# DECEPTION AND FRAUD IN THE DIET INDUSTRY, PART IV



## HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

OF THE

## COMMITTEE ON SMALL BUSINESS HOUSE OF REPRESENTATIVES

ONE HUNDRED SECOND CONGRESS

SECOND SESSION

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WASHINGTON, DC, MAY 21, 1992

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# DECEPTION AND FRAUD IN THE DIET INDUSTRY, PART IV

THURSDAY, MAY 21, 1992

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

The subcommittee met, pursuant to notice, at 10:15 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 on Regulation, Business Opportunities, and Energy examines progress toward solving an important public health problem—fraud, deception, and abusive practices in the commercial diet industry.

The subcommittee began its inquiry, 2 years ago, into the sale of goods and services into this growing economic sector. We found purchases totaling more than $30 billion per year in gross revenues, making the American diet business on a par with total sales of the American lumber and plywood industry.

At any given moment in our country, two women in five may be actively dieting as is one man in four. They buy diet foods and diet aids in the over-the-counter market. They purchase professional services at doctor-operated weight-loss clinics, and they patronize thousands of nonprofessional, diet and weight-loss centers.

Quite simply, many, if not most, fail to lose weight, or keep the weight off if they do lose the pounds. For years, Government ignored what amounted to a wide-scale, consumer ripoff by these purveyors of diet pills, potions, and overhyped programs.

Often, consumers are lured into making expensive, long-term commitments to diet programs based on misleading and deceptive claims of success. These promoters tell the consumers that diet programs are safe, easy, and nearly always effective. Yet, the managers of these programs have consistently failed to present any data to support these claims of success.

Frequently these programs assert that they are run by professionals, when, in fact, these so-called counselors are little more than glorified salespeople. More and more, they use deceptive advertisements employing before and after pictures which may not even be truthful.

Many of these problems are implicit in the promotion of over-the-counter products including so-called appetite suppressants.

Compounding the consumer protection issue is the very real safety risk that some of these programs may present to the morbidly obese, or to those who may have an underlying health problem in addition to their obesity.

This subcommittee has recorded compelling evidence that a cause-and-effect relationship may exist between very low calorie commercial diets and diet products, and illnesses such as heart failure, gallbladder disease, and stroke.

How have consumer protection and public health agencies responded since our investigation began?

The Federal Trade Commission has entered into consent agreements with three liquid-diet manufacturers, and has informed the subcommittee that it is pursuing cases against another 13 diet product and weight loss program companies.

The National Institutes of Health, at the subcommittee's urging, has begun the task of producing straightforward, understandable information that consumers can use to make informed choices about diet programs. This project was formally kicked off this spring with a 3-day consensus conference on diet programs and products.

For the first time, the Federal Government has formally tapped into clinical testimony, exhibits, and technical papers from some of the Nation's leading health authorities in this area.

The Food and Drug Administration, after literally decades of inaction, has finally moved to eliminate more than a hundred chemical ingredients from the diet product market, finding that these agents were unsafe or ineffective.

The FDA continues to assess another chemical agent, PPA, which the subcommittee has identified as having the potential for great harm and little good for a number of dieters, particularly young women with eating disorders. The agency tells us that it will reach closure on this issue before the end of the year.

Finally, a congressional conference committee marking up next years research blueprints for the National Institutes of Health has accepted language submitted by the Chair to establish a significant obesity, nutrition, and research program with an emphasis on nutritional disorders of children. But clearly, there is much more that must be done.

The Federal Trade Commission has told us for months that they will force all of the large center-based and over-the-counter diet programs to advertise truthfully and substantiate their claims. It is time that the big players in the diet industry are told the rules, and that they are required to comply. The long delay in Federal Trade Commission action is giving bad actors in this industry a pass, and the consumers the shaft. We expect the FTC to inform the subcommittee how and when it plans to resolve these pending actions.

Also, it is time for the Government to compile data about what works, what doesn't, and why, in the area of weight loss programs. It is essential that this information be made available to the consumer. Now that the consensus conference is complete, the subcommittee asks the National Institutes of Health to announce its plans for getting this life-saving information to the public, because millions of Americans use questionable weight loss programs.

The Government's efforts to stop fraudulent weight-loss practices must not take as long as the campaign to ratify the 27th Amendment.

Millions of Americans abused by this industry may as well burn their money on the curb for all the good they are getting. It is time for a conclusion which favors the consumer, favors the honest, reputable diet programs, and puts the brakes on deceptive hype and hoopla which permeates this industry.

We are very pleased to have as our first two witnesses Barry Cutler of the Federal Trade Commission and Darla Danford of the National Institutes of Health. Both of them are going to address a number of issues the Chair has talked about.

[Chairman Wyden's statement may be found in the appendix.]

Chairman WYDEN. I want to recognize several of my colleagues who have long been involved in health and consumer protection issues. Our ranking minority member, Congresswoman Meyers' involvement in many of these health issues, dates back to her days in the Kansas Legislature.

Mrs. MEYERS. This subcommittee has conducted a long investigation into fraud and deceptive claims that exist in the diet industry. I commend the chairman for his diligence in pursuing a topic that affects so many Americans.

According to the National Institutes of Health reports, one-fourth to one-third of the adults in this country are overweight. Obesity and being overweight is more prevalent among women, the poor, and certain minority and ethnic groups and is often a contributing factor in the development of serious debilitating diseases.

As we have witnessed in other subcommittee hearings on fraudulent medical devices and practices where there is a need for medical treatment and in this case just to change one's eating habits and exercise level, some scam artists devise an unscrupulous way of making money.

These charlatans prey upon people's lack of knowledge about proper nutrition and how to sensibly achieve weight loss and control of their weight. Unfortunately, these scams survive largely because of some people's willingness to believe claims that are simply too good to be true.

We must continue and increase our efforts to teach the basics of sound nutrition to children and their parents and to help educate consumers on the certain failure of "get thin quick" plans.

In addition, agencies like the Federal Trade Commission must continue their work in identifying and bringing judgment against the pushers of deceptive dietary programs.

Thank you, Mr. Chairman, for your leadership on this issue. I look forward to hearing the testimony of our witnesses today.

Chairman WYDEN. I thank my colleague and look forward to pursuing these issues with her as we have always done on this subcommittee in a bipartisan fashion.

Let me recognize my colleague from North Carolina who has also been involved in many consumer protection efforts.

Mr. LANCASTER. Thank you, Mr. Chairman.

I join Congresswoman Meyers in commending you and your interest in this topic and in your diligence in pursuing this issue. As

you have pointed out in your statement, this is a problem of monumental proportion that demands our attention.

There, of course, is a problem with weight in many American households, one that, oftentimes, leads desperate people to desperate measures. Mrs. Meyers comments about many of these claims are too good to be true, and usually if they are too good to be true, they aren't.

I think it is important that we focus the attention of the consumer on those programs that are, in fact, too good to be true, call attention to the real solutions to overweight, and make it possible then with the assistance of Federal agencies, some of whom will be speaking here this morning, to address those who are abusing the consumer and, in fact, are nothing short of criminal in their conduct when it comes to ripping off poor people who need that money more for nutritious food and for health care than they do for another "get slim quick" scheme that is destined to failure from the beginning.

We have an excellent group of witnesses this morning, and I look forward to their testimony.

Thank you.

Chairman WYDEN. I thank my colleague for his excellent statement, pointing out that money wasted on some of these programs could go for much more healthful practices, is a point that cannot be emphasized enough.

We will now recognize Barry Cutler and Dr. Danford.

Dr. Danford, your colleague is Dr. Susan Pilch, Deputy Director at the NIH Division of Nutrition Research Coordination.

Dr. Pilch, would you anticipate answering some of the questions that might be directed to Dr. Danford?

Dr. PILCH. Probably not.

Chairman WYDEN. Because the subcommittee does swear all the witnesses who come before the subcommittee.

Dr. PILCH. I would be glad to be sworn.

Chairman WYDEN. Dr. Danford, Mr. Cutler, do either of you have objection to being sworn this morning?

Mr. CUTLER. No.

Dr. DANFORD. No.

[Witnesses sworn.]

Chairman WYDEN. We welcome all of you. We are going to make your prepared remarks a part of the hearing record in their entirety.

I would like to ask, in the interest of time, we also have the energy bill on the floor today, and it will be hectic running back and forth, if you could summarize to 5 minutes or so, we will make your prepared remarks part of the records.

Welcome, Mr. Cutler.

## TESTIMONY OF BARRY J. CUTLER, DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION

Mr. CUTLER. Good morning, Mr. Chairman. It is a pleasure to see you and the other members of the subcommittee this morning. We appreciate the opportunity to make the Commission's formal testimony part of the record.

My summary and answers to any questions that the panel may have, of course, represent the views of the Bureau of Consumer Protection.

We are here this morning with good news and bad news. The good news is we have had an active and successful year. Over the history of the FTC, the Commission has brought about 90 cases involving diet products, programs, and gizmos.

In the last year alone, the Commission has had a number of successes that we have been happy to share with the committee.

First, we reached consent agreement subject to final approval, with three of the major promoters of physician supervised very low-calorie diets, the makers of Optifast, Medifast, and Ultrafast.

Within the past few weeks, we obtained a court-ordered, multimillion dollar judgment and a permanent injunction against multistate marketers of a low-calorie diet, weight-loss program marketed through medical clinics.

Working with a number of State attorneys general, we have obtained a permanent injunction and a consumer redress order against the well-known ultimate solution diet program that was marketed under the name Amerdream.

Just last week, the Commission heard a final appeal in the case of Schering's Fibre Trim from the initial decision of an Administrative Law Judge, and the Commission has had, in the past year, additional successful enforcement actions involving weight-loss claims for a passive exercise device, one where you don't have to do much, a weight-loss regimen marketed on Spanish language television station, and an infomercial and its doctor-owners' deceptive promotion of a dietary program marketed under the name Nu-Day Diet, which promised to change consumers' metabolism.

In addition, we have completed the investigations of almost the entire commercial diet industry in the last year.

We are pleased that we have been able to share with the subcommittee and its staff nonpublic information and the progress that we have made in a series of briefings, even a few weeks ago, that the committee requested, and we appreciate your support, not only behind the scenes, but your continuing to bring to public attention the problems through hearings such as this.

The bad news, and it is a matter of timing, is that because of the FTC statutes and operating regulations, we cannot announce today a number of important matters that are near conclusion that we have been able to discuss, but that we hope will soon put the entire commercial diet industry under the same kinds of clear standards that we have provisionally announced for VLCD's.

Fortunately, we don't have to wait for every last case to be completed to provide extensive advice and education to the public and clear guidance to the commercial industry. Through the very low-calorie diet cases announced in the fall, through hearings such as yours, through reports like NIH's, and through an unprecedented cooperative educational effort handled by the National Association of Attorneys General, the FDA, through Dr. Kessler and the Federal Trade Commission, through Chairman Janet Steiger, we have put out a detailed public service announcement and a brochure that I have today that gives great detail to consumers, both about their search for the magic bullet with products like diet patches,

fat blockers, starch blockers, and diet pill magnets; phony devices and gadgets like electrical muscle stimulators, appetite-suppressing sunglasses, and magic weight-loss earrings.

As to the commercial diet programs that are the focus of your hearings, there is an extensive section that includes the seven questions that every dieter should ask before they sign up for one of the commercial programs. There are tips for sensible weight maintenance and clues to fraud.

What Dr. Kessler and Chairman Steiner and the AG's have made public is that if a dieter sees words like easy, effortless, guaranteed, miraculous, magical, breakthrough, new discovery, mysterious, exotic, secret, exclusive, and ancient, they ought to look out. They may be parted from their money.

We are hoping, as the subcommittee does, that we will have dramatic announcements soon that will make clear standards for the entire industry that will continue our efforts with the ripoffs as well as with the nationally advertised consumer programs, and we look forward to further work with your subcommittee.

Chairman WYDEN. Mr. Cutler, thank you. We will have some questions in a moment.

[Mr. Cutler's statement, with attachment, may be found in the appendix.]

Chairman WYDEN. Doctor Danford, welcome.

**TESTIMONY OF DARLA DANFORD, DIRECTOR, DIVISION OF NUTRITION RESEARCH COORDINATION, NATIONAL INSTITUTES OF HEALTH, ACCOMPANIED BY SUSAN PILCH, DEPUTY DIRECTOR, AND VAN HUBBARD, NUTRITION COORDINATION COMMITTEE, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES**

Dr. DANFORD. Mr. Chairman, members of the subcommittee, I am honored to appear before you to summarize the results of the NIH Technology Assessment Conference on methods for voluntary weight loss and control.

I also welcome this opportunity to highlight some other activities of the NIH in this important area today.

Accompanying me today is Susan Pilch, Deputy Director of the NIH Division of Nutrition Research Coordination.

The series of the hearings held by this subcommittee on the important issue of obesity and weight loss has helped to focus deserved national attention on this topic.

Just what kind of problem do we face? The conference panel gave us a pretty clear idea in the first sentences of its statement. A health paradox exists in modern America. On the one hand, many people who do not need to lose weight are trying to do so. On the other hand, most who do need to lose weight are not succeeding. The percentage of Americans whose health is jeopardized by losing too much weight is increasing. That is our challenge.

The conference was held March 30 through April 1, and was a logical outgrowth of earlier NIH activities in obesity and weight loss.

I would like to provide for the record with my written statement a prepublication copy of the conference panel's final statement and just briefly summarize for you the major findings.

The conference was structured like a consensus development conference; that is, an independent non-Federal panel was convened to review the scientific evidence and address predetermined questions. Its planning was unique because it was initiated at the highest level of the NIH with the encouragement of this subcommittee. That encouragement was followed up when you, Mr. Wyden, addressed the conference at its opening session, and thank you for that.

It was the first such conference sponsored by a trans-NIH committee, the NIH Nutrition Coordinating Committee, rather than an individual institute. The extent of interagency participation was unprecedented. Input was obtained from the beginning from over 11 sister agencies.

Let me tell you the questions and a brief statement about what the panel concluded. One, how often and in what ways do Americans try to lose weight?

The panel reviewed data from various Federal surveys and found that most people try to shed pounds by dieting or eating fewer calories and increasing physical activity. It was disturbing to find out that many persons not overweight, particularly young women, were trying to lose weight.

Two, how successful are various methods for weight loss and control? What are the attributes of, and barriers to, successful weight-loss methods and approaches?

The panel concluded that there are relatively few scientific studies evaluating the effectiveness and safety of most weight-loss methods. Diets, behavior modification, exercise, and drugs produce short-term weight-loss with reasonable safety in controlled settings.

The amount of weight loss using different methods varies by personal factors and characteristics of each method, but most people who achieve weight loss through any of these short-term methods regain the weight.

There are no short cuts. For most overweight people, achieving and maintaining a healthy weight is a life-long, lifestyle commitment and challenge.

Three, what are the short- and long-term benefits and adverse effects of weight loss? It improves control of noninsulin diabetes and hypertension. It reduces cardiovascular risk factors, and it enhances self-image, but there is a negative side.

Fasting or very low calorie diets is often associated with a variety of short-term adverse effects—fatigue, hair loss, dizziness, and other symptoms that appear to be transitory. Worse yet, there is an increased risk of gallstones and acute gall bladder disease. The long-term health effects are not as clear.

Four, what are the fundamental principles that should be used to select a personal weight-loss and control strategy?

For almost all people, the panel concluded, a life-long commitment to change in lifestyle, behavioral response and dietary practices is necessary; easy to say, not so easy to do.

Making the commitment depends partially on the risks and benefits of losing weight compared to those of remaining overweight. How should you decide if and how to make the commitment?

You should certainly try to lose weight if you have current health problems that can be lessened by weight loss such as sleep apnia, hypertension, and noninsulin dependent diabetes, coronary heart disease, and elevated blood cholesterol.

If you are tipping the upper limit of the weight range, you should begin efforts now to stabilize your weight.

When is medical supervision necessary? The panel identified those who were severely overweight, pregnant, and lactating women, children, persons over age 65, also those with certain medical conditions. No one should eat fewer than 800 calories a day without medical supervision and monitoring.

A qualified health professional should screen for preexisting eating disorders or underlying psychological problems. Even those without health concerns should give their weight-loss decision very serious thought. They should ask themselves how hard is it really going to be. What are the physical and the psychological risks?

Consider poor nutrition, possible eating disorders, the effects of weight cycling, and the psychological consequences of repeated failed attempts.

The panel seems to be telling us that choosing a life-long weight loss and control program should be like buying any other consumer item such as a new car.

Does it have all the options we want? How long will it run? How do the other drivers rate it? Is there a good maintenance program. Obviously, modest goals and a slow course are the safest and most effective approach to weight loss and control.

Five, what are the future research directions? The panel suggested that research should span the entire spectrum of health areas, from genetic, biochemical, physiologic, and neurophysiologic to the individual community and population studies.

The panel's message on research is strong. These research areas should assume a high priority on the Nation's health agenda.

The NIH considers that the panel dealt with the questions posed to them, and that their statement will be useful. The statement will be considered as our research initiatives and our education strategies are developed.

The panel statement was finalized last week and wide distribution has begun. It will be published in the June issue of the Annals of Internal Medicine.

Because the conference was so rich in new data, we are especially excited that the NIH will publish the proceedings in a peer review journal.

I would like to now quickly highlight some of the obesity-related activities of the NIH Program and biomedical research and training that are detailed in my written statement, and provide for the record a copy of the 14th annual report of the program.

The work of the NIH-supported scientists across this country already spans many of the topical areas suggested for further research by the panel, and we have tried to highlight some in the testimony.

I would also like to quickly direct your focus to also some of our new directed research mechanisms such as the PA, which will support ongoing solicitation by nine Institutes for submission of grant proposals on studies for obesity.

I should also mention our clinical nutrition research units, which have been an innovative and important NIH mechanism for focusing on interdisciplinary research attention on clinical nutrition issues such as obesity. Currently, there are five supported by NIDDK, three by NCI, and recently the NIDDK and NICHD have issued a request for applications on four new centers.

The NIDDK has also established a National Task Force on Prevention and Treatment of Obesity to synthesize current scientifically based information about obesity through the development of summary documents and also has a planned Obesity Information Resource Center.

The NHLBI has launched an Obesity Education Initiative to integrate issues related to obesity and weight control as they evolve from the Institute's other national education programs, and is pursuing a high-risk strategy and population-based prevention that includes diet and exercise.

We are proud of these and other initiatives at NIH that have been undertaken to meet the challenge of nutrition and obesity in this country.

In summary, Mr. Chairman, we are committed to the goal of seeing that all Americans can enjoy the promise of improved health and well being. The findings of the recent conference has provided both discouraging and encouraging news. It has helped to focus public and professional attention on the many problematic issues associated with overweight and weight-loss.

The conference panel's statement has also identified critical concepts that must be incorporated into our thinking about these issues, understanding the chronic nature of the problem of overweight, which like hypertension and other chronic conditions requires life-long attention, recognizing how difficult achieving and maintaining weight loss is, and realizing that undeniable health benefits of reducing overweight make it worthwhile to attempt the necessary lifestyle changes.

What can we tell the American public at this time? We can tell them that although all the answers are not in yet, the best advice for today is encouragement of a personal commitment to a life-long pattern of balanced healthful diet combined with adequate physical activity.

Personal weight-loss approaches should incorporate these elements in an individualized fashion, and they should proceed at a slow course, modest realistic goals. This is not necessarily an onerous task. We can tell the American public that there are added benefits.

Besides losing weight, on the table we have provided for you the Dietary Guidelines for Americans. This is the Federal policy, and the healthful eating patterns and lifestyles promoted in the guidelines can help to keep you healthy, improve your health, and may prevent diet-related chronic conditions such as heart disease and cancer.

Thank you, Mr. Chairman, for conducting this hearing. The NIH looks forward to working with you and other Members of Congress to ensure that our research will continue with a strong focus on this important area of obesity and weight loss.

I appreciate the opportunity to speak to you today and would be pleased to respond to any questions you may have.

[Dr. Danford's statement, with attachment, may be found in the appendix.]

Chairman WYDEN. Dr. Danford, that is very helpful.

Thank you.

I want to make it very clear that Dr. Healy has been extremely supportive of this effort and has talked to me on a number of occasions. We appreciate the work that you are going forward with.

The Chair will have questions in a moment.

I want to recognize my colleague first, Congresswoman Meyers.

Mrs. MEYERS. Thank you, Mr. Chairman.

Mr. Cutler, you mentioned standards for the entire industry that you hoped would be adopted soon, and I wonder if you could expand a little on that statement and tell a bit about what kind of standards, and who precisely will decide on them, adopt them, and what will the standards be, if you could give us some examples, and when will they happen?

Mr. CUTLER. Of course.

In this case, the FTC has undertaken more than a dozen investigations that are now complete, involving virtually every major diet promoter in the United States in terms of commercial programs.

As you know, our rules preclude identifying nonpublic investigations, but we have said if it is a household word, the FTC has investigated it.

The claims that came out in the very low-calorie diet cases announced last fall—many of them are the same in the commercial diet programs—issues such as representations regarding the rate of weight loss, metabolism claims, and maintenance claims; in other words, the ability to keep weight off, testimonials, whether typical or not, representations regarding safety, price, credentials, and supervision of the personnel who take part in the programs.

From both VLCD cases and others that are under wraps, including some where we have signed concepts and others where complaint recommendations are ready, I would expect that in the near future we will have clear advertising standards that make clear that all of these programs have to have hard reliable data to support their claims of weight loss and maintenance; that testimonials or success stories will have to be properly qualified to make clear whether they are typical or not; that claims about safety will have to be truthful and adequately qualified by competent and reliable scientific evidence; that claims about physician or professional supervision will have to be substantiated, that price information will have to be accurate and not misleading; that claims about special expertise of program staff will be accurate and supported and other claims that relate to individual programs, but not the entire industry.

It is clear from the work that we have already announced on the very low-calorie diet programs, and also because we are so far along on all the others, that every major commercial diet promoter

in the United States is well aware of the standards that the FTC is setting, and many have started to comply voluntarily. I suspect so, that when the cases are announced, they can say they have already made the changes.

Where the FTC has proceeded on a case-by-case basis rather than by a protracted industry-wide rulemaking proceeding or by seeking legislation, the rules are approved when the Federal Trade Commissioners vote to accept the agreements or to issue complaints and litigate against the various companies.

Mrs. MEYERS. Thank you for your response.

Dr. Danford, through the NIH conference and the research that you have conducted on how Americans lose weight, did you find that most people are not aware of the fact that the only successful way to lose weight was to watch their nutritional habits and to exercise, or do they simply ignore what they know deep down to be true and hope for some kind of a miracle cure?

Dr. DANFORD. The data presented in terms of what Americans are doing did not at this time provide a lot of information on what the attitude was as it translates into the behavior. However, based on some other studies we have in terms of translating knowledge into behavior, we know that translation is not always automatic.

Obviously, people are aware that people are looking for magic bullets, so to speak, and that probably explains why, when they itemize things, people are trying it, includes many of the items the FTC has just mentioned that seem to be a quick fix without any type of scientific base behind them in terms of what works.

Mrs. MEYERS. The response to the question is important, because I think a great deal is going to depend on how well we can communicate to the public and educate them, and, obviously, the first publication of what you are doing is going to be in a medical journal, but not just everybody reads medical journals.

I would like both of you to comment if you would how you intend to communicate with and educate the American public, because it seems so common sense to many of us, and yet, obviously, it is not, because a great many people are dieting in the wrong way, and doing things that are really injurious to their health.

So, tell us how you intend to educate people, and I would like you both to comment.

Mr. CUTLER. If I could start, the FTC over the years, and especially in the last few years, has made it a very high priority to emphasize consumer education at the same time that we are doing law enforcement.

I will be happy to present to you and others on the staff the brochure, and I hope you might even want to see the public service announcement that Dr. Kessler, Chairman Steiger, and the State attorneys general produced last month.

Obviously, a case we bring, especially a case with national publicity, gets headlines for a day or two, but it is getting the word to children and to consumers through the education efforts of groups like FDA, the Commission, attorneys general, and NIH that we have to hope for the impact.

When we see articles in the New York Times even a few weeks after our VLCD cases with a headline that "crash is out, moderation is in," and "diet companies feel the pinch," diet companies

feeling the pinch is the ultimate test that consumers are getting the message.

While we are proud of the law enforcement we are doing, we can't measure success in terms of numbers of cases. It is whether consumers get the message.

Mrs. MEYERS. How do you distribute that brochure?

Mr. CUTLER. This was distributed largely through a video news release public service announcement that got wide distribution because it was shown in many States through attorneys general.

Mrs. MEYERS. This is television?

Mr. CUTLER. Yes.

Mrs. MEYERS. When they see the commercial or the public announcement, they write in?

Mr. CUTLER. They write in, and the show and the brochure give places to call for additional information. The FTC in 1990 put out a consumer alert, even well before this brochure, that made the point very explicit that for most people, weight loss and dieting is temporary.

So, I think you have hit the nail on the head.

Mrs. MEYERS. Will there be distribution through high schools, for instance, because I think you mentioned, Dr. Danford, that a number of the people who are taken in by this are young women who are trying to diet who don't really need to lose weight, and it is being particularly harmful to their health.

Is it a high school or college thing?

Mr. CUTLER. We haven't put this in high schools or colleges, but in other areas of consumer education, we are trying to find ways to hit grade schools and high schools. That is where consumer education is needed. It isn't just on the commercial programs, but young people and older people still spend a lot of money for just quackery, and it is important to keep the word out about those products as well.

