered.

I know that I will never be the same again. My doctors told me that my surgery was complicated because I had so many stones in my bile duct. All I know is that it hurt me very much and still hurts me today.

Nutri/System never told me any of this could happen to me. They never told me there were any risks at all. If they had told me, there is no way I would have ever gone on the diet. I would have found some other way to lose the weight.

There was never anything wrong with my gallbladder before I went on the Nutri/System diet. I think it’s more than a coincidence that on June 19 I was feeling fine, and then a few months later, I was being wheeled into major surgery.

I don’t believe the Nutri/System people knew what they were doing. While there were peopled called nutritional specialists and nurses who walked around in white coats, they didn’t seem like they knew much about dieting.

I don’t think they were professional, and I certainly don’t think they took care of me like they told me they would.

This has left me angry and hurt, but I’d really hate to see it happen to anybody else.

Thank you for listening to my story.

[Mrs. Steinberg’s statement, with attachments, may be found in the appendix.]

Chairman Wyden. Thank you very much, Mrs. Steinberg.

Mrs. Pameijer.

TESTIMONY OF LORETTA PAMEIJER, MIAMI, FL

Mrs. Pameijer. My name is Loretta Pameijer, and I am here to tell you about what happened to my 13-year-old daughter. She went on what I thought was a safe diet, mainly because it was sponsored by doctors.

I would never even have thought of putting her on such a diet, except for a horribly humiliating experience at school.

Like many 12-year-old girls, being a cheerleader is the high point of their life. She had made the squad when she was 11, but she had gained some weight over the year. When she went to the tryouts, her coach told her she wasn’t even eligible.

What I heard her tell my daughter, I was shocked and hurt. But it hurt my daughter more. She told my daughter that, “We believe in fitness, and it’s un-Godly the way you have abused your body.”

My daughter had to leave the auditorium in front of all of her friends. She was so embarrassed that she couldn’t go to school the next day and became absolutely obsessed with getting off the weight. She was intent on getting back on the cheerleading squad with all her friends, and I intended to help her.

So, I started trying to find a program I could trust. I tried to get her in a program at the hospital in our community, but they
wouldn't take children her age. I saw an ad for the Doctor's Quick Weight Loss Center.

When I called them, they told me that, of course, they took children. In fact, they said they had children who were even 8 and 9 years and that they thought it was important to start kids young so that they wouldn't be fat adults.

They insisted that I come in right away. They wouldn't answer any questions over the phone.

My daughter had 70-75 pounds to lose—she lost 55—and the center told us that it would cost $1,500 for her to do it. I had no idea it would be so expensive, but I wanted to do the best for my child.

When I asked the counselor whether I could pay in an installment plan, she refused. I was supposed to pay in full and up front before my daughter started the diet.

She also made me feel very guilty in front of my daughter. She asked me, "You do want to do what's best for your daughter, don't you?", and my daughter is sitting here looking at me.

We are not rich, but we managed to come up with the money because we knew how miserable our daughter was, and we wanted desperately to help her.

In mid July, she started the program. When we went back, the counselor told us that many weight problems were tied to food allergies that prevent us from breaking food down well.

The allergy test itself cost $500. They told us that it was crucial because that is how they would know what kind of foods she should be eating and how best to help her lose the weight.

Even though it was expensive, it seemed to be thorough and like an individualized program that would be safe.

My daughter saw the program's doctor and was given a physical, I think. I say that because all he did was look in her throat, felt her glands, and checked her blood pressure, and that was it.

He never asked us any questions about her medical history or even about any allergies she might have to drugs. Then we were ushered off to a counselor. The counselor gave us a food chart that supposedly reflected the results of her allergy test with a list of foods she could and couldn't eat.

My daughter followed the diet religiously. She went back to the center for regular visits that never lasted longer than 5 to 10 minutes.

Even though she was following the diet, there were many times when she would stop losing weight. Then the counselors would put her on what they called a "parsley break." It had almost nothing in it but meat and half a cup of parsley a day. It seemed odd, but my daughter was losing weight, and she was feeling good.

She quit going to the center around Christmas time, but she stayed on the diet by herself. In March, she started eating more normally. I noticed that she started gaining the weight back, but I didn't say anything to her.

But at the end of June, one night when my husband, who is a fireman, was at work, she started to have very sudden, very severe pains in her back. She couldn't sit down; she couldn't lie down; and she couldn't get her breath.
I was scared. I didn’t know if it were her appendix, her kidneys, her gallbladder, but I wasn’t going to mess around, so, I managed to get her dressed and rushed her to the emergency room.

Almost as suddenly as the pain had begun, it stopped. We sat in the parking lot of the hospital for a long time because I didn’t want to take any chances. Finally, we decided it must not have been anything serious, so we went home.

Everything seemed to be fine until about a week later. My daughter had eaten at MacDonald’s. About 2 hours later, she had another severe attack like the other one. This time, my husband was at home with her, and I was still at work.

He told me to meet him in the emergency room, that my daughter was in the hospital.

When we got there, they ran a battery of tests. The doctors also asked us if she had any strange eating habits. I told them she had recently lost a lot of weight.

After they got the test results, my doctor came out after 4 or 5 hours and told us that she had one of the worst gallbladder attacks he had ever seen in anyone so young.

They also told us that diets could be a big factor in gallbladder disease. They called the surgeon that night, and he told us that her gallbladder had to come out right away, so we scheduled her for surgery the very next morning.

I thank God that everything was OK. Her surgery went smoothly, and she recovered quickly. I guess kids can bounce back quickly. I was very proud of her and the way she handled the whole thing.

Everything happened so quickly. We were so upset. I had no idea that any diet could do this. I love my daughter very much, and had I known there were risks like this, she could have stayed a happily plump kid for the rest of her life. There is just no way I would have done this to her.

Chairman Wyden. Mrs. Pameijer, if this would be easier for you, we could—

Mrs. PAMEIJER. I am sorry. I don’t know what happened. I was doing so well.

Chairman Wyden. You are doing real well, and don’t you be feeling badly for a moment. Take the time you need, and if at any point you would just rather have us put it in the record, we will be glad to.

Mrs. PAMEIJER. No. I want to read this.

Now, I can’t help but wonder how I could have let her do this. It has been about a year, and she has gained back almost all of the weight. I can’t help but wonder how I could have let her go on such a crazy diet.

But it looked safe. It was supposed to be supervised by a doctor. It was supposed to be designed specifically for her, and the office was busy. So, I thought they must be good.

Now I know better, though. My daughter lost her gallbladder, and my husband and I pray that there won’t be any other long-term, serious health effects.

We are angry because it never occurred to us that we should suspect a doctor’s clinic, but it seems that there are shysters out there making millions and not caring at all about what happens to
people like my daughter. They laugh all the way to the bank, and it just makes me crazy.

My daughter didn’t want me to come here today. But I tried to explain to her that it was important. I didn’t know enough to protect my child, but maybe I can protect someone else.

I’m glad to know that someone in Government is looking at this, and I just hope that you will help us learn what questions to ask and how to judge what is safe and what is not. I don’t think we can do it by ourselves.

Thank you.

[Mrs. Pameijer’s statement may be found in the appendix.]

Chairman Wyden. Thank you very much, Mrs. Pameijer. You have said we are doing something important, but we can only do it because you are willing to come and to speak out. We sure admire your courage and that of your family.

I will have some questions in a moment. Thank you.

Mrs. Householder.

TESTIMONY OF CAROL HOUSEHOLDER, FLAGSTAFF, AZ

Mrs. Householder. My name is Carol Householder, and I am here on behalf of my husband, Michael, who is unable to attend this session for reasons you will learn as I tell you about my story.

I certainly want to thank this committee for allowing me to share the experiences of the devastating effects of a rapid-loss diet.

In the late summer of 1985, my husband was a 44-year-old Ph.D college engineering professor. He had just completed 10 years of college administration and had decided that the 30 pounds he had put on the previous 5 years had to go.

He was 6 foot tall, weighed approximately 215 pounds, and he wanted to lose weight and to weigh approximately 180.

He considered himself to be in good physical condition. He was not a smoker. He had always been a bit overweight, even as a child, but it never prevented him from exercising the majority of his adult life.

He had biked, jogged, swam, played racquetball, skied, et cetera, and as a family, we had hiked the Grand Canyon rim to rim, which is approximately 25 miles, earlier that summer.

I recalled the time he considered several diet alternatives, but he eventually selected the Nutri/System Program for some of the following reasons.

Billboards in our town claim that the Nutri/System diet succeeds where other diets fail. Second, you can barely turn on your TV or pick up a newspaper without reading ads from the Nutri/System folks claiming their successes. They claimed to be medically supervised.

The diets were supposed to be tailor-made to the individual’s needs. Diets were supposedly well balanced, providing you with all the nutrition and minerals you needed. The diets were also supplemented by the vitamins they provided, or you purchased, I should say.

It was very convenient. It was prepackaged. It was already predetermined what it is you could and couldn’t eat and, therefore, very easy to get on and to maintain, and it produced success above all.
He began his diet in late August after filling out a brief medical history. He interviewed with a nurse. They took his blood pressure, and after reviewing a computer printout, his 1,000 calorie diet began.

He was very faithful, once he made a commitment to lose the 30 pounds. He drank their beverages, baked their bread, used their salad dressings, and ate their prepackaged foods.

He attended his weekly checkups, basically a blood pressure checkup test. They reviewed his personal journal where he entered what he ate, what quantities the environment, where he ate them, and how he was feeling.

At the same time, he began jogging, with their blessing and encouragement. He walked, then ran. Slowly, and after 2 to 3 weeks, he was running approximately 3 miles in about 30 minutes, perhaps 3 to 4 times a week.

He self-reported in his journal many times of being fatigued and tired. But he stuck with the diet because he saw results. In about 7 weeks, he had lost approximately 28 pounds.

Then along came a conference in Colorado and with consultation with the Nutri/System people, he decided to go off the diet for 5 days.

However, he still packed his drinks, and he still packed his salad dressings. He took what he could, and he supplemented it with fresh fruits and some salads.

He did not overdo. I was with him, and he was very cautious about the foods he ate.

On a Sunday, 4 days after returning to his diet program to lose the last 2 to 3 pounds, he was jogging with our youngest daughter and upon returning, he commented that he didn't feel well. He told her he felt lightheaded, and he sat down in his lounge chair in the study.

He passed out and kind of slumped back. Our daughter ran to get me from the kitchen, and after a total of a minute or two, he seemed to come to. He was pale and quite woozy. I was very upset, and he promised to discuss the incident on Monday morning with his Nutri/System staff.

Her response at the time was perhaps he should eat more fruit. A week later, he was 1 pound short of his goal. While he was walking back from a track where he ran after his Monday lunch jog, he felt sick and lightheaded. He went down in front of an activity center, and he went into a full cardiac arrest.

Mike was resuscitated by the paramedics, but he remained in a coma, hooked to life support systems for the following 70 hours. While Mike was in a coma, I remained at his side 24 hours a day in intensive care. I observed the treatment he received and talked to every staff member who would listen.

They were kind and helpful in helping me understand what was going on. The treating physician, an internist, explained that the likely scenario and the probable cause of his cardiac arrest—I was tending to use the words "cardiac arrest" and "heart attack" interchangeably, and he was quick to point out that Mike's incident was triggered by potassium deficiency and borderline protein deficiency.
In my laymen’s terms, the potassium is the carrier for the electrical impulse for our hearts to beat, and when that impulse is slowed or stopped, cardiac arrest occurs. Because Mike was protein deficient as well, it’s very likely his heart muscle had been weakened.

Incidentally, that morning he had a banana. I happened to observe that in the trash when I got home 3 days later.

Mike gradually awakened, 70 hours into his coma, but unlike the Hollywood versions, he had lost both his long- and short-term memory. His computer tapes of 44 years had virtually been erased. He didn’t know his name. He couldn’t recognize his family, and it took days, weeks, months for him to begin over again.

He remained hospitalized for 4 weeks. Therapy was begun, and finally he was transferred to Scottsdale Memorial Hospital where it was discovered after testing that he had some degree of coronary disease.

However, his heart was not damaged, and for the past 4½ years, he has remained healthy and has had no other incident.

Our cardiac physician suggested that if Mike had been properly evaluated by a physician, he most likely would not have been recommended for a nonmedically supervised diet, which Mike thought he was on.

So, what’s life like after a close encounter with death? Obviously, Mike lived. But there are many times I feel somewhat like a widow. The man I loved and married 27 years ago is now just a fraction of himself.

He cannot live alone. He will never work again, and his daily activities must be planned and supervised.

He has no text knowledge. Occasionally an equation will enter his brain, but he has no idea what it stands for or what its use is.

He is often confused and forgets current information. He cannot initiate intellectual conversation, and he could barely summarize a Reader’s Digest short article.

His intellect and emotions are significantly impaired. On a recent day in the past, I was feeling upset and depressed, and when I shared how I was feeling with him, his response was, is it all right if I walk home now? Totally unlike his caring and nurturing preincident self.

Our joint income in 1975 was approximately $75,000. Today, our income is $36,000. I had also been working at the University, but after a year and a half of attempting to work, assume our responsibilities for daily life, be both parents to our three daughters, and take care of my husband, I requested a leave of absence, and I have never returned.

Thanks to our loving and supportive daughters, and extended family and friends, and my own strong personal relationship with God, we have survived and are reasonably happy.

I love my husband very much and will always remain his faithful wife and best friend, but our mutual loving and sharing partnership is now changed forever, and I have become his caretaker and protector. I can only hope that our story and experience will somehow impact change so that other families will be spared the tragedy we survived but celebrate daily.

[Mrs. Householder’s statement may be found in the appendix.]
Chairman Wyden. Thank you very much, Mrs. Householder. We, again, really appreciate your being with us. It's just so obvious how difficult it is to talk about these kinds of issues. Of course, this is why it's so important to try and get the message out and make sure people are aware.

I am going to recognize my colleague from Michigan for his questions first, and then I will have some, as well.

Mr. Broomfield. Mr. Chairman, I don't have any questions.

I just want to congratulate these ladies for coming forward today. This testimony is extremely important, and it is what this investigation is trying to stop.

The experiences you related are indeed tragic. I don't know what I could say to change things. However, your experiences will help us a great deal.

I hope that our recommendations will have some bearing on preventing other people from going through the same thing you have gone through.

I congratulate you and appreciate your willingness to come before the committee today.

Chairman Wyden. Let me, if I might, try to ask you a few questions. If these are difficult, you just say so, and we will back it off here.

When all of you enrolled in these programs, did anyone tell you that these diets and this particular approach could really be dangerous? Did anybody really warn you?

Mrs. Pameijer.

Mrs. PAMEIJER. No.

Chairman Wyden. Mrs. Steinberg.

Mrs. STEINBERG. No, sir.

Chairman Wyden. Mrs. Householder.

Mrs. HOUSEHOLDER. Certainly not.

Chairman Wyden. So, really no warning at all, no effort to try to talk a little bit about the downside, that there might be some problems. It was just all upbeat, positive; this is going to be successful?

Mrs. PAMEIJER. Individualized programs.

Chairman Wyden. Individualized—don't worry, we are going to focus on your particular situation. Mrs. Steinberg, is that pretty much it?

Mrs. STEINBERG. Yes; you went in there, you would tell them about yourself, and they would say that they would take care of you. At that time I was very concerned about my blood pressure, and they told me not to worry about it; just don't eat the puddings or the soup, and that I would be OK.

You would think that they knew what they were doing, and they will take care of you. A little later you find out that they haven't had a clue as to what is going on.

Chairman Wyden. Mrs. Householder, anything on this point?

Mrs. HOUSEHOLDER. I concur with her. I think, if anything, they put your mind at ease, implying that it's all under control, that things are well balanced and nutritionally safe, and that, after all, they have your computer output right there, and they know what is best because they have just plugged in all that information and the "variables," quote, into a system, and how could it be wrong?
Therefore, you put your trust in what they seem to present as being truth for you.

Chairman Wyden. There are, obviously, several companies out there, major national concerns that are claiming that their products get you a safe and effective weight loss. What was it about the program that you chose that really drew you in, that really got you to the door? Was it the ads?

Mrs. PAMEIJER. Doctors and quick.

Chairman Wyden. Doctors and quick. That was in the advertising of the program?

Mrs. PAMEIJER. That is the name of the company.

Chairman Wyden. Doctors and quick.

Mrs. PAMEIJER. You are supervised, and you lose the weight quickly. You get it off quick, and that is what everybody wants.

I want to suffer through a diet? Come on, make it disappear quick. I want to wear that size 3, that size 10, or whatever, and that is why I chose it.

Chairman Wyden. Mrs. Steinberg, Mrs. Householder, was it that kind of approach in the ads and the sales pitches that really got you to the company doors?

Mrs. STEINBERG. Well, as I stated, I was overweight, and I did have high blood pressure, and I knew that for my own safety, I had to do something for myself to lose weight and to get my pressure under control.

Going back and forth from work in the car, on the radio all you would hear are commercials, people who are on Nutri/System, how quickly they took off the weight, how safe it is, and how easy it was.

I think when I was at my lowest, I made an appointment, and I spoke to the woman at Nutri/System over the phone.

They were all peppy and very excited, unwilling to answer any questions over the phone, but they wanted you to come in. What drew me to it was the advertisement.

You hear the radio DJ saying how much they lost, and how fast. They have other guests come on, and none of them have a problem.

They all went through it, and I figured, well, if it's good for them, if it's safe, then I am going to do it.

Mrs. HOUSEHOLDER. I concur. I think the magic was also in the fact that it was a commercial that implied nationally. It wasn't just some local quack who had come out with a limited, unusual product that was going to do it, but it was a national.

You could go to any State, or you could read any local paper in any town, and it was advertised, and, therefore, there was a sense of it must be OK because it's happening all over the Nation. Therefore, it must be safe and approved.

Chairman Wyden. Did these particular clinics that you all went to provide some kind of nutritional counseling?

Mrs. STEINBERG. They called themselves nutritionists. You would write out a menu and circle the foods that you were allowed to have for the week. I really disliked most of the foods, so I just stuck to hamburgers and pizza.

Looking back now, that is kind of silly for me to consider that being nutritious. I think what happened is that we took vitamins along with it.
I don't know what kind of nutritionists they are, looking back, if all they had to do was to see that I had seven lunches and seven breakfasts. That is as far as it went.

Chairman Wyden. In your case, though, the person at that clinic called themselves a nutritionist, and you thought that was fairly impressive?

Mrs. Steinberg. Yes.

Chairman Wyden. Mrs. Householder, in your situation?

Mrs. Householder. I don't recall that there was, quote, "a nutritionist," but there was a nurse counselor who supervised my husband's journal and, again, circled what he ate, and how often, and in what quantities.

I think a part of that was the fact that the food was prepackaged. There was no breakdown, as I recall, on the labeling to say exactly what the intake was or what you were receiving, like we are finding on national products today, but you were taking a substance in a can or in a package and without knowing exactly what its contents were.

Chairman Wyden. In your case, they said something. They were nurse counselors. Did you think that this person had expertise, though, in the area of nutrition?

Mrs. Householder. I believe the nurse counselor presented herself as having been trained and informed, well-versed in this area. As I was not the patient, I cannot speak directly about my husband's experience other than what he shared, and it was his general impression that this person was trained and had a thorough background in what she was talking about.

Chairman Wyden. After the fact, do you think that they had the training?

Mrs. Householder. I highly doubt that because of the incident he reported. Someone who had been trained certainly would have picked that up as, perhaps, a signal of potassium deficiency.

Chairman Wyden. In the American Medical Association, virtually all the experts are constantly trying to address key features in terms of a successful weight-loss program, and cite such things as exercise as a component in successful weight loss.

Mrs. Steinberg, in your program, did they say anything about the importance of exercise?

Mrs. Steinberg. Well, the way that came to my attention was that I saw someone else walking out with a video tape, and I had to bring it to their attention, "What was that video tape?"

They said, "Oh, you should have gotten it last week. Let us give it to you now." When you went to speak to this nurse nutritionist, she would ask you if you have done any exercise, but they never told you how much, how soon you should start, or how long you should do it for.

Mrs. Pameijer. My daughter's program did not encourage her to exercise. In fact, they said not to exercise until she got her weight off.

Chairman Wyden. Did they offer any reason for saying don't exercise?

Mrs. Pameijer. No.
Chairman Wyden. We are not talking about trying to be involved in some sophisticated program, but they didn't even suggest such things as walking?

Mrs. Pameijer. Or anything like that; no. I kept asking, what kind of exercise should she be doing, or anything, and they said no; let's not concentrate on exercising now. Let's concentrate on getting the weight off.

Mrs. Householder. I cannot personally attest to whether my husband suggested it or whether they suggested it. I know that they were well-aware of and encouraging him to jog, and because he had historically jogged in the past, he felt it was the most expedient way to combine weight loss with some physical exercise.

Chairman Wyden. So, exercise was mentioned in your case?

Mrs. Householder. Oh, by all means.

Chairman Wyden. Was there any discussion of the rate of failure that the scientific literature showed that frequently you gain the weight back, Mrs. Steinberg?

Mrs. Steinberg. Never. They were always concentrating on the positive part of the program. Never once did they ever mention that people gained the weight back.

They just kept stressing how fast you are going to lose it. You are going to be able to keep it off because they give you a guarantee that you are going to be able to keep it off.

They never, ever once mentioned that you may not be able to do this, and it's OK if you don't.

Chairman Wyden. Did they ever mention the dangers of yo-yoing back and forth where you lose the weight, and then 3 months later you gain it back, and you lose the weight, and you gain it back?

Mrs. Steinberg. Never. Their main thing, and what made me really want to do it, is the fact that they gave you - a guarantee, that you are going to lose this 34 pounds by such and such a date. Never once did they say—as a matter of fact, if you didn't lose a certain amount, they kind of asked you why, and what did you do wrong.

They were always very encouraging that you lose more. As a matter of fact, when I lost 7 pounds, the third week they came in with little horns like you would have on New Year's and started blowing it.

Chairman Wyden. You lost 7 pounds?

Mrs. Steinberg. The first week I lost almost 10. The second week I lost a quarter of a pound, and the third week I lost 7 pounds.

Chairman Wyden. In the first week to lose 7 pounds?

Mrs. Steinberg. Almost 10.

Chairman Wyden. How did you do that?

Mrs. Steinberg. I followed the diet, just as I always did. I just followed what they had told me to do.

Chairman Wyden. Mrs. Householder, were you warned at all in the case of your husband about these rapid weight losses, and anything about the possibility that you would gain it back, and the concerns raised with Mrs. Steinberg?

Mrs. Householder. There was no discussion between he and I on that subject. If it was discussed, it was something that he didn't share.
But I rather doubt it. I read his journal thoroughly, and I read the materials that he had in his files regarding the program, and I don’t recall seeing or reading anything regarding that subject.

Chairman Wyden. Did the three of you just assume that someone in Government was watching to make sure that products like this were safe? Was it sort of implied that someone, State or Federal, was going to be trying to do some oversight and try to monitor what was going on in this area, Mrs. Steinberg?

Mrs. Steinberg. I don’t know if they ever told us that, but they did say that, and I just kept stressing the fact that it’s a quick and safe way to lose weight.

I just assumed that being as big as they are, that someone had to be watching them in order for them to be as big as they are.

Chairman Wyden. Mrs. Householder, was that your view?

Mrs. Householder. I concur with her statement that something that large would be controlled by someone, some place.

Chairman Wyden. Mrs. Pameijer.

Mrs. Pameijer. Yes, yes.

Chairman Wyden. Let me ask you a couple of questions about your situation.

Was your daughter seen by a medical doctor when she began the program that you were involved in?

Mrs. Pameijer. Yes; they said that he was their physician.

Chairman Wyden. In effect, you put your confidence in that physician’s ability?

Mrs. Pameijer. Sure, and in the whole program. I went along with whatever they had to say. At such and such time, she was to go for her doctor’s physical, and we did.

Chairman Wyden. Did he take a comprehensive medical history of your daughter?

Mrs. Pameijer. No, no. I walked out—the physical might have lasted another 5 minutes; enough to do this [witness touches throat], and the blood pressure. He didn’t ask her anything about her medical history, whether she was allergic to drugs or had any allergies. I think he asked her something about did she ever notice any swelling of the joints, or did she ever have a problem with swelling of joints, and that was it.

Thank you very much. You look just terrific, and we are going to get you looking better, and out the door we went.

Chairman Wyden. Did he listen to her heart?

Mrs. Pameijer. No, not that I can remember. No, he didn’t. I asked her that, and she said no.

Chairman Wyden. Now, did your daughter show you various advertisements from publications and suggest that, in effect, these were the kinds of programs that could really help her turn her weight situation around?

Mrs. Pameijer. She saw advertisements on TV and heard advertisements on radio, and threatened to stop eating. I mean, she said, “I am going to stop eating, Mom. This is it. I am never going to put anything in my mouth again. You have to do something. You have to get me on a diet.”

So, I did. I started looking around, and these people took children. They had a feeling toward kids, or so I thought.
They didn't want fat adults. They were going to nip the problem in the bud early in life, and then the kids don't have a problem fighting weight as adults. That was their theory.

Chairman Wyden. What had your daughter done prior to going to this clinic to try to lose weight?

Mrs. Pameijer. She tried to cut down on her own. We would put the measurements over the scale and in the bathroom. We would weigh ourselves and try to keep something up on our own.

We weren't disciplined enough. We needed the discipline to keep going, and we would slack off after a while.

Chairman Wyden. What would you say to other parents and youngsters who want to lose weight and think that one of these programs is the way to go?

Mrs. Pameijer. Talk to your own pediatrician. Talk to your own doctor and see if it's a wise thing to do. See if the child's healthy enough to take this.

Chairman Wyden. Mrs. Householder.

Mrs. Householder. In addition to working with your own physician, as was implied in earlier testimony, not all physicians are well-qualified in the nutritional needs of individuals.

Although we would like to have faith in the AMA and in their physicians, I think this is a really particular problem, and not everyone can know everything that needs to be known on a well-balanced diet.

I guess in conjunction with that is to know that there is nutritionally based information available and to supplement your doctor's information with a thorough physical, a thorough work up, and to be, I guess, more aware.

I guess consumer education in this area is really mandatory. We must be bombarded with more knowledge and with more information regarding the seriousness of not being on a nutritionally balanced and well-designed diet.

Chairman Wyden. Your point about qualifications in order to run these kinds of programs is especially important. One of the things as we did our research in preparing this hearing that concerned me greatly was this pointing by the Association of American Medical Colleges that 60 percent of the medical school graduates don't get adequate training in nutrition.

If, in fact, we are seeing the boom in state-of-the-art diet programs, these clinics and liquid diets that I think is underway, that Mrs. Steiger, the Chair of the FTC, said was underway, clearly we are going to have to work with the physician community to make sure that they are more aware of these issues. So, that is a thoughtful point, and we appreciate it.

Would any of you like to add anything further? I would certainly ask more questions, except I could tell that this is a very difficult subject for all of you, and we appreciate your speaking out.

Because you have, it's going to be a lot easier for us to come up with some reforms to make sure that others don't face these kinds of problems.

If you don't have anything you would like to add further, we excuse you at this time.

Our next panel is Mr. Ray Johnson, assistant attorney general, State of Iowa; Wayne Callaway, M.D., Endocrinologist, American
Board of Nutrition; and Nancy Wellman, Ph.D, and president, American Dietetics Association, Washington, DC.

Chairman Wyden. Dr. Wellman, we welcome you.

Dr. Callaway, excuse me, we appreciate your involvement.

Mr. Johnson, I had a chance to read your statement earlier, and it's extremely helpful, and we are looking forward to your views.

As you have heard, it's the practice of our subcommittee to swear all the witnesses. Do any of you have any objections to being sworn as a witness?

Please rise and raise your right hand.

[Witnesses sworn.]

Chairman Wyden. Let us begin with you, Dr. Callaway, and I also want to be correct, Dr. Wellman. We are happy to have both of you, and we will make your prepared remarks a part of the hearing record in their entirety, Doctor.

If you could possible summarize your principal concerns, that will save us some time for some questions.

TESTIMONY OF C. WAYNE CALLAWAY, M.D., ASSOCIATE CLINICAL PROFESSOR OF MEDICINE, GEORGE WASHINGTON UNIVERSITY, AND FORMER VICE PRESIDENT, AMERICAN BOARD OF NUTRITION

Dr. Callaway. Thank you very much, Mr. Chairman. I am pleased to be here, and I appreciate the opportunity to share these thoughts with you.

As you mentioned, I appear not only as a physician involved in this field but also representing the American Board of Nutrition [ABN]. I have been a member of the board of governors for 10 years or so, and the ABN president has asked me to represent them.

It is my personal view that the weight-loss business in the United States has gotten out of hand. The stories we have heard this morning are all too common. As a human being, like you, I was deeply moved when I heard these tragic events.

As a physician, I am also concerned that millions of Americans are participating in rapid weight-loss programs supervised by people, as you have heard, with little or no knowledge, training, or understanding of the complications of semistarvation.

As one who has been involved in the evolution of our present concepts regarding the variety of human obesities and their treatments, I am distressed that the popular commercially available programs for treating obesity are not based on a thorough understanding of current scientific knowledge. To the contrary, such programs reflect the old notion that obesity is simply a matter of self-control, and all you have to do is eat less, and you will lose weight.

The packaging differs from program to program, but the premise is much the same: Eat less and you will lose weight; if you gain it back, it is your fault.

Before I discuss the risks of rapid weight loss, and the lack of evidence of long-term effectiveness, and make a few recommendations, let me put this issue in a more cultural context. Our current attitudes about body size and shape are highly culturally determined. What we consider overweight, other societies would consider ideal.
For example, over the past 2½ decades, the average weight of professional models has gone down from about 8 percent below average to about 20 percent below average today.

If we look at dieters in the United States, only about 10 percent are dieting for medical or health reasons. Most are dieting in the often vain attempt—and I mean that in terms of unsuccessful attempts—to reach some imagined idea which would bring all kinds of other rewards which unfortunately rarely occur, even if the desired weight is achieved.

Given the cultural distortions that exist, I think it is no wonder that half of adult women are dieting two or more times a year and some of them as many as five or six times annually. Furthermore, the dieting phenomenon is not limited just to adults; in some school systems, as many as 80 percent of 10-year-old girls are already defining themselves as overweight and going on diets.

So, the commercial weight-loss programs we have been hearing about this morning don't exist in a vacuum. They are skillfully—and I think deliberately—exploiting a situation where the cultural norms in our society are way out of sync with biological reality.

Let me bore you for a few minutes with a comment or two about the biology of size and shape. In a society like ours, where there is adequate food and no necessity for exercising, between 25 to 50 percent of the variation in weight from one person to another appears to be inherited. We see from studies of twins and adoptees. Adopted children have heights and weights that correlated with the heights and weights of their biological parents and not of their adopted parents.

The conclusion that some of us draw is that most of us can achieve a healthy weight, but there is no reason on earth why we should all be an ideal weight or the same weight any more than there is any reason why we should all be the same height.