Dr. DANFORD. The NIH is committed to both educating health professionals and the public. The statement, as it will go out in professional literature, will accomplish that, because we are talking about a journal with a 100,000 distribution.

The Technology Assessment Conference is a mechanism to get information out to the public. As you probably have been aware, not only did we enjoy wide media coverage, but it is still being discussed; so it is obviously a topic that had a very important public health interest on the parts of the consumer, not just on the part of ourselves. We will continue to take the statement and put it forth to the various Institutes of NIH, and they will consider it in their development of education programs.

We already have, at NIH, several national-based educational programs and the two new initiatives the NIDDK National Task Force on Prevention and Treatment of Obesity, as well as the NHLBI Obesity Initiative that will be taking the statement forward, and both have plans for mechanisms that will enjoy very wide nationwide input and communication with the American public.

We have other mechanisms, such as this joint USDA-HHS publication Dietary Guidelines for Americans, that will be revised based on new science. It has a section on maintaining healthy weight that looks at three items, which do not disagree with the panel

statement; in fact, the statement reinforces the guidelines. So, I think the exciting thing we have for the public are not only newer findings and some things to help in the commitment to find out those things we don't know at this time, and recommendations are converging into a unified, common message. The dietary and exercise recommendations that are being made are not that different from those that have been made for other disease States.

So, we are committed to a total health package, if you will.

Mrs. MEYERS. Thank you very much.

Mr. Chairman, I do think that the education component of this is extremely important, because we are competing with firms in the past that have been on television 10 times a night with very attractive commercials telling you how easy everything is going to be, and I think there needs to be a counterweight.

Chairman WYDEN. My colleague is absolutely right. We know education is a big part of the ballgame.

Let's see if we can have questions from the gentleman from North Carolina before we have to go vote.

Mr. LANCASTER. You might want to run and vote while I am asking my questions, and then tell them to hold the vote until I get there.

Thank you for your testimony.

I think one of the most successful efforts in behavior modification in substance abuse, and I consider overeating a substance abuse kind of behavioral problem, is Alcoholics Anonymous, which of course, uses recovering alcoholics in that effort.

You folks look awfully thin. Are there, in fact, people involved in either of your programs, either on the FTC or on the NIH, who bring to their perspective the problems that people who have chronic overweight problems?

Is that something that you actually seek out because of the special perspective those people would bring to their work?

Mr. CUTLER. Well, I appreciate the compliment. I have personally been up and down over the years. I am a classic yo-yo dieter, so I bring to this job an appreciation of what people have been through.

If there is one lesson that I have learned personally, and I have seen in the work that the Commission has done, it is that people believe that there is a simple solution out there.

I think what our colleagues at NIH are now convincing the public is that it isn't true.

Another universal phenomenon is that people tend to lose weight in the short-term on the various programs and give all the credit to the programs. Then they put the weight back on and blame themselves.

I think that one of the important aspects of the study is that this is starting to show that it isn't necessarily people's faults. In the 12-step program that you mentioned, people learn that it isn't their fault, that there is a lot going on.

We have a lot of that perspective that is built into our case. One of the reasons we are emphasizing that companies need to have accurate, long-term maintenance data, is that consumers going into a diet program should have a realistic idea of what to expect, and, in the case of the NIH study, to realize that it isn't all their fault.

Dr. DANFORD. Thank you for the compliment, but to be personally honest, it may appear that I have no problem, but I certainly do have to watch what I eat. It may not appear at all times that somebody is underweight or overweight. Medically what we worry about is the percent body fat that a person has.

The lifestyle that I currently find myself in does not encourage exercise. Maybe the scale weight stayed the same, but I notice over the years that my muscle mass has decreased, and my body fat has gotten higher. This is not something that is conducive to lifelong health, and something that I personally have to work on, and I must say that conference in itself gave me a newer inspiration to remember little things—walking up the stairs does not just save on electricity for the elevator—it probably saves your body fat and helps in other ways.

Yes; one does have to watch what they eat, but you have choices. The thermodynamics still works. We are glad that theory has not been disproven. It is a matter of creating a caloric deficit. Obviously, we heard from this conference, that makes a lot of sense, that if you choose to eat less and exercise more, it is not as painful as just thinking you have to deprive yourself of food totally.

That is not the answer to overweight. It is making choices and getting a lifestyle that you can do this sort of thing. I, too, have that problem, and it is something that will be with me the rest of my life, too.

Mr. LANCASTER. You commented in your statement that one of the things that you are doing now is processing the new data that you received, but yet in your more extensive statement where you spell out some of the findings from that conference, it sounds like pretty much the same kind of things that we have heard over and over again.

Mrs. Meyers talked about many people sort of know these things. They just don't admit them to themselves.

Could you give a couple of examples of truly new things that came out at the conference or was it really more of a compilation of what we knew and presenting it in a different light, and more a question of the mass of material that came together at one place as opposed to really new ideas or the results of new research?

Dr. DANFORD. These conferences are traditionally set up to rely on existing data and to bring that data forward to an independent, non-Federal panel who can look at it with a new light and to answer predetermined questions; so they are very focused.

It is not like a scientific meeting where you present research. The presenters are also directed to provide the information so they can rethink and refocus. In this case, we had new data. The FDA and NIH made an effort to have a new survey analyzed in time to have some of the data available for the conference.

This is one of our first opportunities to get hard data on what Americans are doing and trying to get a grasp on things that may be common sense to us, but there may be surprises that we didn't anticipate. Many people weren't expecting to see such a high number of people with low BMI's on diets.

I think that the new findings, in terms of the long-term health consequences, tend to reinforce the need for more research. We have newer techniques and the realization of how important it is

that genetics, tools where we can make genetic maps, that we have an exciting future in terms of potential for being able to address what it means to the individual and making even better recommendations to them.

Mr. LANCASTER. So, most of the new data was behavioral data rather than medical research that actually point to new ways of dealing with this behavior; is that a fair statement?

Dr. DANFORD. It depends where your cutoff point is. This is research that has been ongoing, and it is always very important to have research that reinforces previous findings, particularly when you want to go to public health recommendations.

So, yes; there was newer research presented that had come to similar conclusions to previous such consensus——

Mr. LANCASTER. But it was primarily survey data rather than new medical research?

Dr. DANFORD. There was new medical research presented on the different questions. The first question on what Americans do was primarily behavioral and epidemiological survey data. We relied on other information, including clinical study data in some conference sessions, particularly to answer the question of medical consequences.

Mr. LANCASTER. You have had this ongoing investigation for some time, Mr. Cutler, and it appears to me, and perhaps you can respond, that you are sort of holding off and you aren't going to do anything until you are ready to pounce on everybody at one time.

Is that a correct statement?

Mr. CUTLER. I qualify it. We have brought three very low-calorie diet cases last fall. That involved probably 60 percent of the VLCD industry. We have several others that I hope will be announced soon.

The qualification I put on your observation—it is less a question of pouncing at the same time as appreciating that what the Commission is doing, especially with the national clinic as opposed to the scams.

We go after the scams as soon as we can. We have a lot of competition between the very low-calorie diet programs and the commercial clinics and even within those, and if there are safety allegations that the Commission made last fall about the VLCD's, the Commission and the staff are both going to be very careful about making sure that we don't give one segment of the industry, or one company within a segment, a black eye that isn't deserved and that we maintain what our chairman calls a level playing field.

Because of the difficult scientific questions, that isn't an easy task, but in 2 years, I think we have made extraordinary progress, and I think by the next hearing you will see some great results.

Mr. LANCASTER. My only caution would be that you indicated in your testimony that one of the problems in dealing with this is that makes a case, and there is a lot of publicity, and people forget about it. That is true when you make a big case. People will be up in arms about it at that time, but then they are going to forget about it.

I wonder if you might not accomplish a greater educational impact if you had a series of cases rather than just one, because that drags out the impact of this up and down of public awareness.

Mr. CUTLER. First, we have had a constant series of cases. It is only where we are about the competitors where we have a Coke/Pepsi situation that we have held them together. Second, even the pendency of investigations hasn't precluded us in September 1990 and last month from doing a full-court press on consumer education. That is going ahead even as the cases.

Mr. LANCASTER. The hearing will be in brief recess.

[Brief recess.]

Chairman WYDEN. The subcommittee will come to order.

I want to tell all our guests, we are going to have a very hectic day, and we are going to have votes on the floor, and the subcommittee is going to have to move this along expeditiously.

Let me begin if I might then with some questions for you, Mr. Cutler.

Dick Kelly, your colleague at the FTC, was up here, 20 months ago, and, essentially, said very close to the same kinds of things that you have said today. So, what that means is, for 20 months we have had these commercial diet programs, a host of other diet programs out there, ripoff practices on consumers, practices for which they pay through the nose, practices that can jeopardize their health, and this has been going on for more than 20 months, when, in fact, what we have are three decisions with respect to these very low-calorie programs.

Now, I know that you want to see some real changes, but given the fact that except for these three cases it is hard to see what has changed in the enforcement picture in the last 20 months, how much longer will the public have to wait, and what will they be getting in the near future that will address these kinds of ripoffs that have gone on for a full 20 months since Dick Kelly gave us helpful testimony much like yours 20 months ago?

Mr. CUTLER. Twenty months ago was just a couple months after detailed subpoenas and access letters went out. One thing he didn't say 20 months ago is that we have now completed our investigations involving virtually every major commercial diet program, and as the committee and the staff found out in a briefing a few weeks ago, we have other consent agreements and complaint recommendations that have not been able to be made public yet. So, we have made tremendous progress.

I want to say, Mr. Chairman, I share your frustration. I was an assistant U.S. attorney who had to put people in jail, and I have been a private litigator. I have a staff that gets tired of hearing me say why wasn't it done yesterday, but in defense of the bureau and the staff, by comparison with rulemaking proceedings for industries, it is remarkable that in less than a year-and-a-half the Commission was able to announce cases against $600 million worth of VLCD promoters, which was about two-thirds of the industry.

When you think of the commercial diet programs, how large they are, how sophisticated the health and disclosure and safety issues are, it is remarkable to complete well more than a dozen of these investigations and have many of them ready to roll in this time by comparison with other formats.

I share your frustration that we couldn't have a splash at today's hearing, but it wasn't possible. One of the things that is taking time here is that we have already announced the VLCD cases that

had allegations of safety and safety disclosures that are required, questions about maintenance statistics and maintenance claims that have to be made.

We are talking about industries where there is fierce competition between the commercial programs, the VLCD's, and among companies in each segment. It is what I call the Coke and Pepsi kinds of example.

When the FTC, either the Commission or the staff, is looking at more than a dozen major companies involved in billions of dollars of sales and talking about issues such as safety for maintenance or which one works better than which one, the Commission is going to make sure, as our chairman has said, that we are maintaining a level playing field.

I think the public already has a clear sense from the VLCD's and from the extraordinary consumer education that asks the questions that consumers should ask before signing up for these programs.

By the way, that kind of consumer education was in September 1990 and again last month. So, the information is getting out there. In addition to bringing a cluster of cases and getting the publicity, this Commission is going to make sure that it is treating major competitors fairly and that we are maintaining a level playing field where one company doesn't get a black eye for a safety problem that another company deserves or doesn't get.

We are going to do it as quickly as possible, and like you, I wish it had happened a week, a month, or a year ago, but I think that our track record is one that we can be proud of.

Chairman WYDEN. I want companies to be treated fairly as well, but I want consumers treated fairly also, and 20 months is a long time to see these questionable practices that take such a toll on people's health and people's pocketbooks. What you have told us is that the investigative process has been completed in the last 20 months and that consumer education efforts are on their way.

When do you anticipate coming down with the enforcement decision? Would you anticipate 30, 60, or 90 days?

Given the fact that my particular concern has been that these 20 months seem to be an awful long time, it would be especially helpful for us now to get a target date, just 30, 60, or 90 days, when we could expect enforcement decisions to be coming down.

Mr. CUTLER. All of those dates sound good. If I had a crystal ball, I would be happy to predict all three.

Chairman WYDEN. Is 90 days the outside date?

Mr. CUTLER. I can't say. I would hope so. Then again, I would have hoped it would be complete by this time.

Chairman WYDEN. Is it the policy of the FTC now to, in effect, hold all the enforcement actions until all of them are ready to go? If it is, I would find it helpful for you to enlighten us as to the reasoning behind it.

My concern here again is that what we have is a situation where, again, hundreds of thousands of people are ripped off because the Government says well, we are just going to wait until we bring some recalcitrant in line.

My gut tells me that I would rather see the Commission use a little more muscle and a little less forbearance against the companies that are holding out; drive those people into agreements so

that the consumers are protected rather than this strategy of saying all right, we have got two or three agreements ready to go. Again, I am not anxious to get close to any of the things that relate to the Commission's internal decisionmaking, but I am concerned about this policy that there may be a number of decisions ready to go, but everything is being held to a later date, and that while we are waiting around for some recalcitrants, rather than muscling them so that they are really pushed, the consumer gets the shaft again.

Mr. CUTLER. I am happy to report that it is not the policy of the Commission to sit and wait until the entire kit and kaboodle is ready. In fact, that is why it announced 3 VLCD's in the fall when they were ready. I expect that when we announce other VLCD cases and commercial cases that they will not include every member of the industry at the same time.

Chairman WYDEN. Do you anticipate the next rounds of cases then to be a significant cluster of cases involving the commercial diet companies?

Mr. CUTLER. I would say that——

Chairman WYDEN. Center-based companies, excuse me.

Mr. CUTLER. I am expecting that.

Chairman WYDEN. Would you anticipate more than three agreements in that next cluster?

Mr. CUTLER. I couldn't say that. Let's put it this way—we are not waiting to get any critical mass or magic number. As soon as we have even a couple that are parallel and match up well with the VLCD's so there is a level playing field, it will be out so that everybody has guidance.

I will tell you this, having seen life for 18 years in Washington from the FTC side and the private side, I have one pen, but our agreements have two signature blocks. It isn't just the question of the FTC holding these up. It is remarkable that we can talk to company A one day and company B the next. Company B has a pretty good idea of what we talked to company A about the day before, so these companies I think legitimately are concerned about competition.

In terms of the difficulty of some of these issues, unlike the "lose while you snooze" and diet patch infomercials, we are dealing with questions where experts disagree.

The first time I testified before this subcommittee was at about the time that Nutri/System was a witness, and there were a number of private lawsuits filed against Nutri/System in Florida involving safety questions.

As far as I know, none of them have made it through to a trial and a decision on the merits, and they involve safety issues. I think we are moving at least as quickly as the private litigation, and like the private litigation our cases involve very difficult issues both of recordkeeping and of safety.

I think that when we are done, hopefully sooner rather than later, we will have a project that, given the task to be done and the time involved, will look very impressive.

Chairman WYDEN. I commend you on your ingenuity. I have not had in recent days anyone make the case that we are going as fast as the private legal system. That is why you ought to let us be. I

am advised by the staff that in the case of at least one diet company, there have been several hundred settlements already, but they have been sealed.

So, I find this argument about comparing you to the legal system intriguing.

One area that I had not heard about—you mentioned the problem of the competitiveness of the industry, which is well recognized and while you are moving on company B, somehow company A finds out about it.

Does this raise antitrust issues that this subcommittee ought to be concerned about, and on the basis of that, should this subcommittee, the next time we look at these issues, perhaps have one of the friendly souls from the Department of Justice here?

Mr. CUTLER. I would say it would be rather unique for the private bar in a city like Washington not to have a lot of chats about what is going on with an investigation and what is going on in Government. If it raised antitrust concerns, I suspect Mr. Rowe would have left long before now, but it doesn't.

Chairman WYDEN. These discussions between each other about possible problems for the FTC do not raise antitrust issues?

Mr. CUTLER. No; one of the reasons we either do an industry-wide rulemaking or bring cases is to try to have applicable standards. Now, if these companies got together without Government action and said why don't we agree to advertise A, B, and C, that would be one thing. My God, in my first 6 months as Bureau Director, three trade associations formed because the FTC was looking at various members of new industries.

So, what we are talking about is really the propensity of lawyers to be concerned about when their competitors' cases are going to be announced and to make sure that they are on a level playing field.

Chairman WYDEN. I guess my concern is whether these companies are holding out on the basis of shared information, not just visiting among themselves and saying wasn't it a rough day with Barry Cutler.

Mr. CUTLER. I haven't seen any evidence of anything like that. What we do see is if you say we have a safety problem, I hope you will give equal treatment to C, D, and E, and I think that is legitimate.

Chairman WYDEN. Let me ask you about a couple of practices we seem to know about and are not relevant to other companies, and whether the Commission has moved on those. I know that one of the major players in the center-based diet industry has allegedly appropriated a university logo in what amounted to a magazine implying that its product was endorsed by the Stanford Medical School.

The school demanded retraction. The advertisement was pulled, but it was distributed nationwide. The staff understands that the FTC was aware of this problem. Has the Commission done anything to review this and direct a challenge to the company revolving around this kind of practice?

Mr. CUTLER. That also resulted in some private litigation, and, unfortunately, it is the kind of nonpublic information that I can't disclose in terms of the FTC's current activity.

I agree that is an excellent example of the kind of issue that would apply to one or two companies in an entire industry that would not be industry-wide or typical of other competitors.

It is also a good reason to be doing these cases on a case-by-case basis rather than on a rulemaking basis, because, on a rulemaking basis under our statute, we would have to show that a problem is endemic to an industry, and this would give us a chance to look at individual practices of companies that are out of the mainstream of the industry.

Chairman WYDEN. What I would find troubling is, my understanding of that advertisement which had to be pulled, involved activity of a year ago. This is one company alone, not a question of A and B trying to in some way hold up the process for a competitive advantage.

I don't see any action taken in that regard.

Mr. CUTLER. If you compare that example with some of the others like the diet patch or ones that are ongoing, from a prosecutor law enforcement standpoint, whether the Commission is looking at that or not, I would observe that the problem hasn't recurred. It got a lot of publicity. It is not likely to reoccur.

Knowing the suffering, continuing injury. That is the kind of issue that can be folded in with a number of others. That is a good example of an issue that surfaced, got a lot of publicity, was the subject of private litigation, but there is no continuing deception from that, and to wait a year rather than a week on that one certainly is easier to justify than some of the serious health cases that the FTC brings where if we don't act quickly there are immediate health consequences.

I agree that you have raised an example of issues that apply one or more, but not all companies in the industry, but to lump it all into a question of waiting a week or a year, it is not one where there is continuing injury.

Chairman WYDEN. Well, I think again that what would concern me about this—and your point that this is not as important as some other health issues is one that I certainly wouldn't quarrel with—is we don't want to get into a situation where people get one free ripoff, one pass, go out, and do it once, and if you pull it, that will be the end of it.

I want to ask you about yet another specific company practice, again because of my concern that we do not find this process elongated as a result of these companies just manipulating the system so that they can hold out. The FTC has been very concerned about diet programs which make safety claims that don't accurately reflect the risk to the patient. You have straight forwardly made that clear.

We all understand the problem of people who may be morbidly or dangerously obese; they have an underlying health problem that makes them at greater risk than the average dieter as a result of programs that don't accurately reflect risk.

Are you aware, for example, about a program such as Physicians Weight Loss which by implication implies that a physician supervises the diet, when in fact there have been allegations that a doctor may only see the customer once, and once briefly, at the front end of the program?

Mr. CUTLER. Without addressing specific questions that the Commission is looking at, I will repeat that if any one of these commercial programs is a household word, the Commission has looked at it, and I hope in due course the committee and the public will see the results of our efforts.

Chairman WYDEN. Again, this is a one-program question. This is not a question, as far as I know, that involves the issue that you have felt has held up Commission decisionmaking.

Again, I haven't seen any action with respect to what seem to be some very serious allegations. Would you anticipate the Commission looking into this and resolving this matter, which involved just one company and serious allegations, very soon?

Mr. CUTLER. I would add to your point and say that while that may be an example of a company that uses "physician" in its title, the Commission has looked at a number of cases which imply medical supervision, and, in fact, even in the VLCD's the question of medical supervision and disclosures that have to be made about medical supervision was an important element we raised. Medical clinics is an example of the Commission's willingness to jump when there is an immediate safety question rather than just advertising.

In the medical clinic case, where we got a nationwide injunction and a multimillion dollar order a couple of weeks ago after litigation, we brought that case in 1990 without waiting because the series of clinics allegedly was using a drug as part of its program that not only was not FDA approved for diets, but there were contraindications for diet.

The Commission jumped on that, got a temporary restraining order, a preliminary injunction, and now a final order, and while we are never as perfect as we would like, the medical clinic case stands as an example of the Commission's appreciation that sometimes it has to jump and sometimes it has to spend a little more time being concerned about the competitive issues.

Your point is well taken.

Chairman WYDEN. Is the Commission concerned about the fact that many of the commercial companies have not been candid or straightforward in disclosing risks about specific diseases such as gallbladder disease?

Mr. CUTLER. If I can, I am going to defer to the doctor. One of the problems about gallbladder disease, whether it comes up in the Nutri/System private litigation or otherwise, is that there are a lot of conflicting medical opinions about what caused what and what the factors were, whether obesity, too few calories, or too little fat in the diet.

One of the reasons this has taken 2 years rather than 2 months is it is very easy to talk to an expert and get an opinion. When we ask are you ready to testify to that in court and be cross-examined, we get a little bit of waffling. So, I hope we will get some support from our colleagues at NIH.

Unfortunately, these aren't issues that are as clear-cut as they might be. When they are clear-cut as in the medical clinic case, the Commission goes into Federal court and gets an order, but these are hard questions and, needless to say, all the companies are very concerned about how they are perceived in terms of handling safety risks.

Chairman WYDEN. I guess my concern is that there is more science on the record than the Commission is acknowledging at this point.

Dr. Danford, let me follow up with you. I understand that in your report you have already talked a bit about the link between some of the questionable diet practices and gallbladder disease; is that correct?

Dr. DANFORD. Yes.

In the panel statement, there was a summary of these type of things, and, actually, one of our research scientists had presented the risk of gallstone formation during weight loss. In terms of the NIH research agenda, this has been a very important issue that we have considered.

We have heard this from our investigators. We have several studies underway and have in the past by investigator initiated research trying to titrate, if you will, the relationship here and to get a more definitive handle on exactly what the cause and effect relationship is.

Chairman WYDEN. This is the kind of thing that I find very troubling as the Government looks at this area. We have two agencies, both of whom I think work cooperatively with the subcommittee in debating how to go forward. Certainly, there is a lot of sincerity on all sides.

Mr. Cutler tells us that in his bailiwick, which is advertising, the FTC is in the business of monitoring false and deceptive advertising. When I asked him about whether or not the companies should have to disclose information about the link between rapid weight loss with these programs and gallbladder disease, Mr. Cutler tells me the science has not yet evolved.

We asked Dr. Danford whether or not this is on the record, and Dr. Danford tells us that it is on the record.

Until we get some linkage between these two programs, I think you are going to continue to see a lot of these sleazy questionable practices by companies who can kind of slither away from any kind of Government oversight and regulation and drag out the process through the various clever ploys that they are using with Mr. Cutler's——

Mr. CUTLER. I don't think the question is linkage between NIH and FTC. The question is linkage between the very low-calorie diet programs and the ones involving higher calories. In the cases which the Commission brought last fall, there were allegations and required disclosures involving safety, but the VLCD's involve 400 to 800 calories a day.

I heard your question as much broader. Once you get into the commercial programs where it is 1,000, 1,200, or 1,500 calories a day, I think there the evidence is more prone to expert disagreement.

I read the NIH study as talking about serious concerns about gallstones in talking about the VLCD Programs that the Commission has. I am not sure that there is that degree of consensus when you get up to a 1,000, 1,200, or 1,500 calories.

To the extent we can make sure companies are treated fairly, we are going to make sure that whatever orders by litigation or consent the Commission issues on the commercial programs treats

them as accurately on safety questions as we have with the VLCD's, where you properly point out that there were safety questions on the 400- to 800-calorie-a-day diets.

Dr. DANFORD. As you know, one of NIH's strengths is to try to accumulate biomedical data and do it as rapidly as possible, and to provide it as being available to regulatory agencies, since we aren't a regulatory agency, for their use of that science and translation of it into regulation.

They are privy to additional information that makes them best suited to that.

In terms of the gallbladder relationship, that has been important and intriguing to many of us. NIH does not have a policy per se on it. We have publications from institutes who have amassed the current information to date. This risk association is obviously there on a variety of diets.

We have not only the research underway, but in some of our new education initiatives and other things, they, too, will be keeping their finger on the evolution of that data so that once it is clear-cut, what the recommendation should be to people. As long as these things are listed as risk factors, and it is a composite of risk factors that were presented to this panel, one has to advise the public that they really do some of these things with no guarantee that they won't have this attendant risk.

Chairman WYDEN. Your feeling is, based on your research, that these programs ought to, in a generic kind of way, make sure that people are aware of the risks?

Dr. DANFORD. Yes; all of these advise people to not go on these very low calorie diets without not only medical supervision, but there has to be medical monitoring.

Chairman WYDEN. Mr. Cutler, has the FTC seen a change in diet industry advertising since the inquiry began over the last 2 years?

Mr. CUTLER. I would say the answer is yes. We can still look at the papers and television and see ads we don't like. The ways we have seen improvements, for some of the quackery, the infomercials, and other things in a which you have taken a personal interest has improved greatly.

I would like to take all the credit, but being under oath, Dr. Kessler and a monograph at FDA that prohibited claims for about 111 diet products also made a big difference.

The other thing we see is that unlike the quackery cases, when we deal with the commercial programs, they know from negotiations and what we have done with the VLCD's what standards the Commission is looking for. I think many of their practices have changed probably because by the time these cases are announced, they are going to want to be able to say that they have already changed.

The New York Times and other press that talks about changes in the diet industry is seeing some examples. We certainly haven't gotten to where we want to be, and we see some of the same ads that you do that shouldn't be out there, but has the work of the Commission and your committee and FDA and NIH made a difference in the last couple of years, I would say yes; we are moving in the right direction.

Chairman WYDEN. What concerns me is that some of the most frequent ads that we see on television and in the papers every night still are talking about losing a very large amount of weight very quickly, and there is no requirement of substantiation.

Do you find that troubling? I think you know there are two or three companies that are constantly doing this. You watch the TV, the Portland Trailblazers on their way to the NBA title——

Mr. CUTLER. I don't watch basketball, but——

Chairman WYDEN. You get my drift.

Mr. CUTLER. Yes; I do.

Chairman WYDEN. I still see a lot of those same kind of advertisements, big weight loss, real quick, and no substantiation.

Mr. CUTLER. One of the problems that all the commercial programs have, this committee has heard about it in the past, is that in order to get people to pay $700 or $1,000 dollars, people don't want to lose weight slowly.

The companies want to be able to show a quick change. One of the things that is actually most frustrating about the NIH report that came out is it seems to show that whether you lose it quickly or slowly the long-term prospects aren't very good. It may be that losing it quickly isn't that much worse than losing it slowly. It is a difficult situation in any event.

Chairman WYDEN. Given the fact that you said earlier that as part of the rules that hopefully will be coming forward in less than 90 days at the most, there will be a substantiation requirement with respect to those claims about people losing lots of weight very quickly, does that mean that these big programs, the commercial diet programs, the centers and others, will finally have to keep records so that when you all come around and want proof, they will have to produce records?

It seems to me that until the Government says there has to be some paper out there on this substantiation matter, we will still be going around in circles. Is that something you anticipate?

Mr. CUTLER. Yes; in the VLCD Programs, we don't require recordkeeping unless someone wants to make a claim. If somebody makes a maintenance claim or any other claim that has to be substantiated, they have to back it up.

One of the things that I meant to answer in your previous question, have we seen a difference, if you look at the ads you will see a marked reduction in long-term or permanent maintenance claims.

I think the companies know if they can't substantiate it, that NIH has backed that up, and, if anything, you will see more short-term claims if they make maintenance claims, and you are right, they have to be able to back it up, as other advertisers do.

Chairman WYDEN. We have another vote on the floor. I would like to have you out of here by 12:30. Let's take a very short break for this vote and we will finish with both of you and try to make it 12:30, quarter to one at the latest.

[Brief recess.]

Chairman WYDEN. The subcommittee will come to order.

I appreciate the indulgence of all our witnesses and apologize for the difficulty with the voting today.

Dr. Danford, let me ask you some questions about the NIH effort. A number of these programs strike me as extraordinarily impor-

tant and very useful. I look at the list that you present on page 16, for example, a program to deal with genetic and metabolic factors in obesity, and then later down the page, you talk about a program involving obesity in minority women, two very, very important areas.

Has there been funding made available for work on those two areas? There seems to be some debate as to whether the funds have been made available for those two areas. If you could enlighten us on that.

Dr. DANFORD. For the first one you mentioned, the RFA on genetic and metabolic factors in obesity, by definition there are set-aside funds for that particular mechanism, and it has been funded. The new PA on nutrient control of gene expression, as we have stated it, is in the planning. It will be issued, and the program announcement does not have the money set aside as a RFA does.

However, it sends a message to the investigators that we really feel this is an important area that has a gap, and we would like to solicit more applications. That is in a way how we direct research. We feel this is a very important area, and it has bright future implications for all of us in treatment, as well as prevention that is so important to this problem.

We anticipate release of the PA. Actually, it was released on May 8.

Chairman WYDEN. The nutrient control gene expression?

Dr. DANFORD. Yes.

Chairman WYDEN. With respect to the program to address obesity in minority women, which the subcommittee has found a critical health issue, what is the status of funding for that program?

Dr. HUBBARD. I am Dr. Hubbard——

Chairman WYDEN. Why don't we do this, Dr. Danford. If we are going to have some of your associates, and we welcome them and appreciate that, we must bring them forward and swear them as witnesses.

Would you like the assistance of Dr. Hubbard on this?

Dr. DANFORD. This is Dr. Van Hubbard who serves on our nutrition coordinating committee as well as serving on task forces that we have mentioned.

Chairman WYDEN. Do you have objection to being sworn as a witness?

Dr. HUBBARD. No.

[Witness sworn.]

Chairman WYDEN. If you would tell us the status of the availability of funds for the program for obesity in minority women.

Dr. HUBBARD. There are several different components of that initiative. One is in an early planning phase-in which NIDDK will convene experts to target a new announcement on obesity in minority women and will also work with NICHD in terms of targeting specifically the problem in adolescents.

The other area, which is already effective, was a component specifically within the announcement that went out for the new Obesity and Nutrition Centers. This was a joint announcement between NIDDK and NICHD which instructed all potential applicants to incorporate within their application special efforts to involve investigators that were working in the minority field or had minority con-

tacts as well as having clinics operative with large population pools involving women and minority groups. Applicants were told that there would be special emphasis on how well the institutions submitting their applications for these research centers complied with instructions in that area to try to target specifically research projects that would be effective in addressing this problem in these populations.

Chairman WYDEN. That is helpful, Dr. Hubbard.

Dr. Danford, why don't we do this, because I think these programs on page 16 in particular are very, very useful. Why don't you submit for the record what the funding levels are for each of these programs, because I think that there is a clear consensus that more needs to be done on obesity research, and I want to add that Congress can't have it both ways. We can't say isn't it important that obesity research go forward and then not make available the funds.

What funding is available for this current year, and what has the agency requested for the next fiscal year?

Dr. DANFORD. We would be pleased to do that.

[The information may be found in the appendix with Dr. Danford's statement.]

Dr. DANFORD. With Dr. Healy's Office for Minority Health and other NIH-wide efforts in women's health research obesity and overweight, is targeted and focused-not only at NIH, but in our HHS-wide effort, such as Healthy People 2000, to recognize the importance of obesity and overweight to the groups that bear a disproportionate burden of these problems.

Chairman WYDEN. Another area I am concerned about is children. I recently saw a reference in one of the health journals that said that a very large fraction of youngsters between 6 and 11 are now obese.

Is that in line with what you all are picking up? If it is, that would suggest to me that there is a public health problem there, given the age of those youngsters and the prospects for the rest of their lives, that is really a very urgent health problem.

Is that what you all are picking up, that now a significant fraction of kids between 6 and 11 are obese?

Dr. DANFORD. We share your concern. As we had outlined in terms of our current position and ability to go beyond the panel statement, you have touched on an area looking at this problem in children and adolescents. We have data that shows obesity in adolescents will track into adult obesity and prevention there is very critical.

You don't want the wrong ones dieting for the wrong reasons. With all the other issues that adolescents have to deal with these days, that is an important population to look at. Children are a major concern because, not only is there evidence presented to indicate that they may be having a higher rate of obesity, the evidence showing that it would track into adulthood is not there.

NICHD is looking into this with much research on just exactly what the long term is and how weight tracks, because the danger is people deciding, "If weight loss is good for everybody, it is good for my child, and I will start early." We have growth at issue here, and you don't want to interfere.

We have learned a hard lesson from the past of people prematurely carrying adult recommendations into early years of life and causing irreversible damage in unintended ways.

So, before we would even consider making any recommendations for children, we have to look at this very closely, and, certainly, the panel statement did not address children. We do not have specific advice at this time at NIH or in the Federal Government. The Dietary Guidelines for Americans talks about age 2 onward.

We are very sensitive about knowing what is the best recommendation for children and that is high on our priority list to look at. Because, as you say, the perception is there that children, too, are sharing in this potential health problem of overweight.

Chairman WYDEN. It is gratifying to know that you are going to put it on your priority list as well. That was the thrust of my amendment on the NIH bill this year. It relates to nutritional research and disorders to make sure that we have a stronger focus on kids.

If you start from the standpoint of what they see on Saturday morning, the kind of stuff going out about sugar and fat, it is not hard to see why that fraction of youngsters between 6 and 11 is so high in childhood obesity.

We are anxious to work with you in that regard.

Let's turn to the Technology Assessment Conference for a minute. You brought together a tremendous group, a thousand scientists, medical health care specialists, to examine the data. One of the conclusions was there wasn't a whole lot of good data available to indicate that the commercial diet programs offered to consumers do much more than provide a short-term effectiveness.

Do you think this conclusion represents the mainstream medical thinking at this point as it regards the utility of these diets?

Dr. DANFORD. I can't say in terms of the mainstream. This is one thing that this type of mechanism does do in terms of getting the information out to health professionals, because we anticipate, and will actively solicit, feedback from a variety of sources on this panel statement, not only from extramural scientists, but obviously practitioners.

We hope to find out what people are thinking. One of the striking things was a lack of data on long-term maintenance of any sort to make any decision, and this, too, is something we have identified as a very, very important need, because it really is a big health issue.

We also are committed to finding out along with this what works. Obviously some things work, and we need to give the public some positive feedback and look at both what works and what doesn't work.

Chairman WYDEN. I think more than anything else in this area it is going to be essential to translate the good work that comes out of the Consensus Conference into understandable, coherent language that people can use when they are in their living room, in their kitchen, and they are saying, "I am thinking about a diet program. Maybe I am going to go on Nutri/System, maybe Jenny Craig, maybe Slim Fast. I am going to go on any one of these very large programs that have hundreds of thousands of customers."

How are you going to take what the Consensus Conference has produced so far and make it relate to that decisionmaking process in the living rooms and kitchens across the country where people are saying "I am thinking about going to one of these programs?"

I want to know how to evaluate it and what is the Government going to do as it comes out of the conference to help people get that information so they can make an informed choice.

Dr. DANFORD. Obviously, this is something that NIH thinks is important, and we are committed to. This statement has gone to all of the Institutes involved and will go through the sort of process where we bring in that information, other information we have, feedback, advice, and input from scientists and health professionals and coming up to the sort of thing you are talking about.

In addition, as you are aware, we are very committed to speaking with one voice and giving a message that is not contradictory to any other message the Federal Government comes out with. So, that type of guidance then goes through a review process and involves all sister agencies.

Both the Secretary of Agriculture and the Secretary of Health and Human Services have the final decision and, of course, will go through review to make sure that this is consistent, and that it is the consensus of science, and so forth.

On the output end, I think you will find that such education will be, as has our other education, generic because NIH traditionally doesn't mention brand names; they obviously change as we speak. We take the generic science and can make broad categorical recommendations as we do with categories of drugs to treat different chronic diseases.

This is no different a science issue from a chronic medical problem, and it will engender the same type of educational process in generating the best information we can, without misleading the public and making it understandable.

Chairman WYDEN. Are you saying that, say in 6 months or so, a generic publication along the lines of the ones you brought today would be made available by NIH so that people could use it to evaluate these major commercial diet programs, center programs?

Dr. DANFORD. I couldn't specifically commit to 6 months. I can say we do have some publications that have come out as a part of national education programs already that relate to overweight.

The panel statement has just gone out. The different groups will probably have a variety of committees that will examine the statement as they go forward. We had representation not only from the Institutes, but the same persons on these new education initiatives were involved from the start. We hope this will facilitate it, but it is not a process without many steps.

Chairman WYDEN. Apart from the timetable, though, at some point fairly soon, consumers would be able to get a publication along the lines of some of the materials you brought which would help them to evaluate commercial diet programs?

Dr. DANFORD. Well, I would be presupposing what would be in the works on the other end of the process. I think it is safe to say they will take the information and provide it in a consumer-usable way in terms of——

Chairman WYDEN. I will let it go at that, but that is the ballgame, folks. We know that what people are trying to do is evaluate these programs that have huge advertising campaigns under way, and they are looking for the kind of information that will let them make those choices.

Until we get it in that kind of format, it seems to me we are going to come up short still on the education effort. I know that it appears out of your control as it relates to some of the decisions in terms of getting this information out, but it has to get to people in that kind of fashion or educational efforts will still be coming up short.

The only other question I would ask is I see more and more of these programs now going to prefab foods of one sort or another, and a number of the panels in the health journals are now, in effect, saying that some of these prefab foods are also not all that useful from the standpoint of sensible dieting.

Are you picking that up in the work at the NIH? Do you have any comments in that regard?

Dr. DANFORD. I haven't come across any specific in terms of prefab foods. I think that, historically and currently, we do look at any time—we call chemically defined—any time you try to emulate a food we are always very concerned about the nutrition and health. We do look at things in terms of that.

Chairman WYDEN. We are talking about freeze-dried foods that are sold as part of center-based programs, that kind of thing.

Dr. DANFORD. I am not aware of any studies looking at that.

Chairman WYDEN. Do you think that is something important? They are pushing them pretty hard. They are saying we will make the food available to you as well.

Dr. Pilch.

Dr. PILCH. I would just observe that it violates the principle that if you are looking for something that you can maintain as a lifetime commitment, I am not sure that people would want to eat that kind of a product for the rest of their life. If there is no education in how to use usual foods in a healthful pattern, that is not good progress.

Chairman WYDEN. That says it well. On that point as well, let me ask that you all incorporate that into some of the work that is going forward after the Consensus Conference, because more and more of these programs are stressing their own foods. Again, you can see the extension to the next round of diet programs. There are people who have sold liquid diets and the like. They are now seeing that we are going after those programs as well. We will start shifting to foods.

I have some questions myself starting with the prefab products that are used as part of the diet programs and then going on to some of these other foods that are being touted as so healthy and so helpful to people. I would like you to at least start with the prefab, dried, frozen kinds of foods that are being made a part of the center base programs and have you look at that as part of the next round of activity.

Well, do either of you have anything else you would like to add?

You have been very patient through a long morning. We appreciate the cooperation. Obviously, this is an area that we feel very

strongly about, and we know you all do as well. It seems to me that you have to clear out some of the next rounds of barnacles, putting in place both enforcement actions, sensible education programs that people can use, and we will be talking to all of you frequently as the days pass. We will excuse you at this time.

We will take a 10-minute break and then move quickly to the our next panel. We appreciate the patience of our witnesses.

[Brief recess.]

Chairman WYDEN. The subcommittee will come back to order.

I want to thank all our witnesses for their patience. My apologies for the delay. All the activity on the floor has certainly drawn this out.

Our final panel consists of Dr. Jules Hirsch, M.D., physician-in-chief, the Rockefeller University Hospital; Dr. Arthur Frank, M.D., assistant clinical professor, George Washington University School of Medicine; and Dr. Thomas Wadden, Ph.D., professor, Syracuse University.

All three of you have been very helpful to the subcommittee in our work over these many months, and we appreciate it.

We swear all the witnesses who come before the subcommittee.

[Witnesses sworn.]

Chairman WYDEN. Gentlemen, we will make your prepared remarks a part of the hearing record in their entirety. If I could ask you to try to summarize your principal views in about 5 minutes or so in the interest of time, that would be helpful.

Doctor Hirsch, let's begin with you. You have been just of enormous value to the subcommittee. When I pushed hard for the Consensus Conference at NIH, it was because you were one who said that this was long overdue. We appreciate your leadership.

## TESTIMONY OF JULES HIRSCH, PHYSICIAN-IN-CHIEF, ROCKEFELLER UNIVERSITY HOSPITAL

Dr. HIRSCH. Thank you, Mr. Chairman. I am sure the kindest thing I can do is to be brief, to paraphrase the written remarks, and highlight a few of the features that may be particularly important to your deliberations.

I am what is called a physician scientist. I have worked for 38 years at Rockefeller University, and, for the better part of that time, I have worked on the metabolism of adipose or fatty tissue. This has, of course, led me to an interest in obesity and more generally in nutrition.

It is important for me to recall that when I came to this research, obesity was thought to be simply a matter of careless behavior and lack of nutritional information—that any special diet with good will power and common sense was all that was needed for the treatment of obesity. But over the years, I have seen all kinds of diets come and go—high fat, low fat, high protein, low protein, almost every kind of diet, and we have learned that no single dietary manipulation of any kind is curative of obesity.

So, in answer to a statement by one of our previous witnesses about how experts disagree, one of the interesting things is they disagree less about obesity now than they did years ago. They are now coming to realize that no single simple dietary manipulation

can either prevent or cure obesity. Although a low-fat diet, which is the current vogue, may have value in its own right for the prevention of other illnesses, it is not the treatment or the cure for obesity.

It is important to remember why the American public must remain concerned about obesity. I had the good fortune in 1985 to chair another consensus conference that defines what we mean by obesity and what the harms of it are, and convincing evidence was presented at that conference that some 34 million Americans in 1985 were meaningfully, medically obese in terms of a much greater likelihood of developing type 2 diabetes, hypertension, some of the hyperlipidemias which are risk factors for heart disease, and even some cancers.

It was on the basis of that conference that a number of Government agencies, the Surgeon General's Report, the American Heart Association, the National Academy of Science, and others placed weight reduction high on their list of recommendations of what the American public should do.

I believe that the most recent report from the Department of HHS entitled "Healthy People 2000" again draws on the data that was used for the preparation of that first consensus statement in 1985.

The problem is that if talking about this and repeatedly telling people were to do anything, we would be a slimmer, healthier group of Americans. This is not like cigarette smoking, not like fastening your seat belt. Telling people about it and getting information out about how important it is to lose weight is clearly not the answer. Most people know that.

In fact, the Technology Assessment Conference that you were instrumental in developing indicated that an unusually large fraction of Americans are not only aware of this, but are really trying to do something about it all the time. This is where the problem comes up.

One side item here that you brought up, which is very important, is that some of the ethnically or economically disadvantaged groups, particularly their children, may have an even higher prevalence of obesity than the general public.

We are very worried that this may be a mark of Cain with them in the generation to come when those who are now at the lowest socioeconomic ladder, hopefully advance, but still have this crippling hazard of childhood obesity, and yet they are the individuals who are least likely to be immediately concerned about the matter, and least likely to have the resources or the wherewithal to get the kinds of treatments they need.

The Technology Assessment Conference also showed that many things are being done. Basically, people are trying to eat fewer calories and become more physically active, but there are vitamin preparations, meal replacements, over-the-counter drugs, participation in all types of weight-loss programs, and this does, in fact, constitute something which it is almost an oxymoron to say that this has come before the Small Business Committee. It is a very big business in America at this time.

Mr. Lancaster asked what really new happened at that conference. One very startling new thing happened that I have never

seen happen before, and it is most important for your committee to recognize, and it is the following: In preparation for this conference, a wide variety of the most commonly used commercial and medical treatment programs were given advance warning and told to come down to Washington and help the panel of experts answer the questions about who does lose weight, how effective is it, et cetera.

So, they were begged to bring with them data which would show how effective weight-loss programs are. When this was presented, the Food and Drug Administration helped in the analysis of the data, and here is what you must know: None of the commercial nonmedical groups presented data which in the eyes of the analysts from the Food and Drug Administration could demonstrate the efficacy of their programs.

So, the demonstrated scientific efficacy of the nonmedically administered programs is by ordinary scientific standards zero.

Chairman WYDEN. Doctor Hirsch, excuse me for a second.

This is an extraordinarily important point you are making. You are saying that none of the commercial programs at the point that you talked about could demonstrate the effectiveness and the efficacy of their programs?

Dr. HIRSCH. Dr. Walter Glinsman of the Food and Drug Administration was given data as given from the commercial nonmedically supervised, nonmedically involved programs, and he came to the conclusion that the data were unanalyzable in the normal way.

Chairman WYDEN. I have a list, the centers, Weight Watchers, Nutri/System, Jenny Craig, Diet Center, Physicians Weight Loss, Formula 3, Diet Workshop, Fortunate Life, American Medical Weight Association, Beverly Hills Weight Loss Clinics, Slender Centers, Inches Away, Dietrite Centers, Our Way, Diet Ease, and then you go to the over-the-counter powders and pills and the like, the Slim Fast products, Fiber Full Plan, Dine-a-Trim, Trim Fast, Ultradiet, Shape Weight Loss, Accutrim, Stay Trim, Fibre Guard, and Liqui Slim.

All of these programs are essentially the ones that you are saying there does not exist significant scientific data to back up the claim that they would help you lose weight responsibly?

Dr. HIRSCH. I do believe that, but let me tell you the exact facts. The facts are that when this conference was in preparation, a sampling of these groups—we can get the data so that you will know who were sampled and who were not asked to provide information, so that the Technology Assessment Group could assess the technology since these commercial outfits are providing the technology—Dr. Glinsman looked at the data and reported to us that there were insufficient data to come to the scientific conclusion of efficacy of these diets.

Chairman WYDEN. On the last point, instead of, in effect, saying that we can now make the assertion for all of these, what happened pursuant to the Technology Assessment Conferences, they took a sampling of these programs——

Dr. HIRSCH. That is my understanding. Now, understand, also, that with many of these programs—this is an opinion, and it is an opinion from watching this for some 38 years—people enter the program with high resolve and do tend to lose weight in the short

run, but what we are concerned about is the weight 6 months later, 1 year, et cetera.

So, the evidence for how these individuals do from the programs that were sampled was not available for appropriate scientific statistical analysis in the hands of the representative of the Food and Drug Administration looking into that. We must differentiate with those programs in which there is a major aspect of medical supervision.

Physicians are involved, data are kept—if nothing else, if these databases are to some degree available from such programs varying from poor databases to those done in academic health research centers where we know more about the results—let's look at those in the average. In the average, what happens, and one of your witnesses after me, Dr. Wadden will provide data on one group of them which is approximately concordant with what I am saying—about half of the people who enter a very good medically supervised program will drop out of the program within a year, for whatever reason.

Of those who stay with the program, perhaps a half, maybe a little more, will lose a significant amount of weight, and in many instances this weight will be down at the end of 1 year. Two-year data are very hard to come by. Five-year data are essentially not available in the medical literature.

There are the rare, small papers, but the consensus is that fewer than 5 percent of Americans entering even the most ideal weight-loss program under medical supervision in academic health centers will by the usual dietary means or whatever maintain the weight loss for a 5-year period of time.

So, we are dealing with an extraordinary problem. We have to ask ourselves how did this unfortunate situation come about? Obviously, the development of obesity occurs because of one reason. There is no way in this world of ours for obesity to occur unless individuals consume more calories than they expend.

One of the remarkable mysteries is that you and I and those who don't feel they are particularly obese will over a lifetime consume 75 million or 100 million calories, but will expend that amount and have little change in the storage of fat.

For some reason, the obese individuals has an imbalance for a brief time and stores more fat and then in the obese State comes back into that balance once again.

The reasons for obesity we are now discovering in the scientific community are, of course, to be found in that energy equation, but why the imbalance comes about, modern research shows increasingly that there are fundamental cellular and biologic mechanisms which make some individuals particularly susceptible to all the goodies of our society and the relatively inert lifestyle that is promoted, to elicit the maximum obesity possible.

So, genetic factors, environmental factors, particularly those acting early in life are important. It is this mix which is of concern. To attack the problem only at the psycho-social level, which is what all the current treatment is doing, is simply not effective. We have to come to grips with the facts.

Ask the consumer what he wants to know about a product. He wants to know how effective the product is and why. Under the

best of circumstances, there is no product for the treatment of obesity that is surely effective by the use of the product itself without a remarkable change in lifestyle, great diligence on the part of the user of the products, and, in fact, if you asked me what would I most like to have on such a product, it would be something like the Surgeon General's statement on cigarettes, to say these products and products like them are not in and of themselves effective in the long run for the treatment of weight reduction.

They may be of use to you in the short run, but the long-term treatment of obesity will not be achieved by the use of products of this type. It must only at best be used as part of a more complex program.

Now, time doesn't permit me to go into many details I would like to. Some of these are in what I prepared for you, but some are not.

Let me skip to something that really is terribly important for us to recognize.

The National Institutes of Health had an enormous burst of growth in the early 1950's. They have been at this business for 40 or more years of a lot of medical research, and they have not been sitting on their hands. Things are happening.

We are living in a world of a revolution of new science in medicine, and the new biomedical scientific establishment has grown and is very important. It has been very difficult to attack problems like obesity or other nutritional problems because they act over the person's entire lifetime, are intertwined with psycho-social and other factors which make clear-cut, simple experiments very difficult to do.

Nonetheless, it is becoming clear that there is a fundamental molecular, biologic substrate which promotes obesity. No matter what the substrate is, people can still be forced to lose weight, and those of unusual willpower and who make enormous efforts can lose weight and keep it down; but it is a great burden for people to do this.

The way to help the consumer and the way to stop difficult, fraudulent, or whatever practices is to get to the facts, is to find out why is it that some people are in fact so susceptible to becoming obese. We are beginning to understand this.

First it came from work on adipose tissue, the cells, sizes, and numbers, and how they function, the enzymes that are associated with them. Now it is getting to the molecular genetic level.

I have in my lab, mice that are obese, and they didn't become obese because they watched television Saturday morning. But their children were obese, and they are obese on genetic grounds, and we are beginning to know what the molecular defect is in these animals.