There is a lot of research which explains what happens to people when they go on very-low-calorie diets. This is no longer a mystery. There are three things that happen when we diet. The initial weight loss—you heard a moment ago about a 10-pound weight loss in the first week—is mostly water. As the body breaks down protein and glycogen to make blood sugar for the brain and red blood cells to function, the water surrounding the glycogen and protein is released and excreted by the kidneys.

Unfortunately, if you continue a weight-loss diet of that restriction, you start to retain water. In Third World countries, this is called starvation edema, or refeeding edema. At that point, the dieter becomes frustrated. As you have heard, the so-called counselors, frequently attribute this plateau to noncompliance on the part of the dieter, and the communication process starts to break down.

With semistarvation, the resting metabolic rate goes down so you can survive. This is an adaptive response all of us have programmed in. What this means in terms of weight loss is the more you starve, the harder it is to lose and the easier it is to gain back. Second, we have both human and animal data that show with repeated dieting, you lose more slowly and gain back more quickly. Third, the low metabolic rate is associated with a series of symptoms, including depression, fatigue, cold intolerance, dry skin, dry hair, dizziness on standing, sleep disturbances, et cetera, et cetera.
You raised a good question about exercise. Many programs are acknowledging that, indeed, metabolic rate goes down when you starve, but they are advocating exercise as a means of keeping this from happening. I would urge one word of caution. If you look at starving plus exercise, the drop in metabolic rate gets worse. There are several studies that show that the resting metabolic rate goes down even more. The third victim whose tragedy we have heard about today was probably made worse by the advice to increase his exercise.

So, in people who need to go on very-low-calorie diets, I would urge they hold off on exercise unless they are under very, very close supervision.

The final thing that happens—and again, we have both clinical and animal data to support this—is that starving leads to stuffing. If we look at the extreme, bulimia has not been reported in someone who did not first diet. As long as the person is on the restricted diet, their appetite is suppressed, but when they come off the diet and as they start to eat, the more they eat, the more hungry they get.

These observations are not new. They go back decades. A lot of this work has been done in the last 10 years or so, and there are all kinds of references, and book chapters, and even books on this subject. However, very little of this information has been incorporated into the commercially available weight-loss programs, including the so-called physician-supervised programs.

The reasons for this failure are undoubtedly multiple. One is that the people setting up the programs are unaware of the scientific literature. Another reason is it is hard to take the new scientific information and promise the weight losses we have been hearing about this morning, and as are promised in ads such as the one shown today.

The commercial programs are truly market driven. Market research shows women expect to lose 2 or 3 pounds a week, men 3 to 5 pounds per week, or they don't come back in the third week. You can't achieve this amount of weight loss unless you induce some type of semistarvation. Indeed, as much as two thirds of the early weight loss is due to water loss.

As I said, the dieter thinks the diet is doing well, but when he or she starts to run into the refeeding edema phase, then frustration occurs, and the dieter is often blamed. Blaming the victim is very common. It is, I think, the ultimate cop-out.

When people go off diets and are shifted to what are called, somewhat euphemistically, the maintenance phase, they not only gain water, but they also gain back fat more readily because they are burning less than before. In addition, if they start to get the binges, they blame themselves because they have gone off the diet.

I think a very dramatic example of "blaming the victim" is Oprah Winfrey, who, as many of you know, a year and a half ago announced on national television she had lost over 60 pounds while following Optifast. Self magazine reported that, and I quote, "Optifast director Jim Parsons gleefully credits Oprah Winfrey with making Optifast a household word."

Now that Ms. Winfrey has regained back much of her lost weight, the tune has changed dramatically. Representatives of Op-
tifast, if not the home office, are now blaming Ms. Winfrey for her failure. I have transcripts of a recorded conversation with one purveyor of Optifast in the Washington, DC, area, in which she says, "Oprah Winfrey lost the weight, then went right back and ate the same foods . . . Oprah Winfrey mentioned she was eating three sweet potato pies in a week's time. She gained 17 pounds. Anybody who eats one sweet potato pie can gain 2 pounds. You eat all that and you are setting yourself up for failure."

I can think of no more dramatic example of blaming the victim. Here is a celebrity who announced a specific formula had caused her to lose weight. Throughout the country these programs were forewarned that she would be making this announcement so they could handle what came next. The news media were alerted. I understand that more than 200,000 phone calls came in to Optifast units throughout the country. Nevertheless, as soon as she starts to regain, she is blamed for her own failure.

Now, if this happens to someone as prominent a celebrity as Ms. Winfrey—I don't know Ms. Winfrey, but I suspect she has a fairly strong self-identity and ego strength, and she can withstand this—but can you imagine the devastation felt by the average dieter who suffers alone her quiet desperation of being blamed and of actually blaming herself.

Now, as far as hazards of quick weight loss are concerned, I have already mentioned some of the symptoms that occur with low metabolic rates. In addition, there are, as you heard this morning, severe and dramatic complications, the most dramatic of which is sudden death.

You remember back in the 1960's when there were about 60 people who were identified as dying suddenly on the old liquid protein diets. The current programs are truly a little better. They are using proteins of higher biological value and most have carbohydrates added to reduce the risks of ketosis, and yet sudden death is still occurring.

The fact that we haven't heard much about them until recently reflects the fact we don't have any good tracking mechanism. We have no way of knowing how common these complications are.

When the victim or his or her survivors have raised legal issues, in general, the cases have been settled out of court and the documents sealed. There is no registry for providing data on a national scale. As you can well appreciate, the companies themselves do not volunteer such information to outside researchers. It is only when media attention is brought to bear, as occurred on the instance of gallstones, that the victims start to recognize that they are not simply isolated cases.

Even in the face of documentation of these types of complications, the local program staff often either don't know these complications are part of the diet, or they deny they are part of the diet.

Again, to cite transcripts of recent recorded conversations with diet program people in the Washington area, a prospective dieter asked the staff person about gallstones and she was told, "People who are obese often have gallstone problems. It is from obesity, not from the diet."

This conversation took place within the past month. We have known for over a decade that starvation increases the risk of gall-
stones, and it has been almost a year since there was an excellent study showing that within 8 weeks on a 520-calorie diet, as many as 25 percent of people will develop gallstones. So, this is information on the other side of the world; it is here, available in the United States.

Another dramatic example of dieting is bulimia. Again we have about a decade's knowledge that dieting leads to bingeing, and yet with rare exceptions, this complication is not mentioned in any of the warnings or materials that are handed out to prospective dieters. Likewise, so far I have not seen any mention that you can die of fatal irregularities of heartbeat when I reviewed promotional materials.

Indeed, most promotional materials rely on testimonials. Sometimes the examples are clearly and dramatically inappropriate.

I have here a newsletter from Diet Center, called Health Measures Newsletter, in which there is a story of a 10-year-old boy who lost 34 pounds in 7 weeks, nearly 5 pounds a week, on the Diet Center Program. Such rapid weight reduction, especially in a growing youngster, can be extremely hazardous and should never be undertaken unless there is some clear, urgent medical reason to do so.

Certainly, caloric restriction in anyone, especially children, should not be undertaken without qualified medical supervision, and to my knowledge, none is provided by Diet Centers.

The issue of credentials and supervision is a difficult one. One of the things that was alluded to—I think Mr. Cutler did this—is that many people probably diet on their own. Dr. Stanley Schacter showed that people who diet on their own by cutting back on fat or snacks often were successful and appeared to encounter few risks.

The second alternative which we will hear from Dr. Wellman is to consult a registered dietitian. These are people who can advise you on what is an adequate diet, a safe and adequate diet, which will allow you to lose weight slowly but safely over time.

There are also group programs providing both group support and elements of behavioral modification without severe caloric restrictions that can be undertaken safely without professional supervision.

On the other hand, if someone chooses to go on a low-calorie regimen or undertake very rapid weight loss, this, I believe, should be restricted to individuals who truly need to do so for health reasons, and, in all cases, it is imperative that there be medical supervision, and that the physicians are competent to identify what the complications are and to intervene early and safely if necessary.

In the case of very-low-calorie diets, competent supervision requires something other than graduating from medical school. The average internist, pediatrician, or primary-care physician can certainly advise people as to whether or not weight is presenting a health hazard, and they can certainly refer patients to a dietitian for sensible weight reduction. But, if you are going to go on a program where there are clear and even fatal hazards, it is important to be followed closely by a professional who is trained in the field.

I mentioned I have been affiliated with the American Board of Nutrition. The qualifications for certification by the ABW are that, in addition to primary training, you must have at least 2 years of
nutrition training and have passed an examination to demonstrate your knowledge. I am not saying that every dieter has to see someone who is board-certified in clinical nutrition, but it would be appropriate to see someone at least-board certified in areas that are relevant, like cardiology or endocrinology, and someone who has some evidence of extensive training, not a 1-day course that the commercial program has provided or a couple of reprints that are sent in the mail.

In the past 10 years, we have made some progress in teaching nutrition. NIH funded a number of clinical nutrition research units. Private foundations have also. At the moment, there are 50 recognized nutrition training programs for advanced training. They are turning out anywhere from 50 to 150 people a year. So, there is not a shortage of people well-qualified to take care of the few people who may need to lose weight quickly.

Let me give you a parallel. As an internist, I am very comfortable in prescribing drugs I was trained for, such as digoxin in people with certain heart conditions. But I would not, under any circumstances, do an invasive procedure such as angioplasty, or angiography, or use drugs to treat very difficult cardiac dysrhythmias, because I am not a cardiologist. If I were to do that, I would not only risk my own professional reputation, I would be risking the life of the patient.

But this is what we face with most of the physicians supervising commercial programs. The physicians are frequently itinerant physicians, part-time physicians, here today and gone tomorrow, and they have little or no training in the field. As someone alluded to earlier, going to a physician-supervised program where the physician doesn't know what he or she is doing is perhaps a greater misrepresentation, because you think you are getting safe monitoring, when in essence you are not.

My conclusions are that we are in the midst of a diet craze. If there were no hazard to this phenomenon, we could laugh at it and let the humorists worry about the nuances. However, as I indicated, there are acute, dramatic, and potentially fatal hazards, and there are the long-term hazards of failure and self-blame that occurs.

The supervision of commercial programs varies from none to instantly created "certified counselors," certified by the companies, to physicians with little or no training, to the other extreme of a few physicians, registered dietitians, and behavioral psychologists who work as a team and truly have the required expertise.

The cavalier attitude that is demonstrated by hospitals and commercial programs who hire inadequately trained staff, I think, reflects a couple of misconceptions. One is the wide-spread notion that obesity is simply a matter of eating too much. The programs have either ignored the scientific information, or they are not aware of it.

Second, the programs ignore or are unaware of the complications.

We have no effective tracking mechanism for monitoring the severity and incidence of complications.

I think several things could be done to help correct this.
One is to get out greater information about the hazards and the lack of demonstrated long-term benefit of very-low-calorie diets. In the short run, I think this can best be accomplished by hearings such as this and by collaboration between scientific and health leaders, on the one hand, and the public news media, on the other.

In the long run, I think we should consider establishing a registry or clearinghouse for collecting reports of adverse effects and making this information available to the scientific community and, when documented, to the general public.

Second, weight-loss programs must be held accountable for their outcomes. All known side effects need to be explained up front. Documented complications, such as gallstones, can't be passed off as simply a consequence of obesity.

Similarly, if dieters gain back most of the weight they have lost in the commercial program, we cannot accept this anymore as simply the fault of the dieter. Were the programs truly effective, this would not have occurred. We must hold the program responsible, not the victim.

Third, severely restricted diets should only be undertaken when people have some clear medical reason for doing so. In all cases, such diets should be supervised by someone who has adequate training in the field, not just a 1-day course.

Fourth, we need standardized reporting of long-term outcomes, and we need something other than "How much weight did you lose?" and "How fast did you lose it?" We need to look at quality-of-life indices and functional indices.

The Food and Nutrition Board of the Institute of Medicine has held a workshop on this subject, and, if they can get further funding, they will go ahead with a 2-year study which will give us outcome indicators that we can use to do cost-benefit and risk-benefit studies.

Finally, we need to combine the considerable knowledge base that already exists with the equally considerable power of the media to advance the idea that individualized healthy weights can be achieved, rather than to continue to promote the unhealthy cultural distortion that has led to our current epidemic of dieting.

Attempts are under way to devise operational definitions of healthy weight. Such a definition can certainly be refined as we get new data, but in the meantime all of us can do more to accept the fact that people come in different sizes and shapes, just as we come in different colors and ethnic backgrounds. Biological variability is not disease; it is one of the strengths of the human species.

Thank you for letting me present these remarks.

[Dr. Callaway's statement may be found in the appendix.]

Mr. Wyden. Thank you, and also to the Nutrition Association as well for your involvement, and we will be working with you in the days ahead.

I will have questions in a few minutes.

Mr. Johnson, why don't we go to you next, and we now welcome you and say that we do know the fine work you do.
Mr. JOHNSON. Thank you, Mr. Chairman.

I am Ray Johnson. I am assistant attorney general of the State of Iowa. For the past 3 years one of my primary responsibilities has been the prosecution of health fraud under the Iowa Consumer Fraud Act and the Iowa Food, Drug, and Cosmetic Act. As part of this responsibility, I have prosecuted numerous cases against individuals and companies making fraudulent claims for diet products.

It is estimated that ineffective weight-loss products cost consumers billions of dollars per year. Perpetrators of diet frauds get rich while victims not only lose their money, but endure the heartbreak and frustration of repeated failure to lose weight. Victims often assume it is their fault that the latest "scientific breakthrough" didn't work for them.

Besides being confused by false and deceptive information about weight control, victims taking useless products waste time and effort which could be devoted to seeking medical treatment or to an effective weight-loss program of modified eating habits and increased exercise. Ironically, many fraudulent diet products actually cause people to gain weight because advertisements falsely represent that individuals can eat all they want or eat all their favorite foods.

Consumers taking questionable diet products are often subjected to serious health risks. In one instance, an Iowa consumer suffered an epileptic seizure because the fiber-based diet pill she was taking absorbed the medication meant to control seizures.

In another instance, a grossly obese homeless person was hospitalized due to complications which resulted from taking a diet pill and following a diet program that had not been shown to be safe or effective.

Phenylpropanolamine, a common ingredient in many diet pills, may cause serious adverse reactions, such as elevated blood pressure in individuals taking other stimulants or medications such as cold medications or products with caffeine. Elevated blood pressure is of special concern to individuals taking a drug to control obesity because of the strong relationship between high blood pressure and obesity.

Most fraudulent advertisements for weight-loss products are easily detected by a trained observer. The advertisements appear in newspapers, magazines, and on television, especially cable television. Advertisements for weight-loss products are commonly sent by direct mail.

Virtually any issue of Cosmopolitan, Globe, the National Enquirer, or similar publications will contain one or more questionable advertisements for some weight-loss product, usually a diet pill. The advertisements are similar in content, often proclaiming that some scientific breakthrough has resulted in the development of a pill that allows a person to lose weight without restricting calorie intake or increasing exercise.

Some scientific study is usually of faulty methodology, misrepresented, or both. In some instances, the scientific study may also be fraudulent. The miracle pill is often said to interfere with the
body's absorption of calories, allowing food to pass through the body while calories are unabsorbed.

Other advertisements tout appetite suppressant effects. Testimonials from individuals who purportedly have taken the product and who have lost substantial amounts of weight in a short period of time are very common. The advertisement may also include a "warning" telling the consumer not to "overdo it" and become "too thin." Of course, the warning is nothing more than a cleverly disguised sales pitch for the product, intended to convey the blatantly false impression to the consumer that the diet pill is extremely effective.

In our investigations and litigation, we have repeatedly found testimonials in diet pill advertising to be false, deceptive, or misleading. Testimonials seldom, if ever, represent the typical experience a consumer can expect from taking the product.

While advertisements frequently proclaim substantial weight loss without restriction of diet or increased exercise, little, if any, effort is made by the seller to be certain that individuals giving testimonials did not modify calorie intake, or increase exercise, or, for that matter, whether the person giving the testimonial even took the product being advertised to lose weight. With most testimonials, there is little support for the conclusion that the diet product being advertised actually caused the weight loss represented in the testimonial.

Testimonials are usually from individuals who have been paid for the testimonial, for losing weight, or both. In some cases we have found that perpetrators have used questionable testimonials from immediate family members and friends of the owner of the corporations selling the diet pill.

Some testimonials have been from individuals who have appeared in other diet pill advertisements and who are attempting to attribute their weight loss to the latest diet pill being advertised as well as to the first.

We have found that testimonials used in a television commercial were from paid models from a local talent agency who were told that if they could lose a certain amount of weight in 30 days, they would get the testimonial work and modeling exposure.

One testimonial from a relative of the owner of a diet company was a photograph of a woman holding out an oversized pair of slacks which purported to show a substantial weight loss from taking the diet pill. In fact, the pants were worn by the woman during pregnancy.

Another testimonial was from an individual who had lost a substantial amount of weight, but the advertisement failed to disclose that the individual was also suffering from a serious illness that probably was responsible for his weight loss.

The most frequent problem we encounter with verification of testimonials is the fact that the company is simply unable or unwilling to provide sufficient information to locate the individual giving the testimonial. We can only speculate as to what we would learn about the testimonial if we could locate the person giving the testimonial.

Perpetrators of diet fraud have learned that they can increase their sales by frequently changing the name and appearance of
their product even though the active ingredients remain the same. Since consumers recognize the product only by name, they will try the same product under a new name in their relentless effort to lose weight. Mailing lists are freely exchanged, so that individuals desperate to lose weight can be repeatedly victimized.

Enforcement actions against individuals and companies selling worthless weight-loss products can be brought by State attorneys general, the U.S. Postal Service, the Federal Trade Commission, or the Food and Drug Administrations. Cooperative enforcement efforts are especially important in the area of diet fraud due to the limitations inherent in actions by certain regulatory agencies and the expense involved in litigating diet fraud cases.

For example, the U.S. Postal Service recently brought an action against Health Care Products, Inc., and was successful in enjoining sales of the Cal Ban diet pill through the mail. In response, Health Care Products discontinued orders by mail and now uses toll-free numbers and a private courier to process orders.

Due to action by our office, Cal Ban can no longer be sold by Health Care Products in the State of Iowa. Unfortunately, that leaves 49 other States where the company can still do business despite action by two regulatory agencies. Cooperative efforts can also streamline litigation and reduce the cost through sharing of information and expert witnesses.

At the present time, efforts to combat diet fraud are being substantially hindered by the Food and Drug Administration’s over-the-counter drug review program and FDA’s companion enforcement policy. It would be extremely helpful if the FDA would complete its monograph for weight-control drugs and immediately bring enforcement actions against ineffective diet products.

I will attempt to briefly explain FDA’s over-the-counter drug review program and its enforcement policy for ineffective weight-loss products.

Prior to 1962, the Federal Food, Drug, and Cosmetic Act only required that drugs be generally recognized by experts as safe before they could be marketed. In 1962 the act was amended to require that drugs be generally recognized by experts as both safe and effective for the drug’s intended use.

Any drug not generally recognized as safe and effective for its intended use is considered a new drug under the Food, Drug, and Cosmetic Act and can only be marketed after FDA approval of a new drug application. Diet products are considered drugs unless they are being sold strictly as a low-calorie food. Any product claiming to alter the way the body digests food is clearly a drug.

Since fraudulent weight-loss products are not generally recognized by experts as effective for their intended use, and since the FDA has not approved new drug applications for the products, the products are unapproved new drugs being sold in violation of the Food, Drug, and Cosmetic Act.

The FDA and most States have authority to bring actions against individuals selling unapproved new drugs. The Federal Trade Commission has prevailed in at least one action where the FTC argued that it is deceptive advertising to fail to disclose that the weight-loss product was an unapproved new drug.
Unfortunately, the Food and Drug Administration has not been bringing actions against individuals or companies marketing diet products that are unapproved new drugs unless the agency believes that the product poses a safety problem. At times it appears as if the FDA has actually authorized the sale of diet products being sold in violation of the Food, Drug, and Cosmetic Act.

The FDA has decided that it would be more equitable to drug manufacturers to allow continued marketing of drugs until the FDA completed monographs on certain categories of drugs. These monographs are intended to establish conditions, if any, under which over-the-counter drugs will be considered by the FDA as safe and effective for the drugs' intended use so that no new drug application is required. All other intended uses for a drug will require a new drug application.

The monographs were to be compiled by advisory review panels consisting of experts from outside the FDA. The FDA began reviewing prescription drugs in 1966 and over-the-counter drugs in 1972. The monograph for over-the-counter weight control drugs has not been completed by the FDA and is not expected to be completed in the near future. In Cutler v. Hayes, the U.S. Court of Appeals, DC Circuit, charitably described FDA's over-the-counter drug review program as "sluggish at best."

Since the FDA has repeatedly announced publicly that it will not bring enforcement actions against unapproved new weight-loss drugs unless the product poses a safety problem, perpetrators of diet fraud have nothing to fear from the FDA as long as their worthless products are not branded by the FDA as unsafe.

State enforcement actions repeatedly encounter arguments by defendants that the FDA has approved the marketing of diet products generally recognized as safe and that the States are preempted by the FDA from taking any action against a diet product.

FDA's policy in this area is troubling for several reasons. The FDA's failure to bring enforcement actions against ineffective weight-loss products has given purveyors of diet fraud full rein for nearly 30 years to violate the Food, Drug, and Cosmetic Act. Resulting consumer losses have been in the billions of dollars.

Additionally, the delay in completion of the over-the-counter weight control drug monograph has complicated enforcement efforts. If the FDA would complete its over-the-counter drug review, enforcement actions by State and Federal regulators would be much easier. Actions that now are expensive "battles" of expert witnesses could be streamlined to simply allege that sellers of worthless diet pills are committing unfair practices by selling products in violation of FDA regulations.

It would also be assumed that the FDA would begin bringing enforcement actions of its own. It wouldn't be long before perpetrators of diet fraud would get the message. State and Federal regulators could then be more effective at taking the profit out of the diet fraud business. The result would be a substantial reduction in consumer financial losses and a reduction in emotional distress suffered by individuals who repeatedly fail to lose weight after trying one "miracle breakthrough" after another.

If we are going to be successful in combating diet fraud, it is imperative that the Food and Drug Administration begin immediately
enforcing the Food, Drug, and Cosmetic Act by bringing actions against diet products that are ineffective.

The long overdue monograph for over-the-counter weight control drugs needs to be completed. Cooperative efforts between State and Federal agencies need to be continued and encouraged.

Finally, the Federal agencies, such as the Food & Drug Administration and the Federal Trade Commission, need to be given the resources to combat diet fraud, and the agencies need to allocate those resources to bring enforcement actions that will remove the profit from this lucrative fraud.

What is at stake here is the safety and welfare of hundreds of thousands of vulnerable Americans. These hearings can be an important step in developing more effective protections for these consumers.

I appreciate this opportunity to testify today and look forward to working with the subcommittee in the future.

One additional comment I would like to make is that I am especially grateful for the three consumers who came forward and testified today. One of the problems that we have in this area is getting consumers to come forward and tell about their experiences. If we could encourage more of that, it would be very useful to regulatory agencies.

Thank you.

[Mr. Johnson's statement may be found in the appendix.]

Mr. WYDEN. Mr. Johnson, thank you very much for a very helpful statement. We will have some questions in a moment.

Dr. Wellman.

TESTIMONY OF NANCY S. WELLMAN, Ph.D., PRESIDENT, AMERICAN DIETETIC ASSOCIATION

Dr. WELLMAN. Good afternoon. I am Nancy Wellman, president of the 60,000 members of the professional organization called the American Dietetic Association. I thank you for recognizing the situation on very-low-calorie diets and for inviting us to describe the important role that registered dietitians must play to enhance VCLD safety and long-term effectiveness.

Because most of us who have been in this room since earlier this morning are probably now in a fasting state ourselves, I will try to keep my remarks brief, but I do request that ADA's position on very-low-calorie diets, our licensing fact sheet, and the list of laws that regulate nutrition professionals be included in the hearing record.

Mr. WYDEN. Without objection, your thoughtful comment is noted, and I would say from this side of the dais that we are also concerned about environmental issues, and when we talk too long, it contributes to global warming.

Dr. WELLMAN. We are on the same wave length.

Mr. WYDEN. We will be brief, and we welcome you.

Dr. WELLMAN. Great.

As we heard, millions of us are dieting and spending millions doing it. Weight-control products and programs come in many forms—powder and liquid formulas, prepackaged, portion-con-
trolled foods, diet pills, and an array of special clinics, to name a few.

The ADA has long been concerned about the efficacy of some diet programs. This is where we are particularly concerned—those directly marketed to consumers. Unfortunately, I think all the testimony today supports the fact that the focus is often on the pocketbook and not on the paunch.

We feel that direct marketing encourages their use by inappropriately self-chosen people, people only slightly overweight themselves. These people are more likely to lose lean body mass than are those who are morbidly obese. Direct marketing to the public bypasses the careful screening and selection process that ADA considers essential.

While there are certainly people for whom medically supervised, very-low-calorie diets can be very beneficial, the ADA recommends rapid weight loss only for obese people more than 30 percent overweight. Factors such as medical necessity, health and psychological status, and compliance potential must be evaluated before enrolling a person in a very-low-calorie diet program. They should be undertaken only with the supervision of a qualified health team, including a physician and registered dietitian. I think we have heard that repeatedly today.

Appropriate and responsible administration of a very-low-calorie diet program demands, for the first time in a person's life, the establishment of sound life-long reinforcers. Yet we have heard that even the millions of people who are reinforcing Oprah Winfrey's weight loss are not helping her as much as we would think they would.

Such techniques include behavior modification and exercise to enhance someone's weight loss and their new self-image. We do believe in comprehensive, hospital-based programs that offer a full range of professional services. They require, not only encourage but require, attendance at, and involvement in, all aspects of the program and they provide long-term support.

But even quality VLCD programs are not for everyone. Certainly not for the persons with medical complications such as cancer, type 1 insulin-dependent diabetes, renal failure, cardiac dysfunction, severe psychological disturbances. Also they are not for infants, children, or teenagers. I think it was appalling to see the number of youths who are enrolled in these programs. Certainly they are not for pregnant or breast-feeding women or for our older Americans.

The most significant drawback to these diets is the potential for life-threatening side effects. I think that was clearly demonstrated by the earlier panel.

The loss of body protein—and here we are talking about lean body mass, and we are talking about muscle tissue—may affect cardiac function and could be related to heart failure. Other side effects are anemia, light-headedness, constipation, diarrhea, and menstrual irregularities.

Another significant shortcoming of some weight-control programs is this diversity of credentials, or lack of credentials, among the nutritionists on staff. What is a nutritionist, or who is a nutri-
tionist? There is really no consensus definition. In most States, anyone can call himself or herself a nutritionist.

Even the Federal Government is involved in this dilemma. The Health Care Financing Administration has been struggling for 2 long years to define what a dietitian is, as it revises the conditions for participation in nursing homes.

To cut through this confusion, consumers should know to look to registered dietitians as the bona fide experts in nutrition and health. The letters RD after a professional's name, standing for registered dietitian, signify that he or she has met stringent national requirements established by the National Commission on Dietetic Registration. It means that they have at least a bachelor's degree in food and nutrition from an accredited college or university, not a mail-order college or university, and at least 6 months of supervised experience followed by competency-based examination.

To maintain our RD credential, we dietitians must acquire at least 75 hours of continuing education every 5 years. Our undergraduate education must be up to date. We have a strong accreditation and approval process for university programs, and every program is regularly reviewed, and an accreditation or approval is withdrawn if the program fails to keep up to snuff.

We felt that consumers were adequately protected 20 years ago when we instituted the RD credential, but today we see that, as estimated by the National Council Against Health Fraud, quackery costs Americans billions of dollars, and the most common type of quackery is nutrition fraud.

People can consult licensed nutrition professionals in some States. Last June, Oregon became the 26th State to regulate nutritionists. Unfortunately, Michigan has no regulation.

Licensing is one way to protect the consumer from sometimes dangerous consequences of nutrition fraud. Consumer education is another essential feature.

We have listed a variety of indicators that we share with the public in order to help them understand that if they are self-selecting a weight-loss program, what they can look for. We are encouraging them to look for a variety of foods. We are saying that the program should be individualized and specifically individualized, not quasi-individualized, to fit a person's life style and food preferences.

This individualization will diminish feelings of deprivation which lead to discouragement. Bingeing, discouragement, and rebound weight gain are all hallmarks of what we call the yo-yo diet syndrome. We are interested that our clients take on a weight-loss program that has enough calories. If it is a self-selected program, certainly less than 1,200 calories a day is not a good idea because of the loss of muscle rather than fat.

We think that people should have realistic weight-loss goals. We realize that Americans are into the quick fix, and yet we think a maximum weight loss of about 2 pounds a week is advised and realistic.

We think on these more moderate diets or weight-loss programs that regular exercise can be a healthy part of them. We certainly feel that behavior modification is a critical aspect because we have
to help people change their eating behaviors and responses to foods for the rest of their lives.

Regaining the lost weight, I think, is one of the hallmarks of the consumer rip-off, if there have not been other, more serious physiological consequences. Eventually, all dieters must learn to deal with food. Changing their food habits is a gradual, step-wise process which requires individualization, ongoing monitoring, and reinforcement. Hence, the services of a registered dietitian are essential in helping people make permanent adjustments in their eating habits.

We have a number of examples of clients who have been referred to dietitians after they have been on some of these lesser quality, very-low-calorie weight-loss diets, but I agree with other panel members that we don’t have enough people speaking up about it. Most dietitians can give you a number of stories, but they will also tell you that a number of people who have come to them with personal horror stories don’t want to make them public. They feel stupid. They feel that they have been duped, and they feel guilty themselves.

So, rather than go into those, I think we have had a sound set of examples from the panel members. We won’t cite more examples, but I think there are literally thousands and thousands of them out there.

I thank you for this opportunity to present the views of the American Dietetic Association, and would be pleased to answer any questions.

[Dr. Wellman’s statement may be found in the appendix.]

Mr. Wyden. Doctor, thank you.

Thank all of you. You have given excellent presentations, and we are appreciative.

Dr. Callaway, let me begin with you. It is our understanding that many of the commercial weight-loss programs use a standard 1,000- to 2,000-calorie diet for a large number of their clients. Are you saying that some of these commercial programs might be unsafe for some people?

Dr. Callaway. I think it is probably 1,000- to 1,200-calorie diets.

Mr. Wyden. I'm sorry, yes; 1,000 to 1,200.

Dr. Callaway. Many go down to 400 or 500 calories. Whether it is safe depends on how many calories your body needs. A thousand calories for a 60-year-old lady, who is 5 feet tall, weighs 120 pounds, and is inactive, is not much restriction. A thousand calories for a 20-year-old who weighs 280 is semistarvation. In that setting, if the person stayed on 1,000 calories for a long period of time, they could get into trouble.

Mr. Wyden. One of our witnesses reported she had lost 17 pounds in 3 weeks. What do you assess that kind of diet to be?

Dr. Callaway. That would be a diet that would have to be very, very restrictive in calories and probably also in carbohydrates.

If you look at that, roughly two thirds of that weight loss would be water loss.

Mr. Wyden. Water loss?