So, it is in the sure faith that this kind of information will put fraud out of business, rather than regulation that brings me to you today. Mind you, I think it is enormously important for the American public to know about these products, their harm, and the regulatory things that you are doing are enormously important, but the answer for which we all search is how did all of this come about in the first instance, and what is the molecular biologic substrate for this?

NIH is super at doing molecular science. There has been no organization in the history of the world like it in terms of its promotion of science, and I might add that congressional committees such as these have been the close brothers of that activity over the years, have constructed it, have promoted it, and it is your interest that shows the ongoing link between Congress, NIH, and NIH's responsibility to the American public.

NIH has looked at this carefully. Over the years, new devices have come into being with NIH; new instrumentalities for maintaining molecular science at the highest level, and yet bringing the fruits of this into these difficult areas.

I bring to your attention one of the most extraordinary of these, which is the clinical nutrition research units. This is an effort on the part of scientists to band together in medical settings and bring the best of molecular science immediately to bear on problems such as obesity or other nutritional problems of which there are many of similar type, and to make sure that the science moves easily and quickly from the molecular side to the clinical side and the information gets out to the public appropriately.

We do need within NIH and elsewhere more recruitment of molecular scientists into the clinically relevant areas. NIH is aware of this and is taking measures to do that.

It must be understood that this has to be, to some measure, a trans-NIH activity. Although NIDDK and Child Health and Human Development, to some degree, have taken the lead in these matters, nutrition and obesity is important in cancer, heart disease, in aging, in infectious disease, and, therefore, this has to be to some degree centrally coordinated in NIH, perhaps to a measure greater than has been the case in the past.

It is our hope that Dr. Healy and her colleagues examining the strategic goals of NIH will take this measure very much to heart and make as part of their strategic goals the trans-NIH approach to human nutrition and specifically the problem of obesity.

At this moment, there is language being put together for the authorization of an expenditure of some $12 million for additional nutritional research; $12 million sounds like a lot, but it is very modest, really a pittance in terms of the expenditures we have heard of for misuse of products, for nutritional purposes, and for treatment of obesity.

So, I urge you and the members of your committee to join me and my colleagues in pursuing that kind of basic research. These are moneys specifically for NIDDK, for Child Health and Human Development and Aging, and for the purpose of uncovering the information that will make a different story when we meet a year or two from now, turning nutritional science into one of the mainstays of health maintenance and disease prevention in this country.

It would not be appropriate for me to end without saying one last thing and that is that it is terribly important to give scientists like myself the ability to address you and the other distinguished members of your committee who will be hearing about this testimony, and to indicate to them that money spent on fundamental research and nutritional science are the way to end the present frauds that go on in nutritional practices in this country.

Nothing can compare with that; yet regulation along the way is something you must be involved in, and we laud your efforts.

Thank you, sir.

Chairman WYDEN. Thank you, Dr. Hirsch. That is really a wonderful presentation, and particularly takes us to the next plateau, as you say, to get beyond some of the regulatory changes that need to be implemented quickly and look to the long term.

[Dr. Hirsch's statement, with attachment, may be found in the appendix.]

Chairman WYDEN. Dr. Frank, welcome. We know of your excellent work as well.

Please proceed.

## TESTIMONY OF ARTHUR FRANK, MEDICAL DIRECTOR, GEORGE WASHINGTON UNIVERSITY OBESITY MANAGEMENT PROGRAM

Dr. FRANK. Thank you.

I am Arthur Frank. I have been a biochemist, and I am a physician. For over 30 years, I have been studying the physiology of fat metabolism, primarily as a physician. My medical specialty is internal medicine. Most of my practice deals with medical problems of obese patients. I am very much involved with patient care. I have cared for and shared the achievements and disappointments of over 4,000 patients since 1977. My work is to be a physician caring for obese patients.

I am the medical director of the George Washington University Obesity Management Program. I work with a staff of physicians, dietitians, psychotherapists, counselors, and exercise therapists. I am confident that we have as comprehensive a system for the management of obesity as can be devised.

Life is very difficult for obese patients, but there are at least three nonmedical factors which complicate and add to the burdens of its management.

First, almost every one views obese patients and their disease with contempt. They are regarded as weak people who are out of control of their lives. Their eating patterns are thought to be willful misconduct.

Second, the service that is provided by counselors in commercial programs or by less than qualified professionals may be well intentioned, but it is too often insufficient or incompetent. Too often, also, it is provided with a generous amount of exploitation and quackery.

Finally, the social and medical consequences of obesity are so substantial and so devastating that patient care decisions are often driven by desperation. Bad medical decisions are made when people are desperate.

On the other hand, to soften the harshness of these comments, I would like to consider what we have accomplished in the management of obesity.

We now have a much better understanding of the metabolism of this disease. Given the remarkably meager resources devoted to research and a small group of dedicated scientists, we have accomplished more in the past decade than has been known since the be-

ginning of time about how humans eat and how body weight is regulated.

We now recognize that the various types of obesity are a group of diseases of metabolic regulation. Obesity is not simply a process of overeating.

We have made substantial progress in treating obesity, although the system still fails adequately to provide this proper treatment.

Albat Stunkard, one of the pioneering obesity experts, 35 years ago said, in what surely was a moment of profound pessimistic despair. "Most obese patients will not stay in treatment for obesity. Of those who stay in treatment, most will not lose weight, and of those who do lose weight, most will regain it."

In 1992, at least two of these three statements are no longer necessarily true. In a comprehensive, sophisticated obesity management program such as the one we have at George Washington University, most people will stay in treatment and most will lose weight. We have not solved the awful problem of the maintenance of the weight loss.

But obesity is not a curable disease. Yet, we hold our obese patients to a very high standard of performance and a very high standard of maintenance; higher than we do in most other diseases. We don't cure diabetes. We don't cure congestive heart failure, and we don't cure schizophrenia, but we do expect to establish ways for long-term management of these diseases.

We have not gotten sophisticated the mechanism of setting up successful long-term ways of managing obesity.

What is wrong also is that we don't have enough of the kinds of comprehensive treatment programs which seem to be effective. Much like the treatment of cancer or of pain, what is needed, at a minimum for people with significant obesity, is a multidisciplinary approach with the skills of trained professionals. A high-technology approach can work and probably does work for many people.

Can a simple low-technology approach work? Sometimes it will, but for many it is a trivialization of a complicated medical problem. It will often work for the uncomplicated patient, typically with small amounts of weight to lose, who simply needs dietary information and support. It is a waste, and often a dangerous approach, for the 250-pound, 50-year-old diabetic with complex family stress and overlying depression.

The current system does not work well. Patients don't know where to go and professionals don't know what to do with them. They don't know where to send them. Too few practitioners are well trained at any level of skill.

Commercial weight loss programs often promise much more than they are prepared to deliver. There is a huge waste of resources, and the health insurance companies have totally opted out of their participation in the entire venture.

Consumers are exasperated. They are angry. They have been harmed by flamboyant commercialism. People who are involved with working with obesity can and ought to do better.

I would like to offer a simple proposal for improving both the understanding and the treatment of the disease. It is a plan which I believe will benefit the consumers of this care and the Government, which is responsible for protecting the public health. I think

also that it will rationalize the process for skilled providers who have been offering capable services.

I am not convinced that any new Government agency ought to be involved in the regulation of care. I am convinced, however, that the provision of services in the weight loss industry can be regulated with a few relatively simple procedures that fall well short of what could be considered Government meddling.

Let us establish a program for the voluntary accreditation of obesity treatment programs. Perhaps it could work in the following way:

First, a multidisciplinary commission of recognized experts should be convened to formulate reasonable standards of care, to characterize the types of services provided, and to establish a nongovernmental, nonprofit accrediting agency concerned with weight management programs. The commission itself will then go out of business.

Second, programs and providers can elect to be certified by the accrediting agency at various levels of service, character, and intensity according to standards established by the agency. Obesity treatment programs, including the entire spectrum of self help groups, nonprofessional counselors, professional therapists, comprehensive, multidisciplinary programs, can be accredited at their own level of skills and can be classified according to the types of services they offer. The accrediting agency should not tolerate the mislabeling of professional skills or the misrepresentation of services provided.

Third, the treatment programs should pay for the accreditation; very much like a program of hospital accreditation which has been in place for decades. The system will be financially selfsufficient, and I am sure you would be happy to know, the program should not require any sustaining Government funds.

Fourth, the accrediting agency must provide education for consumers, and guidelines about the kinds of services they might choose, and how to select from those available. It is a waste of resources for a healthy young woman who is 15 pounds overweight to undertake an intensive medical program with complex nutritional intervention and psychotherapy, but it is a dangerous risk of human life for a 350-pound patient with diabetes and cardiac disease to be managed by a counselor who offers compassion, but does not know how to interpret an electrocardiogram. Patients should be able to identify who is providing the care, the skills of those involved, and the cost of the program. The public deserves this kind of protection.

Fifth, the programs may elect not to be accredited, and then take their chance against the marketplace of certification. Accredited programs will be required to submit their data and will need regular recertification to sustain their credentials.

What do we accomplish with all this?

First, we provide a mechanism for public and professional education, guidance, and direction.

Second, we establish minimal and optimal standards at all levels of care.

Third, we enable a larger faction of patients to receive the kind of care that would do them the most good.

Fourth, we will flush out and drive away the worst of the charlatans. They will not be accredited. There will be fewer victims.

Fifth, with a more direct approach to a serious medical problem, perhaps we can get more capable and skilled professionals to participate in the process.

Sixth, perhaps we can even induce the cynical health insurance industry to develop some rational guides for reimbursing patients for the medical treatment of this disease.

Seventh, perhaps we can lower the cost of the care. Surely, we can avoid the waste that suffuses this $33 billion industry.

It is reasonable for our Government to establish mechanisms to protect patients from being manipulated by this year's variety of consumer weight loss fraud. If we routinely condemn all obesity management programs, we will destroy the bad ones, but we will also destroy the good ones. The consumer will then lose what opportunity he has to get competent care.

A certification program will benefit health care professionals and the millions of obese people who want very much to establish some rational and effective way of managing their disease.

Chairman WYDEN. Dr. Frank, thank you. That is a very interesting proposal that you set out. I will have some questions in a moment.

I am very interested in your idea, and I commend you for your initiative and all the good work. You have been a great help to our subcommittee.

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

Chairman WYDEN. Dr. Wadden, welcome. We will make your prepared remarks a part of the record. If you could highlight some of your major concerns, we would appreciate it.

## TESTIMONY OF THOMAS WADDEN, PROFESSOR OF PSYCHOLOGY, SYRACUSE UNIVERSITY

Mr. WADDEN. Thank you, Mr. Chairman.

I am Tom Wadden, professor of psychology at Syracuse University where I am also the director of the Center for Health and Behavior. I have been involved in full-time research on the treatment of obesity since 1981.

Let me first express my admiration for the efforts of the committee to improve the commercial weight-loss industry. I think the committee has made remarkable strides in the past 2 years, and ultimately the efforts will benefit millions of Americans. So, I am honored to participate in this effort.

I am going to briefly discuss three related issues today.

First, I would like to provide an overview of the current effectiveness of weight reduction therapies as determined in university research trials.

Second, I will discuss the results of the first evaluation of a proprietary weight-loss program; and third, will discuss the need or the desirability for all proprietary weight-loss programs to disclose their results of treatment.

When commercial programs begin to disclose the results of treatment, as I think they will, we will need some sort of a yardstick or gold standard by which to assess the results disclosed.

The best research data we have now on the effectiveness of weight-loss programs come from university research programs. I want to describe that briefly.

Patients at these programs usually are treated by a program of lifestyle modification designed to change eating, exercise, dietary, and thinking habits. This program is combined with one of two types of diets, either a 1,200 calorie conventional reducing diet or a very low-calorie diet.

Table 1 of my statement shows that persons who are treated by a 1,200-calorie diet with lifestyle modification would lose about 18 pounds during the space of 15 to 20 weeks of treatment. About 80 to 85 percent of people will complete this program. So, people are losing weight with a conventional reducing diet.

The table further shows, however, that when you bring them back a year later and assess their weight loss, patients have regained about one-third of the loss that they achieved. So, this table points out that weight regain is a clear problem in treatment of obesity.

There have been some efforts to improve the maintenance of weight loss. Dr. Michael Perri at the University Florida has shown that if, following weight reduction, patients enroll in every other week or bi-monthly weight maintenance sessions, they will, in fact, keep off the majority of their weight.

In addition, there is good evidence that exercise helps to promote long-term weight control.

Persons who are significantly overweight, 30 percent or more, who have tried this approach without success, may well be treated by a very low-calorie diet providing 400 to 800 calories per day and combined with a program of lifestyle modification.

Very low-calorie diets, I believe, are generally safe when conducted under appropriate medical supervision with patients who have been appropriately selected.

We have heard some testimony this morning about complications, and there are potential complications that can be controlled with appropriate medical supervision. These diets are very successful. Women treated by very low-calorie diets lose about 40 pounds in 12 weeks. Men will lose as much as 50 pounds during the same period.

So, there is no question that we have methods of inducing weight loss.

When you follow up on patients treated by this approach—and there are few studies on this unfortunately - you will find, as noted in table 2, that people regain about one-third to one-half of their weight in the year following treatment.

There are some efforts to improve the maintenance of weight loss following treatment by very low-calorie diet, and there has been initial success.

Let me summarize my overview of current dietary treatment with 4 points.

First, diets do work on a short-term basis. My colleague, Dr. Albert Stunkard, in fact, does think that we have made progress in the past 30 years in the ability to induce weight loss, whereas in 1959, he could hardly get people to lose any weight.

Second, diets don't work however on a long-term basis. Clearly, in the best university research programs that we have, patients are regaining one-third to one-half their weight in the year after treatment, with increasing weight gain 3 to 5 years later.

Third, we have to improve the maintenance of weight loss. We are going to accomplish that by first recognizing obesity is a chronic disorder requiring long-term care. Dr. Hirsch and Dr. Frank would never think of treating a hypertensive patient for 15 to 25 weeks and then terminate treatment and expect to find benefit of treatment 3 to 5 years later. Obesity is a chronic disorder.

Fourth and final, we need studies to assess the benefits of weight loss followed by probable weight regain. Do, in fact, persons who lose weight and regain have greater or lesser risk to health than individuals who remain obese?

Stated differently: Is it better to have lost and regained than never to have lost at all? We desperately need studies to address this issue so that we can develop sound policies concerning practice.

Let me now turn my attention to describing the first evaluation of a proprietary weight loss program. Back in 1986, I was invited by the Sandoz Nutrition Co., which markets the OPTIFAST Program, to serve as a consultant in helping them improve the behavioral components of their weight loss program. I am still a consultant to Sandoz at this time.

With a team of persons, I developed a 26-week program, to modify eating, exercise, and thinking habits, which included a 12-week very low calorie diet. We described this program in manuals for physicians, psychologists, and dietitians. There is also a 250-page manual given to patients who participate in the program.

It is very well standardized and very well described. After we completed developing the program, we thought the next step was to evaluate its effectiveness.

We began a small pilot study of 171 people treated at eight sites nationwide. What we did was to look at changes in their weight, blood pressure, and cholesterol over the 26 weeks of treatment. That went smoothly. The sites participated.

They sent us the data that we requested at the University of Pennsylvania, where I was at the time. We were encouraged. Dr. Francis Peterson of Sandoz Nutrition asked us to extend our study to have a larger study and also to include a follow-up evaluation. So, we began a second cohort of patients in which we had 346 persons treated at 10 sites. This study was published in this month's Archives of Internal Medicine. This morning I brought some copies.

To summarize the results in four points: First, the majority of persons who entered this program, which is a highly structured program using weekly treatment, the majority of persons stayed in treatment for the full 26 weeks; 55 percent finished the 26-week program.

We cannot really evaluate these data in the absence of other data from commercial programs, but from the data I have seen, they look promising. In other commercial programs you are likely to see only 30 percent of persons still participating after 12 weeks, using an unstructured approach to treatments.

Second, patients in this program achieved large weight losses. The average loss for women was 42 pounds; men, 59 pounds. That is for all persons who came through the door.

Chairman WYDEN. Dr. Wadden, excuse me for interrupting. I am concerned about Dr. Danford.

Mr. Recorder, let us take a break now for at least 5 minutes and have the folks at NIH who said they feel they need a few minutes to assist Dr. Danford. We will take a break to make sure Dr. Danford is helped.

[Recess.]

Chairman WYDEN. The subcommittee will come back to order.

The staff tells me that Dr. Danford will be all right. I guess that is one of the advantages of having so many good doctors in this room. We have second, third, and fourth opinions.

Dr. Wadden, why don't you proceed? Then we will have some questions. I appreciate everybody's patience through a real long morning.

Dr. WADDEN. Again, my apologies for speaking through Dr. Danford's difficulties.

To summarize where we are, we had conducted the first evaluation of a proprietary weight loss program, the Sandoz Program that provides OPTIFAST. We conducted a study of 517 persons who went through this program at 18 sites across the Nation.

We collected information on weight loss, changes in blood pressure, and changes in cholesterol. In a portion of the persons, we were able to conduct a 1-year follow-up evaluation.

As I indicated, this paper is available today, published in the Archives of Internal Medicine. To summarize what we found, 55 percent of persons who began this program completed it.

That means 45 percent did not, and it is difficult to interpret these data. Are they positive or negative? I think, based on the limited information I have seen from other commercial programs, 55 percent completion at 26 weeks is quite good. In other programs you will see as few as 30 percent of the people still in treatment at 12 weeks. These are less structured programs that do not have as much of a multidisciplinary approach as the Sandoz Program does.

Second, the patients in this program did lose large amounts of weight. When you include weight losses of everybody who came through the door, women lost an average of 42 pounds; men, 59 pounds.

Third, patients who were followed up did regain weight. Those followed up regained about 40 percent of their weight loss in the space of a year; 20 percent kept off all the weight; 11 percent on the other side regained everything.

Our data are probably positively biased, meaning we were not able to follow up all the persons who finished treatment. We had only about 74 percent of those who finished treatment. The data may be biased in a favorable direction.

But the fourth and final point about the study is the most important. This study demonstrates that a proprietary weight loss program can evaluate its short and long-term results of treatment in a manner consistent with research trials.

Moreover, programs can provide information that is going to be useful for consumers to evaluate whether it is a program that is

appropriate for them, and if so, how much weight can they expect to lose, and what changes in blood pressure and cholesterol can they anticipate.

My colleagues on this paper, Gary Foster, Kathleen Letizia, and Dr. Albert Stunkard, all at the University of Pennsylvania, are hopeful, as am I, that our results will encourage other programs to evaluate their results of treatment.

As much as we hope this, however, I think the commercial weight loss programs are going to need assistance in tackling this problem of disclosing the results of treatment. Even when you want to conduct research studies, they are difficult to design and compete; and if you do not believe me, you can ask people here from the NIH. They reject probably 80 to 90 percent of the research applications they receive because they think there are hows in research methodology.

So, the commercial programs are not well suited to start tomorrow to collect data that will meet scientific standards. I am afraid, in most cases, they will give you perhaps their best effort, but a panel of scientists will look at their fundings and say, you did not randomly select your patients, or you did not report weight losses for all of those who dropped out.

Rather than proposing the guidelines that I think commercial programs should meet, I would suggest that an expert panel be convened with the charge of developing detailed guidelines that commercial programs should meet in disclosing their results of treatment. This would involve both describing what types of data need to be provided, and second, how these results data be obtained; specifically, how do you sample patients?

In the absence of such guidelines, I am afraid we will probably get less than favorable data, if not junk, from a lot of programs, partly because they do not know how to conduct these studies. A separate issue is whether or not disclosure of results of treatment should be voluntary or mandatory.

It sounds as if we are moving toward mandatory disclosure. The work of the proposed panel would not address that issue, however. I don't think the proposed panel should decide the matter.

Whether you have voluntary or mandatory disclosure, we still need detailed guidelines for the assessment of these commercial programs. Only when we provide commercial programs detailed guidelines can they, in turn, provide American consumers the kind of information that dieters need to select an appropriate treatment program.

Thank you very much. Again, I compliment the committee on the outstanding work it has done in improving the diet industry.

[Dr. Wadden's statement, with attachment, may be found in the appendix.]

Chairman WYDEN. Doctor, thank you. You all have made an enormous contribution up there with your good research. I think the New York Times called it one of the first, if not the first, to really look at some of these issues. We appreciate all the help you have given us and have a couple of questions here in a moment.

Each of you has taken a different tack and, in a lot of ways, begun to move us toward the same kind of goal. Clearly, we have to

think through very carefully the relationship between regulation and research.

I have said from the very beginning that my feeling was that you would need some minimal basic regulation under any set of scientific developments you would have, because, unfortunately, there are always some in an industry this big who try to take advantage and exploit.

But I very much share your view, Dr. Hirsch, that clearly research, as it breaks new ground in telling us what we need to know, is an extraordinary part of any solution. I think the question I have for you was what kind of research, short- and long-term, do you think would be most helpful and what would we get as a result of that short-term research agenda and the long-term research agenda?

Dr. HIRSCH. I am very anxious to see the field of molecular genetics and molecular and cell biology applied to human obesity. I think in both the short and long term, this is the important thing for us to be doing; although some research on clinical trials and that type of thing is useful. In general, the surveys, the epidemiologic work, new treatment trials, I think are not only expensive but are funds not well spent. I think the better thing is for the funds to be spent on behalf of fundamental research.

The reason I say that is because the treatment of obesity is like evolution and genetics itself. We have adapted about as far as we are going to adapt given the present set of lack of information.

What Dr. Wadden presented to you is about as well as anybody is ever going to be able to do unless we get more information of a fundamental sort. So, the further manipulation of this or that diet, one or another circumstances, is not the research approach to follow but rather more fundamental understanding.

The key issue is making sure the molecular and cellular biologists are working with clinicians in the same arena where the results can be developed and easily put in to work in the important problem of treating obesity.

What can we expect?

What we can expect, I think with some luck, are first to be able to develop much better markers for who is likely to become obese. You may remember, I said about a third of the people will become obese in our society and about two-thirds will not, no matter what you do.

So, there it is. It would be wonderful for us to know who that third are and target them as early in life as possible.

The second important research area is what are the developmental steps whereby the genetic information leads to the final production of obesity? In the experimental obese animal, something like 50 percent of the ultimate obesity can be deflected or prevented by early environmental effects, namely, early underfeeding, some early environmental things. We need to know what to do early in childhood.

Finally, I would hope we can understand the molecular biology sufficiently well so as to develop definitive pharmacologic, endocrine, or other treatments so everyone who is obese can expect to be treated and move from the one-third of the susceptible side of the population into the other group.

I think this is what the American public really wants. They do not want to have to live in our society and be marked individuals that if you partake of the good of our society, you will become fat when two-thirds of the people don't.

We have applied for the funds to expend on scientific research that we can move the one-third into the other group by appropriate treatment.

Chairman WYDEN. Doctor, that is very helpful. We will come back to you in the next few minutes.

I want to pick up on the points Dr. Wadden and Dr. Frank made where there seemed to be some similarities, but also some distinctions that I think are important.

Dr. Frank, as I understood you to say, you thought it would be very helpful to set up what amounted to a accrediting organization where, on a voluntary basis, programs could come forward and ask to be accredited and presumably with experts evaluating the program, if they met the various standards set out, that would result in the accreditation being granted.

As I understood you to say, Dr. Wadden, you were concerned that maybe there was not enough data in place and enough information available on these various kinds of programs to get to Dr. Frank's point. Is that the case?

Possibly we ought to look at a two-step kind of approach, possibly the initial effort being Dr. Wadden's, which is to go forward with a further scientific effort to try to collect the data as to what programs would work and then what programs didn't; and then use that to feed into the development of this accrediting organization that Dr. Frank proposes, which certainly strikes me as a very sensible idea.

Both of your ideas strike me as very sensible ones. I am just wondering whether this distinction that I seem to have picked up is real or is this just sort of a hair-splitting exercise that is unimportant?

Dr. FRANK. It is quite real, but I think an accreditation agency accomplishes at least three things. For one, it is a mechanism to inform the public, to provide guidance, to provide information, to provide direction, and to say this is a way we suggest you do things. It is a suggesting agency.

Number two, much of the accreditation process is independent of results. A lot of what it does concerns issues such as the nature of your staff. How well are they trained? What is the nature of their training? Who is providing the services? What kinds of services do I need? How much is it going to cost me?

There is a great deal of information in the accreditation process that is valuable for a consumer and which is independent of the final question, related to "what are your results?"

Now, as Dr. Hirsch pointed out, you can get results at various levels of sophistication. You can get very simple results; you can get very unsophisticated results, which give you guidance and information. But, to get the kind of rigorous, scientific results that Dr. Wadden is talking about, I think we understand that will be further down the road.

But an accrediting agency will accomplish a great deal substantially before it has to get to the problem of looking at results in a structured way.

Dr. WADDEN. I guess I view it somewhat differently. I am certainly in favor of an accrediting agency, as you indicate. One thing I heard from you, Mr. Chairman, was we need to act quickly on some of these issues that have come up. We need to start collecting data. There has been a call from numerous witnesses that we need data on the effectiveness of these programs.

My suggestion is that in order to get usable, useful data, you have to educate commercial programs on the kinds of information we want them to provide, rather than putting all the burden on them by saying give us your data. You have to say we want this specifically; this is how the study should be conducted. I think that is a first step that could be achieved in a weekend, taking experts from the NIH Technology Assessment Conference, and even persons from the commercial programs, to sit on this panel to help educate the industry about how evaluations are conducted.