Dr. Callaway. Yes. I should mention this: The water is coming from inside the cells. When it is lost, the dieter also loses potassium, magnesium, and other electrolytes.
When blood potassium is measured, only 5 percent of the potassium in the body is actually in the blood. If you lose it from the other 95 percent in the cells, you are losing body potassium and you are at risk for fatal irregularities in heartbeat even though your blood level may be normal.

Mr. Wyden. That is what concerns me. Potassium and magnesium loss are associated with heart problems, are they not?

Dr. Callaway. They are, and if you go back to the 1970’s, at least a third of the people who died on the liquid protein diets, died when they came off the diet. In one of the cases mentioned this morning, coming off the diet may have been involved in the complicating. So, refeeding is a hazardous time.

Mr. Wyden. Many of the commercial clinics rely heavily on vitamin and mineral supplements. Do you think that these are being touted as offering more than they actually do?

Dr. Callaway. They are. As Dr. Wellman said, if you go below 1,200 calories, it is difficult to get adequate minerals and vitamins and the diet does not provide it alone. Such dieters should take a supplement.

What you see in the commercial clinics is not simply giving you a single tablet that you can buy $3 for 100 or $5 for a hundred; you are seeing them taking three pills with breakfast, three for lunch, six for dinner, and the pills end up being a substantial part of the cost. This is a packaging and marketing rip-off.

Dr. Wellman. The videotape this morning showed false promises of what the vitamin supplements would do.

Mr. Wyden. Yes.

Dr. Callaway. They also said this will keep your energy up. If your metabolic rate goes down in starvation, yours, mine, or anybody, we will get cold, tired, constipated, and all the rest.

Mr. Wyden. Regardless of——

Dr. Callaway. Regardless of how many vitamins you take. It is calories, not a vitamin issue.

Mr. Wyden. Dr. Callaway, are you concerned that on a widespread basis, clinics are allowing untrained personnel to supervise dieters?

Dr. Callaway. I am concerned. Some of the personnel are totally untrained and have little experience, yet they are called certified counselors. Others include physicians who have minimal or no training in the special problems associated with semistarvation.

I reviewed depositions of physicians who were being sued, where the physicians monitoring these programs attended none of the training programs, could not identify anyone in the field who had expertise, and were unaware of what they were looking for when they got electrocardiograms on patients. This is worse than no supervision at all.

Mr. Wyden. Is it correct, Dr. Callaway, that virtually none of the commercial clinics have conducted scientific, statistical, valid research to determine how well their clients maintain their weight after they leave the program?

Dr. Callaway. That is correct. There are anecdotal reports that have been published, but if you look carefully, what you see is 800 people started the program, for example, and in 6 months they present data on 180 people, and at 2 years they present data on
less than 100. Such distortion in reporting data is not science. It is purely promotion.

Mr. Wyden. I have not seen any of the ads—virtually any sector in the diet business—that talk about poor success rates or the risks from yo-yo dieting, up or down. Have you?

Dr. Callaway. No; I haven't. As part of my humor—probably because I haven't had lunch—it is like a politician running for office saying, "I want to raise taxes." You don't see that very often.

Mr. Wyden. Not in Oregon.

I gather the Nutrition Association that you represent feels this question of yo-yo dieting is a particularly serious problem.

Dr. Callaway. The American Board of Nutrition tests people on what is considered established scientific knowledge; it does not take a position, per se, on any specific subject. However, the question of yo-yo dieting is one in which there is enough scientific information to warrant the National Institutes of Health having funding studies on this subject, even to the point of considering a large multicenter grant application a year ago.

The data are accumulating rapidly, both in human and in animal studies.

Mr. Wyden. But it is true, as in the question of poor success rates, you don't hear anything about the concerns relating to yo-yo dieting; is that correct?

Dr. Callaway. Correct.

Mr. Wyden. Your statement suggests that most people blame themselves when they gain the weight back.

Dr. Callaway. Yes.

Mr. Wyden. Do you think that makes them less likely to complain to the company or the clinic where they went?

Dr. Callaway. I think it does. It is assumed by the people supervising the program that those who fail are noncompliant. Second, almost everybody will veer a little bit from the prescribed diet. When they do, particularly if, for example, they eat a little carbohydrates, they will gain 2 or 3 pounds. They conclude, "I went off the diet, and, therefore, it is I who have failed."

Mr. Wyden. One last question. We have been sitting here for 3½ hours and the subcommittee staff has done considerable research to prepare for this hearing, and essentially what this issue has been all about is that you have to lose weight fast. If you were to find one common denominator in all the products and all the promotions, lose weight fast, do it quickly—seems like overnight. Is it your sense that most Americans actually have to lose this weight in such a short period of time?

Dr. Callaway. Before I answer, let me echo and commend the staff. I think they did an excellent job in preparing background information. That alone will help educate the public.

In answer to your question, there are very few of us who need to lose weight in a hurry. There are very few of us who gained weight in a hurry. If we lose weight at a rate as low as a half pound a week and maintain that weight loss, we are way ahead of the game. If we lose at 6 pounds a week and gain back 8 pounds, we have lost in the long run. There are very few of us who need to lose weight in a hurry.
Mr. Wyden. Less than 10 percent? I have heard discussion that less than 10 percent of our citizens actually need to have this very rapid weight loss.

Dr. Callaway. I personally think that only about 25 percent of Americans are overweight, depending on what criteria you use. Yet, we have 50 percent of adult women dieting and not all the people overweight are dieting.

So, looking at that, I would say far less than 10 percent of the people dieting need to lose weight in a hurry. I would put it down in the 1 to 2 percent range.

Mr. Wyden. What you are saying is, possibly a great many people on these rapid, crash-weight-loss programs may be hurting themselves more than helping themselves.

Dr. Callaway. That is correct, not only on the short term because of the complications we have heard. You referred to the yo-yo or cycling phenomenon. We have good evidence that what you lose is not what you gain. You lose fat and muscle; you gain back primarily fat, and when you gain it back, it tends to come back in the belly, which is the area excess fat is most associated with complications such as heart attacks, diabetes, high blood pressure, and strokes.

So, even if the dieter ends up at the same weight, he or she has a different distribution of that weight, a more hazardous distribution of that weight.

Mr. Wyden. Thank you. Doctor, we appreciate your help and your organization's help.

Mr. Johnson, let me go to you. I was reading your testimony today, and I have been involved in essentially science and health issues almost 20 years now dating back to the days when I was director of the Gray Panthers at home in Oregon, and this is one of the strongest statements I can recall hearing about the Federal Government surrendering its responsibilities in the consumer protection area.

I look at page 15 of your testimony: "Perpetrators of diet fraud have nothing to fear from the Food and Drug Administration. FDA failure to bring enforcement actions against ineffective weight-loss products has given purveyors of diet fraud full rein to violate the Food, Drug, and Cosmetic Act."

I gather from your statement that you feel that the Food and Drug Administration, in particular, has just dropped the ball on an issue that is going to become more and more important in the days ahead.

Mr. Johnson. I don’t think there is any question that in this particular area that has happened.

In 1962, the amendment was passed that required over-the-counter drugs to be not only safe but effective. That is almost 30 years ago.

Ralph Nader's organization brought two lawsuits over just the problem with over-the-counter drugs in general against the Food and Drug Administration. In the diet pill litigation that we brought, and it is not necessarily just diet pills, but diet litigation, we know as soon as we file that lawsuit that we are going to be faced with argument from the defendant that were preempted because of the Food and Drug Administration saying it is OK to
market these products. So, in this particular instance, they are not only part of the solution, they are also part of the problem.

Having said that about the Food and Drug Administration, I would like to add, so that I don’t leave the wrong impression, the Food and Drug Administration in many efforts has cooperated with our office, and we continue to have an ongoing relationship with them. In fact, they have provided expert witnesses and witnesses for us in diet litigation. But the fact remains that until we get that monograph completed, this litigation is going to be very expensive.

Attached to my testimony, you will note a letter to Congressman Waxman. There is one portion of that letter which highlights the problem. It was in regard to the Cal Ban diet pill where the FDA just flat took the position it was OK to market that drug until they completed their drug monograph.

I happen to think that Cal Ban alone has taken $22 million a year from consumers for a product that is totally ineffective and may have some safety concerns. So, that is disturbing.

Mr. Wyden. It certainly disturbs me as well.

I sit on Henry Waxman’s subcommittee as well, which has jurisdiction over Food and Drug, and we are going to follow up on your concerns about FDA right away.

It is quite obvious FDA has plenty of problems. As you know, they have had a very serious problem with regulating generic drugs, which are so important to the elderly, in particular, holding down their medical bills. But there is no excuse for the kind of performance that you have described at FDA, and we are going to follow up on those issues right away, and start with trying to get that survey out, as well, so that regulators like yourselves will have some good faith on which to proceed.

You described the perpetrators of diet fraud as, in your words, a very close group. Has there been any effort by authorities on the Federal and State level to try to target specifically this kind of close group?

I don’t think you are talking about organized crime or anything like this, but when you talk about a very close group, it seems to suggest that there are specific individuals that you can really zero in on, and try to go after those, and make a dent in the problem. Has that been the case?

Mr. Johnson. I should clarify that a little bit in light of the hearing. The hearing is broad based, covering all types of what I would call the blatant diet fraud, and also other types of what I would call deceptive advertising, those types of problems. So, we are talking about a broad-based industry.

When you get within that industry, you are talking about very close-knit groups. That is especially true in the types of advertisements you see for diet pills. That is a very tight-knit industry.

As soon as we file any lawsuit against a diet pill company, we can almost be assured that we are going to get a call from one of three attorneys in the United States, and certainly there are many attorneys in the United States, but we know that we are going to get a call from one of three who is going to be representing that client. We also know that the ad agencies that these companies use are the same.
You mentioned organized crime. While we are not talking about organized crime in terms of what you would think of as people going out and killing individuals, it is not that type of crime, but there is no doubt that we are talking about crime that is organized, and we are talking about a small group of people who continually show up over and over behind these frauds.

Chairperson Steiger mentioned the Fat Magnet case. When Postal took its action against Fat Magnet, they brought the action actually against Allied International and an individual called Harold Martino. We subsequently took Martino's deposition, and it is clear that Martino knew very little about the company that he was running. In fact, the individuals behind Fat Magnet are individuals by the name of Eric and Milton Linder. These two individuals have a long history in this area.

Eric Linder, in fact, was involved in Fat Magnet through an advertising agency. Milton Linder was actually running the company, but his name doesn't show up on any of the documents. So, we are talking about people who are well-organized and well-financed. A group of individuals who are professionals at starting one corporation after another and in fleecing people of their money.

Mr. Wyden. Is it correct to say, though, that what would be needed is an effort to target between Federal and State officials this group that keeps turning up again and again in terms of diet fraud?

Mr. Johnson. It is very important.

One thing I would like to add in that regard is the States can't do it alone. The Federal Government can't do it alone.

In Iowa, when we take an action against a company such as—I will use the same example—against Allied International, we have serious jurisdictional problems of getting at the people who are responsible. The corporation that is actually selling the product in Iowa may be Allied International, but we may have in that case, doctors, other corporations, and individuals who are also involved but who we might not be able to get jurisdiction over. So, it is very important that we coordinate efforts.

Cal Ban is a perfect example of why efforts need to be coordinated. We have enjoined that company in Iowa. Only the FTC, or FDA, or the State where the company is located can stop them nationally.

Mr. Wyden. With respect to these testimonials that you talked about where someone says how helpful it has been to them, do you believe that these are enough of a problem that we ought to eliminate testimonial advertising in the field per se and just bar it?

Mr. Johnson. I am not sure about elimination of it. I personally feel it serves no purpose at all. Blanket, total elimination may cause some First Amendment concerns. But there is no doubt that testimonials are serious problems.

Mr. Wyden. Particularly by celebrities. Is that one of your concerns?

Mr. Johnson. The fact that it is by a celebrity is a problem, but the most serious problem with testimonials is the fact that in no way does the testimonial usually represent the experience that a consumer can expect from taking the product.
Number two, if a consumer is successful in obtaining that result, I believe from what you have heard here, it is not a safe result. If you look at some of the ads we have here representing various losses of weight of 50 to 100 pounds in extremely short periods of time, our experts tell us, and I think the experts here today would agree, that is not a good situation. That is the problem I see with testimonials.

Mr. Wyden. Your position would be that certainly there ought to be some standards in this area?

Mr. Johnson. I think that testimonials first and foremost should be truthful. They should be nondeceptive. The testimonial shouldn't represent some experience that is not going to be a typical consumer experience with the product, and probably, most importantly, the testimonial shouldn't encourage unsafe behavior.

Mr. Wyden. I was interested in your comments about fiber-based diet pills and the ones that contain phenylpropanolamine as well. Do you think that there ought to be an effort to ban over-the-counter sales of these kinds of products unless there is a doctor's prescription?

What is your recommendation in that area?

Mr. Johnson. I think we should enforce the law we have now, that is very good, which is the U.S. Food, Drug, and Cosmetic Act prohibiting the sale of any over-the-counter drug that is not generally recognized by experts as safe, or effective, or for which a new drug application has not been approved by the FDA. From my consultation with our expert witnesses, phenylpropanolamine would not be generally recognized by experts as either safe or effective for the intended use for which it is being sold for.

So, in that respect, I think the law should be enforced that we have, and, yes; it should be banned.

Mr. Wyden. When you discussed this with the FDA, you talk about enforcement in some of these areas that your survey has found the greatest problem. What do they say? Just not interested in enforcing the law, or what?

Mr. Johnson. Our discussions with the FDA always get down to the monograph program, that they are not going to take actions against ineffective weight-loss products that are drugs until that monograph has been completed.

The rationale behind the monograph may have been good 20–25 years ago when, in 1962, Congress suddenly added a requirement that drugs not only be safe but they also be shown to be effective. The problem was that at that time we had literally hundreds of drugs that had to be reviewed to determine whether they were effective, and the FDA wanted to avoid taking all of these drugs off the market, because some of them may have been effective.

So that manufacturers wouldn't suffer huge losses and effective drugs wouldn't be pulled from the market, the FDA started the drug review program, which at that time made sense.

But in the diet area, where 30 years later what may have made sense for 1 or 2 years at that time, doesn't make sense for 30 years. The other problem that I have with FDA's policy is that a lot of these ads you can look at them on their face and you don't need an expert to tell you that those products are not effective for their intended use.
So, I think in this area, the policy makes no sense at all. It is particularly disturbing if the FDA has decided that they are not going to bring enforcement actions. That is one thing; but then to announce to the drug industry that you are not going to bring enforcement actions so that the industry knows that they have a safe and free ride from the FDA, that is a real problem.

In our office we have——

Mr. Wyden. And preempt you at the State level from taking any actions as well.

Mr. Johnson. So that my comments are not used against me in my own litigation, I want to point out that we take the position that we are not preempted, that FDA's rules don't preempt us, and that even if FDA allowed the marketing of ineffective drug products, if there was such a rule, it is what we call ultra vires. It is void because it is in conflict with the Food, Drug, and Cosmetic Act and can't preempt us.

In our office, we also have to allocate resources. Every time I pick up an edition of the National Enquirer or Globe, I figure oh, my God, I could spend 2 years litigating the ads in just this one issue.

So, we have to make resource allocations, too. But to our office, it's very important that we don't announce how we allocate those resources so that people who are selling fraudulent products know that if they sell the product in Iowa, there is a chance that we may bring an enforcement action against them.

So, it's particularly disturbing, number one, for the FDA not to do anything; and number two, to announce that they are not going to do anything.

Chairman Wyden. Your testimony and your discussion here has been very helpful, and I think it really highlights how much work we have to do.

It would seem to me the very least the Federal Government, specifically the FDA, ought to be doing is making your job easier. What you said is, at the most charitable. They are putting more obstacles and hurdles in your way. It's certainly an indication we have a lot of work to do, and we will be pursuing it with you.

Thank you for excellent testimony.

Chairman Wyden. Dr. Wellman, a couple of questions for you, if I could.

You state in your testimony that the ADA has always been concerned about the efficacy of some diet programs, especially those directly marketed to consumers.

What concerns you most about these products, these state-of-the-art products in particular, like the clinics and the liquid protein diets?

Dr. Wellman. I think a solid screening process to make sure that only the appropriate clients who should be enrolled in those programs are enrolled, and I am assuming though that those are quality, comprehensive programs.

Chairman Wyden. Is that the case usually?

Dr. Wellman. That doesn't seem to be the case. It seems the more overtly and directly put to the consumer, the less well-funded is the program. From the quality of the food product to the quality of the staff, we have major gaps.
Chairman Wyden. Are you all concerned about what we have heard today, and I think my staff has talked to you about it in terms of our research, which indicates that there are a fair number of people who seem to be holding themselves out as experts, who really have virtually no training at all, maybe just have a few days worth of training, and suddenly they become a nutritionist or a diet expert.

Do you feel that this is a growing problem?

Dr. Wellman. It's a major concern of the American Dietetic Association because literally, as I said, anyone can call themselves a nutritionist.

We have a number of fairly active mail order universities that will sell you a credential. Depending on the level of credential is how the price is adjusted, and when we try to license nutritionists or registered dietitians in States, we encounter a lot of opposition from the health food store industry because some clerks working in those stores like to call themselves nutrition counselors.

They like to give lots of advice that maybe isn't on the label of the vitamin or mineral because of labeling regulations, but they like to encourage people to buy them with promise that wouldn't be allowed on the label.

Chairman Wyden. Virtually anybody can be registered through the mails.

Dr. Wellman. Right.

Chairman Wyden. Staff says that animals get registered as nutritionists and the like.

Dr. Wellman. Yes; a dietitian in Florida has gotten the credential for her 8-year-old daughter. There is no criteria.

Chairman Wyden. What do professionals like yourself feel we ought to be doing to try to ensure some minimal standards and accountability?

Dr. Wellman. We would like support in our licensing efforts in States. We have now got licensure at about half the States and yet in many States, the opposition is quite strident, and so we need support for licensing.

Chairman Wyden. Who opposes minimum qualifications for nutritionists at the State level?

Dr. Wellman. It ranges from chiropractors to clerks in health food stores, and some of the groups are quite well organized.

Chairman Wyden. How about these national companies, though? Do these national companies?

Dr. Wellman. Yes; they do. In fact, personally, I know we had some resistance from some of the national diet companies in several States.

Chairman Wyden. Which companies in particular oppose some of your efforts at the State level?

Dr. Wellman. I could check on that. I would rather not mention names if I am not positive, but I know there are some very active ones because they want to call their staff nutrition counselors.

Chairman Wyden. Let's hold the record open on that point.

Dr. Wellman. Thank you.

[The information was not received.]

Chairman Wyden. I understand your concern.
Does your organization have a code of ethics that prohibits dietitians from participating in diet programs that are not safe or proven effective?

Dr. WELLMAN. Yes; we do. We have a very strong code of ethics. It's a model for many health organizations, and we have an Appeals Committee, Hearings Committee, and Ethics Committee, and we are very active in that area.

We don't see a lot of dietitians misrepresenting or holding out unfounded promises in these kinds of weight-loss programs.

We understand human metabolism, physiology, human behavior, all of the things that get people into the overweight state that they are in, and we know that it's not a simple, quick fix.

Chairman WYDEN. Is there a uniform definition in the dietary field as to what constitutes medical supervision?

We have been concerned, particularly in the clinics, that it just seems there is virtually no professional supervision at all.

Dr. WELLMAN. Yes; and I think that the concern is well-founded. In fact, our concern is that we have a comprehensive health team, which includes a physician and a registered dietitian.

Dr. Callaway might want to comment on that.

Dr. CALLAWAY. I think it was in 1983 that a panel at the International Congress of Obesity recommended that all weight reduction programs have this team approach, with registered dietitians, physicians, exercise specialists, and behavioral psychologists. This recommendation has been out there now for 8 years, and yet practically none of these programs have implemented it.

Chairman WYDEN. Would any of you like to add anything else?

You all have been very helpful. It's been a long hearing, and let me just say I think in many respects, it's very fitting that we have all of you as experts here to sum up.

For the last 4 hours we have heard a real chronicle of problems that are facing the diet business and diet programs, particularly as it relates to these very new programs, the clinics, and the liquid weight-loss programs.

I think it's obvious that we are going to have to involve the Federal Government, particularly the Federal Trade Commission, we heard from today.

The Food and Drug Administration—Mr. Johnson has outlined a number of areas where that agency has got to step forward and act more aggressively to protect consumers.

We are going to need to consult often with all of you, because you are on the front lines. It's one thing to do the research, and I think the staff in particular has done an excellent job in pulling together the research necessary for this hearing.

But as we look in the days ahead to real reforms, all of you who have to implement these programs and run them in an effective way are going to have to give us your input and your counsel.

So, we appreciate your being with us. It's been a long hearing, but you all have helped us to end it on a fitting note, and we thank you.

Unless you would like to add anything further, we will adjourn at this time.

Dr. WELLMAN. Thank you.
[Whereupon, at 1:45 p.m., the subcommittee was adjourned, subject to the call of the Chair.]
Thank you Chairman Wyden for allowing me to submit these remarks to be included in your hearing record. I want to applaud the leadership you've shown in protecting Americans from dangerous and misleading health related advertising. I also want to join with you in welcoming Mrs. Steiger to this hearing and I congratulate her on her appointment. I concur, Mr. Chairman, with your stated commitment and desire to work closely with both Chairwoman Steiger and the staff of the Federal Trade Commission.

I appreciate Mrs. Steiger's taking the time from her busy schedule to appear before this Subcommittee and discuss some of the advertising issues and trends currently facing the FTC. I have a particular concern over the growing television phenomena known as infomercials. These are program-length commercials shown primarily on independent and cable television stations which sell everything from financial security programs to diet regimes and kitchen utensils.

Mr. Chairman, last year you joined my small business subcommittee in a hearing that specifically focused on one infomercial --- "Money, Money, Money" -- and how that infomercial affected both state and federal small business loan and grant programs. The infomercial told viewers that there was "free money" to be had from the government for starting a small business. It told viewers that government was trying to hide that money from the American people. It told viewers that there was a quick and easy path to obtaining lots of easy money -- money that would never have to be paid back. That infomercial was specifically designed to look like a television talk show, and the required disclaimers informing viewers that the program was a paid commercial message were all too often simply forgotten.
The "Money, Money, Money" infomercial resulted in flood of inquiries and demands for "free" money that severely strained the resources of many state and federal small business support agencies. Other infomercials, selling sunglasses and hair-replacement tonics, promote ineffective or un-workable products. The FTC has taken steps to stop some infomercial rip-off artists. However, continued vigilance is required.

At the time of last year's hearing, Mr. Chairman, you and I expressed to the FTC's Consumer Protection Bureau our concerns over the wide circulation of infomercials that fail to inform viewers that they are seeing a program-length advertisement. Viewers need to know they are watching an advertisement because channels can now be changed from across a room with the push of a button. As a result, viewers constantly flip in and out of programs and can easily miss disclaimers and labels and never realize that they are watching a commercial message.

Viewers who don't know they're watching a commercial message are susceptible to all sorts of questionable claims and products. This is best illustrated by the focus of today's hearing -- advertising in the diet industry. Diet infomercials, in the form of talk-shows and investigative reports abound on cable and independent channels. A viewer tuning-in after a program begins might never see a product disclaimer or a notice that the program is a commercial message. Instead, the viewer will see people claiming to be doctors and health care professionals interviewed in a talk-show or news-show format. These "experts" will claim that their diet program or miracle diet product is a "scientific breakthrough" that is "safe, easy and risk free". Consumers have no yardstick to measure such claims or evaluate the credentials of these self-proclaimed "experts".

Both Congress and the FTC must be concerned with the growth of this potentially misleading advertising method. We must work together and ensure that viewers are afforded all the consumer protection required by law.

Let me be clear, I do not advocate prohibiting infomercial advertising. Program length advertisements can be an extraordinarily effective means of providing consumers with important information about products and services. Rather, I am urging that regulations already on the books to protect consumers from unscrupulous, fraudulent and misleading advertising be enforced.
In short, let's pull back the curtain and let the American public see that the Wizard isn't quite so magical or mysterious.

Mr. Chairman, along with you I believe that the skeptical and informed consumer is a better consumer --- especially where questions of appropriate health care are concerned. Unfortunately, infomercials can cloud considerations crucial to sound health-care choices.

We've passed laws and constructed regulations necessary to protect consumers. The question I hope will be answered today is: Are these rules and regulations being enforced? As you know, we are working together on a future hearing that will focus specifically on some of the problems posed by infomercials. I look forward to working both with you, Mr. Chairman, and with Mrs. Steiger, to further ensure that we effectively enforce the laws protecting consumers from false and deceptive advertising.
PREPARED STATEMENT
OF
THE FEDERAL TRADE COMMISSION
DELIVERED BY
JANET D. STEIGER
CHAIRMAN
BEFORE THE
SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY
OF THE
COMMITTEE ON SMALL BUSINESS
U.S. HOUSE OF REPRESENTATIVES

MARCH 26, 1990
Mr. Chairman and members of the Subcommittee: I am Janet Steiger, Chairman of the Federal Trade Commission, and I am delighted to appear before you today on behalf of the Commission to discuss Commission activities in the area of health care, and, in particular, those activities that relate to our efforts to combat fraudulent and deceptive claims concerning weight loss products and programs.

The Commission has an important, longstanding commitment to protecting the public from deceptive practices in the marketing of health care products and services. Our staff has worked closely with you and your subcommittee staff over the last year regarding the Commission's efforts in this area, and we look forward to continuing our relationship into the future.

Before I describe for you how we have addressed deceptive weight-loss claims in the past, as well as our plans for the future, I want to briefly bring you up to date on a few other health care topics in which you have expressed an interest.

**FTC Efforts in the Fields of Cosmetic Surgery and Infertility Services**

Since your hearings last year on infertility services and on cosmetic surgery, our Bureau of Consumer Protection has contacted dozens of medical professionals and firms about their
advertising. As a result of these inquiries, the Bureau has conducted law enforcement investigations into advertising practices used by a number of providers. Our investigations encompass a myriad of issues, including lack of support for safety and efficacy claims for certain cosmetic procedures and exaggerated success-rate claims made by providers of in-vitro fertilization services.

I am happy to report that several of these investigations are now complete and that staff is actively exploring consent negotiations with the parties involved to obtain voluntary but binding remedies for any alleged violations of the Federal Trade Commission Act. If satisfactory consent agreements cannot be achieved, staff will prepare complaint recommendations to the Commission.

We have also successfully concluded our federal district court case against a provider of infertility services, obtaining a strong injunction against future misrepresentations and up to $250,000 in consumer redress. Additionally, the Commission has recently initiated an injunctive action in federal district court charging that a marketer of courses purporting to teach the application of permanent eyeliner, makes false claims on a number of counts and provides the purchaser with phony credentials as a

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"licensed" and "board-certified dermatologist" through an allegedly phony certifying board.  

On the consumer education front, we have just completed two new "Facts for Consumers" brochures for those considering either in-vitro fertilization or cosmetic surgery. We are working to identify groups who can help us distribute these brochures widely.

We are also working cooperatively with state medical boards, who must regulate not just the promotional activities of physicians but also the overriding issue of physician competence. Next month FTC staff from two of our bureaus, the Bureau of Competition and the Bureau of Consumer Protection, will attend a meeting of the Federation of State Medical Boards to discuss the respective roles of federal and state authorities in the whole health-care arena. Your staff will be there too, I know, to further your own deep concern for greater oversight of this area. FTC staff will deliver the clear message that the Commission encourages strong state-board activity against deceptive advertising.

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2 Federal Trade Commission v. Ronald Dante et al., Civil No. 90 0945 RG(Cx), (Central Dist., Calif., 1990)
I should now like to move on to the principal subject of these hearings, the advertising and marketing of weight-loss products and services.

According to the Food and Drug Administration, as many as a third or more of adult Americans are overweight. For many people these extra pounds can present a clear health risk. Reports from the National Institutes of Health's Framingham Study, the American Cancer Society Study, insurance companies, and others indicate that life expectancy is greater for those who are not overweight and lessens as pounds are added on. The NIH Consensus Conference on the Health Implications of Obesity reported that an increase in body weight of 20% or more above desirable body weight constitutes an established health hazard, and that obesity is clearly associated with hypertension, high cholesterol, diabetes and an excess of certain cancers and other medical problems. Experts tell us that people with diabetes or

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1 Frank Young, M.D., Commissioner, Food and Drug Administration, before Permanent Subcommittee on Investigations of the Committee on Governmental Affairs. U.S. Senate, May 14 and 15, 1985, pp. 136-137.


3 Id. at 1077.
high blood pressure suffer more complications if they are overweight, and massively obese people experience ill-health in many ways as a result of their extra fat tissue.

For these reasons, as well as for cosmetic ones, more than 20-million Americans are on a diet at any given time. Last year, Americans spent over $32 billion on products and services ranging from artificial sweeteners to weight-loss clinic programs, and the market is expected to be over $50 billion in 1995. Many try to starve the pounds off, others try to melt them away, and some even try to sleep them off. Unfortunately, many are victimized by promoters of weight-loss products and diet plans who falsely represent they have found the quick and easy way to shed pounds, often claiming that dieting or exercise are unnecessary. For most people, the loss occasioned by falling for these scams is not simply monetary -- it can often include physical injury and risk to good health.

Diet products and weight-loss treatments involve an area where ordinary consumer expectations are often skewed by the highly personal and emotional nature of the problem that the treatments purport to address.

Let me put into historical perspective the Commission’s involvement with those who seek to take unfair advantage of America’s tendency to want to lose pounds. Since 1926, the
Commission has taken action more than 80 times to halt weight-loss claims that were false and deceptive. The basic scenario has not changed much over the years. The very first case, in 1926, involved a cream which, when applied to the fat on your body caused an alleged "chemical reaction" to take place during which time "the excess fat was literally dissolved away, leaving the figure slim and properly rounded." Product names have changed, and the substances are different, but the advertising claims frequently remain as outrageous as ever in their promises of effortless, miraculous weight reduction.

Despite consistent Commission actions, ineffective weight-loss products of one sort or another have always been on the market. Certainly, there has been a constant availability of diet pills often touted as enabling purchasers to consume a high calorie diet while, at the same time, losing weight and keeping it off. One of the Commission's seminal decisions in the weight-loss area was issued by the Commission in 1977 and then upheld by the Seventh Circuit Court of Appeals in 1979. This case involved a weight-loss product which, according to the Commission, was falsely promoted as allowing users to lose weight without restricting their caloric intake or eliminating any foods from their diet. The case extends several well-established

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6 McGowan Labs., Inc., 11 FTC 125 (1927).

principles of FTC law expressly to the marketing of aids to weight loss:

First, the Commission requires an advertiser to have a reasonable basis for claiming a product or plan will bring about weight loss.

Second, any so-called "scientific support" for such claims must be competently done and fully support the claim at the time the claim is made.

Third, testimonials must not falsely represent, either directly or by implication, that any particular experience with a weight-control product or plan reflects a typical experience that would be duplicated by others.

Additionally, the Commission's order required the product's marketers to disclose in all advertising for the product that dieting is required and that the product poses a serious health risk for some users.