Once you have done that, we can start to put in place mechanisms by which all companies have an opportunity to provide data. Whether they wish to or not is going to be their decision. Perhaps it will be mandatory.

It would get the process started, I think. Within the next few months, you could develop these sorts of criteria. An accrediting agency is, I think, an excellent idea. I think that kind of body will take a longer period of time to develop and is going to have to review a greater number of issues than just "what are your results of treatment?" I certainly do support Dr. Frank's ideas on this, however.

Chairman WYDEN. Well, we are going to want to follow up on both of these. It strikes me that both of you are making very sensible suggestions. Just a couple of other points.

Dr. Wadden, picking up on the matter of furnishing the data, I assume we would learn something pretty instructive in the health field about companies that would not furnish data as well. In other words, if they are serious and want to play the game in a fashion that would be respected by clinicians, they would come forth with their data. If they didn't, we would think that possibly they weren't interested in it and keeping records.

Now, Dr. Wadden, I am reading from the hearing of May 7, 1990. We had a subcommittee hearing. Mr. McCollock, the president and CEO of Nutri/System said, "We believe we are the gold standard in this industry."

I gather what you are saying is that no gold standard exists in the industry at this time; isn't that correct?

Dr. WADDEN. That is correct. I certainly cannot hold up one company and say this is the gold standard for treatment. I can identify some of the companies doing more medically-based research and do commend them for publishing a large number of scientific papers, such as the Sandoz Nutrition Co., with whom I consult.

Some have taken a step forward in bringing science to weight control. I cannot, however, hold anyone up and say there is the gold standard for treatment.

Chairman WYDEN. Let me ask you another question, Dr. Frank, with respect to this accrediting organization.

I gather that you would like to see the Government involved in setting this up to insure independence or enlighten me a little bit on the process of it being set up. The reason I am asking the question is, as you know, after our hearings began a few years ago, there was this kind of flurry of activity by the major center-based programs to set up their own organization. It is not clear to me what has become of that and what they have intended to do in that area.

I am curious as to how you would see the accreditation organization working, say, with a group like that?

Are they still going, by the way?

Dr. FRANK. I have not been participating in that group. I do not know. I know of no sustaining organization representing the diverse segments of the industry. One of the difficulties, I suspect, is that the industry is so diverse and their goals and purposes are so frequently incompatible that it is probably going to be very difficult gathering them altogether. That is my guess.

I see this commission being established as a short-term, governmental effort, mostly because it would probably be quickest that way; that the Government in one form or the other, perhaps NIH, perhaps through HHS, or some other agency, convene an expert panel. The expert panel would function for a period of time, perhaps a year, bringing in experts, bringing in counselors, bringing in committees working with diverse groups to establish a basic framework and basic standards. Perhaps it could even be working with an institution such as the Joint Commission on Accreditation of Health Care Agencies, which already exists and is very sophisticated at accreditation processes for hospitals and other health care institutions.

The commission would set up the basic standards and the basic processes and establish the kind of research protocols, the kinds of information gathering procedures that need to be done, and then turn that over to an accrediting agency which will then be self-sufficient and will derive its income from accreditation fees. There should not be any need for ongoing Government money.

Chairman WYDEN. Any ideas who you would like to have possibly coordinate this other than that Joint Commission? I know there has been some concern about delegation to that kind of group. Would you see another possible agency that could coordinate it such as NIH?

Dr. FRANK. Frankly, sir, that is the kind of thing I would turn to you for counsel. It is often a political kind of decision. I think it could be done through the National Institute of Medicine, through the National Academy of Sciences, or through some other comparable agency.

Chairman WYDEN. One last question for you, Dr. Hirsch.

One of the concerns that we have heard consistently from leading clinicians like yourselves is that the Government's effort in the area of nutrition research is sort of strewn all over Washington. You have all these agencies and all these programs, and the scientists who come before us gnash their teeth, and all say we are trying to do various kinds of interagency agreements.

How serious is that as a problem in terms of getting research done? What would you recommend be done in that regard?

Dr. HIRSCH. I think, Mr. Chairman, it is a serious matter. I think things are getting better in the sense that nutritional science generally has sort of dipped down in its popularity over the years; not that it is not important, but it has been harder and harder to do some of these things. But the new growth of molecular science poses some new opportunities. So, now I think NIH is again becoming centrally involved in this.

What I believe is necessary is for at least oversight of nutritional research from the director's office of NIH across all of the institutes. This is not to say the institutes haven't each taken important initiatives, But it would be important for them to have some direction centrally.

I think we are coming to a new period in nutrition where we may be getting answers about whether people should take vitamins or not for the prevention of some malignancies; whether diet should be changed in different ways and sound information has to be given to the public and the molecular scientists ultimately have to provide us with the rights and wrongs of what is correct to do.

It is not just a matter of information. It is not just more clinical trials and epidemiology; more science is needed. I think NIH is bringing this forth; but it does need a coordinated effort, more so than is present at the moment.

Chairman WYDEN. Well, there is going to be no dip-down in the interest of this subcommittee with respect to nutritional science. You all have been extraordinarily patient today. It has been an excellent way to help us wrap up. Clearly, there is a great deal more to do and the job gets easier because of people like yourselves who are willing to sit in hot hearing rooms for hours on end to help get it done.

Is there anything else that any of you three gentlemen would like to add?

All right. We thank all of you.

The subcommittee is adjourned.

[Whereupon, at 2:15 p.m., the subcommittee was adjourned, subject to the call of the Chair.]

# APPENDIX

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OPENING STATEMENT
REP. RON WYDEN

BEFORE THE SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES & ENERGY

PATIENT SAFETY AND CONSUMER PROTECTION ISSUES INVOLVING COMMERCIAL DIET PROGRAMS

May 21, 1992

Today, the Subcommittee on Regulation and Business Opportunities examines progress toward solving an important public health problem -- fraud, deception and abusive practice in the commercial diet industry.

Two years ago, the subcommittee began its inquiry into the sale of goods and services in this growing economic sector. We found purchases totaling more than $30 billion per year in gross revenues, making the American diet business on par with total sales of the American lumber and plywood industry.

At any given moment in this country, two women in five may be actively dieting, and one man in four. They buy diet foods and diet aids in the over-the-counter market, they purchase professional services at doctor-operated weight-loss clinics, and they patronize thousands of non-professional, diet and weight-loss centers

Quite simply, many -- if not most -- fail to lose weight, or keep weight off if they do lose the pounds. And for years, government ignored what amounted to a wide-scale, consumer rip-off by these purveyors of diet pills, potions and over-hyped programs.

Often, consumers are lured into making expensive, long-term commitments to diet programs based on misleading and deceptive claims of success. These promoters tell consumers that diet programs are safe, easy and nearly always effective. Yet the managers of these programs consistently have failed to present any data to support such assertions. Frequently, these programs claim to be run by trained personnel when in fact these "counselors" are little more than glorified salespeople. More and more, they use deceptive advertisements employing before-and-after pictures which may not even be truthful.

The Chair adds that many of these problems are implicit in the promotion of over-the-counter products including so-called appetite suppressants.

Compounding the consumer protection issue is the very real safety risk that some of these programs may present for the morbidly obese, or for those who may have an underlying health problem in addition to their obesity.

This subcommittee has recorded compelling evidence that a cause-and-effect relationship may exist between very-low-calorie commercial diets and diet products, and illnesses such as heart failure, gallbladder disease and stroke.

How have consumer protection and public health agencies responded since our investigation began?

-- The Federal Trade Commission has entered into consent agreements with three liquid-diet manufacturers, and has informed the subcommittee that it is pursuing cases against another 13 diet product, and weight-loss program companies.

-- The National Institutes of Health, at the subcommittee's urging, has begun the task of producing straightforward, understandable information consumers can use to make informed choices about diet programs. This project was formally kicked-off earlier this spring with a three-day consensus conference on diet programs and products. For the first time, the federal government has formally tapped into clinical testimony, exhibits and technical papers from some of the nation's leading health authorities in this area.

-- At this subcommittee's insistence, the Food and Drug Administration, after literally decades of inaction, finally moved to eliminate more than 100 chemical ingredients from the diet product market, finding that those agents were unsafe or ineffective. The FDA comtinues to assess another chemical agent -- PPA -- which the subcommittee has identified as having the potential for great harm, and little good, to the average dieter. The agency tells us that it will reach closure on this issue before the end of the year.

-- Finally, a congressional conference committee marking up next year's research blueprint for the NIH has accepted language submitted by the Chair to establish a significant obesity and nutrition research program with an emphasis on nutritional disorders of children.

But much remains to be done.

The Federal Trade Commission has told us for months that they will force all of the large center-based, and over-the-counter diet programs to advertise truthfully and substantiate their claims. The big players in the diet industry need to be told the rules, and be required to comply. The long delay in FTC action is giving the bad actors in this industry a free pass, and consumers the shaft. We expect the FTC to inform the subcommittee how and when it will resolve these pending actions.

Also, it's time for the government to compile data about what works, what doesn't and why in the area of weight-loss plans -- and make that information available to the consumer. Now that the consensus conference is complete, the subcommittee asks the National Institutes of Health to announce its plans for getting this life-saving information to the public.

Because millions of Americans use questionnable diet programs, the government's effort to stop fraudulent weight-loss practices must not take as long as the campaign to ratify the 27th Amendment.

Millions of Americans abused by this industry may as well burn their money on the curb for all the good they get. It is long-past time for a conclusion which favors the consumer, favors the honest diet programs, and puts the brakes to the deceptive hype and hoopla which pervades this industry.

Our first two witnesses, today, are Barry Cutler of the FTC, and Darla Danford of NIH. Mr. Cutler will address some of the consumer protection issues we have raised. Dr. Danford will detail the results of the recent NIH consensus conference.

PREPARED STATEMENT

OF

THE FEDERAL TRADE COMMISSION

DELIVERED BY

BARRY J. CUTLER

DIRECTOR FOR THE
BUREAU OF CONSUMER PROTECTION

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES,

OF THE

COMMITTEE ON SMALL BUSINESS

U.S. HOUSE OF REPRESENTATIVES

MAY 21, 1992

Mr. Chairman and members of the Subcommittee. I am pleased to appear before you today to report on the progress of the Commission and the staff of the Commission's Bureau of Consumer Protection in addressing misleading and deceptive marketing for programs and products that purport to promote weight loss or prolonged weight maintenance. The views expressed in this statement are the views of the Commission. My oral presentation and responses to questions are my own and do not necessarily reflect the views of the Commission or any individual Commissioner.

It is estimated that at least one third of adult women and nearly one quarter of adult men are currently trying to lose weight, and an additional 28 percent of both sexes are trying to maintain their weight.[1] Based on data from Marketdata Enterprises, we estimate that consumers spent over $7 billion on diet products and programs in 1990.[2] The Commission staff, as you know, has undertaken a broad-scale investigation of the weight loss industry that has targeted the major companies involved in marketing weight loss programs to consumers. At the same time, the Commission has continued its long-standing efforts to challenge the fraudulent or deceptive promotion of weight-loss

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[1] National Institutes of Health Technology Assessment Conference Statement, "Methods for Voluntary Weight Loss and Control," April 1, 1992, at p. 6.

[2] See Barbara Presley Noble, "Crash Is Out, Moderation Is In, And Diet Companies Feel The Pinch," New York Times, November 24, 1991, p. 1 D.

products. In the last year, the Commission has made progress in both areas, announcing:[3]

- consent agreements, subject to final approval, with three of the major promoters of physician supervised, very-low-calorie diets,[4]

- a court-ordered, multi-million dollar redress judgment against a multi-state marketer of a low calorie diet weight loss program,[5]

- a permanent injunction and redress judgment against the promoters of the "Ultimate Solution diet,"[6]

- additional successful enforcement actions challenging weight loss claims for a "passive exercise" device,[7] a weight-loss

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[3] Copies of Commission press releases concerning each of these matters are attached to the testimony.

[4] Sandoz Nutrition Corporation, File No. 912 3023 (accepted for public comment Oct. 1991), Jason Pharmaceuticals, Inc., File No. 902 3337 (accepted for public comment Oct. 1991), and National Center for Nutrition, Inc., File No. 912 3024 (accepted for public comment Oct. 1991).

[5] Federal Trade Commission v. Pacific Medical Clinics Management, Inc., et al, No. 90-1277-GT (CM) (S.D. Cal., Apr. 8, 1992).

[6] Federal Trade Commission v. Amerdream Corp., et al, Civil Action No. CIV-91-0505 PHX RCB (D. Ariz., Jan. 1992).

[7] Slender You, Inc., File No. 882-3134 (accepted for public comment Nov. 1991).

regimen marketed on Spanish-language television stations,[8] and an "infomercial's" deceptive promotion of dietary programs and products that allegedly changed the consumer's metabolism.[9]

Over the years, the Commission has brought numerous cases that have challenged deceptive weight loss claims for products, programs and devices. These actions have resulted either in consent settlements, litigated administrative cease and desist orders, or in Federal District Court injunctions. The investigations in the weight-loss industry have involved both the promotion of over-the-counter products -- the pills, powders and devices promising easy, rapid and, often permanent weight loss -- as well as diet programs that purport to combine caloric reduction with behavior modification and exercise to promote both weight reduction and the ability to maintain the weight loss over time. Programs under investigation include suppliers of hospital-based or physician supervised very-low-calorie diets as well as the major commercial, store-front programs.[10]

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[8] Nicholas Telemarketing Industries, Inc. et al, File No. 902-3090 (Jan. 1992).

[9] Nu-Day Enterprises, Inc. et al, File No. 882-3156 (Apr. 1992).

[10] The very-low-calorie diet products generally consist of powdered food supplements providing between 400 and 800 calories per day. The commercial, store-front programs usually consist of "real food" and provide between 1000 and 1200 calories per day under regimens referred to as low calorie diets.

A major area of concern to the Commission is whether companies are making safety claims that do not accurately reflect the health risks associated with the products or program protocols. As with any claim involving health and safety, marketers should disclose known health risks or properly qualify the safety claims.

Another primary concern for the Commission are claims, express or implied, that diet products or programs promote weight reduction without reducing calories or increasing exercise. The Commission requires such claims to be substantiated by an adequate scientific basis. Depending on the specificity of the claim, the Commission may require well-controlled clinical trials demonstrating that the product works as advertised. Another area of concern in the promotion of diet products is whether testimonials imply, within the context of an advertisement, that certain weight loss results are typical of the users of the product.

The Commission also examines whether maintenance success claims can be substantiated. As you know, Mr. Chairman, losing weight is only part of the dilemma for overweight persons; keeping the lost weight off is frequently more problematic. As noted in the NIH Technical Assessment Conference Report, the primary failure of most weight loss programs and products is that dieters fail to maintain their weight loss. Studies relied on in

the Technical Assessment Statement indicate that dieters typically regain almost all of their lost weight after five years.[11] The investigations have, therefore, focused on claims involving promises of long-term or permanent weight loss success and the companies' substantiation for such claims.

In contrast to the pills, powders and other products, the weight loss programs usually involve a long-term commitment, requiring weekly visits to a service facility for monitoring, counseling and, often, group support. As a result, staff investigations have also examined claims concerning weight loss achieved, training and qualifications of program staff, program costs, and adequacy of the program protocol to accomplish the results claimed.

Most of the matters staff is currently pursuing, like Commission investigations generally, are non-public, and will remain non-public until the Commission either: (1) issues an administrative complaint, (2) files an injunctive action in Federal District Court, (3) announces provisional acceptance of an administrative consent agreement with the parties, (4) files a consent decree in Federal District Court, or (5) closes the matter without taking any enforcement action. These nonpublic matters are at various stages of completion.

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[11] National Institutes of Health Technology Assessment Conference Statement, "Methods for Voluntary Weight Loss and Control," April 1, 1992, at p. 11.

Regarding those matters mentioned earlier, in October of last year, the Commission accepted subject to public comment[12] three consent settlements with major marketers of very-low-calorie diet programs. The marketers of these programs, known to the public as Optifast,[13] Medifast[14] and Ultrafast,[15] have agreed to consent order provisions under which they would be required, among other things, to qualify safety claims, have a reasonable basis for weight loss achievement or maintenance claims, and make various disclosures in connection with any future maintenance success claims.

As of this time, the Commission has not yet adopted these settlements as final agency orders. During the public comment period on the settlements, two parties filed comments critical of the consent agreements, and one of the respondents filed a comment supporting its agreement with the Commission.

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[12] As required by Commission Rule 2.32, these consent agreements were placed on the Commission's public record for a period of 60 days to permit interested persons to provide their views on the substance of the agreements.

[13] Sandoz Nutrition Corporation, File No. 912 3023 (accepted for public comment Oct. 1991).

[14] Jason Pharmaceuticals, Inc., File No. 902 3337 (accepted for public comment Oct. 1991).

[15] National Center for Nutrition, Inc., File No. 912 3024, (accepted for public comment Oct. 1991).

Just last month, the Commission successfully concluded its Federal District Court case against Pacific Medical Clinics,[16] a California based company that had promoted its program based on false claims that its dietary supplements would adjust the metabolism of dieters so that they could lose "up to a pound-and-a-half a day." In granting the Commission's motion for summary judgment, the court permanently enjoined the defendants' false and misleading promotional claims and ordered the defendants to pay over $21 million dollars in consumer redress. Nevertheless, it remains to be seen whether we will find enough money to satisfy the entire judgment.

In January 1992, a Federal District Court in Arizona granted a Commission request for a permanent injunction against the marketers of the "Ultimate Solution Diet Program," barring among other claims, an advertising representation that a Harvard University study showed an ingredient in the diet product to be effective in achieving significant weight loss and reducing cholesterol levels and blood pressure. The court's order, which also applies to false claims for a gasoline additive product, requires the defendants to pay $622,624 in consumer redress.[17]

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[16] Federal Trade Commission v. Pacific Medical Clinics Management, Inc., et al, No. 90-1277-GT (CM) (S.D. Cal., Apr. 8, 1992).

[17] Federal Trade Commission v. Amerdream Corp., et al, Civil Action No. CIV-91-0505 PHX RCB (D. Ariz., Jan. 1992).

In September of last year, an initial decision of the administrative law judge presiding over the Commission's adjudication of the complaint against the marketers of Fibre Trim upheld the complaint and entered an order prohibiting deceptive claims concerning the amount of fiber or other nutrient in any food, food supplement or drug. The judge's order also required that claims that any such product provides any appetite suppressant, weight loss or weight maintenance benefit be substantiated by two well-controlled, double-blinded clinical trials.[18] The decision is currently on appeal before the Commission, and the Commission heard oral argument on May 12.

In the past eight months, the Commission has also accepted consent settlements with companies marketing, respectively, the Nu-Day program which had claimed that consumers using its program could change their metabolism and lose weight without exercising;[19] "Slender You" continuous passive motion exercise tables that claimed weight loss and physical fitness benefits without the effort and pain associated with traditional exercise;[20] and "Faja Fantastica," a weight loss regimen marketed on Spanish-language television stations that claimed, among other things, that its regimen will cause consumers to lose

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[18] Schering Corporation, Docket No. 9232 (Sept. 1991).

[19] Nu-Day Enterprises, Inc. et al, File No. 882-3156 (Apr. 1992).

[20] Slender You, Inc., File No. 882-3134 (accepted for public comment Nov. 1991).

weight without increasing exercise or decreasing caloric intake.[21]

As you know, the Commission is not alone in challenging the fraudulent or deceptive promotion of weight loss programs or products. In April, as part of its ongoing cooperative working relationship with other law enforcement agencies, the Commission, the Food and Drug Administration and the National Association of Attorneys General launched a major consumer education campaign to assist consumers in selecting diet programs and products. This collective effort resulted in publication of a pamphlet entitled "The Facts About Weight Loss Products and Programs." This free pamphlet contains information about recent weight loss scams that have been the subject of legal action by each of these agencies, and it provides guidance on how to evaluate weight loss products and programs before purchase.

It is very difficult to quantify the real consumer injury as a result of the deceptive promotion of weight loss products and programs. First, some of these programs can result in weight loss for persons who abide by the product instructions or program protocols, albeit weight loss that may be only temporary for most dieters. Second, it is still unresolved within the medical

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[21] Nicholas Telemarketing Industries, Inc. et al, File No. 902-3090 (Jan. 1992).



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community whether consumers who ultimately regain lost weight achieve more permanent health benefits.[22]

As the Commission continues its investigations in this area, it is appropriate to remind consumers of their need to remain skeptical of claims of easy, pain-free weight loss or weight loss maintenance. There are no magic pills, devices, potions or programs that can result in quick and easy weight loss, even on a temporary basis. Consumers must remain the first line of defense against marketers who seek to mislead consumers.

The Commission has been, is and will be committed to challenging unfair and deceptive acts and practices. While much work has been completed, the Commission will continue its efforts to investigate and to respond to those abuses.

That concludes my prepared remarks. I will be pleased to respond to any questions you may have.

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[22] National Institutes of Health Technology Assessment Conference Statement, "Methods for Voluntary Weight Loss and Control," April 1, 1992, pp. 16-17 and 18-19.

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR RELEASE: OCTOBER 16, 1991

**FTC CHARGES MARKETERS OF ULTRAFAST, MEDIFAST AND OPTIFAST LIQUID DIET PROGRAMS**
**Consent agreements to settle charges**

The Federal Trade Commission today announced for public comment three separate settlement agreements with the marketers of Ultrafast, Medifast, and Optifast liquid diet programs. The agreements would settle charges that the marketers made deceptive and unsubstantiated advertising claims regarding the safety and long-term efficacy of their programs. These are the first three cases to emerge from the FTC's ongoing, industry-wide investigation of claims made by medically-supervised and commercial diet programs.

The FTC's complaints name the Minneapolis, Minnesota-based Sandoz Nutrition Corporation ("Sandoz"), which markets Optifast 70 and similar programs and related products; Jason Pharmaceuticals, Inc. and the Nutrition Institute of Maryland (collectively, "Jason"), both based in Owings Mills, Maryland, and which market the Medifast 70 and similar diet programs and related products to consumers through Medifast Associate physicians; and the National Center for Nutrition ("NCN"), of Newington, Virginia, which markets Ultrafast diet programs and products.

Popularly known as liquid diets, these very-low calorie diet (VLCD) programs typically involve a nutrient-supplemented fast -- usually a liquid protein diet -- of 420 to 800 calories per day for 12 to 16 weeks, followed by a "refeeding" period during which the patient returns to a normal, reduced-calorie diet of 1000-1200 calories per day. In many cases, the programs include optional longer-term maintenance sessions designed to help patients continue their behavior modification and nutritional education efforts. The cost of the programs ranges from approximately $1,400 to $2,800.

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Low-calorie (LCD) or "commercial" diet programs, on the other hand, are 1,000 to 1,200 calorie-per-day regimens of real foods instead of dietary supplements. Like VLCDs, LCD programs often include optional maintenance sessions, but LCDs typically cost less than VLCDs.

In its investigation of diet programs, the FTC is examining the support that companies have for their advertising claims, particularly claims relating to the safety and efficacy -- both short- and long-term -- for the programs.

Sample claims for the three VLCD programs cited as misleading by the FTC in its complaints include:

-- "The One That's Clinically Proven Safe and Effective." (Optifast program)

-- "Studies have shown that supplemental fasting, when medically supervised, is the quickest, safest way of losing excess body weight." (Ultrafast program)

-- "...more than 300,000 formerly obese patients had already been helped by Medifast without one instance of serious side effect associated with their treatment." (Medifast program)

Specifically, the FTC has charged, these and other statements misrepresent the programs to be either unqualifiedly safe or free of serious health risks when, in fact, the reason for physician supervision is to minimize the potential for health risks. (There is some empirical evidence that, during the period in which they are dieting, patients on VLCDs may be at increased risk of developing gallstones.) Moreover, the FTC charged, NCN falsely represented that the Ultrafast program is safer than all non-VLCD programs. There is no competent and reliable scientific evidence to support this claim, the FTC said.

The FTC does not allege in its complaints that these diet programs are unsafe but, rather, that the respondents' claims were deceptive in light of their failure to disclose either the health risks associated with them, or the need for physician monitoring to minimize these risks.

Other claims cited in the FTC complaint included:

-- "You can call the OPTIFAST program today, and have all you need to control your weight for the rest of your life." (Optifast program)

-- "...you will not experience a rebound phenomenon [regain lost weight] after you attain your goal." (Medifast program)

-- "Weight Loss Myth #4: Once You Lose it, You'll Gain It Back . . . with the support of the ULTRAFAST Program, you get a new attitude. The weight stays off." (Ultrafast program)

The agency charged that these and other claims made by the companies about the success of their programs in helping patients keep off the weight lost -- and Sandoz' claims that the Optifast program is superior at weight-loss maintenance -- were not substantiated.

Finally, the Commission charged that Jason falsely claimed that its physicians are certified through an objective evaluation process in the treatment of obesity.

The proposed consent agreements settling the charges against the companies contain prohibitions against misrepresentations about the likelihood of regaining lost weight, and against any unsubstantiated claims about the success of former patients in achieving or maintaining weight loss. The proposed orders set out the following minimum requirements for substantiation:

-- substantiation for claims that a certain weight loss is typical must be based on a sample of all patients who have entered the program, or all persons who entered and completed the entire program or a portion thereof (where the claim only relates to such persons);

-- substantiation for claims that weight-loss is long-term must be based on the experience of patients followed for at least two years after they complete the program; and

-- substantiation for claims that weight-loss is maintained permanently must be based on patients followed for a period of time generally recognized by experts as sufficient for such a claim, or for a period of time demonstrated by reliable survey evidence to permit such a prediction.

The proposed orders would require any claim about the safety of these programs to be accompanied by a clear disclosure about the need for physician monitoring to minimize the potential for health risks. Claims that patients have successfully maintained weight loss would have to include disclosures of the average weight-loss maintained by those patients and how long they have maintained the loss, as well as the statement, "For many dieters, weight loss is only temporary."

The proposed order against Jason also would prohibit false claims that physicians are certified.

(VLCD Programs--10/16/91)

The vote to accept the consent agreements for public comment was 4-0, with Commissioner Dennis A. Yao not participating.

**NOTE:** Consent agreements are for settlement purposes only and do not constitute admissions of law violations. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of $10,000.

The proposed consent agreements will be published in the Federal Register shortly and will be subject to public comment for 60 days, after which the Commission will decide whether to make them final. Comments should be addressed to the FTC, Office of the Secretary, 6th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

Copies of the complaints and consent agreements are available from the FTC's Public Reference Branch, Room 130, at the above address.

# # #

MEDIA CONTACT: Bonnie Jansen, Office of Public Affairs
202-326-2161

STAFF CONTACT: Richard Kelly, Bureau of Consumer Protection
202-326-3304

(Sandoz File No. 9123023)
(Jason File No. 9023337)
(NCN File No. 9023024)

(VLCDiets)

FTC news

Federal Trade Commission *Washington, D.C. 20580*

**FOR RELEASE: APRIL 10, 1992**

**FTC WINS $21.5 MILLION JUDGMENT AGAINST WEIGHT-LOSS CLINICS**

The Federal Trade Commission has won a $21.5 million judgment against Pacific Medical Clinics Management, Inc., and its principal, James Norman Wells, who were charged by the FTC with falsely advertising that, through their medically-formulated program, consumers could adjust their metabolism and lose up to one and one-half pounds a day. The court also granted a permanent injunction prohibiting the defendants from misrepresenting the efficacy of any weight-loss or health-care program in the future.

The judgment stems from the FTC's October 1990 complaint against Pacific Medical Clinics Management, Inc., and two individuals, James Norman Wells and Karin Lynn Norred, who operated a chain of weight-loss clinics in California, Nevada, Texas, Georgia, and Virginia. The FTC charged that Pacific Medical Clinics, in television, radio and print advertisements, claimed that its weight-reduction program was medically safe and that by adhering to its recommended diet, and ingesting its "Growth Hormone Releaser" (GHR) tablets, protein supplements, and, in some instances a synthetic hormone called Synthroid, consumers could adjust their metabolism and lose up to one and one-half pounds a day. The FTC also charged that the defendants failed to disclose to prospective customers that the Food and Drug Administration has not approved Synthroid as safe and effective for the treatment of obesity and has, in fact, required that the drug bear a label warning against its use as a treatment for obesity. In September 1991, the Commission accepted a settlement with Karin Lynn Norred.

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(Pacific Medical Clinics/Judgment--04/10/92)

On April 6, 1992, U.S. District Judge Gordon Thompson, Jr. found that consumers were promised a medically-approved weight-loss program and that they would lose a certain amount of weight. Instead, the judge found, the defendants failed to fulfill their promises regarding the amount of weight loss, and even when consumers did lose weight, it was attributable to the low-calorie diet that the defendants encouraged consumers to follow rather than any medically-approved system. Less than 2 percent of those who stayed on the program for at least 10 days lost a pound or a pound-and-a-half a day as promised in defendants' advertising, the judge continued, adding that "[i]ndividuals lost weight because they were put on a rigorous low-calorie diet, which is not what they were paying defendants to do."

The judge further stated that the GHR tablets were nothing more than food supplements similar to those contained in many commercially-available diet drinks. "Despite the plain and simple fact that defendants' program itself did not alter metabolic rates, defendant Wells refused to change the advertisements' claim that the diet caused an adjustment in metabolism because he believed this representation gave PMCM a competitive edge over other diet programs," the court said.

The court awarded the judgment of $21,551,669, the amount of total sales, because no consumers -- even those who lost weight -- received what was promised. "As a result, the proper remedy is the rescission of each of the purchases of diet packages -- the full $21 million...." The amount of money distributed to consumers may be much less and will depend on how much of the judgment is actually collected from the defendants.

The judgment was issued by the U.S. District Court for the Southern District of California, in San Diego.

Copies of the judgment will be available soon. Copies of the news release issued when the FTC first filed charges against the defendants are available from the FTC's Public Reference Branch, Room 130, 6th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Brenda A. Mack, Office of Public Affairs
202-326-2182

STAFF CONTACT: Richard Kelly, Bureau of Consumer Protection
202-326-3304

or

Sondra Mills, Bureau of Consumer Protection
202-326-2673

(Civil Action No. 90-1277-GT (CM))

(Med-clin4)

FTC news

Federal Trade Commission *Washington, D.C. 20580*

FOR RELEASE: JANUARY 16, 1992

FEDERAL COURT BANS FALSE AND MISLEADING CLAIMS
FOR DIET PROGRAM AND PURPORTED GAS-SAVING DEVICE
FOLLOWING FEDERAL TRADE COMMISSION CHARGES

A federal court in Arizona has permanently banned false and misleading claims made by Amerdream Corporation for its "Ultimate Solution Diet Program," and by Advanced Automotive Technologies, Inc. for the "PetroMizer," a purported gasoline-saving device, following Federal Trade Commission charges. The court also ordered the companies -- and an Arizona man who is president of both these firms -- to pay nearly $675,000 for consumer redress.

The default judgments stem from an April 1991 FTC complaint against the makers and marketers of Ultimate Solution and the PetroMizer, and alleging that they made numerous false and deceptive claims in their advertising and marketing practices. Among the claims were that consumers of the Ultimate Solution program would receive a 100 percent money-back guarantee and a $1,000 U.S. Treasury Bond just for buying and testing a two-month supply, which the court now has found to be false. The court also found that Amerdream and its president Frank J. Sarcone, who is also president of Advanced Automotive, falsely claimed that a Harvard University study showed an ingredient in the Ultimate Solution's "Night Trim" diet tablets to be effective in achieving significant weight loss and reducing cholesterol levels and blood pressure.

In addition, the court found that Advanced Automotive and Sarcone falsely represented that the PetroMizer increases gas mileage by more than 28 percent, increases automobile horsepower and acceleration by 11 percent, and reduces automobile emissions, including a 100 percent reduction in carbon monoxide emissions, and that various federal and state organizations helped develop or had tested the product and proven its effectiveness.

- more -

(Amerdream/AAT Injunctions--01/16/92)

Upon the filing of the FTC complaint containing these allegations last April, the court immediately granted a temporary restraining order pending review of the case, and froze the assets of the corporate defendants and the president of both firms, Frank J. Sarcone of Arizona.

After finding that the defendants did, indeed, violate the law as alleged by the FTC, the court now has entered permanent injunctions banning the false and misleading claims, determined that the consumer injury resulting from the claims amounted to a total of at least $673,496, and ordered the defendants to pay that amount into a fund the FTC may use to compensate consumers who purchased the products.

The permanent injunction naming Sarcone and Advanced Automotive, signed by the judge Dec. 16, permanently prohibits them from making any false or misleading statement in the promotion or marketing of any after-market automotive product (for Sarcone, the prohibition extends to any product, program or service). Further, the defendants must possess a reasonable basis for making any statement about the performance or efficacy of these types of products. In addition, they are ordered to pay $622,634 for consumer redress.

The other permanent injunction, naming Sarcone, Amerdream, and Amerdream Securities Corporation, prohibits them -- in connection with the marketing of any diet product, program or service -- from making any misrepresentations as to:

-- gifts that purchasers of such products, programs or services receive;

-- the terms and conditions under which refunds will be given to dissatisfied customers; and

-- the identity of those who have tested the product, program or service, or the results of such a test or tests concerning the performance, safety or efficacy of these products, programs or services.

Sarcone, Amerdream, and Amerdream Securities must have substantiation for any representations regarding the performance, safety or efficacy of diet products, programs or services. The court also ordered them to pay $50,862 for consumer redress. This permanent injunction and order was signed by the judge last Oct. 30.

(Amerdream/AAT Injunctions--01/16/92)

Not yet decided by the court are related FTC charges against the remaining defendant in this case, Robert H. Morrison, Jr., a director of Advanced Automotive Technologies, Inc.

The injunctions announced by the FTC today were issued by the U.S. District Court for the District of Arizona, in Phoenix. Amerdream has offices in North Miami Beach, Florida, and in Kula, Hawaii. Advanced Automotive is located in Phoenix, Arizona.

Copies of the permanent injunctions and orders are available from the FTC's Public Reference Branch, Room 130, 6th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Bonnie Jansen, Office of Public Affairs
202-326-2161

STAFF CONTACT: Eileen Harrington, Division of Marketing Practices, 202-326-3127
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(Civil Action No. CIV-91-0505 PHX RCB)
(amer-aat)

# FTC news

Federal Trade Commission *Washington, D.C. 20580*

**FOR RELEASE: November 27, 1991**

**FTC CHARGES MARKETER OF "CPM" TABLES WITH MAKING UNSUBSTANTIATED WEIGHT-LOSS CLAIMS; CONSENT AGREEMENT WOULD SETTLE CHARGES**

The Federal Trade Commission has charged Slender You, Inc. with making false and unsubstantiated weight-loss claims for the continuous passive motion ("CPM") exercise tables it manufactures and sells to health and fitness centers. Under a consent agreement issued today for public comment to settle these charges, the company would be prohibited from making such claims in the future.

Slender You sells its CPM tables contending that they offer users weight-loss and physical fitness benefits without the effort and pain associated with traditional forms of exercise. The tables generally come in sets of five to seven, with each table designed to exercise a different group of muscles, as in isometrics -- pushing, pulling and stretching muscles with or without user resistance.

The FTC complaint alleges that Slender You has falsely claimed that consumers who exercise on CPM tables can lose weight, lose inches, remove cellulite, tone and firm muscles, and achieve physical fitness benefits comparable or superior to those provided by rigorous exercise. The complaint also alleges that the company has not had a reasonable basis for making these claims. Finally, the FTC complaint alleges that the company's advertising used testimonials or endorsements to falsely represent that inch-loss or weight-loss experienced by consumers using the Slender You CPM products was typical or ordinary.

- more -

(Slender You--11/27/91)

Under the proposed consent agreement settling these charges, Slender You would be prohibited from making misrepresentations in the advertising, labeling, packaging, sale or distribution of its CPM tables to consumers, and from misrepresenting the benefits of any diet or fitness programs it offers. Specifically, the order would prohibit Slender You from misrepresenting that any such machine or program:

- reduces or helps to reduce overall body fat or fat in any particular area of the body;

- results in, or contributes to, inch-loss or weight-loss or the reduction of the body;

- tones or firms human tissue, including muscle;

- removes or eliminates cellulite or any other form of subcutaneous body fat;

- flushes out or contributes to the removal of fat including acid waste, toxic waste or any other bodily waste; or

- provides health or physical fitness benefits similar or superior to those provided by rigorous exercise for normal, healthy individuals.

The agreement also would prohibit Slender You from representing that a consumer endorsement or testimonial represents the typical or ordinary experience of those who use the exercise programs or CPM machines, unless that is the case.

Slender You, Inc. is based in Crossville, Tennessee.

The consent agreement is scheduled to appear in the Federal Register shortly, and will be subject to public comment for 60 days, after which the Commission will decide whether to make it final.

Comments should be addressed to the Office of the Secretary, Federal Trade Commission, 6th St. and Pennsylvania Ave., N.W., Washngton, D.C. 20580.

**NOTE:** A consent agreement is for settlement purposes only and does not constitute an admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions of the respondents. Each violation of such an order may result in a civil penalty of $10,000.

(Slender You--11/27/91)

Copies of the complaint, consent agreement and an analysis to assist the public in commenting are available from the FTC's Public Reference Branch, same address as above; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Brenda A. Mack, Office of Public Affairs, 202-326-2182

STAFF CONTACT: Theresa M. McGrew and Thomas S. Jefferson, Chicago Regional Office, 55 East Monroe St., Suite 1437, Chicago, IL 60603

(FTC File No. 882-3134)

(SLENDER-YOU)

OFFICE OF PUBLIC AFFAIRS
(202) 326-2180

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

**FOR YOUR INFORMATION.....January 7, 1992**

The Federal Trade Commission has given final approval to a consent agreement with Spanish Telemarketing Industries, Inc., Nickolas Telemarketing Industries, Inc., Sylvia George, Inc., and Stewart Brown, settling charges that they made false and misleading weight-loss claims for "Faja Fantastica" -- a weight-loss regimen -- in Spanish-language television commercials.

Under the final consent order, the respondents must pay $100,000 for consumer redress and are prohibited from making claims that Faja Fantastica -- or any other substantially similar product or service -- will cause an individual to lose weight without increasing physical exercise or without decreasing caloric intake. The consent order also prohibits the respondents from misrepresenting the efficacy or performance of any weight-control product, device, or service, and from making any health-related benefit claim about any food, drug, product, device, or service they sell, unless they possess competent and reliable scientific evidence to substantiate the claim. Further, any weight-loss claims they make in the future must be accompanied by a prominent disclosure that weight loss is achieved only through an increase in physical activity and/or a decrease in caloric intake.

The Commission vote to issue the order in final form was 4-0, with Commissioner Dennis A. Yao not participating.

The agreement was announced for public comment on Oct. 10, 1991 and issued in final form on Dec. 20, 1991 (Docket No. C-3353.)

**NOTE:** A consent agreement is for settlement purposes only and does not constitute an admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of $10,000.

- more -

(Spanish Telemarketing2--01/07/92)

A news release summarizing the complaint and consent was issued at the time the Commission accepted the consent agreement for public comment. Copies are available from the FTC's Public Reference Branch, Room 130, 6th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

# # #

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(FTC File No. 902-3090)

(spanish2)

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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

**FOR YOUR INFORMATION.....December 4, 1991**

The Federal Trade Commission's proposed consent agreement with Nu-Day Enterprises, Inc., its owner, Jeffrey S. Bland, and its parent company, Healthcomm, Inc. appears in the November 13 Federal Register. It will be subject to public comment for 60 days, until January 13, 1992.

The proposed agreement, announced by the FTC on October 30, would settle charges that Nu-Day falsely claimed that the Nu-Day Diet program could change consumers' metabolism and enable them to lose weight without exercising. The FTC also charged that the program-length television format Nu-Day used for making these claims was deceptive. Under the proposed settlement agreement, Nu-Day would be prohibited from making similar false and unsubstantiated claims in the future. In addition, Nu-Day has agreed to disclose every 15 minutes during any program-length television commercial that the "infomercial" is a paid advertisement.

Comments should be addressed to the Office of the Secretary, FTC, 6th St. & Pennsylvania Ave., N.W., Washington, D.C. 20580.

**NOTE:** A consent agreement is for settlement purposes only and does not constitute admission of any law violations. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions of the respondent. Each violation of such an order may result in a civil penalty of up to $10,000.

Copies of the Federal Register notice and of the news release summarizing the complaint and consent agreement are available from the FTC's Public Reference Branch, same address as above; 202-326-2222; TTY 202-326-2502.

# # #

MEDIA CONTACT: Brenda A. Mack, Office of Public Affairs, 202-326-2182

STAFF CONTACT: Timothy Hughes, Chicago Regional Office, 55 East Monroe Street, Suite 1437 Chicago, IL 60603 312-353-4431

(FTC File No. 882-3156) (Nu-Day2)

RELEASE UPON DELIVERY

STATEMENT BY

DARLA DANFORD, M.P.H., D.Sc., R.D.

DIRECTOR

DIVISION OF NUTRITION RESEARCH COORDINATION

NATIONAL INSTITUTES OF HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

HOUSE COMMITTEE ON SMALL BUSINESS

SUBCOMMITTEE ON

REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

MAY 21, 1992

Mr. Chairman, Members of the Subcommittee, I am honored to appear before you to summarize the results of the recent technology assessment conference on methods for weight loss and control and to tell you about the activities of the National Institutes of Health (NIH) in this important area. Accompanying me today is Dr. Susan Pilch, Deputy Director of the NIH Division of Nutrition Research Coordination.

## OBESITY AND WEIGHT LOSS: A NATIONAL HEALTH PARADOX

The series of hearings held by this subcommittee on the issue of obesity and weight loss has helped to focus deserved national attention on this topic. I would like to open by quoting from the introduction of the technology assessment conference panel's statement, which in my view crystallizes the problems we must address:

> A health paradox exists in modern America. On the one hand, many people who do not need to lose weight are trying to. On the other hand, most who do need to lose weight are not succeeding. The percentage of Americans whose health is jeopardized by too much weight is increasing. Thus, consideration of voluntary weight loss must encompass a continuum from persons of normal or low weight who wish to lose weight for cultural, social, or psychological reasons to severely overweight persons who suffer clear adverse medical consequences.

I will describe the background of NIH activities leading to the recent technology assessment conference, summarize the development of the conference and the findings of the independent conference panel, and discuss the ongoing activities and future plans of the NIH in the area of obesity and weight loss and control.

## BACKGROUND

The prevention and treatment of overweight and obesity have been topics of long-standing concern to the NIH. This is appropriate given that the NIH mission -- as Dr. Bernadine Healy, Director, NIH, has so aptly described it -- is science in the pursuit of knowledge to extend healthy life and reduce the burden of illness and disability. Overweight has serious adverse effects on health, well-being, and longevity. It is associated with elevated serum cholesterol, elevated blood pressure, and noninsulin-dependent diabetes. Overweight also increases risk for gallbladder disease and some types of cancer and has been implicated in the development of osteoarthritis of the weight-bearing joints.

Overweight clearly affects a large proportion of the U.S. population -- from one-fourth to one-third of adults, depending on the definition used. The prevalence of overweight is disproportionately high in women, the poor, and members of certain ethnic groups, and it contributes to the burdens of illness and disability borne by these groups. Overweight is multifactorial in origin, reflecting inherited, environmental, cultural, socioeconomic, and psychological conditions.

In 1958, Dr. Albert Stunkard succinctly summarized the results of the previous 30 years' efforts to control obesity by dietary means, stating, "Most obese persons will not stay in treatment for obesity. Of those who stay in treatment, most will not lose weight, and of those who do lose weight, most will regain it." However, as Dr. Thomas Wadden concluded in his presentation to the technology assessment conference, ". . . investigators have made significant progress in the treatment of obesity in the 30 plus years since Stunkard's review."

In order to address the unknowns in the area of obesity and weight loss and control, the NIH has over time supported research designed to provide an understanding of the fundamental causes, the health effects, and the genetic/environmental/ nutritional interactions of obesity, as well as to develop and improve methods for its prevention and treatment. For overweight as for other disorders, the conduct of research and the application of discoveries in the laboratory to the prevention and treatment of disease alone are not sufficient to fulfill the mission of the NIH -- these discoveries also must be communicated to the American public. To that end, educating the public and health professionals about the prevention and treatment of obesity has been made an important focus in many trans-NIH and interagency activities. These include:

- NIH Consensus Development Conference on the Health Implications of Obesity, sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases; the National, Heart, Lung, and Blood Institute; and the NIH Office of Medical Applications of Research, 1985
- *The Surgeon General's Report on Nutrition and Health,* 1988
- *Dietary Guidelines for Americans,* 1990
- Establishment of the NIH Nutrition Coordinating Committee's Obesity Work Group, comprising representatives of the 11 NIH institutes and centers that support obesity-related research, 1990
- The nutrition priority area of *Healthy People 2000: National Health Promotion and Disease Prevention Objectives,* 1990
- NIH Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity, sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases and the NIH Office of Medical Applications of Research, 1991

I will elaborate on more recent ongoing and planned NIH-supported research and education activities later in my presentation but will now focus on the technology assessment conference.

## TECHNOLOGY ASSESSMENT CONFERENCE

The NIH Technology Assessment Conference on Methods for Voluntary Weight Loss and Control was held March 30-April 1, 1992. I would like to provide for the record a prepublication copy of the conference panel's final statement and, with your permission, summarize the planning of the conference and some of the major findings of the panel.

### Conference Planning Process

Because of plans initiated in 1990 to pursue trans-NIH obesity research and public information activities by the NIH Nutrition Coordinating Committee's (NCC) Obesity Work Group, Dr. Bernadine Healy assigned the NCC responsibility for scientific aspects of developing the conference. The logistical aspects were the responsibility of the NIH Office of Medical Applications of Research. The structure chosen for the meeting was that of a technology assessment conference, with a format similar to that of a consensus development conference in which an independent panel is convened to review scientific evidence and address predetermined questions. Unique to the planning of this conference, however, were the following features:

- It was initiated at the highest level of the NIH, with the encouragement of this Subcommittee. That encouragement was followed up when you, Mr. Wyden, addressed the conference at its opening session.

- It was the first such conference sponsored by a trans-NIH committee rather than an individual institute.

- The extent of interagency participation was unprecedented. Input was sought and obtained in the planning process from 11 of our sister agencies to ensure that the conference would speak to issues of concern to all.

- An excellent group of 21 speakers, many of them NIH-supported researchers, presented some very interesting and provocative new data at the conference, in addition to summaries of data already in the literature. They made themselves available on extremely short notice.

A complete list of the 31 federal and non-federal partners who joined in the planning process is provided in the panel statement. What that list cannot convey is the spirit of enthusiasm and cooperation generated among the planners, speakers,

panel members, and the scientific community. That the result of this planning process was truly a coordinated and cooperative effort is exemplified in the successful outcome and continued followup.

The 3-day conference brought together scientists with expertise in obesity, clinical nutrition, nutrition, metabolism, behavior, exercise physiology, and other disciplines. The first 1 and 1/2 days were devoted to presentations by recognized experts and discussions by the audience. Evidence for diet, exercise, behavior modification, and drug treatment was considered. Information provided by academia, industry, and other sources was evaluated, and opportunity was provided for public comment. An independent, non-federal panel then weighed the scientific evidence and agreed on answers to the following key questions posed by the planning committee:

1. How often and in what ways do Americans try to lose weight?
2. How successful are various methods for weight loss and control? What are the attributes of and barriers to successful weight loss methods/approaches?
3. What are the short- and long-term benefits and adverse effects of weight loss?
4. What are the fundamental principles that should be used to select a personal weight loss and control strategy?
5. What should be the future directions for research on weight loss and control?

## Major Findings of the Conference Panel

*Question 1*

The panel reviewed data on the percent of persons trying to lose weight and the methods used from three recent federal surveys of adults and one of adolescents, including preliminary data from a new weight-loss practices survey sponsored by the Food and Drug Administration and the National Heart, Lung, and Blood Institute. In these surveys, 33-44 percent of adult women, 44 percent of female students, 20-24 percent of adult men, and 15 percent of male students reported they were trying to lose weight. Dieting or eating fewer calories and increasing physical activity were the methods reported most frequently. The data also indicated that many persons who were not overweight, particularly young women, were trying to lose weight.

*Question 2*

The panel reviewed the available scientific evidence concerning the **effectiveness of various weight loss methods** used in both commercial and academic settings, noting the following specifics:

- For most methods, including many commercial programs as well as unsupervised weight loss efforts, there are relatively few scientific studies evaluating their effectiveness and safety.

- Diets, behavior modification, exercise, and drugs produce short-term weight loss with reasonable safety in controlled settings.

- The weight losses achieved using different methods can be expected to vary according to a number of personal factors and method characteristics.

- Most people who achieve weight loss with any of these methods regain weight.

- For most overweight persons, achieving and maintaining a healthy weight is a lifelong challenge.

*Question 3*

With regard to the **short-term consequences of weight loss,** the panel noted that

- Successful weight loss improves control of noninsulin-dependent diabetes mellitus and hypertension, reduces cardiovascular risk factors, and enhances self-image.

- Fasting and very low calorie diets are associated with a variety of short-term adverse effects such as fatigue, hair loss, dizziness, and other symptoms that appear to be transitory and, more seriously, with increased risk for gallstones and acute gallbladder disease.

**Long-term health effects** are much less clear. Several epidemiological studies showed an association of weight loss with increased relative risk of mortality. Most of these studies cannot distinguish voluntary weight loss from that associated with illness, psychosocial distress, or other reasons. The relevance of these findings to voluntary weight loss programs is not yet clear; rather, they speak to a compelling research need.

*Question 4*

The panel concluded that a **fundamental principle of weight loss and control** is that for almost all people, a **lifelong commitment** to a change in lifestyle, behavioral responses, and dietary practices is necessary. Whether one should make such a commitment depends partially on the risks and benefits of losing weight compared with those of not losing weight. The panel noted the following considerations for individual decisionmaking:

- Weight loss is indicated for persons with current health problems that can be lessened by weight loss (such as sleep apnea, hypertension, or noninsulin-dependent diabetes).

- A weight control program may be appropriate to prevent further increases in weight for persons near the upper limit of the healthy weight range.

- Contraindications to nonsupervised weight loss exist for severely overweight persons, pregnant or lactating women, children, persons over the age of 65, and those with medical conditions that make such an undertaking dangerous. A trained physician or other qualified health professional should assess contraindications and screen for preexisting eating disorders or underlying psychological problems. For persons at high medical risk, a properly trained physician should be involved in a multidisciplinary approach to care throughout the weight loss process.