In 1976, the Commission brought an action against a chain of medically supervised clinics that used what was referred to as
the "Simeon" method for weight reduction. These clinics were advertised as safe, effective and medically approved. The treatments offered by these clinics, however, involved injection of a prescription drug that had been approved by FDA as safe and effective for some uses, but not for treatment of obesity. The Commission's order, which was upheld by the Ninth Circuit Court of Appeals, required that the clinics disclose in advertising, and individually in writing to each prospective patient, that the drug had not been approved by FDA as safe and effective for the treatment of obesity.

In the 1980s, the Commission continued its active case-by-case law enforcement effort in the diet advertising area. In fact, in the last ten years, the Commission has brought twelve different actions running the entire gamut of weight-loss cases. These cases concern diet pills, food supplements, dietetic foods, a starvation/binge diet plan, a massage cream, and such esoteric weight-loss devices as one that you put in your ear, and one you use for exercising. During this period, the Commission has sued several national, mail-order marketers, two national retail store chains, a leading manufacturer of health-related special foods, as well as a national pharmaceutical manufacturer and a major cosmetic firm.

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8 Simeon Management Corp. v. F.T.C., 579 F.2d 1137 (Ninth Cir. 1978)
In the mid-1980s, the Commission issued a complaint against the widely advertised, mail-order diet plan called "The Rotation Diet." It was advertised in major newspapers such as The New York Daily News, and The National Enquirer. It was touted in magazines like TV Guide and Women's Day. It was a tremendously appealing starvation/binge diet plan with psychological underpinnings. Dieters were told they could eat virtually unlimited quantities of any food they wished for 4 out of 7 days each week, and still lose substantial weight if, for the other three days, they followed a severely restricted low calorie diet, supplemented by large quantities of water, and the company's vitamins and wafers to suppress their appetite. Dieters were advised to alternate or "rotate" between "free" days, when they could eat as much of anything as they wanted, and "balance" days when their food intake was severely restricted. The idea was that once dieters were given the freedom to binge, which was only a day away, they would not need to eat all they wanted and they would cut down voluntarily. Most people, however, did not lose weight. More significant, such diets are considered potentially harmful. The claims were halted, and through the order issued against the marketer, the Commission sought once again to emphasize a simple fact -- weight loss depends on the reduction of total caloric intake.

Food supplement pills have also caused concern. In 1988, the Commission accused a major franchisor of food supplement stores with falsely claiming that three of its products would enable users to lose weight, build muscle, or promote healing. The franchisor, which has about 150 retail outlets coast-to-coast, claimed such things as: "Lose While You Snooze;" and "When you go to sleep, GHR Formula-PM goes to work burning away fat, building lean muscle tissue and firming." These products were supposed to stimulate the body to release human growth hormones from the pituitary gland. The company agreed to entry of a consent order that prevents it from making deceptive claims for its products.

In 1988, the Commission charged a nationwide chain of more than 1,100 retail outlets that sells a wide range of health food products, including vitamins and mineral supplements, weight-loss products, and cosmetics with making similar claims for six of its food supplements. The company claimed that users of its amino acid and growth hormone food supplements -- including an item marketed as the "24-Hour Diet Plan" -- would lose weight, retard aging or build muscle. The company was prohibited from making false and unsubstantiated claims in the future. In addition, the

1988 settlement required that the company pay a total of $600,000 for research in nutrition, obesity, or physical fitness.

And it's not just diet pills and food supplements that are touted as weight reducers. The Commission has also investigated claims for diet foods and devices.

In 1983, a major specialty food maker was ordered to halt claims that its desert and snack foods were useful or appropriate for diabetics or dieters just because they did not contain sugar. In fact, the foods contained other sweeteners like fructose and sorbitol, which are not useful for weight-control by anybody. The company paid $25,000 for diabetes research as a part of its settlement with the FTC.

The Commission has also successfully challenged a weight loss device called "Acu-Form" -- an ear mold made of plastic embedded with small steel pellets which were supposed to stimulate the precise acupuncture points that modify appetite and eating habits. Customers were told to wear the ear mold and press on the mold before eating. The "Acu-Form" program was sold for $300 -- a very expensive investment for little or no return.

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In the last several years, the Commission has tried to "up the ante" in appropriate cases -- by filing actions in federal district court and seeking refunds for consumers in addition to injunctions against future sales of the ineffective products. This approach has been successful, most notably against a marketing firm for selling "Dream Away" diet pills. The product was advertised on cable television with such claims as:

"Just take Dream Away before going to bed. You will wake up the next morning slimmer, trimmer, and looking better than you did before."

The company charged $19.95 for a 21-day supply of pills consisting of small amounts of amino acids found in abundance in ordinary diets. The company was required to send refunds to over 50,000 consumers, amounting to over $1.1-million dollars.

Earlier, in 1985, the Commission went into federal district court in Florida and successfully enjoined the advertising claims made by a mail-order company for several brands of diet pills that were alleged to produce weight loss without dieting or exercise. In this case, however, the court, without explanation, refused to grant the Commission's request that consumer redress be awarded.

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Just this January, the Commission went into court again, in California, to halt the claims made for "Fat Magnet." The Commission's complaint alleges that newspaper ads for the product claimed that this diet pill:

"breaks into thousands of particles, each acting like a tiny magnet, 'attracting' and trapping many times its size in undigested fat particles. Then, the trapped fat is naturally 'flushed' right out of your body 'before' it has a chance to become ugly bulging fat."

The Commission's complaint also challenges claims that no special diet was necessary, nor were rigid calorie counting and exercise, as well as the claim that the pills were "100% safe." I want to note that the U.S. Postal Service, the U.S. Food and Drug Administration, the Attorneys General of California, Colorado, Florida, Illinois, Iowa, Missouri, Texas, West Virginia, and Vermont all assisted the Commission in developing its case against the sellers of Fat Magnet. The issues of the deceptiveness of these claims and whether consumer redress is appropriate are still pending before the federal district court.

Currently the Commission has three matters in litigation before administrative law judges that involve various types of

weight-loss products, including an "anti-cellulite body cream," a diet pill promoted as an appetite suppressant and high fiber supplement, and an exercise device called the "Gut Buster." Because I may be called upon to hear appeals of the decisions rendered by the administrative law judges in these matters, I will refrain from commenting on any of these matters.

We also have underway a number of non-public investigations that involve both nationally advertised diet products as well as claims for weight loss at salons and clinics located throughout the United States. These investigations focus on many of the same issues presented above, and may lead to additional law enforcement actions by the Commission in the future.

It appears that a new and significant trend in marketing weight-loss services involves the medically supervised plans. Recent data indicate, for example, that approximately 2600 hospitals have weight-loss centers that accounted for a national market of $5.49 billion in 1989. Many of these plans involve very-low-calorie liquid diets that are dispensed to the public through hospitals that purchase the programs under licensing or

franchising agreements from national distributors. These distributors grant the local hospitals or clinics the right to use their name and sell them the diet powders for the liquid formulas.

Also very popular are plans that combine a counseling approach by a medical doctor or a dietician with a predetermined caloric intake goal that may also include the requirement that diet food products be purchased as an integral part of the plan.

Because the liquid diet plans and other hospital based plans are purportedly medically supervised, some consumers may be inclined to view them as safer and more effective than over-the-counter dietary supplements or appetite suppressants. To the extent that there is indeed competent professional supervision of the individual patient’s participation in such programs, they should be viewed as a positive development in the area of weight loss assistance. We are aware, however, of the concerns recently expressed regarding these liquid diet plans that they should be available only to persons who are severely overweight; that such plans require strict and frequent medical supervision; and that physicians working with these programs should be properly trained.20

20 Thomas A. Wadden, PhD, Theodore B. Van Itallie, MD, and George L. Blackburn, MD, PhD, “Responsible and Irresponsible Use of Very-Low-Calorie Diets in the Treatment of Obesity,” JAMA, Vol 263, No 1 (January 5, 1990), 83.
We are also aware of studies that indicate that weight loss achieved by reducing caloric intake without an accompanying permanent increase in the level of physical activity or exercise and other lifestyle modifications is rarely permanent. Promoters of these plans should therefore avoid representations that weight loss achieved through the plans will be permanent unless they have evidence to substantiate their claims.

Additionally, if the advertising for these plans helps foster the notion that the plans are medically supervised, it would be appropriate to ask whether the franchisees and licensees have the requisite multi-discipline professional backgrounds, are adequately trained, and provide the promised professional medical oversight in dispensing these plans to the public.

The Commission's exercise of its authority over the advertising and promotion of these plans, however, cannot by itself prevent possible injury to the public. Professional competence varies within the medical profession as it does in any other field. It is important, therefore, that consumers exercise the same care in selecting a medically supervised diet program that they would use in selecting any other form of professional

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medical service. Moreover, since many of these programs are sold through local hospitals and physicians, state consumer protection officials and state medical boards have a responsibility to protect the public from programs that are incompetently run or deceptively promoted.

I hope it is clear from this overview that the Commission is committed to alleviating deception in the marketplace as it relates to dieting -- in whatever form the deception may appear. It seems to me that our record of accomplishment is remarkable given that during the 1980s, the Commission's resources and staff had been cut by nearly one-half. While there are hopeful signs that this disturbing trend has been halted, and perhaps even reversed, the Commission must, of necessity, divide its scarce resources into literally dozens of important law enforcement areas. My job, and the difficult job of my fellow Commissioners, is to ensure that the Commission gets the most for its enforcement dollars.

With that caveat, the FTC's Bureau of Consumer Protection will continue its efforts in the health care area, both through its program at headquarters and in the regional offices, to seek out and challenge deception by unscrupulous marketers of health care products and services. We will be especially vigilant with respect to sellers who seek to deceive consumers about the efficacy or safety of these programs. An examination of diet
programs will continue to be an important focus of our health care initiative. As part of that initiative, we are undertaking a coordinated effort involving headquarters and regional office staff to examine advertising claims made by the major diet-clinic chains as well as hospital and physician based weight-loss programs.

Our efforts provide a signal to those who seek to take advantage of consumers in this area that the Commission stands ready to aggressively use its enforcement weapons to protect the public. The Commission will be happy to provide you with continued reports on the progress of our efforts in this and other important areas that affect the health and economic welfare of our citizens, should the Subcommittee so request.

**SHARED JURISDICTION**

I want to note that the FTC is not the only participant in this important arena. We share responsibility with a number of other government agencies at both the state and federal level as well as the private sector.

At the federal level, the FTC and the FDA share jurisdiction over the advertising and labeling of foods, drugs, cosmetics and devices. A liaison agreement between the two agencies allocates
responsibility between them according to their respective areas of expertise. Except for prescription drug advertising, the FTC has primary responsibility under the agreement for regulating the advertising of food, drugs, cosmetics and devices. Matters involving the labeling of those products are the primary responsibility of FDA. Since first becoming effective in 1954, the agreement has resulted in close and continuing contact between the two agencies on a variety of issues, including the advertising and marketing of products and services to promote weight loss.

We also share responsibility with the state attorneys general in regulating fraud and deception in the advertising and promotion of products and services -- and with the state medical boards in regulating deceptive promotional claims by physicians. Because many promoters of health care services are limited to discrete localities, and because the Commission is operating with limited resources, we must and should rely on state and local agencies as the primary regulators of practices that are limited to their localities. In recognition of our shared responsibilities, the Commission recently agreed to establish a staff level, joint committee with the FTC Working Group of the National Association of Attorneys General to discuss ways to improve enforcement against health fraud and deception. Diet

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22 Updated FTC-FDA Liaison Agreement - Advertising of Over-The-Counter Drugs, CCH Trade REG. RPTS. § 9851 (1971)
products and services are likely to be one of the areas targeted by the joint committee.

**PROGRAM-LENGTH COMMERCIALS**

Let me now briefly turn to the subject that has been of particular concern to Representative Sisisky, namely, program-length commercials or, as they are often called, "infomercials." This is a relatively new form of advertising which, unlike the typical broadcast ad of 60-seconds or less, may run for 30 minutes or more. Many of these infomercials have appeared in "talk show" or "investigative report" format, creating viewer confusion about whether they are programming or advertising. In addition, many of these programs have also focused on the promotion of questionable health care products such as weight-loss products, baldness cures, and impotence treatments. Representative Sisisky's hearings last May were instrumental in bringing potential problems in this area to light.

Industry sources indicate that while expenditures for this form of advertising are small compared to broadcast advertising as a whole, it is a rapidly growing form of advertising.

The Federal Trade Commission is active in monitoring infomercials, conducting investigations, and bringing law enforcement actions when they appear to be deceptive. We have
committed, and will continue to commit, a substantial amount of resources to this effort. In the past eighteen months, the FTC has taken four public law-enforcement actions involving claims made in program-length ads. The first action involved a half-hour infomercial for a reputedly improved type of sunglasses. In that case, the Commission issued a complaint charging the advertiser with falsely claiming that its infomercial -- called "Consumer Challenge" -- was an independent investigative program similar to "60 Minutes." In fact, the infomercial was produced and paid for by the marketer of the sunglasses. In addition, the Commission alleged that, contrary to the advertiser's claims, the producers and reporters appearing on Consumer Challenge had not conducted an independent and objective investigation of the sunglasses.  

The Commission accepted a consent agreement in this case prohibiting future misrepresentations by the company that any consumer product has been independently investigated, or that any advertisement is an independent consumer or news program. In addition, the company must prominently disclose in any future infomercial, for a period of ten years, that the "program" is actually an advertisement.  

In November 1988, the Commission also filed separate federal district court actions against two infomercial marketers of hair loss products. The Commission charged that these widely-distributed ads for the Helsinki Formula and a product called New Generation contained false and unsubstantiated claims concerning the effectiveness of the products in stopping hair loss and promoting new hair growth. One of these infomercials is in the format of an independent review of the product, while the other simulates a consumer talk show. The goals of these cases are to enjoin the advertisements and obtain redress for consumers who purchased these products. The cases are currently in litigation.24

Last month, the Commission issued an administrative complaint against another marketer and two affiliated corporations.25 The complaint alleges that the respondents made several misrepresentations in the course of their 30-minute commercial "Money Money Money" relating to the availability and ease of obtaining government grants for small businesses. The case will be tried before an administrative law judge in the next several months.


In addition, the Commission staff has under active investigation a number of infomercials relating to the two primary problems in this area: allegedly false or deceptive claims for the product advertised and potentially misleading format claims about the nature of the "program." Several of these investigations involve health and cosmetic products.

These inquiries are not limited to the advertisers themselves. Infomercial advertising involves a number of participants with varying degrees of responsibility. They include, in addition to the marketers of the product, the producers of the programs and the companies that buy large blocks of broadcast or cable time on which they run their own or others' infomercials. These companies may receive a large portion of the profits generated by sales of the advertised products. The staff is exploring the roles of all parties concerned. I am hopeful that the Commission will be able to announce in the near future the resolution of at least some of these investigations. Commission actions should send a clear message to the infomercial industry that they, like traditional advertisers, must abide by the rules against deception.

I believe the problem presented by potentially misleading format of infomercials could also be alleviated, at least in part, if media on which they are appearing were to assume increased responsibility for the accuracy of both the format and
the claims made in these ads. All major television networks have clearance departments that review and pre-clear ads. While the Commission does not always agree with those determinations, it is certainly true that this review process eliminates a considerable amount of potentially deceptive advertising on the networks. Infomercials, however, generally run on cable and independent stations. Some of these stations may not review ads sufficiently for accuracy before they are aired.

CONCLUSION

In conclusion, I want to again express my strong support for your efforts to bring national attention to the problems presented by the deceptive promotion of health care services, whether found in traditional advertising or in infomercials. I also want to assure you that we will continue to work with both of you in your efforts to eliminate fraud and deception in these areas.
STATEMENT OF SHERRI STEINBERG

My name is Sherri Steinberg and I live in Coral Springs, which is in Broward County, Florida. I am married to Steven Steinberg and we have a son named Jason who's six years old.

Like many people, I wanted to lose weight and didn't know where to turn. All of the different diet companies and weight loss programs claim how safe and effective they are. And it was confusing.

But one diet company stood out among the others to me. I'd always seen and heard so much about the Nutri/System diet program in various advertisements that I believed it had to be a safe program. I thought they would take care of me. I was overweight and I had high blood pressure, so it was important for me to go to people I could trust.

I went to my local Nutri/System center on about June 17 in 1989. I met with the Nutri/System representative and told her that I wanted to lose weight, but was concerned for my safety because of my high blood pressure. She specifically told me I had nothing to worry about because I would be watched closely by Nutri/System's professional staff of nurses and nutritional specialists while I was on the diet. I was accepted into the program and given the standard meal plan.

She never had me fill out a questionnaire about my health history and she never told me to see my doctor to get approval first. They never did anything but weigh me and take my blood pressure and measurements.
I asked her how much weight I should lose. She told me that I should lose 34 pounds by August 24th and wrote it down on my "Service Guarantee." I left that first meeting feeling confident that I could lose an average of over three and a half pounds a week like they told me. And somehow the guarantee gave me confidence that they were sure I could really do it, or they wouldn't have actually signed that guarantee with me.

Just as Nutri/System promised, I began to lose weight very fast. I lost almost 10 pounds in the very first week, one quarter of a pound in the second and seven pounds in the third week. I'd lost 17 pounds after only three weeks and I was really pleased. I lost another 11 pounds.

But then after just a couple of months into the program, in early September I found myself doubled over in excruciating pain. I'd never felt anything like that pain before. I thought I was having a heart attack it hurt so much. It was in the middle of the night and I was really scared. I woke up my husband and he immediately called 911 and called my mother.

The police came to my house and gave me oxygen. When the paramedics arrived, they gave me an EKG test. They told us that it wasn't my heart. But they said they didn't know what was causing the pain. My husband took me to the emergency room. After they'd looked at me, they told me that it was my gallbladder. They removed my gallbladder several days later—and I was in pain the whole time.
After my surgery, I told Nutri/System how upset I was about what had happened to me and demanded a full refund of my money. The lady from Nutri/System told me that I should come back on the program and go on a special low salt diet. I refused and they sent me a refund check for half what I'd paid them.

I couldn't possibly go back on their diet because I was convinced that their diet program was what caused me to lose my gallbladder. I was afraid what else might happen to me if I went back to them. I didn't trust them anymore.

This has been a nightmare for me and my family. I have gone through enormous pain as a result of having major surgery. The tests were painful and humiliating. Recovering from the surgery has been slow and I've still never fully recovered. I know that I'll never be the same again. My doctors told me that my surgery was complicated because I had so many stones in my bile duct. All I know is that it hurt me very much and still hurts me today.

Nutri/System never told me any of this could happen to me -- they never told me there were any risks at all. If they'd told me, there's no way I would have ever gone on the diet. I would have found some other way to lose the weight.

There was never anything wrong with my gallbladder before I went on the Nutri/System diet. I think it's more than a coincidence that on June 19th I was feeling fine and then a few months later I was being wheeled into major surgery.

I don't believe the Nutri/System people knew what they were doing. While there were people called nutritional specialists...
and nurses who walked around in white coats, they didn't seem like they knew much about dieting. I don't think they were professional and I certainly don't think they took care of me like they told me they would.

This has left me angry and hurt, but I'd really hate to see it happen to anybody else.

Thank you for listening to my story.
SERVICE GUARANTEE

After evaluation of the successful weight loss results recognized by thousands of men and women who have completed our weight control program, NutriSystem Weight Loss Centers herewith offer this written, personal, weight loss guarantee to you.

[Signature]
Name

[Address]
City

We provide a comprehensive weight loss program consisting of professional supervision, diet counseling, behavior education, exercise and medication program.

Commencement Date of Program: 6/1/89
Weight Loss Goal: 30 Pounds
Guaranteed Days: 30
Non-Refundable Evaluation Fee: $25

If, for any reason, you fail to achieve these results, NutriSystem will continue your program until you have lost the amount of weight indicated above WITHOUT ADDITIONAL CHARGE FOR OUR SERVICES.

This guarantee is not transferable and is valid only when you follow the NutriSystem Weight Loss Program prescribed below and when payment is received in full or in accordance with payment terms.

The cost of Food Products is not included in this guarantee. It is an additional cost and non-refundable.

A one-year maintenance program is included in this guarantee at NO ADDITIONAL CHARGE.

PROGRAM REQUIREMENTS:

For best weight loss results and in order to keep your guarantee in effect, these 4 easy steps must be followed:

ONE: A minimum of one visit per week with the professional staff for nutrition information and behavior education.

TWO: Only purchase and consume NutriSystem foods and NutriSystem. Choose from breakfast, lunch and dinner as prescribed by NutriSystem.

THREE: Participate in some form of self-directed exercise during the Program, unless medically contraindicated.

FOUR: Your weight loss must be evidenced by weight loss monitoring procedures.

I hereby acknowledge that I have read and understand the foregoing service guarantee and that I have received a copy.

[Signature]
Date

[Address]
City

Printed in U.S.A.
October 27, 1989

Ms. Sherri Steinberg
9282 N.W. 13th Place
Coral Springs, Florida 33071

Dear Ms. Steinberg:

This correspondence is in reference to your request for a refund of your monies paid for the Nutri/System Weight Loss Program which you purchased from our Coral Springs center on June 19, 1989.

I am sorry that you feel that Nutri/System was responsible for your elevated levels of fat and sodium. I can assure you that our program is well balanced and nutritious. It meets all USDA standards and the American Heart Association’s Guidelines for Healthy American Adults; specifically the recommendation for total fat, saturated fat, cholesterol and salt.

Per your discussion with Susan Seager, Director of Health Care, we are refunding 50% of your program because of your inability to continue with our Maintenance Program. Enclosed please find a check for $205.00, representing a 50% refund.

We regret that we cannot count you among the millions of successful Nutri/System clients who have achieved their weight loss goals on our program.

Sincerely,

Nutri/System of Florida Associates

Yours truly,

Pamela Jayasich
Customer Service

Enclosure

CC: Philip Voluck
Susan Seager
Tamra Rosengarten
Robin Mullins
Eileen Dobson/COS
**Nutri/System TREATMENT FLOW CHART**

**Name:** Henri Steinberg  
**Phone (Home):** 753-3249  
**Phone (Work):** 753-3430

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**DAIRY PROTEIN REQUIREMENTS**

**SPECIAL INSTRUCTIONS:**  
**INELIGIBLE FOR RE-START**

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**MEDICATIONS**

**ALLERGIES**

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**DATE:**  
**WEIGHT:**  
**HEIGHT:**  
**SEX:**  
**ACTIVITY:**  
**PLANNED TREATMENT:**

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**PROTEIN REQUIREMENTS**

- **Protein:**
  - Eggs
  - Meat
  - Oatmeal

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**SPECIAL INSTRUCTIONS:**

- Walking
- Minimal activity
Grand Opening

HIALEAH
TAMARAC
BOCA EAST
BOCA WEST
CUTLER RIDGE

Lose weight the effective, safe, easy way with the All New Nutri/System.

Lose 30, 50, 75 lbs. or more. Lose all the weight you can for only $89

"I'm Starting Life Over! 51 Pounds Lighter! I've Tried Other Diets Before but With Nutri/System the Weight Came Off and is Staying Off."

Jean Nany, Bradenton, Florida

The Nutri/System Weight Loss Program includes a variety of delicious meals and snacks, nutritional and behavioral counseling, light activity, and weight maintenance.

We Succeed Where Diets Fail. You Can Too.

CALL TOLL FREE 1-800-344-THIN

Over 100 Centers Internationally

For more information, call your nearest Nutri/System Weight Loss Center.
My name is Loretta Pameijer and I'm here to tell you about what happened to my 13-year-old daughter when she went on what I thought was a safe diet -- mainly because it was sponsored by doctors.

I would never even have thought of putting her on such a diet, except for a horribly humiliating experience at school. Like many twelve-year-old girls, being a cheerleader is the high point of their life. She'd made the squad when she was eleven, but she had gained some weight over the year. When she went to the tryouts, her coach told her she wasn't even eligible.

What I heard her tell my daughter shocked and hurt me. But it hurt my daughter more. She told my daughter that, "we believe in fitness and it's un-Godly the way you've abused your body." My daughter had to leave the auditorium in front of all of her friends. She was so embarrassed that she couldn't go to school the next day and became absolutely obsessed with getting off the weight. She was intent on getting back on the cheerleading squad with all her friends.

And I had to help her.

So I started trying to find a program I could trust. I tried to get her in a program at the hospital in our community, but they wouldn't take children her age. I saw an ad for the Doctor's Quick Weight Loss Center. When I called them, they told me that, of course, they took children. In fact, they said they had children that were even eight and nine years and that they thought it was important to start kids young so that they
wouldn’t be fat adults.

They insisted that I come in right away.

My daughter had fifty-five pounds to lose and the Center told us that it would cost $1,500 for her to do it. I had no idea it would be so expensive, but I wanted to do the best for my child. When I asked the counselor whether I could pay in some kind of installments or pay them half of it up front and the rest later, she made me feel terribly guilty in front of daughter. She asked me, "you do want to do what's best for your daughter, don't you?"

We're not rich, but we managed to come up with the money because we knew how miserable our daughter was and we wanted desperately to help her.

In mid July, she started the program. When we went back, the counselor told us that many weight problems were tied to food allergies that prevent us from breaking food down well. The allergy test itself cost $500. They told us that it was crucial because that's how they would know what kind of foods she should be eating and how best to help her lose the weight. Even though it was expensive, it seemed to be thorough and like an individualized program that would be safe.

My daughter saw the program's doctor and was given a physical, I think. I say that because all he did was look in her throat, felt her glands and checked her blood pressure. He never asked us any questions about her medical history or even about any allergies she might have to drugs.
But the counselor gave us a food chart that supposedly reflected the results of her allergy test with a list of foods she could and couldn't eat.

My daughter followed the diet religiously. She went back to the Center for regular visits that never lasted longer than ten minutes.

Even though she was following the diet, there were times when she would stop losing weight. Then the counselors would put her on what they called a "parsley break." It had almost nothing in it but meat and half a cup of parsley a day. It seemed odd, but my daughter was losing the weight and she was feeling good.

She quit going to the Center around Christmas time, but she stayed on the diet by herself. In March, she started eating more normally. I noticed that she started gaining the weight back, but I didn't say anything to her.

But at the end of June, one night when my husband -- who's a fireman -- was at work, she started to have very sudden and very severe pains in her back. She couldn't sit down, she couldn't lie down and she couldn't get her breath.

I was scared. I didn't know if it were her appendix, her kidneys, her gallbladder. But I wasn't going to mess around, so I managed to get her dressed and started to drive her to the emergency room.

Almost as suddenly as the pain had begun, it stopped. We sat in the parking lot of the hospital for a long time because I didn't want to take any chances. But finally, we decided it
must not have been anything serious, so we went home.

Everything seemed to be fine until about a week later. My daughter had eaten at MacDonald's. About two hours later, she had another severe attack like the other one. This time, my husband was at home with her and I was still at work. He called me and told me he was taking her to the emergency room immediately.

When we got there, they ran a battery of tests. The doctors also asked us if she had any strange eating habits. I told them she had recently lost a lot of weight. After they got the test results, my doctor came out after four or five hours and told us that she had the worst gallbladder attack he had ever seen in anyone so young. They also told us that diets could be a big factor in gallbladder disease. They called the surgeon that night and he told us that her gallbladder had to come out right away, so we scheduled her for surgery the very next morning.

I thank God that everything came out O.K. Her surgery went smoothly and she recovered quickly. I guess kids can bounce back quickly. But I was very proud of her and the way she handled the whole thing.

Everything happened so quickly we were so upset. But, I had no idea that any diet could do this. I love my daughter very much and had I known there were risks like this, she could have stayed a happily plump kid for the rest of her life. There is just no way I would have done this to her.
Now, I can't help but wonder how I could have let her do this. It's been about a year and she's gained back almost all of the weight. I can't help but wonder how I could have let her go through this crazy diet?

But it looked safe, it was supposed to be supervised by a doctor, it was supposed to be designed specifically for her and the office seemed so busy that I thought they must be good.

Now I know better, though. My daughter lost her gallbladder and my husband and I pray that there won't be any other long-term, serious health effects. But we're angry because it never occurred to us that we had to be suspicious of a doctor's clinic. But it seems that there are sheisters out there making millions and not caring at all about what happens to people like my daughter. They laugh all the way to the bank and it just makes me crazy.

My daughter didn't want me to come here today. But I tried to explain to her that it was important. I didn't know enough to protect my child, but maybe I can protect someone else.

I'm glad to know that someone in government is looking at this and I just hope that you'll help us learn what questions to ask and how to judge what's safe and what's not. I don't think we can do it by ourselves. Thank you.
Statement by Carol Householder

I want to thank the Committee for the opportunity to share our experience of the devastating effects of a rapid weight loss diet.

In the late summer of 1985, my husband was a 44 year-old Ph.D. college engineering professor. He had just completed 10 years of college administration and he decided that the 30 pounds he had put on over the previous five years had to go. He is six feet tall and weighed about 217 pounds, and wanted to get down to somewhere from 180 to 185. He considered himself in good physical condition, he was not a smoker, he had always been a bit overweight but it never prevented him from exercising the majority of his adult life. He had hiked, jogged, swam, played racquetball, skied and so forth. As a family, we had hiked the Grand Canyon, rim to rim -- over 25 miles earlier that summer.

I recall at the time he considered several diet alternatives, but eventually chose the Nutri-System Diet Program for some of the following reasons:

1. billboards in town claimed Nutri-System diets succeeded where other diets failed;
2. T.V. and newspaper ads were everywhere -- you couldn't pick up the paper or turn on T.V. without seeing an ad;
3. they claimed that the diet was medically supervised;
4. they claimed that the diets were "tailored" to the individual's needs;
5. the diets were supposed to be well balanced if you just ate their foods and took their vitamin supplements;
6. it was convenient for him; and
7. they promised success.

He began his diet in late August after filling out a medical history report and interviewing with the nurse. They took his blood pressure and after reviewing a computer print-out, his 1000 calorie diet began. He was very faithful once he made the commitment to lose the 30 pounds. He drank their beverages, baked their bread, used their salad dressing and ate their prepackaged foods. He attended his weekly check-up (blood pressure check), showed them his journal where he entered the food intake, environment (where and when he ate) and how he felt.

At the same time, he began jogging, with their blessing and encouragement. He walked, then ran slowly, and after two to three weeks he was running three miles in about 30 minutes, three to four times a week. He self-reported being tired a good deal of the time, but he saw results and so he religiously stuck with the program. In about seven weeks he had lost approximately
28 pounds. Then along came a conference in Colorado and he went off the diet with their consent and suggestions to eat light, and continue with vitamin supplements, their beverages, salad dressings, etc. I was with him and he was very careful.

On a Sunday four days after resuming his diet to lose the last two or three pounds, he was jogging with our youngest daughter. Upon their return, he commented that he didn't feel well. He told her he felt light-headed and as he sat down in his lounge chair in the study, he passed out and slumped back.

Our daughter ran to get me from the kitchen and after a total of a minute to a minute and a half, he came to. He was pale and woosey. I was very upset and he promised to discuss the incident on Monday morning with the Nutri-System staff nurse. Her response was that he should probably eat more fruit.

A week later (he was one pound short of his goal) while he was walking back from the track after his Monday lunch jog, he felt sick and light-headed. He went down in front of an Activity Center and he went into a full cardiac arrest. Mike was resusitated by the Paramedics but he remained in a coma, hooked up to life support systems, and remained in intensive care twenty-four hours a day.

While Mike was in a coma, the treating physician, an internist, explained the likely scenario and the probable cause of his cardiac arrest. I tended to use heart attack and cardiac arrest interchangeably until he explained that Mike's incident was triggered by a potassium deficiency and borderline protein deficiency. In my layman's terms, potassium is the carrier for the electrical impulse for our hearts to beat and when that impulse is slowed or stopped cardiac arrest occurs. Because Mike was protein deficient, it's very likely his heart muscle had been weakened as well.

Seventy hours into his coma, Mike gradually awakened. But unlike the Hollywood versions, he had lost both his long- and short-term memory. His computer tape of 44 years had been erased. He didn't know his name or recognize his family and it took days, weeks, months for him to begin over again. He remained hospitalized for four weeks. Therapy began and finally he was transferred to Scottsdale Memorial Hospital where it was discovered after testing that he had some coronary disease. However, his heart was not damaged. For the last four and one half years he has never had another episode or problem. Our cardiac physician suggested that if Mike had been properly evaluated by a physician he most likely would not have been recommended for a non-medically supervised diet.

So what's life like after a close encounter with death? Obviously, Mike lived, but there are many times I feel like a widow. The man I loved and married 27 years ago is now just a fraction of the man he was. He will never work independently
again, he cannot live alone and his daily activities must be
planned and supervised. He has no technical knowledge.
Occasionally an equation will surface but he doesn't understand
it. He's often confused and forgets current information. He
cannot initiate intellectual conversation or summarize even a
short Readers Digest article. His emotions are significantly
impaired. As a case in point, I was recently feeling upset and
depressed and when I told him about how I was feeling, his
response was, "Is it alright if I walk home now?" -- totally
unlike his caring, nurturing pre-incident self.

Our joint income in 1985 was $75,000. Today our income is
$36,000. I had also worked at the University, but after one and
a half years of attempting to work, assume all responsibilities
for daily life, be both parents to our three daughters and take
care of my husband, I requested a leave of absence and never
returned.

Thanks to our very loving and supportive daughters and
extended family and friends and my own strong personal
relationship with God, we have survived and are happy. I love my
husband very much and will always remain his loving and faithful
wife and best friend. But our mutual, loving and sharing
partnership is now changed forever, and I have become his
caretaker and protector.

I can only hope our story and experience will somehow help
bring about change so that other families will be spared the
tragedy we survived and still celebrate.

Thank you.
Testimony of

C. Wayne Callaway, M.D.
Associate Clinical Professor of Medicine
George Washington University
Former Vice-President, American Board of Nutrition

Before the

Subcommittee on Regulation and Business Opportunities
Committee on Small Business
U.S. House of Representatives
March 26, 1990
Thank you for the opportunity to participate in today's hearings. My comments reflect my own views as a physician who specializes in internal medicine, endocrinology and metabolism, and clinical nutrition. In addition, I also speak on behalf of the American Board of Nutrition, the certifying board for subspecialty qualification in this field. I was a member of the Board of Directors of the American Board of Nutrition for most of the past decade, and served as secretary/treasurer and vice-president of the Board for four of those years. Although I am not currently a member of the Board of Directors, I have been asked by the president of the Board, Dr. Russell Merritt, to represent the Board at these hearings.

It is my personal view that the weight loss business in the United States has gotten out of hand. The stories that we have heard this morning are, unfortunately, all too common. As a human being, I am deeply moved by the tragedy such stories convey. As a physician, I am concerned that millions of Americans are participating in rapid weight loss programs, supervised by people with little or no knowledge, training or understanding of the complications of semi-starvation. As one who has been involved in the evolution of our present concepts regarding human obesities and their treatments, I am distressed that (with rare exceptions) none
of the popular commercially available programs for treating obesity is based on current scientific knowledge. To the contrary, such programs reflect the simplistic notion that obesity is purely a matter of "self control" and that effective treatment consists of low calorie or very low calorie diets.

To be sure, most weight loss programs attempt to differentiate themselves from the other programs in the market. Some add what they call "behavioral modification;" others provide prepackaged foods; several very popular programs have resurrected formula diets; others require the dieter to purchase a variety of supplements; and we still have programs using thyroid hormone and drugs that act like amphetamines on the premise that such agents will "alter our metabolism."

Before I discuss the risks and lack of evidence of effectiveness of most of the weight loss programs that are out there, let me say a word about the environment in which this dieting craze is taking place.

Cultural Distortions

Our attitudes about body size and shape are largely culturally determined. What we consider overweight, many societies consider ideal. For example, over the past three
decades, the average weight of professional models has declined from 8% to approximately 18% below normal. A century ago, we witnessed the other extreme; Lillian Russell, one of the beauties of the time, was 210 pounds.

If we look at dieters in the United States today, only one out of ten is dieting for medical or health reasons. Some are dieting in an attempt to prevent the development of health problems in the future, but most are dieting in order to achieve some imagined ideal, at which both they and their spouses, family, friends, and society will somehow accept them as being more worthy of those things that are valuable to us -- love, admiration, respect, even economic security.

Given these cultural distortions, it is no wonder that half of adult women diet two or more times a year, and some as much as five or six times annually. The problem is not confined to adults; in some school systems, as many as 80% of 10 year old girls are already defining themselves as "overweight" and attempting to control their weight by dieting. Even in kindergarten, one can demonstrate early prejudices against chubbier children.

Thus, the commercial weight loss programs do not exist in a vacuum. They are skillfully and deliberately exploiting a situation where cultural norms are dramatically out of "sync" with biological reality.
The Biology of Human Size and Shape

There is now ample evidence that genetics or heredity contributes substantially to who we are. Adopted children, when they grow up, have body heights and weights which resemble those of their biological parents, but show no correlation with the heights and weights of their adopted parents. Identical twins have twice the likelihood of coming out at similar adult weights compared with non-identical twins. In the case of twins, most often both twins are growing up in the same household and are exposed to the same environmental factors. Professor Claude Bouchard has estimated that between 25% and 50% of the variation in weight from person to person is heritable.

Some people have argued that, given the inheritability of size and shape, there is very little that we can do to alter it. Others have argued that, in spite of genetic predisposition, we must all achieve some arbitrary ideal. The reality is somewhere in between. Most of us can achieve a healthy weight, but there is no biological reason why we should all be the same weight, any more than there is a biological imperative for being the same height.
The Biology of Starvation

There is now abundant scientific information explaining the changes which occur in response to low calorie and very low calorie diets. We are all programmed to respond to starvation by adaptive mechanisms that allow us to prolong our survival. Since, in the long sweep of history, famine has been a greater threat to human survival than gluttony, it is not surprising that those of our ancestors who survived were those who were most efficient in adapting to sudden declines in food availability.

Briefly, there are three things which happen when we diet:

1. In the first few weeks, water is lost from inside the cells because stored glycogen and protein are broken down to provide blood sugar for the brain and the red blood cells. The initial water loss is followed by salt and water retention, leading to what is called "starvation edema." With refeeding, fluid retention gets worse and results in "refeeding edema."

2. With semi-starvation, resting metabolic rate -- the number of calories you burn at rest -- declines. The lower metabolic rate allows you to survive famine much longer than would otherwise be the case.

Unfortunately, it is accompanied by symptoms which
severely compromise one's quality of life. These symptoms include fatigue, depression, sleep abnormalities, cold intolerance, dry skin, dry hair, loss of hair, constipation, delayed emptying of solid food from the stomach, a fall in blood pressure associated with dizziness and even loss of consciousness on standing, and alterations in perceptions of time and space. Furthermore, there are now studies in laboratory animals showing what humans have reported for decades, namely, that with each diet, weight loss is slower and rebound weight gain occurs more rapidly.

(3) Undereating leads to overeating. There are both human and animal studies showing that food suppresses appetite in the fed subject, but stimulates appetite in the subject who has been undereating, either experimentally or in an attempt to control weight. Indeed, to my knowledge, bulimia (which is binge eating accompanied by self-induced vomiting) has never been seen in someone who did not first diet.

These observations are not new. Some of the scientific work that supports them goes back to the early twentieth century. In the past decade, alone, there have been dozens of papers, review articles, book chapters, and even whole books devoted to the changes in energy metabolism, water
balance, and appetite that are seen in response to caloric restriction. However, very little of this information has been incorporated into currently available commercial weight loss programs. I am sure the reasons are multiple. No doubt, ignorance of the scientific information leads the list. In addition, it would be hard to incorporate current scientific information into commercial weight loss programs and still promise the rapid weight loss that is characteristic of most of the promotional materials such programs provide.

**Market Expectations and Exploitations**

The commercial programs are truly market driven. Women expect to lose 2-3 pounds, and men 3-5 pounds, per week when they diet; failure to meet these expectations results in a rapid drop-out from the program. In order to achieve this degree of weight loss, the dieter must restrict calories sufficiently to bring about the fluid loss which I have mentioned. Indeed, as much as 2/3 of the early weight loss on very low calorie diet regimens is due to water loss. The dieter, of course, thinks the diet is working well.

Unfortunately, with prolonged or repeated dieting, the water retention phase occurs sooner and sooner, and the dieter begins to plateau. At this point, the dieter is not losing as rapidly as predicted; indeed, she/he may even be
experiencing weight gain. More often than not, the dieter is considered "non-compliant." If the dieter happens to eat more than what was prescribed, she will frequently concur in "blaming the victim," in this case, herself -- for failure to meet weight loss expectations.

Blaming the Victim

Blaming the victim is the ultimate cop-out. When people go off very low calorie diets or are shifted to the so called "maintenance phase," they not only gain water, but they are now burning fewer calories than before they dieted and, therefore, they have a greater tendency to regain body fat. Thirdly, as they begin to eat more food, their appetite increases, and binging becomes more common. At this point, it is almost inevitable that both the diet program staff and the dieter herself will conclude that the dieter simply is not following the program and, therefore, she has only herself to blame.

A dramatic example of the phenomenon is Oprah Winfrey. Following Ms. Winfrey’s announcement on national television that she had achieved a substantial weight loss on Optifast, Self magazine reported that "Optifast director, Jim Parsons gleefully credits Oprah Winfrey with making Optifast a household word" (Self, November 1989, pg. 190). Now that Ms. Winfrey has regained much of her lost weight, the tune
has changed. Representatives of Optifast are now blaming Ms. Winfrey for her failure. I have transcripts of a recorded conversation with one purveyor of Optifast in the Washington, D.C., area who says, "Oprah Winfrey lost the weight, then went back and ate the same foods .... Oprah Winfrey mentioned that she was eating three sweet potato pies in a week's time. She gained 17 pounds. Anybody who eats one sweet potato pie can gain ... two pounds. You eat all that and you are setting up for failure."

Can there be any more dramatic example? Here is a celebrity who announced on national television that a specific formula diet program had resulted in her losing more than 60 pounds. Optifast programs throughout the country were forwarned that she would make this announcement. News media were alerted. I understand that more than 200,000 phone calls came in to Optifast centers within the next 48-hours. Nevertheless, as soon as Ms. Winfrey starts to regain her weight, she is blamed for her own "failure." If this happens to someone as prominant as Ms. Winfrey, consider what the psychological costs are to millions of dieters who experience similar "failures", but suffer the quiet desperation of being blamed and of blaming themselves.
Hazards of Quick Weight Loss

In addition to the side effects I have already mentioned, there are several well documented, life threatening hazards to sustained, severe, or inappropriate calorie restrictions.

The most dramatic is sudden death. In the mid-1970's, nearly 60 people died while ingesting liquid protein formulas or shortly after going off such formulas. In most cases, the formula was a "predigested protein" of low biological value. The current formula diets have improved upon the old formulas in that they tend to use proteins of higher biological value and most of them include sufficient carbohydrate to prevent ketosis from occurring.

However, sudden deaths still occur. The fact that we have not heard about them until recently reflects our lack of any type of tracking mechanism. We have no way of knowing how common these occurrences are. When the victim or her survivors have raised legal issues, the cases have
generally been settled out of court and the documents sealed. There is no registry for providing data on a national scale and, as you can well appreciate, the companies themselves do not volunteer such information to outside researchers.

It is only when media attention is brought to bear on this problem, as occurred with the extremely high frequency of gallstones in people on low calorie diets, that victims recognize that they are not simply isolated cases.

Even in the face of documentation that certain complications are real, the local program staff often deny that they are the result of the diet. Again, to cite transcripts of recorded conversations with diet program promoters in the Washington, D.C., area, when the prospective dieter asked the staff person about gallstones, she was told simply, "people who are obese often ... have a gallstone problem. It's from the obesity, not the [formula]."

This conversation took place within the past month, more than a decade after the association between dieting and gallstones was first recognized, and nearly a year after an
excellent study was published in the Archives of Internal Medicine, showing that in eight weeks of dieting on a 500 calorie diet, 25% of dieters developed gallstones, as demonstrated by ultrasound examinations of the gallbladder before and after the diet. In contrast, equally overweight individuals who did not diet, showed no development of gallstones during that brief eight week interval.

Another dramatic complication of dieting is bulimia. In spite of the fact that it has been nearly a decade since Drs. Janet Polivy and Peter Hermann brought attention to the fact the dieting leads to binging, this very serious complication of semi-starvation is barely (if ever) discussed as a potential side effect when dieters are enrolled in the commercial programs. Nor, have I seen any warning in the promotional literature that fatal irregularities in heartbeat could result from prolonged semi-starvation.

Instead, most of the promotion of existing weight loss programs consists of testimonials. Sometimes the examples are clearly inappropriate. I have in front of me a copy of the Diet Center Health Measures Newsletter, Vol. XIII, No. XII, containing a front page story about a 10 year old boy who lost 34 pounds in seven weeks -- nearly 5 pounds a week! -- on the Diet Center program, reducing his weight from 137
to 103 pounds. Such rapid weight reduction, especially in a
growing youngster, can be extremely hazardous and should
never be undertaken unless there a clear and urgent medical
reason. Certainly, severe caloric restriction in anyone,
especially children, should not be undertaken without
qualified medical supervision. None is provided by Diet
Center.

What is Qualified Supervision?

Several decades ago, Dr. Stanley Schacter reported that
many people diet on their own and are often successful in
keeping their weight off. My suspicion is that people who
increase their physical activity or cut back on snacks and
fats may do better than people who go on low calorie
commercial weight loss programs. Unfortunately, we lack
current data on self prescribed dieting behaviors and
outcomes.

A second alternative is to see a registered dietician.
There are more than 50,000 registered dieticians who are
qualified to provide dietary advice, especially in regard to
adequate and balanced diets which can allow for slow but
sustained weight reduction without the hazards I’ve
mentioned.
Several group and programs, including self-help programs, provide group support and elements of behavioral modification without severe caloric restriction. They can also be undertaken safely without professional supervision.

On the other hand, low calorie diets and rapid weight loss should be restricted to individuals who truly need to lose weight for health reasons and who have some medically justifiable indication for losing weight rapidly. In all such cases, it is imperative that there be medical supervision and, furthermore, that the medical supervision be competent to monitor the types of complications which are known to occur.

In the case of very low calorie diets, competent supervision requires special training and knowledge. Physicians who are trained in family practice, internal medicine, pediatrics, or other primary care specialties are certainly in a position to advise patients as to whether or not they should undertake weight reduction. However, in the absence of formal training and demonstrated knowledge, such physicians are not qualified to supervise the care of patients who are undergoing semistarvation regimens.

What constitutes appropriate qualifications? In addition to board certification in a primary care specialty, the physician should also have completed residency training
in an appropriate subspecialty, such as endocrinology or clinical nutrition.

**The American Board of Nutrition**

I mentioned earlier that I have served as member of the Board of Directors of the American Board of Nutrition. The Board was established forty years ago, to certify Ph.D. and M.D. candidates as specialists in human or clinical nutrition, respectively. For board certification, such candidates must provide evidence that they have successfully completed the two years of training in a recognized nutrition training program and they must pass a written and oral examination of their knowledge and clinical skills. They must also provide letters of reference attesting to their personal character. (I would be happy to provide the Committee with detailed descriptions of the areas of knowledge tested, if the Committee so desires).

In the past ten years, especially with the institution of special Clinical Nutrition Research Units, funded by the National Institutes of Health, and other clinical nutrition research centers funded by the Pew Foundation and other private foundations, advanced training in clinical nutrition has taken its place along the side of other medical subspecialties. The most recent survey of clinical
nutrition training programs identified fifty active programs in the United States and Canada. These programs run in length from 2 to 4 years of training, and accept between one and four applicants per year. Thus, there is a growing number of well trained physicians who are capable of providing competent supervision for those few individuals for whom rapid weight loss may be indicated.

The old charge that physicians know little about nutrition is only partly true. Today's graduating physicians tend to have some general knowledge of nutrition, more than was the case a decade ago. However, in the absence of subspecialty training, the average primary care physician would not have the detailed knowledge that is required to supervise programs that carry clear and potentially fatal complications. The situation is similar to that which we see in other subspecialties. For example, as someone who is board certified in internal medicine and endocrinology and metabolism, I feel comfortable in interpreting most electrocardiograms and in prescribing commonly used medication, such as Digoxin, beta-blockers, and calcium channel blockers. As an internist, I am familiar with the usual mechanisms of action and side effects of these medications. However, I would not consider myself qualified to prescribe medication for unusual or severe disturbances in heart rhythm. And, obviously, I would not undertake invasive diagnostic or treatment
techniques such as balloon angioplasty or coronary angiography.

Similar standards should apply to other potentially hazardous treatments, including semi-starvation diets. In the absence of formal training and demonstrated knowledge of the physiology of starvation, its complications, their recognition and treatment, physicians who undertake to supervise such programs do so at their own risk and at the risk of the dieter. Hospital based programs which hire part-time, untrained physicians should also bear responsibility for the adverse outcomes.

Pseudo-qualifications

A number of commercial programs, where physicians are not involved, refer to their staff as "certified" nutrition counselors, behavioral therapists, or whatever. In most cases, the only certification comes from the company offering the program. The extent of training is minimal, at best. No objective standard of evaluation is applied. Nevertheless, the "certified" label is worn on the lapel as a false promise of professional competence.

Conclusions and Recommendations
We are in the midst of a diet craze. Nearly 10 billion dollars are spent annually by 50 million Americans who are dieting to lose weight. Thousands of programs and products are promoted to exploit this cultural distortion. If there were no hazard to the weight loss programs that are on the market, we could view this phenomenon as simply another foible of our civilization. However, as I have indicated, semi-starvation diets do carry hazards, both acute and catastrophic, such as sudden death, and long-term, such as the symptoms of lowered metabolic rate and the frustration and negative self image that come from repeated dietary failures.

 Supervision of such programs varies from none, to instantly created "certified counselors", to physicians with little or no training in this area, to a few physicians, registered dieticians, and behavioral psychologists who truly have the required expertise. I believe that the cavalier attitude which is demonstrated by hospitals and commercial programs who hire inadequately trained staff reflects the notion that weight loss is simply a matter of eating less, and their refusal to accept the documented hazards that we have discussed. Scientific information is available, but it is either not known to the purveyors of such regimens or it is blatantly and cynically disregarded.
We have no existing effective mechanism for tracking the incidence and severity of complications of unsupervised and poorly supervised weight loss programs. At present, our main recourse is through the media. For the victim, the only recourse is through civil suits. Surely, we can improve upon this situation.

I have several recommendations:

(1) Greater information on the hazards and lack of demonstrated long-term benefit of very low calorie diets should be made available to the public. In the short run, this can best be accomplished by joint efforts of the scientific/health community and the public news media. Consideration should be given to establishing some type of registry or clearing house for collecting reports of adverse effects and for making this information available to the scientific community for further evaluation and, when documented, to the general public.

(2) Weight loss programs should be held accountable for their outcomes. All known side effects should be explained clearly to the prospective dieter in advance. Documented complications, such as the high incidence of gallstone formation during low calorie diets, cannot be simply dismissed as due to the dieter's obesity. Similarly, if most dieters gain back the weight that they have lost on commercially available programs, we can no longer accept that it is the fault of the dieter. Were the
programs effective, this would not have occurred. The programs must be held responsible, not the victim.

(3) Severly restricted diets should be undertaken only by people for whom there is a clear and urgent medical reason. In all cases, such diets should be supervised by physicians who have both the training and the knowledge to recognize the complications of semi-starvation, and who can treat those complications promptly and effectively. This does not necessarily mean that they should be certified by the American Board of Nutrition. However, they should have evidence of appropriate subspecialty training in areas related to the hazards of semi-starvation -- more than a few lectures here and there, or an occasional reprint of an article provided by the formula manufacturer.

(4) We need standardized reporting on long-term outcome and indicators of success or failure which reflect functional status and quality of life, rather than how much or how fast weight is lost. As I have already discussed, current evidence suggests that the more rapidly one loses, the more likely one is to gain the weight back. Furthermore, recent studies suggest that repeated weight loss and weight gain is associated with increased fat within the abdomen, a site which is associated with most of the hazards of obesity.
A small step has already been taken in regard to defining better outcome criteria. Last fall, the Food and Nutrition Board of the Institute of Medicine held a one day workshop to address this subject. (I believe the committee is already in possession of a copy of that report.) I hope that the Food and Nutrition Board can obtain funding to proceed with a proposed two year study of this issue and prepare a report which would review what has been published in this field, propose standardized data collection and reporting, and provide appropriate indicators of functionality and quality of life, as has been done for other chronic conditions. Such a report could allow us to good data more quickly, so we could then assess the real risks and costs, versus long-term benefits of different weight reduction approaches.

We are a few years away from this goal, but I can forsee a time when all weight loss programs will be obligated to tract their outcome data and to analyze and publish such data in an open, verifiable way. If dieters knew in advance the real hazards, side effects and probability of long-term success of a given program, they might still choose to spend their money unwisely, but at least they would have been forwarned.

(5) Finally, we need to combine the considerable scientific knowledge base that we now have with the equally
considerable power of the media to advance the idea of individualized healthy weights, rather than continuing to promote the unhealthy cultural distortion that has led to our current epidemic of dieting. Again, attempts are underway to devise an operational definition of "healthy weights". Such a definition can certainly be refined as new data become available. In the meantime, however, all of us can do more to accept the fact that people come in different sizes and shapes, just as we come with different skin colors and ethnic backgrounds. Biological variability is not a disease, it is one of the strengths of the human species.

Thank you, again, for the opportunity to share these ideas with you. I would be happy to respond to any questions.
March 26, 1990

BUSINESS OPPORTUNITY AND ENERGY

SUBCOMMITTEE ON REGULATION

BEFORE THE

ASSISTANT ATTORNEY GENERAL RAY JOHNSON

TESTIMONY OF
Chairman Wyden and other members of the subcommittee, my name is Ray Johnson. I am an Assistant Attorney General for the State of Iowa. For the past three years one of my primary responsibilities has been the prosecution of health fraud under the Iowa Consumer Fraud Act and the Iowa Food, Drug and Cosmetic Act. As part of this responsibility, I have prosecuted numerous cases against individuals and companies making fraudulent claims for diet products.

It is estimated that ineffective weight loss products cost consumers billions of dollars per year. Perpetrators of diet frauds get rich while victims not only lose their money, but endure the heartbreak and frustration of repeated failure to lose weight.\(^1\) Victims often assume it's their fault that the latest "scientific breakthrough" didn't work for them. Besides being confused by false and deceptive information about weight control, victims taking useless products waste time and effort which could be devoted to seeking medical treatment or to an effective weight loss program of modified eating habits and increased exercise. Ironically, many fraudulent diet products actually cause people to gain weight because advertisements falsely represent that individuals can "eat all they want" or eat all their favorite foods.\(^2\)

\(^1\) The letters attached as Exhibits 6-10 are typical of many letters obtained in our diet fraud litigation. Individuals repeatedly mention the frustration of not being able to lose weight with diet products they have purchased.

\(^2\) See for example Exhibits 1-5.
Consumers taking questionable diet products are often subjected to serious health risks. In one instance, an Iowa consumer suffered an epileptic seizure because the fiber-based diet pill she was taking absorbed the medication meant to control seizures. In another instance, a grossly obese homeless person was hospitalized due to complications which resulted from taking a diet pill and following a diet program that had not been shown to be safe or effective. Phenylpropanolamine, a common ingredient in many diet pills, may cause serious adverse reactions, such as elevated blood pressure in individuals taking other stimulants or medications such as cold medications or products with caffeine. Elevated blood pressure is of special concern to individuals taking a drug to control obesity because of the strong relationship between high blood pressure and obesity.

The Consumer Protection Division of the Iowa Attorney General's Office has been active in litigation against individuals and companies engaged in sales of worthless diet products. Today I am submitting with my testimony a list of diet fraud cases the Consumer Protection Division of the Iowa Attorney General's Office has prosecuted to date, including information concerning the disposition of these cases.


4 Exhibit 15.
It has become very clear to me that the amount of money involved in diet fraud is substantial. In January of 1988 we obtained a court order restraining a company from obtaining consumer orders and payments it received in response to a solicitation for a diet pill called Neutralizer G.H. In a single mass mailing, the perpetrators of the fraud had received $1.5 million dollars worth of orders. Another company, Health Care Products, Inc., had Iowa sales of a diet pill called Cal Ban in excess of $200,000 for 1989 alone. Since the Iowa market is less than 1% of Health Care Product's sales, it is estimated that Health Care Products sold more than twenty million dollars worth of Cal Ban in 1989. A San Diego company named Meditrend International sold more than twenty million dollars worth of a "diet patch" in one year. The diet patch was nothing more than a band-aid with a solution that was to be placed on the wrist. After action by the FDA and the Iowa Attorney General's Office, the owner of the company, Gert Van Zijl, fled to South Africa with a substantial amount of money obtained from the scam. Obviously, Cal Ban, Neutralizer G.H., and Meditrend's diet patch have been only a small percentage of the total sales of diet products.

Perpetrators of the most blatant diet frauds frequently recognize that their activities could expose them to civil and criminal liability. As a result, diet pills are often sold

A copy of the solicitation is attached as Exhibit 5.
through elaborate corporate structures designed to insulate principals of the fraudulent operation and designed to limit jurisdiction of state regulators over the corporations and individuals holding assets and profits from the schemes. It is common to find that multiple corporations have been formed to market the diet product, with assets concentrated in the least visible corporations. In some cases, officers of these closely held corporations know very little about the day to day business activities or financial affairs of the corporations. These officers are actually "fronts" for those individuals who profit most from the schemes. Perpetrators hope that if state or federal regulators bring enforcement actions, the actions will be brought against shell corporations and the corporate "fronts." That way the perpetrators of diet fraud can keep the profits from their sales and they will not be hindered by injunctions when they form new corporations to carry out a new diet fraud operation.

It is also clear that the diet fraud industry is a very close group. Investigations repeatedly turn up the names of individuals who have been the subject of previous regulatory actions or who have been involved in other health fraud schemes. Customer lists are routinely rented or exchanged between the companies. Perpetrators misrepresent the same scientific studies in their advertising and rely on the same studies to support their claims for their products. They often use the same expert witnesses to provide testimony and affidavits in litigation.
Perpetrators frequently use the same attorneys. Many times they use the same advertising agencies. Attorneys and advertising agencies are often deeply involved in creation of the deceptive advertisements. Many advertisements are so similar in content that it is unmistakable that the advertisement was either stolen from a competitor, a cooperative effort, or the work of one or more individuals simultaneously running several diet scams.

Most fraudulent advertisements for weight loss products are easily detected by a trained observer. The advertisements appear in newspapers, magazines and on television (especially cable television). Advertisements for weight loss products are commonly sent by direct mail. Virtually any issue of Cosmopolitan, Globe, the National Enquirer, or similar publications will contain one or more questionable advertisements for some weight loss product - usually a diet pill. The advertisements are similar in content, often proclaiming that some scientific breakthrough has resulted in the development of a pill that allows a person to lose weight without restricting calorie intake or increasing exercise. Some scientific study is usually referenced. The scientific study is usually of faulty methodology, misrepresented, or both. In some instances the scientific study may also be fraudulent. The miracle pill is often said to interfere with the bodies absorption of calories, allowing food to pass through the body while calories are

See Exhibits 1-5.
unabsorbed. Other advertisements tout appetite suppressant effects. Testimonials from individuals who purportedly have taken the product and who have lost substantial amounts of weight in a short period of time are very common. The advertisement may also include a "warning" telling the consumer not to "overdo it" and become "too thin." Of course, the "warning" is nothing more than a cleverly disguised sales pitch for the product, intended to convey the blatantly false impression to the consumer that the diet pill is extremely effective.

In our investigations and litigation we have repeatedly found testimonials in diet pill advertising to be false, deceptive or misleading. Testimonials seldom if ever represent the typical experience a consumer can expect from taking the product. While advertisements frequently proclaim substantial weight loss without restriction of diet or increased exercise, little if any effort is made by the seller to be certain that individuals giving testimonials did not modify calorie intake or increase exercise—or for that matter, whether the person giving the testimonial even took the product being advertised to lose weight. With most testimonials, there is little support for the conclusion that the diet product being advertised actually caused the weight loss represented in the testimonial.

Testimonials are usually from individuals who have been paid for the testimonial, for losing weight, or both. In some cases we have found that perpetrators have used questionable testimonials from immediate family members and friends of the
owner of the corporations selling the diet pill. Some testimonials have been from individuals who have appeared in other diet pill advertisements and who are attempting to attribute their weight loss to the latest diet pill being advertised as well as the first. We have found that testimonials used in a television commercial were from paid models from a local talent agency who were told that if they could lose a certain amount of weight in thirty days they would get the testimonial work and modeling exposure. One testimonial from a relative of the owner of a diet company was a photograph of a woman holding out an oversized pair of slacks which purported to show a substantial weight loss from taking the diet pill. In fact, the pants were evidently worn by the woman during pregnancy. Another testimonial was from an individual who had lost a substantial amount of weight, but the advertisement failed to disclose that the individual was also suffering from a serious illness that probably was responsible for his weight loss. The most frequent problem we encounter with verification of testimonials is the fact that the company is simply unable or unwilling to provide sufficient information to locate the individual giving the testimonial. We can only speculate as to

Attached as Exhibit A are three different advertisements for three different diet products sold by three different companies. Sheree Coppick appears in testimonials for all three products. While the individual giving the testimonial for Fat Burning System 1 is identified as "Myna Manka", Ms. Manka clearly is Sheree Coppick.

See Exhibit 4A.
what we would learn about the testimonial if we could locate the 
person giving the testimonial.

Perpetrators of diet fraud have learned that they can 
increase their sales by frequently changing the name and 
appearance of their product even though the active ingredients 
remain the same. Since consumers recognize the product only by 
name, they will try the same product under a new name in their 
relentless effort to lose weight. Mailing lists are freely 
exchanged, so that individuals desperate to lose weight can be 
repeatedly victimized.