- Diets of 800 or fewer calories per day should not be undertaken without medical supervision and monitoring.

- For those who do not have health reasons for weight loss, the decision to lose weight should take into account the difficulty of the task, as well as the potential adverse physical and psychological consequences of weight loss regimens -- risk of poor nutrition, possible development of eating disorders, effects of weight cycling, and psychological consequences of repeated failed attempts to lose weight.

The panel noted that no matter how much weight one would like to lose, modest goals and a slow course will maximize the probability of both losing the weight and keeping it off. They recommended further that the choice of an individual weight loss method should be based not merely on weight loss goals, but should become part of a general long-term approach with the goal of better health. This goal should reflect accepted guidelines for healthful eating and include regular physical activity. The panel also noted that the most important feature of a successful weight loss program is maintenance of stable weight or of reduced weight and that, in formal programs, continued regular contact with a supervising professional may be necessary to maintain weight loss.

The panel urged that persons choosing a weight loss method or program:

- Consider a variety of personal factors in making that choice and setting a weight loss goal.

- Obtain data on effectiveness and safety and detailed information on the characteristics, including the maintenance phase, of any weight loss program they are considering before undertaking it.

- Recognize that, in any case, new behaviors must be learned and adopted, which can be difficult.

The panel concluded that methods with a primary goal of short-term rapid or unsupervised weight loss, or those that rely on diet aids (such as drinks, prepackaged foods, or pharmacologic agents) but do not include education in and eventual transition to a lasting pattern of healthful eating and activity have never been shown to lead to long-term success. Recognition of this by society and individuals and a focus on approaches that can produce health benefits independently of weight loss may be the best way to improve the physical and psychological health of Americans trying to lose weight.

*Question 5*

The panel suggested **further research is needed** in the following areas spanning the entire spectrum of health research from genetic, biochemical, physiologic, and neurophysiologic to individual, community, and population studies:

- Characterization of the genetic contribution to regulation of body weight and body fat, resting metabolic rate, and metabolic efficiency to facilitate understanding of their biochemical, physiological, and neural bases.

- Studies of how interactions between genetic makeup and environment and the effects of environment alone in early childhood may influence the development of obesity.

- Physiologic research to identify, define, and explore weight loss mechanisms, such as suppressing appetite, stimulating lipid oxidation, increasing thermogenesis, and others, that may be useful in therapy.

- Well-designed long-term clinical trials to evaluate various methods for voluntary weight loss, especially in minority populations and persons who are mildly to moderately overweight.

- Compilation of data from commercial weight loss programs on participant characteristics, attrition rates, degree and duration of weight loss, and adverse effects for all participants.

- Studies of methods to improve compliance with weight loss regimens.

- Studies to clarify the long-term effects of voluntary weight loss and weight cycling, including further analysis of existing data sets and survival studies of mortality and morbidity following voluntary weight loss.

- Population studies to determine the range of healthy weights by age, gender, and ethnicity.

- Studies of the effects and long-term consequences of obesity in childhood, as well as obesity treatment and prevention in children, and research on the prevention of obesity and unhealthy weight gain at all ages.

- Interdisciplinary research to develop and evaluate programs that encourage Americans to adopt healthful eating habits and lifestyles that will effect lifelong control of weight and deal with unhealthy cultural ideals and weight loss behaviors.

The panel concluded that because of the importance of these issues, research on the biologic and social influences on weight and weight control and the health consequences of weight and weight loss should assume a high priority on the nation's health agenda.

### Current NIH Position and Planned Followup on Panel Statement

The panel was asked to conduct an assessment of the data presented to them on methods for voluntary weight loss and control and to provide their evaluation of the state of the science. The NIH considers that the panel dealt with the questions posed to them and finds the report useful as an assessment of voluntary weight loss programs. The panel statement was finalized within the past week. The NIH institutes and centers and their scientific advisory committees will consider the statement as their research initiatives and education strategies for the public are developed.

The findings and recommendations of the panel have been provided to all federal participants in the conference and the NIH is committed to wide dissemination of the panel statement to health professionals and the public. As a direct followup to the conference, the NIH is ensuring wide distribution of the panel's final statement through various channels, publishing the panel statement in a variety of biomedical journals , and publishing the scientific papers from the conference in a peer-reviewed journal that reaches a large number of health professionals.

The NIH is impressed by the chronic nature of the problem and the need to focus on maintenance skills. We agree that overweight is a chronic condition that needs lifelong attention and is best dealt with by behavioral and lifestyle change. We also need to go beyond the issues considered by the panel and address concerns such as overweight in adolescence and childhood and the prevention of obesity.

## ONGOING ACTIVITIES AND FUTURE PLANS OF THE NIH PROGRAM IN BIOMEDICAL AND BEHAVIORAL NUTRITION RESEARCH AND TRAINING

Nutrition research is an important, cross-cutting, "trans-NIH" program area supported by 13 institutes and 4 centers at the NIH. I would like to provide for the record a copy of the *14th Annual Report of the National Institutes of Health Program in Biomedical and Behavioral Nutrition Research and Training--Fiscal*

*Year 1990.* The Nutrition Coordinating Committee (NCC) was established in 1975 to function as the forum and locus for the review and coordination of nutrition activities, helping NIH to avoid duplication of effort and to speak with one voice on nutrition. Trans-NIH coordination of nutrition research and training was established as a permanent and identifiable position at the NIH in 1988 with the creation of the Division of Nutrition Research Coordination (DNRC) within the Office of Disease Prevention in the Office of the Director. The creation of the DNRC also recognized the additional responsibilities acquired over time by the NCC. The DNRC and its NCC participate in coordinated trans-NIH activities and collaborative interagency activities at the departmental and federal levels.

With respect to the coordinated trans-NIH activities, the mandate of the NCC is to review, stimulate, and encourage the necessary support of nutrition research and training in order to define better the role of nutrition in the promotion of health and the prevention of disease. The committee identifies areas in which nutrition research and research training need to be enhanced and seeks to address these needs through joint program announcements (PAs) and requests for applications (RFAs) developed by the committee and sponsored by more than one institute. Committee representatives are also encouraged to have their individual institutes develop PAs, RFAs, and requests for proposals (RFPs).

The formation of special work groups, such as the Obesity Work Group, under the aegis of the NCC is a useful mechanism for addressing collectively cross-cutting issues and for exchanging information about individual institute plans. In addition, cooperative action is ensured by the participation in individual institute initiatives of representatives of other institutes.

The spectrum of ongoing and planned NIH activities in the area of obesity and weight loss and control encompasses the biomedical research base supported by the institutes and centers comprising the NIH Program in Biomedical and Behavioral Nutrition Research and Training. The work of NIH-supported scientists across the country already spans many of the topical areas suggested for further research by the panel. Most of the NIH support for research in the area of obesity and weight loss (as in others) is provided through the mechanism of investigator-initiated grants. With respect to weight loss methods, NIH-supported studies include investigations of lifestyle changes, such as dietary interventions, behavior modification, and increases in physical activity; drug interventions; other approaches to weight loss and control; and the effects of weight loss. A few examples of NIH-supported studies selected to illustrate work in progress specifically related to conference topics are provided in the attachment.

The Clinical Nutrition Research Units (five supported by the National Institute of Diabetes and Digestive and Kidney Diseases and three supported by the National Cancer Institute) have also been an innovative and important mechanism for focusing interdisciplinary research attention on clinical nutrition issues such as obesity, as well as strengthening training, enhancing patient care, and generating

nutritional information for the public. An RFA sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases and the National Institute of Child Health and Human Development for 4 new obesity/nutrition centers and other recent NIH activities to stimulate research efforts in obesity and weight loss are described in the attachment.

Also detailed in the attachment are two major new initiatives -- the NIDDK National Task Force on Prevention and Treatment of Obesity and the NHLBI National Obesity Education Initiative -- as well as other activities concerned with obesity and weight loss in which NIH is a sponsor or an interagency participant. The NIDDK Task Force will synthesize current scientifically based information about obesity through the development of summary documents; these documents and other information will be disseminated through the establishment of an Obesity Information Resource Center. The NHLBI Obesity Education Initiative will integrate issues related to obesity as they evolve from the Institute's other education programs and pursue a two-pronged approach (high-risk and population-based), incorporating diet and exercise.

We are proud of the initiatives the NIH has undertaken to meet the challenges of nutrition and obesity in this country.

## SUMMARY

I believe, Mr. Chairman, that we have committed ourselves to the goal of seeing that all Americans can enjoy the promise of improved health and well-being. Attaining and maintaining appropriate body weight can have significant beneficial effects on both an individual's physical and emotional health and well-being. This issue involves both the quantity (lifespan) and quality of life. We believe it is a serious issue deserving of a high priority on the nation's health agenda.

The findings of the recent NIH Technology Assessment Conference on Methods for Voluntary Weight Loss and Control have provided both discouraging and encouraging news. It helped to focus public and professional attention on the many problematic issues associated with overweight and weight loss. The conference panel's statement has also identified critical concepts that must be incorporated into our thinking about these issues. One is understanding the chronic nature of the problem of overweight which, like hypertension and other chronic conditions, requires lifelong attention. Another is recognition of the difficulty in achieving and maintaining weight loss. Nonetheless, reducing overweight, like smoking cessation, has undeniable health benefits that make it worthwhile to attempt the necessary lifestyle changes.

What can we tell the American public at this time? The situation should not be regarded as hopeless, despite the difficulties. Even though all the answers are not yet in, the best advice for today is encouragement of a personal commitment to a lifelong pattern of a balanced, healthful diet and adequate physical activity. Personal

weight loss approaches should incorporate these elements in an individualized fashion and proceed on a slow course to modest goals. Following this advice need not be an onerous task. In addition, the dietary pattern recommended for weight control may also provide the added advantage of contributing to prevention of other diet-related chronic diseases such as heart disease and cancer.

How do we impact education of the public about these issues? Encouraging lifestyle changes is challenging. In translating the results of research efforts, we have learned important lessons from the successes of several national education campaigns of the National Heart, Lung, and Blood Institute. All such federal education programs are based on scientific data and consensus, are dynamic and change with new scientific information, learn from the audiences they seek to reach, and rely on partnerships of federal and non-federal groups. The cultural and environmental characteristics of the United States in general and of particular minority groups in this country pose a challenge to the widespread acceptance of our educational messages. We believe that individuals and communities must be approached and involved with sensitivity and enthusiasm as well as scientific expertise. It is the latter that the NIH is especially well suited to develop and provide.

Our best hope for future progress lies in research to expand our understanding of the fundamental controls of body weight. The goal of NIH research is to extend healthy life and reduce the burden of illness and disability. We must assess the discouraging problems we face in the prevention and treatment of overweight and turn them into research opportunities, which we have an obligation to pursue on behalf of each American today and for the benefit of the generations of tomorrow. Just as pursuing the research opportunities identified by the 1985 Consensus Development Conference has led to important insights into the mechanisms by which obesity may cause increased health risks, meeting the research needs noted at the technology assessment conference will improve our understanding of the fundamental biology of obesity and the nature and effects of methods for voluntary weight loss and control.

We recognize that achieving progress in this area depends on individual and collective action among government, professional societies, business, industry, professional and voluntary organizations, the media, families, and individual citizens. To that end, we have developed an ambitious agenda to address the problems of obesity and weight loss, particularly as they affect individuals with other disease conditions. Today more than ever, we have the capacity -- the tools and models -- to help us meet the challenge of preventing and treating overweight, and our continued cooperative efforts indicate our commitment to do so.

Thank you, Mr. Chairman, for conducting this hearing. The NIH looks forward to working with you and other members of Congress to ensure that our research will continue with a strong focus on the important area of obesity and weight loss. I appreciate the opportunity to speak with you today and would be pleased to respond to any questions you have.

Attachment

## SELECTED EXAMPLES OF NIH-SUPPORTED RESEARCH RELATED TO METHODS FOR VOLUNTARY WEIGHT LOSS AND CONTROL

Dietary Intervention

- Protein sparing during treatment of obesity -- to define optimal composition of a weight reduction diet for treatment of obesity
- Factors affecting caloric regulation in human feeding -- to study regulation of food intake following different levels of dietary fat and carbohydrate
- Low fat ad libitum diet and weight loss -- to compare results of low-fat ad lib diet and calorie restricted diet

Behavior Modification

- Behavioral weight loss for adults with diabetes mellitus -- to examine effects of a structured exercise program and a structured very low calorie diet used singly or in combination within the context of a long-term behavioral treatment program
- Patterns of eating in lean and obese humans -- to elucidate variables that control food intake (meal size and meal frequency) and determine whether behavioral changes can either promote or interfere with weight loss
- Effectiveness of enhanced family based obesity treatment -- to examine effects of including mastery criteria on teaching eating and exercise behavior change as part of family-based treatment program for obese children
- Biobehavioral factors influencing weight in adolescents -- to develop interventions to prevent adoption of unhealthful weight reduction strategies
- Obesity treatment: self-management vs. dependence models -- to compare, in moderately obese women, effectiveness of treatment based on self-management behavioral model and that based on therapy for eating disorders

Exercise

- Physical activity and energy metabolism in aging man -- to assess how physically active and inactive lifestyles regulate appetite and resting energy metabolism in old and young men

- Noninvasive measurement of energy metabolism in man -- to apply method in studies to quantify level of physical activity needed to prevent weight gain

- Thermogenesis and exercise in lean and obese men -- to determine how exercise may improve defects in glucose and energy metabolism in the obese

- Exercise in the long-term control of childhood obesity -- to assess effects of lifestyle exercise program and/or a program designed to reduce sedentary behavior

- Growth and health study -- to assess physical activity as a factor in development of obesity and cardiovascular risk factors in black and white preadolescent girls

Culturally Appropriate Programs

- Weight loss/exercise in aged blacks with chronic disease -- to evaluate efficacy of weight loss and exercise program to improve health status

- Long-term outcome of obesity treatment in minority women -- to develop appropriate program for African American and Latino women and transfer to community for implementation by minority health professionals and lay workers

- Cross-ethnic nursing study of weight management in women -- to compare patterns and processes and develop nursing model of weight management based on experiences of Anglo, Black, and Mexican-American women

- Computer-assisted instruction in weight management -- program is being studied for appropriateness in low-literacy populations, including whites, Hispanics, and blacks

- Exploratory research center: minority adolescents' health -- includes study of body weight, diet, and exercise modulation in Hispanic teens

Effects of Weight Loss Products

- Prospective study of diet and cancer -- to examine associations of dietary constituents, including artificial sweeteners, with cancer

- Tryptophan as an adjunct to smoking cessation therapy -- to evaluate effects of tryptophan on affect and food consumption to help prevent relapse after smoking cessation

- Pharmacologic intervention for postcessation weight gain -- to study effects of nicotine gum and phenylpropanolamine gum on weight gain and withdrawal symptoms of smoking cessation

- Stress and responses to phenylpropanolamine and caffeine -- to obtain new information on safety of PPA in groups at risk for adverse reactions, e.g., oral contraceptive users or persons with family history of hypertension

Safety of Weight Loss

- Gallstone formation and prevention during weight loss -- to evaluate incidence of gallstone formation and methods for its prevention during weight loss

- Long-term outcome of obesity treatment in minority women -- to examine long-term effects of reduction to healthy weight (10% loss) on risk factors, morbidity, and mortality in African American and Latino women

- Metabolic rate and protein turnover in obesity -- to study possible metabolic disadvantage in reduced obese subjects

- Vascular/metabolic effects of repeat weight loss/regain -- to examine, as part of a broader study, effects of 3 cycles of weight loss/regain in macaca monkeys as a model for humans

Maintenance of Weight Loss

- Follow-up of behavioral childhood obesity treatment -- to provide continued followup from 5-10 years for sample of obese children and parents treated using behavioral treatments

- Weight trends, behaviors, and cardiovascular disease -- to study, retrospectively (by history) and prospectively, weight maintenance behaviors, weight trends, and behavioral differences between healthy normal weight and mildly obese adults

- Study of weight loss maintenance in severe obesity -- to evaluate new method for introducing food following a very low calorie diet



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## NEW AND PLANNED NIH-SUPPORTED ACTIVITIES RELATED TO OBESITY AND WEIGHT LOSS

### NIH EFFORTS TO STIMULATE ADDITIONAL RESEARCH IN OBESITY AND WEIGHT LOSS

- In order to encourage more research on identifying genetic and metabolic markers of obesity prior to the condition's onset in childhood, the National Institute of Child Health and Human Development and National Institute of Diabetes and Digestive and Kidney Diseases issued an RFA entitled **Genetic and Metabolic Factors in Obesity.**

- Under the auspices of the NIH NCC Obesity Work Group, the ongoing PA, **Studies on Obesity**, was issued in September 1991 by the National Institute of Diabetes and Digestive and Kidney Diseases, National Heart, Lung, and Blood Institute, National Institute of Child Health and Human Development, National Cancer Institute, National Institute on Aging, National Center for Nursing Research, National Institute of Neurological Disorders and Stroke, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute on Deafness and Other Communication Disorders, and the National Institute of Mental Health to encourage research grant applications on the biomedical and behavioral aspects of endogenous obesity, including molecular, metabolic, and genetic factors; neurological and endocrine factors; behavioral and developmental factors; and the prevention and treatment of obesity.

- In November 1991, the National Institute of Diabetes and Digestive and Kidney Diseases and the National Institute of Child Health and Human Development issued an RFA to invite proposals for **Obesity/Nutrition Research Core Centers** for conducting basic and clinical research on obesity and the related fields of energy metabolism, body composition, satiety, adipocyte metabolism, eating disorders, and weight management. The award of three Centers by the National Institute of Diabetes and Digestive and Kidney Diseases and one Center by the National Institute of Child Health and Human Development is anticipated in Fiscal Year 1992.

- To stimulate research at the molecular level on dietary factors which have direct and specific regulatory effects on gene expression, the National Institute of Diabetes and Digestive and Kidney Diseases will issue a PA on **Nutrient Control of Gene Expression.** The institute is also exploring the possibility of issuing an RFA on **Obesity in Minority Women.**

- In concert with the panel's recommendation for "interdisciplinary research to develop and evaluate prevention programs that encourage Americans to adopt healthful eating habits and lifestyles that will effect lifelong control of

weight," the National Heart, Lung, and Blood Institute has proposed a research initiative for the **primary prevention of obesity in young American Indians/Alaska Natives.** This includes a 3-year planning and feasibility study and a 6-year intervention study focusing on school-based interventions in preadolescent Native Americans.

## NEW INITIATIVES

- NIDDK National Task Force on Prevention and Treatment of Obesity

To emphasize its commitment to the area of nutrition and obesity, the National Institute of Diabetes and Digestive and Kidney Diseases has undertaken a major obesity initiative. To complement this effort, the Institute has established a National Task Force on Prevention and Treatment of Obesity to determine from a science-based perspective what is known and what should be communicated to researchers, health care providers, and the public regarding the prevention and treatment of obesity. As a by-product of this analysis, concepts will be identified for possible future clinical studies in obesity, including their relative scientific priority and estimated cost. Critical to the success of this endeavor will be development of position statement documents on such topics as: Very Low Calorie Diets for Rapid Weight Loss, Guidelines for the Assessment of the Obese Patient, Prevention Strategies, The Role of Exercise in Weight Loss and Weight Management, The Role of Behavioral Approaches in Weight Loss and Weight Management, The Role of Medications in Weight Loss and Weight Management, and the Relationship of Weight Loss to Gallstones.

The NIDDK then proposes to foster the transfer of this research knowledge to health care professionals and the public through its planned Obesity Information Resource Center. The Resource Center will act as a catalyst for national level strategy and planning in the obesity area, bringing together the products of more specialized information programs and aiding in the development of intervention programs. Representatives from the Obesity Centers, the Clinical Nutrition Research Units, the NIDDK Diabetes Research and Training Centers, and the Task Force will meet annually in an advisory capacity to report on current activities related to obesity and nutrition information. The Task Force also plans to sponsor workshops in the coming year on the Pharmacological Approach to Obesity and on Exercise Physiology and Obesity.

- NHLBI Obesity Education Initiative

In January 1991, the National Heart, Lung, and Blood Institute Obesity Education Initiative (NHLBI OEI) was initiated in order to integrate the many issues related to obesity and weight control as they evolve from the various national education programs, including the National Cholesterol Education Program (NCEP), the

National High Blood Pressure Education Program (NHBPEP), and the Smoking Education Program (NHLBI SEP), and to allow for a more effective mechanism to address obesity, and weight control per se. Obesity appears to be not only an independent risk factor for cardiovascular disease, but also increases the severity of other cardiovascular disease risk factors, such as high blood pressure and high blood cholesterol, and is associated with the pulmonary disorder of sleep apnea. The Institute has now begun a more concerted effort to educate the public and health professionals about these relationships. The role of physical activity in weight control, as well as its effects on the other cardiovascular risk factors will be an important component of the initiative.

The initiative includes a Task Force of Institute representatives and, when appropriate, experts from academia who would consider the various scientific issues related to obesity's relationship to cardiovascular disease and the risk factors. In August 1991, the Task Force convened experts for two planning meetings, one to discuss issues related to the determinants of obesity and one on the consequences and treatment issues related to obesity. The participants were asked to consider and recommend educational strategies, as well as the needs for further research. Based on recommendations from these meetings, the OEI Task Force is pursuing a two-pronged approach -- a high-risk strategy and a population-based prevention strategy.

The high-risk strategy includes providing input into the revision of two major reports, namely the NCEP's "Expert Panel Report on the Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults" and the NHBPEP's "Fifth Joint National Committee Report on the Detection, Evaluation, and Treatment of High Blood Pressure." These reports represent the consensus of medical experts concerning clinical decisions about the treatment of high blood cholesterol and high blood pressure, respectively. In addition, the OEI Task Force plans to convene an expert panel to consider indepth the issues related to the identification, evaluation, and treatment of obesity in individuals with other risk factors for cardiovascular disease.

Preventing obesity in children, adolescents, and young adults is an important focus of the population approach. In order to address many of the issues related to weight control in these groups, a Strategy Development Workshop for Public Education on Weight and Obesity is planned to examine the extent of the problem, look at available data, and consider possible target audiences and appropriate messages, as well as the various channels for getting out the different messages. The workshop will also consider in detail the information presented at, as well as the conclusions from, the recent technology assessment conference. The workshop will bring together individuals with different areas of expertise from a variety of organizations and federal agencies. Another component of the prevention strategy is providing input to the NHBPEP's Working Group on Primary Prevention which is considering weight control, diet, and exercise as important to preventing high blood pressure.

The National Heart, Lung, and Blood Institute has routinely incorporated messages pertinent to obesity, weight control, and physical activity into professional, patient, and public education materials prepared under the aegis of the NCEP, the NHBPEP, and the NHLBI SEP. The NHLBI Obesity Education Initiative represents a further commitment on behalf of the Institute to educating these various audiences about the relationship of obesity and overweight to the cardiovascular disease factors through its major national education programs, as well as through new channels specifically targeted to address this need.

## HEALTHY PEOPLE 2000

Another ongoing activity in which the NIH is participating actively, as a co-lead with the Food and Drug Administration, is the implementation phase of the nutrition objectives for **Healthy People 2000**. Because reducing the prevalence of overweight is one of the flagship objectives selected for special emphasis in the nutrition priority area, great attention is being given to establishing and promoting federal/State/community/industry partnerships to accomplish this objective.

## LECTURES, CONFERENCES, AND WORKSHOPS

- The NIH NCC Obesity Work Group sponsored a planning meeting on **Biomedical Aspects of Obesity--Prevention and Treatment** in August 1990 to identify the major issues in obesity that should be addressed by the NIH and to make recommendations on activities to address these issues.

- The National Heart, Lung, and Blood Institute sponsored a workshop on **Physical Activity and Cardiovascular Health: Special Emphasis on Women and Youth** in August 1991 to review the state of the art of science on physical activity and cardiovascular health in these two population groups, in particular, and to make recommendations regarding research opportunities and public education needs.

- The NIH NCC sponsored scientific seminars on Obesity and Physical Fitness: Challenges for the 1990s and Assessment of Human Body Composition Using Bioelectric Impedance in 1991 and on Physical Activity and Lifestyle for Better Health in 1992.

- The National Institute of Diabetes and Digestive and Kidney Diseases, in conjunction with the Nutrition Department of the NIH Clinical Center, is currently sponsoring a **Clinical Nutrition and Obesity Lecture Series.** These lectures feature nationally or internationally known speakers who are currently involved in research related to clinical nutrition or obesity, and should promote a fuller understanding of the prevention, etiology and treatment of several clinical nutritional conditions or disorders.

- The upcoming National Heart, Lung, and Blood Institute **Fourth National Minority Forum on Cardiovascular Health, Pulmonary Disorders, and Blood Resources,** scheduled for June 26 and 27 in Washington DC, will include a workshop on Health Implications of Obesity in Minority Populations. This workshop will provide participants an update on the science in these areas since the National Heart, Lung, and Blood Institute-sponsored Conference on Obesity and Cardiovascular Disease in Minority Populations in August 1990.

National Institutes of Health
Technology Assessment Statement on

# *METHODS FOR VOLUNTARY WEIGHT LOSS AND CONTROL*

March 30 - April 1, 1992

## Introduction

A health paradox exists in modern America. On the one hand, many people who do not need to lose weight are trying to. On the other hand, most who do need to lose weight are not succeeding. The percentage of Americans whose health is jeopardized by too much weight is increasing. Thus, consideration of voluntary weight loss must encompass a continuum from persons of normal or low weight who wish to lose weight for cultural, social, or psychological reasons to severely overweight persons who suffer clear adverse medical consequences.