Enforcement actions against individuals and companies 
selling worthless weight loss products can be brought by state 
Attorneys General, the U.S. Postal Service, the Federal Trade 
Commission, or the Food and Drug Administrations. Cooperative 
enforcement efforts are especially important in the area of diet 
 fraud due to the limitations inherent in actions by certain 
regulatory agencies and the expense involved in litigating diet 
 fraud cases. For example, the U.S. Postal Service recently 
brought an action against Health Care Products, Inc. and was 
successful in enjoining sales of the Cal Ban diet pill through

9 The consumer letters attached as Exhibits 7 and 10 make 
reference to multiple solicitations. This results from 
mailing list being exchanged between perpetrators of diet 
 fraud and resolicitation by the perpetrators under another 
company name and product name. Ironically, perpetrators of 
diet fraud only resolicit the same consumers for different 
diet products because they know that their “miracle” diet 
pill is ineffective and the consumer will soon be in the 
market for the next “scientific breakthrough” in the 
consumer’s desperate attempt to lose weight.
the mail. In response, Health Care Products discontinued orders by mail and now uses toll free numbers and private courier to process orders. Due to action by our office, Cal Ban can no longer be sold by Health Care Products in the State of Iowa. Unfortunately, that leaves 49 other states where the company can still do business despite action by two regulatory agencies. Cooperative efforts can also streamline litigation and reduce the cost through sharing of information and expert witnesses.

The Federal Trade Commission can be very effective in stopping diet fraud if the agency is given the resources to pursue diet fraud cases. A good example is the Federal Trade Commission’s recent action against Allied International who was selling the Fat Magnet diet pill. With cooperation from several states who were also investigating Allied International, the Federal Trade Commission obtained a court order freezing the assets of Allied. The Federal Trade Commission’s authority to obtain nationwide injunctive relief, civil penalties and provide restitution to consumers serves the dual purpose of stopping the deception and taking the profit out of diet fraud.

In an effort to coordinate some aspects of enforcement in the health fraud area, which may very likely include some diet fraud cases, the National Association of Attorneys General and the Federal Trade Commission have now undertaken a review of current enforcement practices with the goal of recommending

\footnote{See Exhibit 1.}
action to enhance coordination and cooperation in the prosecution and prevention of health fraud.

While federal action is important in combating diet fraud, there is also a role for state enforcement. It is extremely important that Congress and federal regulatory agencies are careful not to preempt state enforcement when promulgating rules or enacting statutes in the trade regulation and food and drug areas. For example, one of the most effective state enforcement tools in combating diet fraud is litigation initiated by the state where orders for worthless diet products are being received. The action our office took against the company selling Neutralizer G.H. is a good example of the role states can play in this effort. The restraining order against the sellers of Neutralizer G.H. resulted from a cooperative effort with the U.S. Postal Service. The Federal Trade Commission was also consulted. In the Neutralizer G.H. case, it was decided that state enforcement action would be the most effective since the State of Iowa could act faster than the Federal Trade Commission, could restrain mail that had already passed through the Postal Service where the Postal Service couldn't and, in this instance, could obtain jurisdiction over orders sent to Iowa from throughout the nation. The result in the Neutralizer G.H. case was more than $1.5 million in restitution was provided to 30,000 consumers and a substantial monetary loss was incurred by the perpetrators of the diet fraud.
It is important in investigating diet fraud that regulatory agencies do not wait for consumer complaints before they take action. Even though consumers are unsuccessful in losing weight with a particular product, they seldom complain to regulatory agencies. Even where a consumer has suffered serious adverse health effects from taking a diet product, a complaint if received will usually come from a health care professional rather than a consumer. Consumers often think it is their fault that they do not lose weight or they do not want others to know that they have taken a diet pill in an attempt to lose weight. Many consumers believe it just isn't worth the trouble to file a complaint simply to get their money for the diet pills back. Certainly, lack of complaints should not be equated with satisfaction with the product. In our diet pill investigations and litigation, we have informally surveyed consumers of phenylpropanolamine and fiber based diet pills. We have found nearly unanimous dissatisfaction with the pills. Dissatisfaction stems from the consumers' failure to lose any significant amount of weight as well as complaints about side effects experienced from taking the product.

At the present time, efforts to combat diet fraud are being substantially hindered by the Food and Drug Administration's over-the-counter drug review program and FDA's companion enforcement policy. It would be extremely helpful if the FDA would complete its monograph for weight control drugs and immediately bring enforcement actions against ineffective diet
products. I will attempt to briefly explain FDA's over-the-counter drug review program and its enforcement policy for ineffective weight loss products.

Prior to 1962, the federal Food, Drug and Cosmetic Act only required that drugs be generally recognized by experts as safe before they could be marketed. In 1962 the Act was amended to require that drugs be generally recognized by experts as both safe and effective for the drug's intended use. Any drug not generally recognized as safe and effective for its intended use is considered a new drug under the Food, Drug and Cosmetic Act and can only be marketed after FDA approval of a new drug application. Diet products are considered drugs unless they are being sold strictly as a low calorie food. Any product claiming to alter the way the body digests food is clearly a drug. Since fraudulent weight loss products are not generally recognized by experts as effective for their intended use, and since the FDA has not approved new drug applications for the products, the products are unapproved new drugs being sold in violation of the Food, Drug and Cosmetic Act. The FDA and most

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12 For a detailed discussion of the 1962 amendment to the Food, Drug and Cosmetic Act which added the requirement that drugs be generally recognized by experts as effective for their intended use, and for a discussion on FDA's over-the-counter drug review program, see Cutler v. Kennedy, 475 F. Supp. 838, 840-846 (D.C. 1979); and see Cutler v. Hayes, 818 F. 2d 875, 882-885 (D.C. Cir. 1987).

13 See Nutrilab v. Schweiker, 713 F. 2d 335 (7th Cir. 1983); FDA Advisory Opinion, Exhibit 12; Underwood Letter, Exhibit 13.
states have authority to bring actions against individuals selling unapproved new drugs. The Federal Trade Commission has prevailed in at least one action where the FTC argued that it is deceptive advertising to fail to disclose that the weight loss product was an unapproved new drug.

Unfortunately, the Food and Drug Administration has not been bringing actions against individuals or companies marketing diet products that are unapproved new drugs unless the agency believes that the product poses a safety problem. At times it appears as if the FDA has actually authorized the sale of diet products being sold in violation of the Food, Drug and Cosmetic Act.

The FDA has decided that it would be more equitable to drug manufacturers to allow continued marketing of drugs until the FDA completed monographs on certain categories of drugs. These monographs are intended to establish conditions, if any, under which over-the-counter drugs will be considered by the FDA as safe and effective for the drugs' intended use so that no new


15 In a letter from the FDA to Congressman Waxman regarding Cal Ban, the FDA stated that "[i]t is FDA's position that while guar gum (the active ingredient in Cal Ban) is under the OTC Drug Review for use as an active ingredient in weight control products and does not present a health hazard, it may be marketed at the manufacturer's discretion pending the outcome of the final monograph for OTC weight control." Exhibit 11, p. 2.
drug application is required. All other intended uses for a drug will require a new drug application. The monographs were to be compiled by advisory review panels consisting of experts from outside the FDA. The FDA began reviewing prescription drugs in 1966 and over-the-counter drugs in 1972. The monograph for over-the-counter weight control drugs has not been completed by the FDA and is not expected to be completed in the near future. In Cutler v. Hayes the United States Court of Appeals, D.C. Circuit, charitably described FDA's over-the-counter drug review program as "sluggish at best."

Since the FDA has repeatedly announced publicly that it will not bring enforcement actions against unapproved new weight loss drugs unless the product poses a safety problem, perpetrators of diet fraud have nothing to fear from the FDA as long as their worthless products are not branded as unsafe. State enforcement actions repeatedly encounter arguments by defendants that the FDA has approved the marketing of diet products generally recognized as safe and that the states are preempted by the FDA from taking any action against a diet product.

FDA's policy in this area is troubling for several reasons. The FDA's failure to bring enforcement actions against ineffective weight loss products has given purveyors of diet fraud full rein for nearly 30 years to violate the Food, Drug

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15 Cutler v. Hayes at 885.

Resulting consumer losses have been in the billions of dollars. Additionally, the delay in completion of the over-the-counter weight control drug monograph has complicated enforcement efforts. If the FDA would complete its over-the-counter drug review, enforcement actions by state and federal regulators would be much easier. Actions that now are expensive "battles" of expert witnesses could be streamlined to simply allege that sellers of worthless diet pills are committing unfair practices by selling products in violation of FDA regulations. It would also be assumed that the FDA would begin bringing enforcement actions of its own. It wouldn't be long before perpetrators of diet fraud would get the message. State and federal regulators could then be more effective at taking the profit out of the diet fraud business. The result would be a substantial reduction in consumer financial losses and a reduction in emotional distress suffered by individuals who repeatedly fail to lose weight after trying one "miracle breakthrough" after another.

The diet pill advertisement attached as Exhibit 3 is a good example of just how far perpetrators of diet fraud have gone in flaunting the regulatory authority of the FDA. The diet product advertised in Exhibit 3 is clearly an unapproved new drug being sold in violation of the Food, Drug and Cosmetic Act. The drug couldn't possibly be generally recognized by experts as safe and effective for its intended use, and it is inconceivable that the FDA would have approved the product for the use intended in the advertisement. Nevertheless, the FDA's name is being used in a false and deceptive manner to fraudulently market the product.
If we are going to be successful in combatting diet fraud, it is imperative that the Food and Drug Administration begin immediately enforcing the Food, Drug & Cosmetic Act by bringing actions against diet products that are ineffective. The long overdue monograph for over-the-counter weight control drugs needs to be completed. Cooperative efforts between state and federal agencies need to be continued and encouraged. Finally, federal agencies such as the Food & Drug Administration and the Federal Trade Commission need to be given the resources to combat diet fraud and the agencies need to allocate those resources to bring enforcement actions that will remove the profit from this lucrative fraud.

What is at stake here is the safety and welfare of hundreds of thousands of vulnerable Americans. These hearings can be an important step in developing more effective protections for these consumers. I appreciate this opportunity to testify today and look forward to working with the subcommittee in the future.
TESTIMONY PRESENTED
by
NANCY S. WELLMAN, Phd, RD
PRESIDENT
of
THE AMERICAN DIETETIC ASSOCIATION
before the
U.S. HOUSE OF REPRESENTATIVES
SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES & ENERGY
COMMITTEE ON SMALL BUSINESS
for a hearing on
VERY LOW CALORIE DIETS
2359A Rayburn House Office Building
10:00 a.m.
Monday, March 26, 1990
Good morning. I am Nancy S. Wellman, PhD, RD, President of The American Dietetic Association (ADA), the professional organization representing 60,000 registered dietitians (RDs), technicians, and students nationwide. Thank you, Chairman Wyden and members of the Subcommittee, for recognizing the significance of the very low calorie diet (VLCD) issue and for inviting The American Dietetic Association to describe the important part that registered dietitians must play to enhance VLCD safety and long-term effectiveness. I request that ADA's position on very low calorie diets, our licensing fact sheet and the list of laws that regulate nutrition professionals be included in the hearing record.

We are a nation preoccupied with weight control and diets. Last year, 48 million of us were dieting. We spend more than five billion dollars each year on diet books, products, and foods to lose weight.

Weight control programs and products come in many forms: liquid formulas, portion-controlled foods, diet pills, and special clinics, to name a few. ADA has always been concerned about the efficacy of some diet programs, especially those directly marketed to consumers. Too often the emphasis is on the pocketbook, not the paunch!
While we recognize the increased popularity of VLCDs because of the high incidence of obesity in this country, direct marketing encourages their use by overweight people, who are more likely to lose lean body mass than are those truly obese persons.

Direct marketing to the public bypasses the careful screening and selection process that ADA considers essential. While there are people for whom medically supervised very low calorie diets can be beneficial, ADA recommends rapid weight loss programs only for obese people who are more than 30 percent overweight. Factors such as medical necessity, health and psychological status, and compliance potential need to be evaluated before enrolling a person in a very low calorie diet program. VLCDs should be undertaken only with the supervision of a qualified health team, including a physician and a registered dietitian.

Just as the proper setting is important to highlight a diamond's beauty to its best advantage, the conditions within which a VLCD is administered also affects its appraisal. Appropriate and responsible VLCD administration demands—perhaps for the very first time in a person's life—the establishment of sound, lifelong "reinforcers." Such techniques include behavior modification and exercise to enhance maintenance of the individual's weight loss...and new self-image!

Comprehensive, hospital-based programs offer a full range of professional services, encourage attendance at and involvement in all aspects of the program, and provide long-term support. Conversely, putting profitability ahead of quality shortchanges clients.

Even quality VLCDs are not for everyone. They are not for people with certain medical conditions such as active cancer, insulin-dependent diabetes, renal failure, cardiac disfunction, or
severe psychological disturbances. These diets are not for infants, children, teenagers, pregnant and breastfeeding women, or older Americans.

The most significant drawback to these diets is the potential for life-threatening side effects. The loss of body protein may affect cardiac function and could be related to heart failure. Other side effects include anemia, light-headedness, constipation, diarrhea, and menstrual irregularities.

Another shortcoming of some weight control programs is the diversity of credentials among the "nutritionists" on staff. What is a nutritionist? There is no consensus definition, and in most states, anyone can call himself or herself a nutritionist.

Even the federal government is involved in this definition dilemma. The Health Care Financing Administration has been struggling for two years to define what a dietitian is as it revises the Conditions of Participation for nursing homes.

To cut through this confusion, consumers can look to registered dietitians as the acknowledged experts in food, nutrition, and health. The letters "RD" after a professional's name signify that he or she has met stringent national requirements established by the Commission on Dietetic Registration. These include at least a bachelor's degree in food and nutrition from an accredited U.S. college or university and at least six months of supervised experience, followed by a competency-based examination. To maintain their RD credential, dietitians must acquire at least 75 hours of approved continuing education every five years.
Dietitians' undergraduate education must be up-to-date, too. ADA accreditation or approval of university dietetic programs is an ongoing process. ADA requires that every program submit an annual report and a five-year evaluation document. Reevaluation occurs every 10 years. Accreditation or approval is withdrawn if a program fails to comply with ADA's role delineation-based Standards of Education. Twenty years ago, dietitians felt consumers were adequately protected by our high professional standards.

But today, the National Council Against Health Fraud estimates that quackery costs consumers between 25 and 50 billion dollars a year—and nutrition fraud is the most common type. In 1984, Representative Claude Pepper wrote in his committee's report on quackery, "Enforcement efforts at the local, state, or national level to prevent such fraud are nonexistent."

Six years later, people can consult licensed nutrition professionals in some states. Last June, Oregon became the 26th jurisdiction to regulate nutritionists.

Licensing is one way to protect consumers from the sometimes dangerous consequences of nutrition fraud. Consumer education is another essential ingredient. Registered dietitians help overweight people identify quality indicators in weight loss programs:

1. A variety of foods. Weight control programs should be individualized to fit people's lifestyles and food preferences. Individualization diminishes feelings of deprivation, which leads to discouragement, bingeing, and rebound weight gain—all hallmarks of the yo-yo diet syndrome.
2. Enough calories to maintain good health. Consuming less than 1200 calories a day may result in loss of muscle instead of fat and may compromise nutritional status as a result of deficient nutrient intakes.

3. Realistic weight loss goals. To lose body fat and not just water, a maximum weight loss of two pounds per week is advised.

4. Regular exercise. Especially as we age, exercise can be the key to weight loss and, or maintenance of a desirable weight.

5. Behavior modification. Registered dietitians counsel people to keep lost weight off by integrating healthy eating habits into their lifestyles.

Regaining lost weight is a serious problem for people who have been on very low calorie diets. Oprah Winfrey admits to already putting back 17 of the 67 pounds she lost. A high percentage of dieters using VLCDs gain back more than half the weight lost.

Eventually, all dieters need to learn to deal with food. Changing eating habits is a step-wise, gradual process which requires individualization, ongoing monitoring, and reinforcement. Hence, the services of the dietitian are vital in helping people make permanent adjustments in their eating habits.

As food and nutrition experts, registered dietitians are consulted by clients who have been on very low calorie diets that were deficient in some way. In Michigan, a girl just 14 years old had been on a VLCD for an entire year. Here's what she told the dietitian to whom she was finally referred:

"I was a patient of a quick weight-loss clinic. The idea of this clinic was wonderful, but they really need more medical supervision."
My total caloric intake for one day was close to 500. I felt very weak all the time. Some days, I couldn't even get out of bed. I got very sick, and my doctor took me off the diet. I gained back all the weight, plus more."

Thank you for this opportunity to present our views. I would be pleased to answer any questions you may have.
THE U.S. WEIGHT LOSS & DIET CONTROL MARKET

An Investigation of Market Potential, Demographics, Consumer Demand, and the Competitive Situation

New Market Research

Summary

How much do American consumers spend to lose weight each year? What methods do they use most often? What do individual programs cost, and how effective are they? Which market segments are growing most rapidly? How are consumer attitudes shifting?

The U.S. Weight Loss & Diet Control Market, published in March, 1989, is a comprehensive and timely analysis of this huge and fast-growing market. This $33 billion market is actually made up of nine separate sub-markets: Commercial Weight Loss Clinics, Hospital/Physician-Sponsored Weight Loss Programs, Low-Calorie Prepared Foods, Diet Sodas, Artificial Sweeteners, Diet Books & Audio Cassettes, Non-Prescription Appetite Suppressants, Health Spas/Exercise Clubs, and Residential Resorts/Spas with Weight Loss Programs.

The report costs $995. It is 159 pages in length, and contains 36 statistical tables and charts, in-depth discussions, analyses, forecasts, and findings from government and trade association surveys on consumer dieting and obesity demographics, and competitor profiles are included. Much of the market potential estimates (such as diet books, hospital weight loss clinics, etc.) have never been seen before before.

Major Findings of the Report:

1) The total national market for weight loss products and services was estimated in 1988 to be worth $29 billion in 1988. Product categories include diet products (low-calorie foods, beverages, and soaps), exercise clubs, and diet programs. The core market includes weight loss clinics, diet books, and low-calorie prepared foods.

2) In 1987, there were nearly 13,000 “weight control services” operating across the U.S. The top 7 diet center chains accounted for more than 6,100 of them, and an estimated 67% of a $1.78 billion commercial weight loss clinics market.

3) Profitability of large commercial diet centers is an available 10-20% of sales. Revenues per center average from $200,000 to $2 million.

4) Hospital/Physician-sponsored medically supervised weight loss programs are gaining in popularity, and constitute a $5.7 billion market that is growing at 15% yearly.

5) Currently, the trend is shifting toward liquid protein/meal replacement diets, hospital/physician-sponsored programs, diet soft drinks, diet books, and low-calorie microwaveable prepared entrees, and away from exercise clubs and diet pills. As recently as 1988, surveys showed that consumers were least likely to attend weight loss classes and use meal substitutes, and were most likely to use exercising as a dieting method.
CONFUSED ABOUT ALL THE COMPANIES & PRODUCTS, THEIR
EFFECTIVENESS & COSTS?

NOT SURE WHETHER A MEDICALLY-SUPERVISED OR SELF-HELP
PLAN IS RIGHT FOR YOU?

CONCERNED ABOUT SAFETY & POTENTIAL SIDE EFFECTS?

READ THIS GUIDE FIRST—KNOW ALL YOUR OPTIONS,
THE COSTS, HOW PROGRAMS WORK, BEFORE YOU INVEST
YOUR TIME AND HARD-EARNED MONEY!

Marketdata, a totally independent, nationally quoted market research
company, has just released a new, in-depth 92-page guide (February 1990):
(See other side for complete table of contents)

Consumer Guide To Weight Loss & Diet Control Programs

The research was performed over the past 12 months and is up-to-date,
unique, and comprehensive. In-depth descriptions are provided for more
than 30 of the most popular diet programs and companies, as well as the
most popular medically-supervised and non-prescription liquid protein
diets. But be warned—VLCDs are not for everyone, and many dieters
experience serious side effects. Marketdata has absolutely no financial or
other interest in any diet companies—that's why we tell it like it is!

THE GUIDE COSTS $21.95, plus $1.76 (8% NYS Sales Tax) and $3.50
shipping/handling (allow 3-4 weeks delivery) NY buyers only

TO ORDER, FILL OUT THE FORM BELOW, CLIP IT AND SEND IT WITH
A CHECK OR MONEY ORDER FOR $26.71, PAYABLE TO:

Marketdata Enterprises, P.O. Box 436, Lynbrook, NY 11563.
Call us at: 516-791-6579 if you have questions

ORDER FORM

Yes, please send me ___ copies of the Consumer Guide To Weight Loss
Programs, at $26.71 each. Total enclosed: ___________

Name ___________________________________________________________
St. Address __________________________________________________________________________
City ____________________________ State ______ Zip ______________
ORDER FORM

Please Complete This Form, Clip and Send To: Marketdata Enterprises, P.O. Box 436, Lynbrook, NY 11563 Phone: 516-791-6579 FAX: 516-536-1801

___ Yes, please send me ___ copies of THE U.S WEIGHT LOSS & DIET CONTROL MARKET, at $9.95 per copy

___ Please send me ___ extra copies, to same company, at $200 each

___ Enclosed is my check for $______, payable to Marketdata Enterprises.
(Take 10% discount for pre-paid orders)—no postage/handling.

Note: NY State buyers add 8% sales tax. Overseas orders must be pre-paid, in U.S. dollars. Add $30 airmail postage.

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For more information: call John LaRosa, Research Director. If using your own purchase order, please enclose this form as well.
THE LIQUID PROTEIN DIETS MARKET

April 1990  40+ Pages  Price: $595

This timely new report by Marketdata investigates the booming liquid protein diets (VLCDs—very low-calorie) marketplace—medically monitored (prescription only) and over-the-counter types. Analysis of market potential, size/growth estimates (early 1980s-1995). Dieter demographics, impact of celebrity endorsements. Detailed descriptions of top 10 medically monitored plans offered via MDs and hospitals (OptiFast, HFR, Medifast, Medibase, Baylor Fast, Nutrilmed, New Direction, ToppFast, Ultrafast, United Weight Control)—program lengths, costs (to MDs and consumers: supplements, lab tests, doctor fees), how plans work—fasting/maintenance phases, other activities.

Historical development of VLCDs since mid-1970s, FDA regulation, side effects, difference between today’s plans vs. predecessors. Covers growing number of hospital & MD proprietary formulas and programs. Strategic profiles of the major market competitors (estd. sales, mkt. share, no. of clients served, marketing strategies, advertising, distribution channels, field support & profit margins for MDs & hospitals, supplement contents & calories, research activities, taste comparisons, etc.). Also examines market for retail, non-prescription liquid protein diet powders and shakes (11 popular brands such as Slim-Fast).
About This Report

The report is a completely new and pioneering investigation of the U.S. Weight Loss & Diet Control Market. The table of contents below data was obtained from a comprehensive variety of sources, from the government, trade associations, university sites, newspapers, reports, private sector sources, telephone interviews, business newsletters, etc., encompassing both primary and secondary market research, to ensure maximum accuracy and completeness.

The report is divided into 13 self-contained sections:

- Executive Overview & Major Findings
- The Demographics of Obesity
- Weight Loss Treatment Methods/Obesity Research
- Consumer Dieting Habits, Usage of & Attitudes Toward
  Low-Carb Food Products
- Governmental Population of Ultra-Light Foods, Beverages
- Mail Order Diet Plans & Products
- Weight Loss Market: Segments/Relative Sizes & Growth
- The Appetite Suppression Market
- The Low-Carb Prepared Foods Market
- The Diet Snack & Artificial Sweetener Market
- The Commercial & Home-Prep Diet Clinics Market
- The Hospital-Sponsored Weight Loss Clinics Market
- The HHS Longitudinal Exercise Clubs Market
- The Market for Diet Snacks with Weight Loss Programs
- The Diet & Fitness Books & Audio Cassette Market

Each section addresses the following topics:

- Strategic Profiles of the Market Leaders
- Market Structure & Nature of the Competition, Financial Operating Ratios of the Industry’s Firms
- Analysis of National Brand Advertising

The report contains in-depth competitive profiles of:

- Diet Center, Weight Watchers, Scarsdale (Lean Cuisine), Jenny Craig Inc., Nutrisystem, Optifast, Jenny Craig, Inc., Holiday Inn, etc. Weight Loss Centers. Also included are computer-sourced database abstracts of recent market/company developments.

Doesn’t it make sense to get all the information in one place, in one convenient report, at less cost? Why spend valuable time collecting bits and pieces of market data, when you need to manage your business? Information is a competitive tool—plain and simple.

The report brings together in one convenient place the major market segments, the historical/current/forecasted size of the total market, competitive intelligence, national market potential, operating expenses, and more. The report will be an invaluable strategic planning tool for all participants in this fast-growing market, as well as industry consultants, securities analysts, banks, public relations firms, agencies, and merger & acquisition consultants.

**THE U.S. WEIGHT LOSS & DIET CONTROL MARKET**

**MARCH 1992**

**TABLE OF CONTENTS**

<table>
<thead>
<tr>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction: Report Scope, Source Use, Methodology</td>
</tr>
<tr>
<td>Executive Overview</td>
</tr>
<tr>
<td>The Demographics of Obesity/Overweight</td>
</tr>
<tr>
<td>* Interpretations of 1993 Simmons Market Research Survey data on reasons for dieting, use of diet pills used by age, sex, occupations, income, education, etc.</td>
</tr>
<tr>
<td>* Calculator Council 1988 survey (monos on dieting and attitudes toward low-carb foods &amp; beverages)</td>
</tr>
<tr>
<td>* Bils and Hatt Health Survey findings: % of population that is obese or overweight, by age, sex, race, etc., difference in under vs. overweight females (1960-90 trends)</td>
</tr>
<tr>
<td>Tables</td>
</tr>
<tr>
<td>* Percent of overweight persons, age 20-74, by race, sex (1976-80)</td>
</tr>
<tr>
<td>* Median calorie intakes of persons, by age, race, sex (1971-74)</td>
</tr>
<tr>
<td>* Percent of population desiring to lose or more from desirable weight, by age, sex (1980-84)</td>
</tr>
<tr>
<td>* Percent of population desiring to lose 10-10% of desirable weight (as above)</td>
</tr>
<tr>
<td>* Chart: Adult smokers in the U.S.—who are they, why are they smoking, how do they diet?</td>
</tr>
<tr>
<td>Weight Loss Treatment Methods &amp; Obesity Research</td>
</tr>
<tr>
<td>* Reasons why diets fail, and dissection of major diet methods, which ones are effective for short- vs. long-term use, side effects, drug used, behavior modification, rolls of electricity, hereditary factors</td>
</tr>
<tr>
<td>Consumer Dieting Habits, Usage Of &amp; Attitudes Toward Low-Carb Products</td>
</tr>
<tr>
<td>Summary of eleven 1986 survey by Calculator Council—usage of low-carb foods &amp; beverages Trends, usage differences by age, operative product usage, interest in</td>
</tr>
</tbody>
</table>
more low-cal products, initial use of low-cal products, taste for usage, importance of \( \vdots \) 

**Examples**
- New babies are low-cal foods & beverages & \( \vdots \) 
- By name, most popular kind of products
- \( \vdots \) 
- Importance ratings in use for low-cal foods & beverages
- Methods of dining \( \vdots \) 

**Government Regulation of Life/Weight Foods**
- FDA rules, labeling, selection, classification of foods & beverages as "tongue, taste, diet, dietetic, and low-calory"
- Some of the minor differences in market share on the market and how they are policed by the U.S. 
- Private Service, FDA, FTC Council of Better Business Bureau

**Weight Loss & Diet: Central Market Segments**
- Subcategory & analysis of various industry market segments, how they intersect and compete with each other, comparisons of dollar size and projected rates of growth

**The Appetite Nourishment Market: Diet Ailments & powders & low-cal/yogurt, eggs, smoked meat, chickens, soft drinks, breads, soups, nuts, beef, fish, chicken, eggs, smoked meat, canned meat, breads, soups, nuts, beef**
- Discussion of market size, major competitors, market share forecasts to 1995
- Company profiles of companies, marketing strategies, programs, distribution channels, etc.

- Thompson Medical Co.

**Advertising Analysis:**
- Total media spending, by brand, by market share, by reducing aids (1980, 82, 84, 86, 87)
- Sample media ad for Carb-in 2000 Diet Tablets
- Computer database analysis of recent market & company developments, apparel, accessories, soft drinks, etc.

**Low-Calorie Prepared Foods Market**
- Discussion of market size and growth of low-cal. supermarket entered market, market share by leading companies, speciality foods, recent advertising by major firms, forecasts to 1995
- Company profiles for:
  - Weight Watchers International
  - Lean Cuisine (Stouffer Foods)
  - Dieting Advertising of Top 10 Brands (1997) diet-prepared foods and artificial sweeteners
  - Computer database abstracts of recent diet foods market developments, company developments

**the Diet Soft Drinks & Artificial Sweeteners Market**
- Discussion of diet soft drinks as \( \vdots \) 
- Total soft drink sales, historical growth, 1995 forecasts, consumer buying patterns, market leaders (Coca-Cola, Pepsi, etc.)

**Sales analysis:**
- Total soft drink sales of \( \vdots \) 
- \( \vdots \) 

**Marketing:**
- Total soft drink sales of \( \vdots \) 
- \( \vdots \) 

**Advertising:**
- Total media spending by brand, by top 10 companies, for artificial sweeteners (1982, 84, 86, 87)

**Commercial & Non-ProfỚit Weight Loss Centers & Diet Clinics**
- **Overview** of analysis of 1984 market size, 1995 forecasts, major market trends, consumer usage, weight loss clinics
- **Number of weight control services by state:**
- **Company profiles:** new programs/changes for \( \vdots \) 
- **Weight Loss Centers:** National/(non-profit weight loss centers)
- **Drug Control Companies:**
- **Adjustment:**
- **OxiFree:**
- **Diet Information:**
- **Dietary:**

**Hospital-Related Weight Loss Clinics**
- **Summary:**
- **National/Regional Exercise Clubs & Health Spas**

**Hospital-Related Weight Loss Clinics**
- **National/Regional Exercise Clubs & Health Spas**
- **Hospital-Related Weight Loss Clinics**

**The Diet & Fitness Books Market**
- **Discussion**: of diet & fitness books market, sales relatively high for health, offers publishers to evaluate new books, as of copies sold of many popular books, current diet books new, new edition, recent book sales, what makes a bestseller, etc.

**List of popular diet books since 1976, inc. Scarsdale Medical Diet, Beverley Hills Diet, The Statin Diet, Elizabeth Taylor Taps Off, Eat To Win, The Weight Watchers Diet, The New American Diet, Weight Watchers Cookbooks, etc.**
- **Marketing:**
- **Advertising:**
- **Publication:**

**Bibliography:**
- **List of major industry trade associations, non-profit groups, pertinent to weight loss, food products, etc.**
- **List of magazines covering weight loss regularly:**

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LIQUID PROTEIN (FASTING) DIET PLANS

Hospital-based, medically monitored weight loss programs have become very popular in recent years, especially after receiving heavy media exposure when the talk show hostess Oprah Winfrey credited the OptiFast program with her 65+ pound loss.

The difference between these programs and other commercial plans such as Weight Watchers and Nutrisystem, is that they are available only through a doctor's prescription. The products/formulas used in these "very low calorie diets" (VLCDs) are not available via over-the-counter retail channels. These diets are medically supervised by the patient's own doctor, or are run by dietitians and nurses under a doctor's supervision.

The medically supervised fasting portion of the program typically lasts 12-16 weeks, although the OptiFast program runs for 26 weeks. This fasting period is usually followed by a longer (as much as 1.5-2 years) follow-up maintenance phase, to maintain one's "goal weight". The typical amount of weight one can expect to lose averages 2-5 pounds per week.

Typical success rates (measured at 1 year or more after the program has been completed) are 40-65%, or a relapse or recidivism rate of 35-60%. This is according to databanks developed from clinical experience with thousands of patients taking part in the major companies' programs (OptiFast, HMR, MediFast).

As of early 1990, there were nine major companies or institutions offering medically monitored fast diet programs. Their names and phone numbers are as follows:

<table>
<thead>
<tr>
<th>Company/Institution/Program Name</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Health Management Resources (HMR)</td>
<td>617-357-9876</td>
</tr>
<tr>
<td>59 Temple Place, Suite 704</td>
<td></td>
</tr>
<tr>
<td>Boston, MA 02111</td>
<td></td>
</tr>
<tr>
<td>2. Ross Laboratories' &quot;New Direction&quot;</td>
<td>614-898-4107</td>
</tr>
<tr>
<td>625 Cleveland Ave.</td>
<td></td>
</tr>
<tr>
<td>Columbus, OH 43216</td>
<td></td>
</tr>
</tbody>
</table>
Liquid protein diets are most appropriate for people that are substantially overweight or are obese—not for those who'd like to take off a few pounds. VLCDs (under 800 calories per day restriction) are applicable for those who are medically at risk, 50 lbs. or 30% or more above their ideal body weight. According to various media sources and industry experts, 160,000 people have lost 40 lbs. or more on such fast diets, and more than 1 million people have tried liquid protein diets so far.
and behavioral modifications. It takes most patients 15 weeks to lose the weight—then they spend 29 weeks on a maintenance program. Monthly charges are $200 for the formula and $300–$380 in medical fees.

**Private Physician Diet Programs**

Competition amongst MDs has also increased in recent years, and many have added such services as medically-supervised diet programs affiliated with local hospitals, to enhance their practice’s revenues.

A typical example is a program that uses a filling protein-rich supplement that is mixed with a diet beverage, to create a "milkshake" full of all the necessary daily vitamins and minerals. Besides four shakes per day, patients are allowed two slices of diet bread, two pieces of fruit, a green salad of unlimited size and a 300-calorie frozen dinner available in any grocery store. Such a diet will result in a loss of 3–5 pounds per week.

The patient’s physical condition is monitored via a weekly visit to the doctor, and tests are performed as needed. When the patient reaches his/her goal weight, they can use a less strict “graduate-level” maintenance program.

Since the weight loss will be accomplished with the help of one’s physician, the patient’s medical insurance (incl. Medicare) will probably pay for the cost of weekly visits and necessary tests. Again, only the most liberal insurance plans will cover the cost of the supplements.

Even chiropractors are jumping on the fasting diet bandwagon. A scan of a recent issue of the trade publication *Dynamic Chiropractic*’s advertisements found several programs—"Doctor’s Fast" (a modified fast diet program) and "health-fast", a program developed by Charles E. Gibson, a chiropractor and guru of the practice management/marketing seminars designed to increase business for chiropractors.

Among the stated goals of the “health-fast” program, advertised in a full-page ad, are to:

1. retain weight loss patients, rather than lose them to M.D.s and store front programs (commercial diet clinics like Weight Watchers, NuTrition System, etc.)
2. attract large numbers of new chiropractic patients
3. provide large profits for the chiropractor
4. further enhance the chiropractic image and exposure in the community.

The program was said to be developed by "a team of the finest liquid protein specialists, nutritional scientists, and chiropractic nutritionists." However, consumers should be wary. Chiropractors, although trained in nutrition, are not M.D.s., and liquid protein diets are not to be taken lightly. It is Marketdata's opinion that the main motives for developing such a liquid protein product are numbers 2. and 3. above, especially due to the fact that chiropractic is a very competitive profession seeking to enhance its practitioners' revenues, and that the program was developed and introduced by a person whose focus and income is heavily skewed toward marketing.

Over-The-Counter, Non-Prescription Liquid Protein Diet Products

There are several liquid protein powders and mixes the consumer can purchase in drug chain stores, natural food stores (General Nutrition Centers-1100 stores nationwide), and other retail outlets, as well as via the mail order.

The popularity of medically supervised diets such as Optifast and Medifast has translated into increased sales of the over-the-counter (unsupervised) formulas as well. Most nutritionists agree that these formulas should not be used as a person's sole source of calories, without supervision.

Each package of the over-the-counter diet formulas must contain an insert required by the Food & Drug Administration, which describes the use of the formula as meal replacements, and other information about eating at least one well-balanced meal of regular food per day.

Most over-the-counter liquid diets have a lower ratio of protein to carbohydrate than medically supervised diets. Since they rely on carbohydrates as their main calorie source, they do not suppress one's appetite as the high-protein diets do.

Nonfat milk is the most common source of protein in these formulas. Other sources include: egg white, lactalbumin, soy, tofu, casein (a form of calcium), and whey. For carbohydrates, most formulas use fructose, as maltose.
brand Slim-Fast contains the most sugar—5 different sweeteners. Slim-Fast and Ultra Slim-Fast contain the artificial sweetener Nutrasweet. Very few of these formulas contain added fat. Some brands contain fiber, while others do not.

These formulas are usually mixed with milk, to create a shake. These shakes can act as substitutes for breakfasts, lunches, or snacks, and are consumed in combination with regular food. Generally, 1,100-1,200 calories per day are taken in to lose weight. One Ultra Slim-Fast milkshake, for example, contains 220 calories.

Some of the advantages of these non-prescription diets are that:

1. They involve high fiber formulas that make the dieter feel full, not hungry.
2. They are nutritionally complete, containing all the U.S. RDA recommended protein, calcium, vitamins and minerals.
3. They contain no drugs, resulting in more natural weight loss and a minimum of side effects, if any.
4. They come in various flavors.
5. They are convenient and easy to use.
6. They may be more appropriate for dieters that want to maintain their weight, or lose a small-moderate amount of weight (5-25 lbs.).
7. Cost—they are inexpensive.

As in any diet, the consumer would do best to consult his/her physician first, and follow carefully the directions and instructions the manufacturers of such liquid protein mixes supply on the packages.

Important Warning:

In a January 5, 1990 article of the Journal of the American Medical Association (JAMA), several prominent physicians that have studied liquid protein diets, both medically-monitored and over-the-counter types, reported that they were alarmed by the possible consumption of very-low-calorie diets by people who are not severely overweight or who do not receive proper medical supervision. They are afraid that the recent "zealous marketing of various formula products to physicians-as well as the public's appetite for such diets, could lead to yet another round of complications and fatalities" (as in the 1976-77 period).

They go on to report that VLCDs are potentially appealing to people who
their goal weight within a few short weeks. Some VLCD programs have been offered to persons as little as 15% overweight, an alarming practice, because the majority of studies demonstrating the safety of these diets have examined their effects only in severely obese persons. Findings from this group are not applicable to the more mildly overweight.

The doctors point out significant possible short-term complications, such as: dehydration, electrolyte imbalance, increased uric acid concentrations, fatigue, dizziness, muscle cramping, headache, gastrointestinal distress, and cold intolerance. These complications are easily corrected with medical supervision, but dieters using such retail liquid protein diets should be aware that everyone's body is unique, and what may not affect one dieter may indeed be bad for another.

The current perception is that nearly anyone can start a very-low-calorie diet program and become an expert in the treatment of obesity. It is clear that practitioners have an obligation not only to ensure the safe use of very-low-calorie diets, but also to help patients obtain access to the skills needed to facilitate long-term weight control.

Probably the most successful in terms of sales, consumer acceptance and recent publicity is the Slim-Fast and Ultra Slim-Fast brand, manufactured by Thompson Medical Co. of New York, NY. Thompson is also the maker of such appetite suppressants as Dexatrim diet capsules, Slim-Mint, and Fiber Full.

There are some other brands, as follows:

* Slim-Safe Bahamian Diet (Dick Gregory's formula).....$26/can for a 16 oz. can.

* Diet Fast (Advantage Supplements, P.O. Box 476, Carnegie, PA 15106).....$10.99/can for a 16 oz. can. Flavors are: strawberry, vanilla, chocolate.

* Twin Fast (Twin Laboratories, Inc., Ronkonkoma, NY 11779).....$24.99 per can for a 1.88 lb. can.

* Slim & Trim (Nature's Way Products, 10 Mountain Springs Pkwy, Springville, UT 84663).....$12.99/can for a 1 lb. 8 oz. can.
* Firm-a-Loss Diet (Welder Health & Fitness, Woodland Hills, CA 91367) $7.99/can for a 14 oz. can. (Joe Welder's company specializes in products for male/female bodybuilders).

There are several others, which Marketdata could not find on retail shelves, but do exist nevertheless. They are:

* Naturade Herbal Diet (160 calories, 22 g protein, 16 g carbo., price per scoop: 40 cents).

* Naturade Weight Reduction Program (200 cal., 20 g protein, 27 g carbo., price per scoop: 80 cents).

* Slim Difference (160 cal., 22 g protein, 16 g carbo., price per scoop: $1.04).

* Twinsport Endurance Meal & Weight Control Formula (190 cal., 15 g protein, 31 g carbo., price per scoop: 48 cents).

Also, there are so-called "multi-level" or "networking"-based companies that sell their products via word-of-mouth, through independent distributors that usually sell in small, local areas around their neighborhood. You will not find these products on retail shelves.

One such company, that does about $50 million in sales (1989), and is growing rapidly, is:

Nu-Skin International
P.O. Box 801
Provo, Utah 84603

Nu-Skin sells a full line of hair and skin care products, as well as dietary supplements and dieting aids. Their "nutrition package" or "interior design" system consists of Shape Essentials (vitamin & mineral complex), Splash Morning Essentials (morning orange drink), Essentials weight loss formula (chocolate, vanilla), Image Essentials (daily caplets), and a subliminal tape (Take Charge: Control Your Appetite). This total package costs $159. The meal replacement formula alone costs $30 for a 1 lb. 6 oz. can. It contains 155 calories per serving.
THE U.S. WEIGHT LOSS AND DIET CONTROL MARKET

An Investigation of Historical and Projected Market Potential, Consumer Demand, and Competitive Products & Services.

This business information report has been prepared by using a comprehensive variety of primary research techniques and secondary information. It brings together in one place the most up-to-date, pertinent, and accurate data from trade associations, government health agencies, experts/practitioners in the field, the business media, financial and other private sector services, computerized databases, and special surveys.

This report will be equally useful to marketing/strategic planning directors at companies involved in the industry, as well as consultants, securities analysts, banks, and merger & acquisition candidates.

Publication Date: March 1989

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EXECUTIVE OVERVIEW OF THE WEIGHT LOSS & DIET CONTROL MARKET

Nature of the Market

Not one season passes without at least one diet book high on the best-seller list. Americans are bombarded with TV and radio ads touting quick and easy weight loss, by a variety of programs—some safe and effective, some that are mere shams. The latter are policed regularly by the U.S. Postal Service, the FDA, the Federal Trade Commission, and the Council of Better Business Bureaus. Media personalities that lose weight are especially convincing role models, and boost the fortunes (at least in the short run) of the programs or products they use.

As this report is being published (March), we are entering the “season” for dieting. During 1987, at least $205 million was spent on various media to advertise diet clinics, health spas, diet soft drinks, diet pills, and other weight loss services and products. The demand for diet aids does tend to be seasonal; as people are more likely to diet during the Spring and Summer. Obviously, women prepare to shed a few pounds to fit into their summer bathing suit, people are outdoors more often, and as the weather warms, less clothes are worn, making their out-of-shape condition more noticeable.

The cost to the consumer varies tremendously, depending on the dieting methods used. Appetite suppressants found on drugstore shelves typically cost about $7 per package (2-week supply). Commercial diet clinics’ costs are as follows: Diet Center -- $35-75/week, Weight Watchers -- $7.50 per weekly meeting (plus cost of company frozen food entrees purchased), a one-time $185 fee at Jenny Craig Intl. (plus cost of Jenny’s Cuisine frozen entrees purchased at $3 each), and $40-50 weekly at Nutri/System.

Yearly health club memberships can range from $40 to $300-500. Hospital weight loss clinics can range from $120 for a multi-session program such as the one offered by the John Hopkins University, Maryland program, to $145/week or more at metropolitan area hospitals. Medically-supervised programs such as Optifast can run $1,500-2,500 for a 6-month program. For the Medifast program, an initial visit can cost $170, plus $70 for each weekly one after that (medical monitoring, counseling, food supplements). This typically works out to $1,200 for a 4-month period.
And, the most expensive of all are the residential health spas like the Pritikin Longevity Centers, Bonaventure, FL spa, LaCosta, CA spa, and others--typically costing clients $2,200 to as much as $8,000 for a total 2-week health and fitness program, lab tests, seminars, etc.

Much of the failure and relapses experienced by dieters is due to unrealistic expectations that fad diets, pills, potions, or devices will quickly and magically "burn away" excess pounds. And, the plethora of women's magazines on the newsstand is all too happy to feed women's appetites for these quick fixes with the latest trendy diet plans.

Some people, due to physical factors related to metabolism, may be "pre-programmed" to be overweight. Nothing they do will help them lose weight. However, many others can and do lose weight by using a combination of increased exercise, behavior modification, and lifestyle changes in eating habits.

Americans seem to be maturing somewhat in their realization that permanent weight loss and maintenance of their ideal weight is hard work, and involves some real commitment. There is a renewed concern for health issues, side effects, and safe diets. During the late 1970s, there were heightened concern and federal hearings regarding doctor-prescribed amphetamines and other drugs used for weight loss. Stiffened government regulations followed.

**Market Potential**

By Marketdata's estimates, Americans currently spend over $29 billion per year to lose and/or maintain their weight. We expect this figure to climb 11.6% to $32.4 billion in 1989, and to grow 10.6% annually, to a level of $50.7 billion by 1995. These figures and growth rates apply to the total market, which includes such "indirect" markets as health spas & exercise clubs, artificial sweeteners, and diet sodas.

The "core" market, refined to those market segments related directly to weight loss (commercial, non-profit, and hospital-run weight-loss clinics and programs, non-prescription appetite suppressants, and diet books and audio/video cassettes), is growing significantly faster. Marketdata estimates that this core weight loss market was worth $8.2 billion in 1998, will grow 19% to $9.8 billion during 1989, and thereafter will average 15% growth, to a level of $16.9 billion by 1995.
These market estimates apply to the definable, "legitimate" industries, products and services associated with weight loss/maintenance. If one adds in all the oddball, mail order remedies such as herbal body wraps, pressure belts, kits, vitamins and meal supplements that consumers get taken for each year (a figure that probably can never be determined), the market is probably at least 20% higher than Marketdata's estimates.

**Market Structure & Competition**

The weight loss and diet control market is largely dominated by the large soft drink manufacturers, large national and/or regional commercial weight loss clinics such as: Weight Watchers International, Nutrisystem, Diet Centers (American Health Companies), Jenny Craig International, and several non-profit organizations such as Overeaters Anonymous and Take Off Pounds Sensibly (TOPS), hospital/medically-supervised weight loss clinics, and the pharmaceutical firms such as Thompson Medical that make appetite suppressants.

In 1987, there were nearly 13,000 "weight control services" listed in the national Yellow Pages directories. The top 7 companies in the business are estimated by Marketdata to account for over 6,100 of these centers, with Weight Watchers and Diet Center each operating more than 2,100.

Companies like Weight Watchers and Stouffer's Lean Cuisine food line have seen sales mushroom with the popularity of convenient, frozen, microwaveable prepared food entrees and the clout of national advertising under a larger corporate umbrella (Weight Watchers is owned by H.J. Heinz). Franchising has also been a major contributor to these companies' growth.

Low-calorie entrees now account for 20% of all sales dollars spent by consumers on frozen single dishes and dinners. This is the fastest-growing frozen food segment, in terms of shelf space. Some feel that the success of diet soft drinks paved the way for the success of low-cal frozen foods. As convenience, availability, menu variety, and quality improved, these products enjoyed broader appeal by a variety of age groups.

Profitability for commercial diet clinics is quite good. For the most recent year, net income as a percent of revenues stood at 19.6% for Diet Center, nearly 10% for Weight Watchers (operating income), and was said to range from 10-30% for Jenny Craig International centers.
Annual revenues per clinic or facility range from $600,000 to $2 million for Jenny Craig operations and $370,000 for Nutri/System centers. By comparison, after-tax profit margins at health & fitness clubs average about 5%.

**Consumer Demand Factors**

What's fueling this boom in America's quest for thinness? Several of the more important factors are that:

* People who are 40% overweight visit their doctors and miss work twice as often as the average weight person. Obesity research commands an estimated $500 million each year in the U.S.

* 25% of all adults in the U.S. are obese, 13 million are severely overweight, and there are an estimated 65 million dieters--50% of women and 25% of men. 60% of all women are usually dieting in some form. 18% of all adults are constantly dieting.

* Many women are having children at older ages, combining two situations--middle age and childbirth--each of which alone can bring on weight problems. Surveys have found that the largest concentration of dieters are in the 25-44 year old group.

* Only 2% of dieters retain their desired weight seven years after they undertake a weight loss program--making for a large number of "recycled" dieters that try one diet after another over a period of many years.

**Shifting Consumer Attitudes Toward Dieting**

A 1986 study by the Calorie Control Council of Atlanta found that exercising was one of the most popular methods of dieting, along with cutting out foods containing sugar, starches, or fat. Attending weight loss classes (such as Weight Watchers) and using meal substitutes (such as the liquid fast diets prescribed by Optifast and Medifast) were then among the least popular methods.

However, a major shift seems to have occurred in the three years since then, judging by the recent successes of several companies and products available to the consumer. Weight Watchers and Nutri/System have enjoyed very robust growth in recent years. Over-the-counter appetite...
suppressants in the form of diet pills, mixes, gums, etc. have been strong
sellers. The so-called exercise boom has slowed and major exercise/spa
chains are consolidating and competing fiercely for slow-growing
revenues by diversifying into non-exercise activities. And, the recent
successes of some prominent media personalities such as Oprah Winfrey
and the credibility they gave to such products as Optifast, have boosted
interest in liquid protein diets and enrollments in programs offering them.

How Do Consumers Diet?

As of the latest study (1986), 45% of people use low-calorie, sugar-free
products, mostly sugar-free soft drinks, sugar substitutes, gum, or candy,
etc. Women are more likely to be users of these products, and they use a
greater number of different products than men.

Of those dieting, 50% diet to lose weight while about 33% diet to
maintain their current weight. Fully 56% of female users of low-cal
products use them to maintain an attractive physical appearance. This is a
very important reason.

Major Segments of the Weight Loss & Diet Control Market

Market data, for the scope of this study, has identified and examined nine
distinct, yet inter-related market segments, essentially "industries" in
themselves. Their estimated sizes for 1989, and long-term projected
rates of growth through 1995, are as follows:

<table>
<thead>
<tr>
<th>Segment</th>
<th>1989</th>
<th>1988-1995 Annual Growth Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Ranked by size)</td>
<td></td>
<td>($ Millions)</td>
</tr>
<tr>
<td>1) Diet Soft Drinks</td>
<td>$11,390</td>
<td>9.0%</td>
</tr>
<tr>
<td>2) Health Clubs</td>
<td>$11,390</td>
<td>9.0%</td>
</tr>
<tr>
<td>(nonresidential)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Hospital-sponsored Weight Loss</td>
<td>$5,490</td>
<td>15.4%</td>
</tr>
<tr>
<td>4) Low-Calorie Prepared</td>
<td>$1,750</td>
<td>12.8%</td>
</tr>
<tr>
<td>5) Entrees/Prepared Foods</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
We can further subdivide the market into a "core" market related directly to weight-loss products and services. Marketdata defines this "core" market as:

- Commercial weight loss clinics
- Hospital weight loss clinics
- Low-calorie, prepared, frozen and "lite" foods
- Appetite suppressants
- Diet books & cassettes

When examining this more focused market, we see that it is estimated to be worth $3.22 billion in 1988, and is expected to grow at a faster 19.2% rate, to $9.8 billion during 1999. Through 1995, the annual rate of growth is forecast to be 15%, bringing revenues to $16.0 billion.
From now until 1995, certain market segments will rise and fall in popularity, according to shifting consumer preferences, fads, successes of well-known media personalities, health concerns and federal regulatory pressures, cost-effectiveness, status of the economy and its effects on consumer disposable income, and other factors. All of this will affect the growth rates of these individual market segments.

Right now, the tide seems to be shifting toward liquid/fast diets, hospital-run weight loss clinics, diet soft drinks, diet books, and low-calorie, easy-to-prepare microwaveable entrees and away from non-residential health clubs, transdermal drug delivery systems (skin patches), and diet pills that may involve undesirable side effects or addiction for some consumers.

The number of prescriptions filled for anti-obesity drugs has fallen substantially in recent years, due to a growing awareness by doctors that they may be addictive and that they have limitations as successful weight control agents. But, this has been more than compensated for by increased use of non-prescription diet pills.

**Theoretical Profiles of The Typical American Dieter**

Below, Marketdata attempts to put a yearly dollar figure on what a typical dieter might spend, under various scenarios and combinations of weight loss/maintenance methods.

**Low-Cost Diet Program**

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Regular use of non-prescription appetite suppressants (assumes $7 retail price for 2-week supply of diet pills X 50 weeks)</td>
<td>$175</td>
</tr>
<tr>
<td>* Join a moderately priced health club chain</td>
<td>200</td>
</tr>
<tr>
<td>* Drink diet soda regularly (47 gallons per capita avg estimated for 1989, 26% of soda consumed is diet type, equals 16 6-packs at $2 ea.)</td>
<td>52</td>
</tr>
<tr>
<td>* Purchase one hardcover diet book avg price $16</td>
<td>16</td>
</tr>
</tbody>
</table>

Total: $223
## Moderate-Cost/Involvement Diet Program

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Join hospital weight loss clinic, to get down to goal weight (4 months)</td>
<td>$1,200</td>
</tr>
<tr>
<td>Join moderately priced health club, for ongoing exercise routine</td>
<td>200</td>
</tr>
<tr>
<td>Join and stay with Weight Watchers for 1 year (includes $7.50 per weekly meeting, plus 7 low-cal meals per week at $3 each)</td>
<td>1,092</td>
</tr>
<tr>
<td>Purchase one hardcover diet book</td>
<td>16</td>
</tr>
<tr>
<td>Drink diet sodas regularly</td>
<td>32</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$2,915</strong></td>
</tr>
</tbody>
</table>

## High-Cost/High Involvement Diet Program

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attend 2-week residential spa program, to get motivated</td>
<td>2,200</td>
</tr>
<tr>
<td>Join moderately priced health spa for ongoing exercise program</td>
<td>200</td>
</tr>
<tr>
<td>Regularly attend Nutril/System clinics for 1 year, at $45 per week</td>
<td>2,250</td>
</tr>
<tr>
<td>Purchase 2 diet books</td>
<td>32</td>
</tr>
<tr>
<td>Drink diet sodas regularly</td>
<td>32</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$4,714</strong></td>
</tr>
</tbody>
</table>
According to Marketdata Enterprises, a research and consulting firm based in Valley Stream, NY, roughly half of all hospitals sponsor some sort of weight-loss program including VLCDs.

"What we’re seeing is a splintering in the marketplace," says Patty Reupke, vice president of sales and marketing for BaylorFast, a VLCD program and wholly owned subsidiary of Baylor Health Care System. "There are just as many consumers, but as they’re going to 10 times as many alternatives before they enroll in a program."

However, the fierce competition within the weight-loss market doesn’t mean that hospital-based VLCDs will fade away along with the infamous Grapefruit Diet. They’re likely to endure for several reasons:

First of all, the demand for programs providing a rapid weight loss will continue as long as being overweight remains a potentially life-threatening problem for one in four adults.
Hospitals also are likely to find strong motivation to remain in the weight-management arena, given the relatively low start-up costs of VLCDs and the potential for quick and healthy profits.

Marketdata Enterprises reports that consumers spent $5.5 billion last year on hospital- and physician-sponsored weight-loss programs of all kinds. That amount is expected to increase by 19 percent to $6.54 billion this year.

Ideally, this is what you might expect:

For Julie Fovell, director of operations for HHA, one of the largest VLCD suppliers, says that one large program operating at capacity with 250 fasting patients grossed $1.25 million by the end of 12 months. It reaped revenues of $1.8 million by the end of year two. A mid-sized program with 150 fasting patients generated first-year sales of $745,000 and revenues of $1.7 million by the close of the second year. (The higher figures for the second year reflect patients enrolled in the maintenance phase, who may also buy formula to control their weight.)

Fovell adds that about 25 percent of revenues for nutrition programs will cover costs, including supplies and formula sales. The remaining 25 percent is profit, a yield commonly quoted by other suppliers.

In addition, many facilities recognize the value of VLCDs in marketing other services. For instance, approximately one in four persons interested in taking part in a supplemental fast needs a physician referral in order to get the physical exam required by most programs, according to Sandy Burress, product manager for Optifast. Those people also frequently suffer from multiple medical problems resulting in the need for other health care services.

And because typically 70 percent of those on medically supervised fasts are women, the sponsoring institution stands to gain the loyalty of a powerful group of health care decision makers.

However, the success of a hospital-based VLCD program requires much more than a product with a recognizable name and a flashy sales pitch.

Industry experts agree that a profitable operation depends on the long-term commitment of both the sponsor and the VLCD vendor to delivering a solid, comprehensive program.

For your reference, phone numbers for some of the VLCD suppliers follow:

Baylortest 214/360-9635  New Direction 617/273-5773
CareFast 714/358-6418  Optifast 800/670-5600
Hill-Bur 212-947-4441  Weight Control 800/316-6447
Optifast 800/670-5600
Medifast 800/626-7862  Ultrastar 800/670-5600

[Part Two will take a look at specific marketing strategies found most successful].

by Elaine Ochorn Bogensen
GOING ON ANOTHER DIET?

* CONFUSED ABOUT ALL THE COMPANIES & PRODUCTS, THEIR EFFECTIVENESS & COSTS?

* NOT SURE WHETHER A MEDICALLY-SUPERVISED OR SELF-HELP PLAN IS RIGHT FOR YOU?

* CONCERNED ABOUT SAFETY & POTENTIAL SIDE EFFECTS?

--- READ THIS GUIDE FIRST --- KNOW ALL YOUR OPTIONS, THE COSTS, HOW PROGRAMS WORK, BEFORE YOU INVEST YOUR TIME AND HARD-EARNED MONEY ---

Marketdata, a totally independent, nationally quoted market research company, has just released a new, in-depth 92-page guide, (See other side for complete table of contents).

**Consumer Guide To Weight Loss & Diet Control Programs**

The research was performed over the past 12 months and is up-to-date, unique, and comprehensive. In-depth descriptions are provided for more than 30 of the most popular diet programs and companies, as well as the now popular medically-supervised and non-prescription liquid protein diets. But be warned—VLCDs are not for everyone, and many dieters experience serious side effects. Marketdata has absolutely no financial or other interest in any diet companies—that’s why we tell it like it is.

THE GUIDE COSTS $21.95, Plus $1.76 8% NYS Sales Tax and $3.50 shipping/handling. (allow 3-4 weeks delivery) **NY** buyers only TO ORDER, FILL OUT THE FORM BELOW, CLIP IT AND SEND IT WITH A CHECK OR MONEY ORDER FOR $26.71, PAYABLE TO:

Marketdata Enterprises, P.O. Box 436, Lynbrook, NY 11563

Call us at: 516-791-6579 if you have questions.

---------

**ORDER FORM**

--- Yes, please send me --- copies of the Consumer Guide To Weight Loss Programs, at $26.71 each. Total enclosed $---.

Name ____________________________

St. Address ____________________________

City ____________________________ State __________ Zip __________

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Guidelines for Evaluating Commercial Weight Loss Promotions

Established February 6, 1981
by the National Council Against Health Fraud

NCAHF disapproves commercial weight loss or control programs which:

1. Promise or imply dramatic, rapid weight loss (substantially more than one percent of total body weight per week).

2. Promote diets that are extremely low in calories (below 800 calories per day; 1200 calorie diets are preferred) unless under the supervision of competent medical experts.

3. Attempt to make clients dependent upon special products rather than teaching them how to make good choices from the conventional food supply. (This does not condemn the marketing of low-calorie convenience foods which may be chosen by consumers.)

4. Do not encourage permanent, realistic lifestyle changes including regular exercise and the behavioral aspects of eating wherein food may be used as a coping device. (Programs should focus upon changing the causes of overweight rather than simply the effects, which is the overweight itself.)

5. Misrepresent salespeople as “counselors” supposedly qualified to give guidance in nutrition and/or general health. Even if adequately trained, such “counselors” would still be objectionable because of the obvious conflict-of-interest that exists when providers profit directly from products they recommend and sell.

6. Require large sums of money at the start or require that clients sign contracts for expensive, long-term programs. Such practices often have been abused as salespeople focus attention upon signing up new people rather than delivering continuing, satisfactory service to consumers. Programs should be on a pay-as-you-go basis.

7. Fail to inform clients about the risks associated with weight loss in general, or the specific program being promoted.

8. Promote unproven or spurious weight loss aids such as human chorionic gonadotrophin hormone (HCG), starch blockers, diuretics, sauna belts, body wraps, passive exercise, ear stapling, acupuncture, electric muscle stimulating (EMS) devices, spirulina, amino acid supplements (e.g., arginine, ornithine), glucomannan, and so forth.

9. Claim that “cellulite” exists in the body.

10. Claim that use of an appetite suppressant or methylcellulose (a “bulking agent”) enables a person to lose body fat without restricting accustomed caloric intake.

11. Claim that a weight control product contains a unique ingredient or component unless it is unavailable in other weight control products.
WASHINGTON, D.C. -- Consumer protection and patient safety are being compromised in the burgeoning and un-regulated diet services and diet products business, Oregon Rep. Ron Wyden said Thursday. And these problems, Wyden added, are being compounded by an explosion of false and deceptive advertising.

"American consumers are spending over $30 billion on weight-loss programs and products," said Wyden. "All too often the results are poor, and occasionally even life-threatening. And federal regulators are doing very little to assure that products and procedures are safe, and that consumers aren't being ripped-off by grossly misleading advertising."

The Small Business Subcommittee on Regulation, Business Opportunities and Energy, which Wyden chairs, will explore problems in the $33 billion-per-year weight-loss industry during a Monday hearing:

10:00 a.m.
Monday, March 26, 1990
2359A Rayburn H.O.B.
Washington, D.C. 20515

The hearing follows an extensive investigation by the subcommittee which found the following:

-- There are 65 million dieters in this country -- 50 percent of all women, and 35 percent of all men. One adult American in four is considered obese.

-- The American Medical Association recently warned that "the recent and zealous marketing of various formula products" could lead to numerous "complications and fatalities" among ill-informed and ill-monitored dieters.

-- The U.S. Surgeon General recently stated that we lack basic scientific knowledge regarding the causes of obesity. Therefore, our ability to prevent and treat the condition is limited, and the effectiveness of a large number of popular weight-loss and weight-control programs is questionable.

-- Despite impressive success claims by some diet plans, all programs have a high drop-out rate. Among those who complete programs, an estimated 90 percent who lose 25 pounds regain that weight within two years.
Wyden is especially concerned about the absence of public regulation of a business in which there is little peer review or self-policing. The Food and Drug Administration has largely ignored its responsibility to review the health and safety of diet foods and diet supplements. The Federal Trade Commission and the Federal Communications Commission -- which police false and misleading advertising in print and over the airwaves -- have done little in the health and diet field.

"The result has been a tidal wave of false and misleading advertising in a field already awash in gross over-promotion," Wyden said. "We're going to look real close at how well the bureaucracies are doing their jobs."

Witnesses will include:

Janet Steiger, Chairwoman, the Federal Trade Commission
Dr. Wayne Calloway, American Board of Nutrition
Ray Johnson, Assistant Attorney General, State of Iowa

The subcommittee also will hear testimony from persons who have been victimized by diet-related injuries, and from the American Dietetic Association. The subcommittee invited testimony from representatives of major, commercial weight-loss programs, but the invitations were declined.
MEMORANDUM

TO: CHAIRMAN WYDEN
FROM: SUBCOMMITTEE STAFF
DATE: MARCH 1, 1990

SUBJECT: SMALL BUSINESS COMMITTEE CONTINUES INQUIRY INTO FAST-GROWING HEALTH INDUSTRIES: MONDAY HEARING TO FOCUS ON THE FEDERAL GOVERNMENT'S ABILITY TO OVERSEE $33 BILLION DIET BUSINESS

Mr. Chairman, over the last three years, the subcommittee has conducted investigations into the changing medical marketplace to determine trends in delivery of medical services, training of physicians, performance of procedures, how traditional peer review functions or fails, how consumers choose their physicians, and how physicians compete for patient dollars. Specifically, we found in both infertility and cosmetic surgery that false and deceptive advertising is at the heart of many of these issues. Deceptive ads, marketing and promotion pose risks to the public's health and to their pocketbooks.

Unfortunately, we found advertising that should benefit consumers by offering them more choices has been clouded by blatant fraud and half truths. These ads sell false security about the safety and effectiveness of procedures and products. They mask incompetent health care providers or other "experts" practicing in ill-equipped and poorly staffed outpatient facilities. They help the unscrupulous and unqualified to operate outside the watchful, protective eye of government regulators and legitimate peer review.

At a hefty $33 billion in 1989, the diet industry is expected to nearly double in the next five years. It is another example of a largely unregulated health industry which touches millions, potentially putting too many of our citizens in the way of harm -- medical and financial.

According to new research by MarketData Enterprises, there are 55 million dieters in this country -- 50% of all women and 25% of all men. Sixty percent of all women are usually dieting in some form and 16% of all adults are constantly dieting. Twenty-five percent of all adults in the U.S. are obese, with 13% being severely overweight.
The American Medical Association's Council on Scientific Affairs recently warned, "the recent and zealous marketing of various formula products to physicians, as well as the public's appetite for such diets could lead to yet another round of complications and fatalities."

The Surgeon General's Report on Health and Nutrition, the causes of obesity are poorly understood and, therefore, knowledge about how to prevent and treat it is also limited.

The National Council on Health Fraud has called the new trend toward half-hour infomercials -- paid ads on television that gain credibility through the use of talk show and news formats -- an "abuse of public airways." With impressive "doctors," complete with white coats and stethoscopes, these experts tout "original clinical studies," "scientific breakthroughs" and "doctor-recommended programs" with dramatic testimonials from grateful former patients. "Snake oil on a bandaid" was what the Council dubbed the "Diet Patch." Not surprisingly, the patch's manufacturers called it a "fat fighting weapon."

Americans are ripe for rip-offs in this environment. Indeed, Former Food and Drug Administration Commissioner Frank Young told the subcommittee last year that medical quackery costs American consumers as much as $40 billion per year.

Despite impressive claims of the "guaranteed success" of many diet programs and products, an estimated 90% of all dieters who lose 25 pounds in a diet program regain that weight within two years.

But that kind of information rarely makes its way into slick sales pitches or glossy ads and brochures. And in this Madison-Avenue-gone-mad environment, the qualified and the unqualified compete side-by-side. Bogus gimmicks share shelf space with bona fide products.

Ads hawk everything from the "Jet Trim Cellulite Nozzle," "Fat Magnet diet pills," and the "Space Suit Slenderizing System" and the "Gut Buster," to the "Ultimate Solution Diet," the "Thin for Life" diet to prepackaged foods, appetite suppressing drugs claiming to be "weight loss secrets" or programs and supplements to "burn fat overnight." It seems that many are capitalizing on our insatiable desire to lose weight in ways that are quick, painless and which do not force us to give up unhealthy behaviors.
With those statistics, it's no surprise that from a $31 billion pie, one-third of it or nearly $10 billion goes toward diet clinics alone. The worrisome trend is away from exercise, and toward liquid protein diets -- virtually all of them sponsored by physicians and hospitals -- and so-called fast diets which ignore nutritional safety.

And despite the $500 million spent annually on obesity research, it appears from our investigation that we know little about the short- and long-term safety and effectiveness of most of these plans and products. In fact, our common understanding of the dynamics of weight loss are colored by misconceptions -- misconceptions frequently fed by false and deceptive advertising.

MISCONCEPTION #1 -- IF IT WERE DANGEROUS, THE GOVERNMENT WOULD STOP IT.

THE FOOD AND DRUG ADMINISTRATION -- SITTING ON THE SIDELINES

The Food and Drug Administration has the authority under the Food, Drug and Cosmetic Act to regulate any food, drug, device or cosmetic that is adulterated or misbranded. But in reality, few if any of these diet gadgets, drugs or foods have been tested for safety and effectiveness before patients and consumers become unsuspecting guinea pigs. Nearly 20 years ago, the FDA began drafting regulations on over-the-counter weight loss products. In 1982, that monograph was published for comment. Eight years later, that monograph still sits, unimplemented, in the bowels of FDA's bureaucracy.

False labelling is at the heart of many of the FDA's fraud cases. Unfortunately, since most of the deception appears in pamphlets, brochures, books, lectures and the mass media -- not on the labels themselves -- many bogus products simply slip through the cracks. Such is the case with the grapefruit pills which are said to "give faster weight loss." It looks like a drug; it's marketed like a drug, but the FDA considers it food product -- and one that's correctly labeled, at that.

To its credit, FDA has maintained an impressive consumer education program on quack advertising. One of the FDA's "Health Fraud Notices" tells us that "all is not harmless fun and games in the health fraud business. Tragedy is written between the lines of much of the copy."

Unfortunately, few consumers seem to complain when they get ripped off, or even when they're injured. They're embarrassed by their obesity. They are embarrassed that they've been taken in by a consumer confidence game. And at some level, many consumers blame themselves for failure to lose weight.
Experts tell us that people typically think that it's their lack of willpower, not a bogus or merely ineffective product or service, which stymies weight-loss efforts.

Nevertheless, Americans continue to be duped by increasingly sophisticated ads.

THE FEDERAL TRADE COMMISSION -- THE SLEEPING WATCHDOG

The subcommittee's previous investigations into infertility and cosmetic surgery advertising found that the FTC's ill-conceived policies failed to protect the public from false and deceptive advertising. From 1982 to 1988, the Reagan FTC forced competition in medicine down our throats at the expense of the quality of health care. "Claim anything medical advertising" became the rule, not the exception.

Former FTC Chairman Dan Oliver couldn't even get the support of the majority of the Commission when he testified before this subcommittee on their recalcitrance on enforcing false and deceptive advertising laws.

The FTC took dramatic steps which hampered the medical profession's efforts to self-police. It threw open the door to professional advertising, in both the legal and medical profession in 1975. The goal was to bring competition to medicine and improve and expand consumer choice.

Had the FTC maintained an active consumer protection component to its policy on competition, consumers could well have been served by the agency's policies. But our record shows that competition without protection from hucksters and their bag of tricks leads to consumer exploitation and public health risks.

Furthermore, state medical boards testified before the Subcommittee last year that their state attorneys general told them not to police these ads because they would be sued by the FTC for restraint-of-trade. And medical specialty groups testified that they, too, feared restraint-of-trade lawsuits.

In all fairness, however, it appears that the FTC may have been more effective in the diet and weight loss arena than in many others. Over the last seven years, the agency has stopped false claims for the "Rotation Diet" and the "Freedom Diet," the "Dream Away" diet pill, the "Acu-Form" Ear Mold Diet Device, a number of diet products that help consumers shed pounds "without dieting or exercise," and other food supplements touting disease-preventing or retarding properties.
In January, the FTC stopped the sale of the Fat Magnet diet pill — a pill whose manufacturers promised it "breaks into thousands of particles, each acting like a tiny magnet, attracting and trapping many times its size in undigested fat particles. Then, the trapped fat is naturally flushed right out of your body before it has a chance to become ugly bulging fat". Further, "the fat magnet pills alone automatically help you reduce calories by eliminating fat, with no special diet menus to follow, no rigid calorie counting, and no exercising," — and they're "100% safe."

The FTC obtained a temporary restraining order to stop such claims and freeze the assets of two companies.

While the FTC has focused on print advertising -- newspapers, magazines, and yellow pages -- massive use of radio spots is a favored tool of several weight-loss plans. According to the Washington Post, Nutri/System -- with its 1,400 centers nationwide -- has an airwaves army of 1,000 DJs who helped attract 750,000 consumers in 1988 alone.

Other popular programs like The Diet Center seem to prefer TV spots. Celebrities who are supposedly satisfied customers promote the centers.

The power of these slick promos has not gone unnoticed by the grandmother of weight loss programs, Weight Watchers. Since being acquired by Heinz Foods a little over three years ago, they have aggressively moved into promotion and expansion of their frozen food line. Heinz now projects that with its current growth, the Weight Watcher label will represent the most profitable of all its food products within the next three to four years.

Much of the growth in the industry has been fueled by rampant advertising, which has been largely ignored by the FTC. But, there are encouraging signs emanating from the FTC under its new Chair, Janet Steiger. Numerous meetings with subcommittee staff and FTC staff raise hopes that Mrs. Steiger will outline new initiatives at the subcommittee's March 26th hearing. A new, tougher FTC attitude regarding consumer protection and false and deceptive advertising is warranted and long overdue.

THE U.S. POSTAL SERVICE -- SENTINELS OF MAIL

The U.S. Postal Service can crack down on fraudulent marketing promotions conducted by mail. Using its authority to stop or hold the mail, the Postal Service has effectively applied the brake to a number of purveyors bogus diet pills, products and services. Despite this limited authority which is hampered by the lack of civil investigative demand authority, the Postal
Service has aggressively brought 74 cases over the last two years. Among their successes was stopping the marketing of the Fatblocker, which warns users to "avoid becoming thin to fast" and of Cal-Ban 3000, a pill that claims to "mobilize fat, flab and cellulite, destroying fat without dieting". But the hucksters have cleverly found a loophole. If they get shut down, they simply shift gears to an "800" number and UPS delivery. This safety net has gaping holes too.

THE FEDERAL COMMUNICATIONS COMMISSION -- A SHORT CIRCUIT

The FCC licenses TV and radio stations, although cable stations escape this oversight. In conjunction with the FTC, the FCC is authorized to police misleading broadcast advertising. Labs and disclaimers are required on all paid advertisements, regardless of the length of the ad.

During the last decade, the FCC abandoned many of its enforcement responsibilities. In an embarrassing disclosure to Congress last year, commission officials proclaimed they did not "watch television," but instead limited investigations to complaints filed from outside the agency -- an attitude that resulted in minimal investigative and enforcement activity.

Other changes in FCC policy unrelated to advertising will likely increase infomercials on cable.

A January FCC ruling will force cable casters to remove certain entertainment shows that are also run on local broadcast stations -- the so-called syndicated exclusivity ruling. Analysts believe that these newly opened entertainment slots will be filled by infomercials. We are concerned that this phenomenon will increase the volume of false and misleading advertising, and in particular promote ineffective and dangerous weight-loss plans.

MISCONCEPTION #2 -- DIETING IS SAFE AND EASY, I JUST DON'T HAVE ANY WILLPOWER.

According to researchers, most of the millions of Americans on ineffective diets believe that they're the problem, not the countless pills, prepackaged foods or devices they've tried to lose weight. And many who are not really overweight -- much less obese -- have succumbed to continuous pressure that you can never be too thin or too rich.
Growing evidence of the risks of poor nutrition and lack of exercise has prompted the government to initiate massive public education campaigns for us to "Know our Cholesterol". We know that being overweight increases the threat of heart disease, high blood pressure and diabetes -- three leading causes of death in this country.

Desperation for quick weight loss can cause consumers to make bad choices based on scant knowledge. Many Americans, for example, know little about the health risks posed by some weight loss programs. These include potential risks from appetite-suppressing drugs and doses of megavitamins. This is a market fueled by a variety of prepackaged foods, special vitamins and nutritional counseling, often of dubious value.

Consumers are buying health based on the smooth patter of salesmen with meaningless credentials who use unscientific success rates to separate health conscious consumers from their money. These professional counselors, nutritionists and behaviorists are frequently poorly trained laymen who dispense information with no proof or scientific basis.

According to the Surgeon General's Report on Health and Nutrition, the causes of obesity are poorly understood and, therefore, knowledge about how to prevent and treat it is also limited. Medical management of obesity is almost universally unsuccessful. An estimated 90% of all dieters who lose 25 pounds in a diet program regain that weight within two years. Attrition rates for all commercial programs are extremely high. But this information seldom makes its way into slick sales pitches or glossy ads and brochures. To the contrary, most diet programs loudly proclaim phenomenal success rates, and fail to mention that few customers their weight off for even one year.

Diets by their nature are artificial -- and temporary. Consumers assume that after starving themselves and losing 20 or 30 pounds, they can return to eating "normally." But research now suggests that starving inevitably leads to stuffing. The weight is gained back faster and it's lost more slowly the next time around.

As previously stated, disappointed consumers are unlikely to complain to the manufacturers of the pills or the operators of the programs. Therefore, there are no statistics available on how many people are being hurt, or by which products or services.
MISCONCEPTION #3 -- THE EXPERTS KNOW WHAT THEY'RE DOING.

If one were to believe all the ads, we would think we're fortunate to have countless nutrition and diet experts. Beyond the self-proclaimed lay experts lies an even more confusing and muddled choice among health care professionals -- the doctors who have associated themselves with various weight loss plans.

Understandably, many Americans think that their doctors are the best hope of helping them lose weight safely and effectively.

But despite their medical degrees, most physicians know little about how to treat the overweight and/or obese. In a 1984 report, by the Association of American Medical Colleges, 60% of 1983 medical school graduates felt they spent an inadequate amount of time in the study of nutrition. This means that even the most conscientious physicians may well lack even the basic understanding of the complicated physiological and psychological factors in obesity.

Several ethical professional societies claim an interest in the field of obesity but the qualifications of their membership are frequently difficult to assess. Recognizing the lack of standardization, the American Board of Nutrition has developed criteria that will ensure an adequate knowledge in nutrition for the practitioner. They have applied to the American Board of Medical Specialties for official sanction to grant board certification in nutrition.

Promising doctors' a "competitive edge" for little capital investment, liquid diet manufacturers aggressively market their wares to doctors. A sample come-on suggests that a physician can net over $22,000 yearly treating only 20 patients, and over $70,000 if treating 100. Hyping the ease of start-up and offering an all-inclusive marketing and training package, companies can easily find willing physicians to sign on.

Dieticians and nutritionists further complicate consumers' choices. While education for the dietician is fairly standardized, only a few states specifically regulate who can call themselves a nutritionists. For nonprofessionals the distinction between a dietician and a nutritionist is usually blurred. Recognizing the risk to consumers, 25 states and the District of Columbia regulate nutrition professionals.

There are undoubtedly highly qualified, committed health care professionals in this field. But can patients separate them from the quacks? Probably not.
WHO'S WHO IN THE DIET INDUSTRY

This $33 billion business has many players. MarketData Enterprises research subdivides the industry into nine separate submarkets/industries: commercial weight loss clinics; hospital/physician-sponsored weight loss programs; low-calorie prepared foods; diet sodas; artificial sweeteners; diet books and audio cassettes; non-prescription appetite suppressants; health spas/exercise clubs; and residential resorts/spas with weight loss programs.

The report found that in 1987, there were 13,000 "weight control services" operating across the country. The top seven diet center chains accounted for more than 6,100 of them -- and for 67% of the nearly $2 billion bill. Individual centers average from $600,000 to $2 million with profitability ranging from 10 to 30%.

Hospital/physician-sponsored, medically supervised weight loss programs are increasingly popular with a hefty $5.5 billion share of the market.

The only industry people who seem to be losing money are those running exercise clubs and selling diet pills.

Costs for consumers vary widely. Ranging from a low of a few dollars per week to more expensive programs like Diet Center, or Nutri/System, which typically cost at a minimum $600 to $1,200, which includes the initial cost and prepackaged food costs for ten weeks. For liquid and other very low calorie diets, costs range from $1,200 to $2,500 over a six-month period.

Attesting to the appeal of this industry, a new clinic or new product pops up virtually everytime one turns on the TV or opens the morning newspaper. And undoubtedly some of them offer safe and effective weight loss when properly used and administered. But it's impossible for consumers to know which are good ones and which are bad.

SCOPE OF THE SUBCOMMITTEE'S INQUIRY

Our investigation will try to determine how the government can best protect consumers from out-and-out scams and from unsafe programs and products. We suggest that our efforts cover two broad fields: (1) an assessment of the industry, overall, including a survey of training of persons offering professional services, the research supporting claims for different products
and services, and the need for further research into the field for the protection of consumers, and (2) an appraisal of federal enforcement efforts to mitigate or eliminate false and deceptive advertising, and to assure that weight-loss foods and drugs now being marketed are safe.

Dr. Antonio Gotto of Baylor College of Medicine warned in 1982 that "physicians and behavioral scientists have failed to develop a treatment regimen that is effective and long-lasting for the majority of those treated." He went on to explain that, even at that time, the proliferation of weight loss clinics demanded a much higher degree of consumer education because of the compelling need for "a strong caveat emptor."

Today, eight years later, we still know little about who's dieting, how they're dieting, who's qualified and who's not to treat dieters, whether particular diet products and plans are safe and effective, the depth of program dropout rates, how much patients typically lose during treatment, how many gain back the weight and how soon, and what the short- and long-term adverse health effects may be.

Sixty-five million Americans are affected by being overweight or thinking they're overweight. Most are willing to try nearly anything to lose the weight. It is unconscionable that so many questions remain unanswered.

Our inquiry will attempt to fill those gaps and examine what initiatives the government, the medical profession and industry itself must take to protect the public.
"Diet or die... that's what he said!"

You may never have heard those exact words... at least, not yet. But, if you're fighting a losing battle with obesity, you know it can lead to heart disease, diabetes, hypertension... even cancer.

That's why we urge you to learn more about The OPTIFAST® Program—a proven treatment for the disease of obesity. Unlike simple diet plans, the hospital-based OPTIFAST Program is the medical weight management program that succeeds... because it combines our medical, nutritional and behavior modification professionals with your own commitment.

The first step is the easiest. To attend our free OPTIFAST Orientation Session, just call us. We're ready to help.
# We Will Pay You $1,000.00* To Lose Weight

*Payment made by guaranteed U.S. Government Security Bond

If You Will Help Us Test Our New All Natural, Safe and Effective Diet Program

Answer questions 1-11 and return this notice within 21 days!

1. Approximately how long have you been trying to lose your excess weight? ____ yr. ____ mos.
2. Your sex? ( ) female ( ) male
3. What is your present weight? ______ lbs.
5. Your height? ______ ft. ______ in.
6. Approximately how many diet programs have you tried in the past? ______
7. Will you promise to give "The Ultimate Solution Diet Program" a fair and honest chance to work? ( ) Yes ( ) No
8. Will you follow "The Ultimate Solution Diet Program" for a minimum of two weeks? ( ) Yes ( ) No
10. Is your frame size Sm. ____ Med. ____ or Lg. ____?
11. Name, if you can, the last diet program that you tried ______

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Payment of your $1,000.00 government bond will be made by American Corporation.
Marketing Support for the Competitive Edge

In today's fast paced marketing environment, effective advertising and promotional materials are requisites for success. The National Center of Nutrition understands the value of marketing and supports you with the following:

Camart Ready Artwork
High quality ad sticks are supplied to each program. Artwork is ready for insertion in newspapers, magazines, fliers or your choice of media.

Direct Mail Letters
Introduce past and present patients, colleagues, and the general public to Ultrast with our promotional letters. Print our sample letters on your letterhead and mail out with an Ultrast patient brochure.

Radio Spots
Two sample 60 second radio spots which can be adapted to your medical facility.

Patient Brochure and Display Holder
At your request, we supply patient brochures for waiting rooms, examination rooms, and mailings. An attractive display holder is included.

Advertising Assistance
Our advertising department will help you design a unique ad or marketing piece. We can also assist in creating new ideas and methods to help you market your new service.

National Referral Network
Patients around the country call NCC to request sources of Ultrast programs in their area. We respond promptly with a Patient Referral Kit, which includes a letter, product samples, shaker jar, product recipe book, patient brochure, program guide and your phone number.

Program Flip Chart
A 30 page flip chart to be used as a teaching and educational tool for the program lectures.

Orientation Flip Chart
Ten page flip chart to be shown during an orientation. Outlines the Ultrast program in specific detail.

Orientation Video
A 12-minute videotape to orient new patients to the Ultrast program. Outlines the medical aspects of the program, and features past and present patients describing Ultrast from their own point of view. This video is an excellent marketing tool and comes with a presentation instruction booklet.

Ultrast Wall Posters
Promote your program in house, in your waiting room, etc. or at other institutions like stores, banks, libraries & schools with our eye-catching, clever posters which remind patients to find out about Ultrast.
If today were Monday... on Wednesday morning you'd awake up to 6 POUNDS SLIMMER

You can
LOSE up to
A FULL
POUND
(of fluid and fat)
EVERY
8 HOURS
with this super
"crash-burn"
diet program for
LIFETIME
SLIMNESS

Eat what you please
Wear what you please
Do what you please
Take no risky medicine

Now You Can Reduce
2 to 4 Lbs. in a Night

Thousands of smart women have found this easy way to take off 2 to 4 pounds once a week. The women who take regular Fayro baths in the privacy of their own homes.

Fayro is the concentrate of the natural mineral salts that makes it effective as an enema of the hot springs of America, England and Continental Europe. For years the spas and hot springs, lasting resorts, have been the retreat of all women and well-groomed men.

Fayro weight loss has been removed, diets have been made more healthy, bodies more shapely and minds brighter.

The Hot Springs Are Now Brought to You

You can now have all these benefits in your own bath. Simply use Fayro just as you pour your bath. In minutes results. You will notice and enjoy the pleasant surge of the hot, soft, disinfecting salts. Then, 3-4 times a week, put two cups of the salts in the bath. Add Fayro so your bath is not too hot and insensitive. You will enjoy the rest, comfort and elimination of the bath. As the body begins to retain the salts, the fat and water is eliminated. The body becomes cleaner, whitener, and more vital. Your physician will tell you that Fayro is certain to do the work and that it is beneficial beyond description.

Fayro baths once a week will help every body throw off excess fat and bodily poisons. Your skin will be clearer and smoother. You will sleep better, and FAYRO baths are proving the final answer to your weight problems, helping to tone the body and improve the health and beauty of the skin.

Now You Can Reduce 2 to 4 Lbs. in a Night

Lose Weight Where You Most Want To

Fayro reduces weight quickly; but you can control its effect on abdomen, hips, knees, ankles, etc. or any part of the body you may wish.

Results Are Immediate

Within yourself, and after your Fayro bath, you will find the gain has been a permanent one. A few simple things you can do after each bath will help you to maintain these gains. Look up your nearest Fayro outlet and find out more.

Buy Fayro at Your Risk

The regular price of Hot his is $5.00 a package. With the coupon you get 3 full-fledged packages and an interesting booklet. Send 50c for Hot his plus the enclose package. Send for more information on how to get the most out of your bath. Fayro is the answer to your weight problem. Fayro 100% money-back guarantee if you are not satisfied.
LOSE UP TO 30 LBS IN 30 DAYS* OR YOUR MONEY BACK!

CAL-BAN 3000™ IS SWEPTING THE NATION BECAUSE IT WORKS... WITHOUT RIGID DIETS
- WITHOUT STRENUOUS EXERCISE
- WITHOUT EXPENSIVE THERAPY
- Actual weight loss will vary
  depending on a variety of factors.

FORMULA ACCIDENTALLY DISCOVERED
BY EUROPEAN SCIENTISTS
Two scientists from the University of Paris
Brown University
discovered a compound that helped
patients lose weight. The compound
was then tested in scientific studies
where it was found to be effective.

HOW CAL-BAN 3000 WORKS
Cal-Ban 3000 is derived from a natural
plant source and contains no drugs or stimulants.
It helps to reduce appetite and increase
the feeling of fullness.

TESTED FOR SAFETY
Cal-Ban 3000 has been rigorously tested
for safety and effectiveness.

RESULTS WILL AMAZE YOU
Many people have lost up to 20 pounds in the first 30 days
and even more in subsequent months.

ACT NOW TO CHANGE YOUR LIFE
This is the perfect opportunity to change your life and
increase your energy levels.

FREE! Direct From the Orient
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3-weeks supply $39.95.... (SAVE $12.00) $32.95
6-weeks supply $69.95.... (SAVE $36.00) $63.95
12-weeks supply $119.95.... (SAVE $72.00) $57.95
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We Succeed Where Diets Fail You.
**SHELL WAS TOO FAT!**

And then she made up her mind to get thin and did, without hard exercise or starvation diet.

Nobody has a fat gut—don't why you ever see one in public. After all, what are you supposed to do, sit and look at it? You can get rid of that damn gut by means of the gut and you can cut your weight just like a piece of meat.

Many years ago medical science discovered that weight can be reduced by cutting the flesh. This is the method of weight reduction that has been practiced in thousands of overweight women. With Dr. Livy's new Japanese Super Pill you can get rid of the weight and still eat all you want.

**ELIMINATES DIETING**

Thrilling Japanese Super Pill Guarantees Rapid Weight-Loss!

**Before:**

June 15-Weight: 169 lbs.

**After:**

July 20-Weight: 118 lbs.

"LOST 51 LBS IN JUST 6 WEEKS"

"I LOST 51 LBS IN JUST 6 WEEKS"
QUIT SMOKING
IN JUST TWO HOURS
WITH OUR HYPNOSIS PLUS™ PROGRAM
WRITTEN GUARANTEE $39
COMPLETE
NO WILL POWER NECESSARY
NO SHOTS OR DRUGS
NO WEIGHT GAIN
ATTEND OUR STOP SMOKING SEMINAR AND BECOME A NON-SMOKER NOW.
YOU WILL STOP SMOKING GUARANTEED. DR. GIL and SHEPARD HAVE BEEN
TEACHING OUR STOP SMOKING METHODS THROUGHOUT CALIFORNIA AND ACROSS THE
COUNTRY. OUR SUCCESS RATE IS 98% FOR MEMALE AND 90% FOR MALE SMOKERS.
YOUR FEES ARE NON-REFUNDABLE IF YOU CANCEL IN THE FIRST 10 DAYS OF THE PROGRAM.
WRITTEN GUARANTEE.

WEIGHT CONTROL
IN JUST ONE EVENING
WITH OUR HYPNOSIS PLUS™ PROGRAM
WRITTEN GUARANTEE $39
COMPLETE
NO WILL POWER NECESSARY
NO SHOTS OR DRUGS
NO PRE-PACKAGE FOOD
ATTEND DR. GIL and DR. SHEPARD'S
HYPNOSIS PLUS™ SEMINAR AND LEARN HOW TO
CONTINUE YOUR LEAN HABITS FOR
EVER.

These advertisements were found in separate editions of the same newspaper. We found no case where the advertisements appeared together in the same edition.
DIETS DON'T WORK

If you've tried dieting and nothing works...

YOU ARE NOT ALONE!

This is a well-known problem that affects millions of Americans. It's not just about eating less or exercising more; it's about finding the right approach for your unique body and lifestyle.

THE LAST DIET

Finally, a medically supervised weight loss program that will help

YOU reach your weight goal... permanently.

WEIGHT PROBLEMS?

DOCTOR'S WEIGHT LOSS PROGRAM

- No dangerous drugs
- No embarrassing gimmicks
- Personalized treatment

Let us help you take off that last stubborn pound.

GASTRIC STAPLING FOR MORBID OBESITY

- Complete Program
- Behavioral Modification
- Nutritional Education
- Mentally Supportive

BARIATRIC ASSOCIATES

of Northern Virginia

Dr. Douglas Shales & Dr. Lewis Choplin
620-3212

WEIGH IT LOSS SCAMS FACT: YOUR METABOLISM CANNOT BE ADJUSTED, ALTERED, OR ACCELERATED IN ORDER TO LOSE WEIGHT.

BEWARE OF THE big fat lie

YOU CAN'T DO IT ALONE. Get a medical support team.

Don't go on a diet

When you are serious about losing weight, decreasing cravings and lowering cholesterol, we succeed with individualized nutrition coaching. Change your attitudes toward food. 80% success rate.

NUTRITION CONNECTION

JANET RAZAN, M.S.
770-0550 362-2380

Director
**THE WALL STREET JOURNAL**

**MARKETPLACE**

**THE WALL STREET JOURNAL, FRIDAY, MARCH 23, 1935**

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**ENTREPRENEUR**

**Lawsuits May Pound Diet Sellers**

By ART M. BEITMAN

Maurice S. Goetzman

Counsel for the United States

Lawsuits filed against the National Diet Association, Inc., by two New York State consumers to stop a nationwide diet industry. The suit was filed in the U.S. District Court in New York. The plaintiffs claim that the association is engaged in an unlawful conspiracy to restrain trade and to monopolize the diet industry. The association has been accused of using false and misleading advertising to promote its diet plans.

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**ENTREPRENEUR**

**Suits Threaten to Pound Diet Industry**

By A. M. BEITMAN

From Page 51

Suits have been filed against the National Diet Association by two New York State consumers. The plaintiffs claim that the association is engaged in an unlawful conspiracy to restrain trade and to monopolize the diet industry. The association has been accused of using false and misleading advertising to promote its diet plans.

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**ENTREPRENEUR**

**Leaders in the Diet Industry**

By A. M. BEITMAN

From Page 51

The leaders in the diet industry have been accused of using false and misleading advertising to promote their plans. The plaintiffs claim that the association is engaged in an unlawful conspiracy to restrain trade and to monopolize the diet industry. The association has been accused of using false and misleading advertising to promote its diet plans.