Being overweight can seriously affect health and longevity. It is associated with elevated serum cholesterol, elevated blood pressure, and noninsulin-dependent diabetes mellitus. Excessive weight also increases the risk for gallbladder disease, gout, coronary heart disease, and some types of cancer and has been implicated in the development of osteoarthritis of the weight-bearing joints.

Body mass index (BMI, weight [kilograms]/height [meters]$^2$) is a widely used means to define overweight. (See Table 1 to convert height and weight into BMI.) Although there is agreement about the general range of BMI that constitutes a "healthy" weight, agreement on an exact range has not been established; the range varies according to age and gender, for example. Ideally, healthy weight would fall within a range of BMI levels at which morbidity and mortality rates are lowest, and "overweight" would be the BMI level at which adverse effects increase. Government and scientific groups have suggested slightly different desirable ranges of BMI, extending from 19 to 27 for adults through middle age. Obese persons have an abnormally high proportion of body fat. Most overweight persons are obese.

Approximately one quarter to one third of adults in the United States are classified as overweight, depending on the BMI cut point used. The prevalence of overweight has increased during the last two decades. The prevalence is disproportionately high in many populations, especially in women, the poor, and members of some ethnic groups.

The underlying causes of overweight are unknown. The basic mechanism is an imbalance between caloric intake and energy expenditure, but why this imbalance occurs is unclear. Evidence suggests that overweight is multifactorial in origin, reflecting inherited, environmental, cultural, socioeconomic, and psychological conditions. Increasing physiologic, biochemical, and genetic evidence suggests that overweight is not a simple problem of will power, as is sometimes implied, but is a complex disorder of appetite regulation and energy metabolism.

Many persons have a chronic tendency for becoming overweight that needs lifelong attention. Many persons attempting to lose weight use methods such as caloric restriction, exercise, behavior modification, drugs, or combinations thereof, with or without medical supervision. Some attempts may be successful in the short term, but too often the weight lost is regained. Repeated weight gain and loss may have adverse psychological and physical effects.

To evaluate methods for voluntary weight loss and control, the National Institutes of Health (NIH) Nutrition Coordinating Committee and the Office of Medical Applications of Research held a technology assessment conference 30 March to 1 April 1992. The conference brought together scientists with expertise in obesity, clinical disciplines, nutrition, metabolism, epidemiology, biostatistics, behavior, exercise physiology, and other disciplines.

Evidence for diet, exercise, behavior modification, and drug treatment was considered. Information from industry and other sources was evaluated, and opportunity was provided for public comment. Methods such as surgery, liposuction, and medical devices were not the focus, and some other important topics, including the economics and ethics of weight loss practices and regulatory issues, were not considered. Similarly, overweight and obesity in children could not be considered because the panel did not have adequate data.

The panel considered the evidence and agreed on answers to the following questions:

- *How often and in what ways do Americans try to lose weight?*
- *How successful are various methods for weight loss and control? What are the attributes of and barriers to successful weight loss methods/approaches?*
- *What are the short- and long-term benefits and adverse effects of weight loss?*
- *What are the fundamental principles that should be used to select a personal weight loss and control strategy?*
- *What should be the future directions for research on weight loss and control?*

**Table 1. Body Weights in Pounds According to Height and Body Mass Index***

| | Body Mass Index (kg/m²) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 35 | 40 |
| Height (in.) | Body Weight (lb.) | | | | | | | | | | | | | |
| 58 | 91 | 96 | 100 | 105 | 110 | 115 | 119 | 124 | 129 | 134 | 138 | 143 | 167 | 191 |
| 59 | 94 | 99 | 104 | 109 | 114 | 119 | 124 | 128 | 133 | 138 | 143 | 148 | 173 | 198 |
| 60 | 97 | 102 | 107 | 112 | 118 | 123 | 128 | 133 | 138 | 143 | 148 | 153 | 179 | 204 |
| 61 | 100 | 106 | 111 | 116 | 122 | 127 | 132 | 137 | 143 | 148 | 153 | 158 | 185 | 211 |
| 62 | 104 | 109 | 115 | 120 | 126 | 131 | 136 | 142 | 147 | 153 | 158 | 164 | 191 | 218 |
| 63 | 107 | 113 | 118 | 124 | 130 | 135 | 141 | 146 | 152 | 158 | 163 | 169 | 197 | 225 |
| 64 | 110 | 116 | 122 | 128 | 134 | 140 | 145 | 151 | 157 | 163 | 169 | 174 | 204 | 232 |
| 65 | 114 | 120 | 126 | 132 | 138 | 144 | 150 | 156 | 162 | 168 | 174 | 180 | 210 | 240 |
| 66 | 118 | 124 | 130 | 136 | 142 | 148 | 155 | 161 | 167 | 173 | 179 | 186 | 216 | 247 |
| 67 | 121 | 127 | 134 | 140 | 146 | 153 | 159 | 166 | 172 | 178 | 185 | 191 | 223 | 255 |
| 68 | 125 | 131 | 138 | 144 | 151 | 158 | 164 | 171 | 177 | 184 | 190 | 197 | 230 | 262 |
| 69 | 128 | 135 | 142 | 149 | 155 | 162 | 169 | 176 | 182 | 189 | 196 | 203 | 236 | 270 |
| 70 | 132 | 139 | 146 | 153 | 160 | 167 | 174 | 181 | 188 | 195 | 202 | 207 | 243 | 278 |
| 71 | 136 | 143 | 150 | 157 | 165 | 172 | 179 | 186 | 193 | 200 | 208 | 215 | 250 | 286 |
| 72 | 140 | 147 | 154 | 162 | 169 | 177 | 184 | 191 | 199 | 206 | 213 | 221 | 258 | 294 |
| 73 | 144 | 151 | 159 | 166 | 174 | 182 | 189 | 197 | 204 | 212 | 219 | 227 | 265 | 302 |
| 74 | 148 | 155 | 163 | 171 | 179 | 186 | 194 | 202 | 210 | 218 | 225 | 233 | 272 | 311 |
| 75 | 152 | 160 | 168 | 176 | 184 | 192 | 200 | 208 | 216 | 224 | 232 | 240 | 279 | 319 |
| 76 | 156 | 164 | 172 | 180 | 189 | 197 | 205 | 213 | 221 | 230 | 238 | 246 | 287 | 328 |

* Each entry gives the body weight in pounds (lb.) for a person of a given height and body mass index. Pounds have been rounded off. To use the table, find the appropriate height in the left-hand column. Move across the row to a given weight. The number at the top of the column is the body mass index for the height and weight. Adapted with permission from Bray, G.A., Gray, D.S. Obesity. Part I. Pathogenesis. West J. Med. 1988;149:429-41.

QUESTION 1: ***How Often and in What Ways Do Americans Try To Lose Weight?***

Who Is Trying To Lose Weight?

The frequency and nature of weight loss efforts in the U.S. population were estimated from participant self-reports in four recent Federal surveys of health practices. Data from these surveys indicate that 33% to 40% of adult women and 20% to 24% of men are currently trying to lose weight, with an additional 28% of each group trying to maintain weight. Among women and men trying to lose weight, the reported time on a weight loss regimen in the past year averaged 6.4 and 5.8 months, respectively, and the number of attempts to lose weight in the past 2 years averaged 2.5 and 2.0 attempts, respectively. Weight loss efforts were not restricted to persons with high BMI. The percent trying to lose weight varied with age (lower in the youngest and oldest persons), increased with increasing education and family income and was positively related to BMI. The percent of men trying to lose weight varied with race (highest in Hispanic men and lowest in African-American men). In women, the percent trying to lose weight did not differ by race even though a higher proportion of African-American and Hispanic women are overweight than are white women.

A self-administered questionnaire of a nationally representative sample of high school students showed that 44% of female and 15% of male students were trying to lose weight; 26% of female and 15% of male students were trying to keep from gaining weight.

Reasons For Weight Loss Efforts

Americans try to lose weight for several reasons. Many seek to improve their self-images. These people may or may not be overweight or have physical or emotional health problems caused by their weight; in fact, some are of normal or even low weight. Some persons are severely overweight by current medical standards and attempt to lose weight to reduce their risk for weight-related health problems. Some persons who are not severely overweight also attempt weight reduction to improve their perception of their health. Another reason involves our society's discrimination against overweight individuals. Some of these persons attempt weight reduction to gain greater acceptance.

Concerns about future and current health, fitness, and appearance were cited frequently by survey respondents as the most important reasons for trying to lose weight. Health concerns were cited more frequently by persons with higher BMI; appearance and fitness concerns were cited more frequently by persons with lower BMI. Appearance was more important than fitness to women, whereas the reverse was true for men. Other reasons cited included trying to lose weight gained after smoking cessation or pregnancy.

Methods Used for Weight Loss

The four national surveys asked about weight loss methods, each in slightly different ways. Among women trying to lose weight, 84% were eating fewer calories, and 60% to 63% were increasing physical activity. Among men trying to lose weight, 76% to 78% were eating fewer calories and 60% to 62% were increasing their physical activity. Use of these methods varied with race, education, income, and age.

In another survey of adults, diet and exercise were the most frequently cited methods for both men and women attempting weight loss, each at a frequency of more than 80%. Vitamins, meal replacements, over-the-counter products, participation in a weight loss program, and diet supplements were cited by both sexes in decreasing order from 28% to 3%. The methods used varied with BMI.

Students reported using the following weight loss methods in the week preceding the survey: exercise (51% of females and 30% of males), skipping meals (49% and 18%), using diet pills (4% and 2%), and self-induced vomiting (3% and 1%). The percentage of students who reported ever using these methods was generally much higher: exercise (80% of females and 44% of males), diet pills (21% and 5%), and vomiting (14% and 4%).

QUESTION 2: *How Successful Are Various Methods for Weight Loss and Control? What Are the Attributes of and Barriers to Successful Weight Loss Methods/Approaches?*

Understanding of the likelihood of success is a key element in making informed choices from among the dietary, exercise, and behavioral options for weight loss. In this section, these various weight loss methods are discussed with respect to their effectiveness in facilitating weight loss.

For most weight loss methods, there are few scientific studies evaluating their effectiveness and safety. The available studies indicate that persons lose weight while participating in such programs but, after completing the program, tend to regain the weight over time. Further, there are examples where weight loss strategies have caused medical harm. Thus, the panel cautions that before individuals adopt any weight loss program, the scientific data on effectiveness and safety be examined. If no data exist, the panel recommends that the program not be used. The lack of data on many commercial programs advertised for weight loss is especially disconcerting in view of the large number of Americans trying to lose weight and the over $30 billion spent yearly in America on weight loss efforts. Some research data and considerable anecdotal information support successful short-term loss for some users of these programs; however, data are limited on the proportion of persons who complete programs, how much weight they lose, and their success in maintaining the weight loss.

Considerable diversity in response exists within each of the broad categories of weight loss strategies. Success rates can be expected to vary according to initial weight, the length of the treatment period, the magnitude of weight loss desired, and the motivation for wanting to lose weight. The effectiveness of unsupervised efforts to lose weight is difficult to judge because of limited data on strategies, compliance, and follow-up. Surveys indicate that many overweight persons have tried to lose weight on multiple occasions; because many of these persons presumably are using these unsupervised strategies, their long-term success rates may be low.

Dietary Change

Dietary change is the most commonly used weight loss strategy. Methods range from caloric restriction to changes in dietary proportions of fat, protein, and carbohydrate or use of macronutrient substitutes. Short-term success for some of these methods has been documented, but information on long-term effectiveness and safety up to 5 years is limited. Appropriate dietary programs can have positive health effects on factors other than weight loss.

Weight loss at the end of relatively short-term programs can exceed 10% of initial body weight; however, there is a strong tendency to regain weight, with as much as two thirds of the weight lost regained within 1 year of completing the program and almost all by 5 years. Importantly, however, a small percentage of participants do maintain their weight loss over more extended periods. Key aspects of the evaluation of programs are their duration and dropout rates. The duration of most programs appears to be from several weeks to a few months. Dropout rates can be as high as 80% and seem to vary considerably.

Two levels of caloric restriction are commonly used. The low-calorie diet (LCD) of about 1,000 to 1,500 calories (approximately 12 to 15 Kcal/kg body weight) per day may involve a structured commercial program with formulated and calorically defined food products or guidelines in selecting conventional foods. The very-low-calorie diet (VLCD) at 800 (approximately 6-10 Kcal/kg body weight) or fewer calories per day is conducted under physician supervision and monitoring and is restricted to severely overweight persons. Both diets may produce adverse side effects, including excessive loss of lean body mass. Attempts to use VLCD's in unsupervised settings have been associated with severe complications. In the short term, VLCD's produce greater weight loss than do

LCD's; however, with both types of programs, participants tend to return to preprogram weight within 5 years.

There is evidence that altering the proportion of the calories in the diet from fat, carbohydrate, and protein can have a limited effect on weight loss; however, the effects appear to be quite small in comparison with the direct effect of caloric restriction.

Exercise

Weight loss that can be achieved by exercise programs alone is more limited than that which can be obtained by caloric restriction. However, exercise has beneficial effects independent of weight loss, including increased high-density lipoprotein cholesterol and an increase in lean body mass. Further, exercise can be an important adjunct to other strategies and can, if continued, diminish the tendency for rapid postprogram weight gain. The amount of weight lost through exercise usually ranges from 4 to 7 pounds. This amount is usually in addition to that lost through caloric restriction.

Behavior Modification

Behavior modification involves 1) identifying eating or related life-style behaviors to be modified, 2) setting specific behavioral goals, 3) modifying determinants of the behavior to be changed, and 4) reinforcing the desired behavior. The goal of behavior treatment is to modify eating and physical activity habits, typically focusing on gradual changes. Behavior modification can be undertaken through group or individual sessions, under the guidance of professional or lay personnel, and alone or in conjunction with other approaches.

When used alone, the typical program takes about 18 weeks and can generate a 1- to 1.5-pound/week weight loss. Typically about one third of this weight will be regained at the end of 1 year and most regained by 5 years. As with other methods, however, a small percentage of participants are able to maintain weight loss over an extended period.

Drug Treatment

In carefully controlled research programs, treatment with investigational drugs has been effective in producing weight loss. Combined with some degree of caloric restriction, weight loss with these drugs can be equivalent to that from VLCD's over comparable periods. Some studies show that prolonging use can result in a slowing of weight loss and eventually a weight plateau. Long-term benefits and complications need to be evaluated.

Phenylpropanolamine, an over-the-counter appetite suppressant approved by the Food and Drug Administration, has some efficacy in producing weight loss. The long-term benefit of this drug is not well documented, and as with other over-the-counter preparations, there is potential for its misuse.

Combination Therapies

Dietary and exercise changes and these changes, reinforced by behavior modification, are the most frequently used combination therapies. Combining changes in diet and exercise can lead to greater short-term weight loss than changes with either alone. Further, behavior modification appears to help extend the interval before weight is regained, especially if contact between the program deliverers and participants is continued and maintenance strategies are used.

Attributes and Barriers

In general, successful programs are those based on realistic goals that involve a caloric deficit leading to a slow, steady weight loss. Success requires a diet that can be adhered to long enough to reach the goal. Developing new dietary practices that could lead to a lifetime of weight control is also important. Other attributes of successful programs involve preparing the person to deal with high-risk emotional and social situations, self-monitor progress, solve problems, reduce stress, and maintain continual professional contact. Barriers to success include lack of feelings of self-efficacy, failure to lose weight early, premature termina-

tion of diet modifications or exercise or both, and lack of social and professional support. Serious underlying social or psychological problems such as depression also can be barriers to success.

The effectiveness of the different weight-loss programs may vary among different cultural groups; however, the data to evaluate this possibility are limited. As these programs are studied further, it is important to consider that some may also be effective in preventing overweight.

### QUESTION 3: *What Are the Short- and Long-Term Benefits and Adverse Effects of Weight Loss?*

Although there seems to be little doubt that overweight individuals have increased risk for morbidity and mortality, it does not immediately follow that weight loss reduces that increased risk. Understanding the health consequences of weight loss requires data on what happens to those who have lost weight. Such data should derive from either observational studies of persons who by self-report or measurement have lost weight or clinical trials in which how the weight was lost is known. Much of the longer term data come from observational studies because follow-up in trials has generally been short; however, clinical trials would provide clearer evidence of the relationship between weight loss and health.

The incidence and severity of noninsulin-dependent diabetes mellitus and hypertension in overweight persons are reduced by weight loss. Recent studies have shown that a diet and exercise program leading to weight loss can prevent the onset of hypertension and that the same may be true for diabetes mellitus. Persons with diabetes who can lose weight will improve glycemic control and may eliminate their need for oral agents. Similarly, randomized trial data indicate that weight loss in hypertensive patients is also associated with significant reductions in blood pressure and the need for continued drug therapy. Weight loss also affects other risk factors for cardiovascular disease: The positive effects on lipid and lipoprotein levels are well documented. Given the high likelihood that weight will be regained, it remains to be determined whether these time-limited improvements confer more permanent health benefits.

Among very obese individuals, weight loss has been followed by greater functional status, reduced work absenteeism, less pain, and greater social interaction. The prevalence and severity of sleep apnea also can be substantially reduced by weight loss, but monitoring for weight regain is important.

Very-low-calorie diets and fasting are associated with a variety of short-term adverse effects. Patients frequently report fatigue, hair loss, dizziness, and other symptoms, but these appear to be transitory. More serious is the increased risk for gallstones and acute gallbladder disease during severe calorie restriction. Serious complications such as cardiac arrhythmias or death, seen in early studies, have largely been eliminated by enriching diets with high-quality protein, minerals, and electrolytes.

Data on short-term adverse health effects of weight loss come from programs that only include overweight persons. Some of these effects may be greater in persons who are not overweight but are severely restricting calories. Laboratory evidence suggests that weight loss in lean persons leads to a greater proportional loss of lean body mass than in severely overweight persons and may well increase adverse effects such as fatigue.

Participants in formal weight loss programs may reduce baseline depression and anxiety, but only if they successfully lose weight. Little is known about the emotional impact of lesser degrees of success or of failure. There also is increasing evidence that mildly to moderately overweight women who are dieting may be at risk for binge-eating without vomiting and purging. Whether involvement in a well-designed dietary modification program increases the risks for bulimia is unknown and in need of careful study.

The evidence that reductions in mortality follow weight loss is meager. Most epidemiologic studies suggest that weight loss is associated with increased mortality, although in most of these studies the reason for weight loss is not known. Intentional weight loss during healthy states cannot be distinguished from that associated with illness, psychosocial distress, or other reasons. Finally, the fact that many people who stop smoking gain weight complicates the interpretation of the data on weight gainers and weight losers. Thus, although the data on higher mortality are provocative, they are not sufficiently conclusive to dictate clinical practice. Specific research efforts to address this question are urgently needed.

Data on the health effects of repeated weight gains and losses, or weight cycling, are also inconclusive. Weight cycling appears to affect energy metabolism and may result in faster regaining of weight, but the evidence that cycling has longer term negative effects on psychological and physical health needs confirmation.

Although currently used weight-reducing drugs appear to be safe in controlled studies, the studies are short term and have involved populations where the potential for abuse may be low. The fact that many adolescents and young adults use over-the-counter preparations urges further study of their safety in real-world use.

QUESTION 4: ***What Are the Fundamental Principles That Should Be Used to Select a Personal Weight Loss and Control Strategy?***

A fundamental principle of weight loss and control is that for almost all people, a lifelong commitment to a change in lifestyle, behavioral responses, and dietary practices is necessary. Whether one should make this commitment depends partially on the risks and benefits of losing weight compared with those of not losing weight. The more an individual's BMI exceeds he healthy range, the higher the risk for medical problems and the greater the need for weight reduction. Weight loss is indicated for persons with current health problems that can be lessened by weight loss (such as sleep apnea, hypertension, or noninsulin-dependent diabetes mellitus). Finally, for persons near the upper limit of the healthy weight range, a weight control program may be appropriate to prevent further increases.

Contraindications to nonsupervised weight loss exist for severely overweight persons, pregnant or lactating women, children, persons over the age of 65, and those with medical conditions that make such an undertaking dangerous. A trained physician or other health professional should assess contradictions and screen for preexisting eating disorders or underlying psychological problems. For persons at high medical risk, a properly trained physician should be involved in a multidisciplinary approach to care throughout the weight loss process. Diets of 800 or fewer calories per day should not be undertaken without medical supervision and monitoring because of attendant health risks.

For those within the healthy weight range who desire to lose weight for other reasons, such as improved appearance or sense of well-being, the decision to lose weight should take into account the difficulty of the task as well as the potential adverse physical and psychological effects of weight loss regimens. These effects include the risk of poor nutrition, possible development of eating disorders, effects of weight cycling, and the sometimes serious psychological consequences of repeated failed attempts to lose weight.

No matter how much weight one would like to lose, modest goals and a slow course will maximize the probability of both losing the weight and keeping it off. In setting goals, it should also be recognized that even in highly structured, medically supervised plans, the dropout rate is often high, and even for those who complete the program, maximum weight loss rarely exceeds 10% of the initial body weight. The rate of weight loss in these plans is

generally less than 1.5 pounds per week. In addition, if the pattern of eating and activity is not permanently altered after the conclusion of the structured portion of such programs, most participants will regain lost weight over the next 1 to 5 years. In less structured or self-monitored settings, the degree of weight loss and maintenance is unknown. These realities should help an individual avoid disappointment by providing guidelines for reasonable goals for how much weight one wants or needs to lose, how fast one wants to lose it, and how long weight loss can be maintained. These facts also should help one recognize that, for most people, achieving body weights and shapes presented in the media is not a reasonable, appropriate, or achievable goal, and thus the failure to do so does not represent a weakness of will power or character. Other characteristics to consider in setting weight loss goals include weight history, the weights of biological relatives, the outcomes of past weight loss efforts, and the individual's emotional profile.

Important considerations when choosing a weight-loss method or program include personal food preferences; the desire for structure in the program; and the degree of support in the home, workplace, or a chosen group. Logistic details to consider include time; money (for the costs of programs and special diet foods or supplements); transportation; and the ability to integrate the eating pattern of the dieter with others in the home, particularly if the dieter is a primary food preparer.

In evaluating a weight loss method or program, one should not be distracted by anecdotal "success" stories or by advertising claims. Information about program success that should be obtained includes:

- the percentage of all beginning participants who complete the program,
- the percentage of those completing the program who achieve various degrees of weight loss,
- the proportion of weight loss that is maintained at 1, 3, and even 5 years, and
- the percentage of participants who experienced adverse medical or psychological effects and the kind and severity.

Valid and reliable statistics of this kind are important but not routinely provided by commercial diet plans or programs. Such data, preferably in the form of peer-reviewed published studies, should be available for all supervised programs, including those based in hospitals or clinics.

Additional information on program characteristics that should be obtained includes:

- the relative mix of diet, exercise, and behavior modifications,
- the amount and kind of counseling: individual and closed groups (membership does not change except by attrition) are both more successful forms of counseling than open groups (in which members may come and go),
- the nature of available multidisciplinary expertise (including medical, nutritional, psychological, physiologic, and exercise),
- the training provided for relapse prevention to deal with high-risk emotional and social situations,
- the nature and duration of the maintenance phase, and
- the flexibility of food choices and suitability of food types, and whether weight goals are set unilaterally or cooperatively with the program director.

The most important feature of a successful weight-loss program is maintenance of stable weight or of reduced weight. In formal programs, continued regular contact with a supervising professional may be necessary to maintain weight loss. In any case, new eating behaviors must be learned and adopted, which can be difficult. These behaviors include modifying quantity and kinds of food, and possibly developing a different attitude toward eating and toward oneself. Therefore, an individual weight-loss method should be based not merely on weight loss goals but should become part of a general long-term approach, the goal of which is better health. This goal should reflect accepted

guidelines for healthful eating. Even though a caloric deficit must be achieved, the diet must provide all essential nutrients. A regular exercise regimen, which could be as simple as walking, is essential both to better health as well as long-term weight loss maintenance.

Methods whose primary goal is short-term rapid or unsupervised weight loss, or that rely on diet aids such as drinks, prepackaged foods, or pharmacologic agents but do not include education in and eventual transition to a lasting pattern of healthful eating and activity, have never been shown to lead to long-term success. It has been fairly said that such programs fail people, not vice versa. Recognition of this by society and individuals and a focus on approaches that can produce health benefits independently of weight loss may be the best way to improve the physical and psychological health of Americans seeking to lose weight.

QUESTION 5: *What Should Be the Future Directions for Research on Weight Loss and Control?*

The panel often had inadequate or no data with which to answer the questions about voluntary weight loss and control methods. Because voluntary weight loss has important health implications and because Americans frequently attempt it, an appropriate scientific base must be developed to maximize the chance for all Americans to achieve a healthy weight.

Evidence suggests that the causes of overweight and obesity are multifactorial. Thus, an appropriate research base must span the entire spectrum of health research from genetic, biochemical, physiologic, and neurophysiologic to individual, community, and population investigations. Research is needed within and across these areas; the biomedical perspective should be incorporated into clinical trials and population studies.

Obesity in humans has a substantial genetic basis. Numerous animal models of obesity are attributable to defects in as yet unidentified genes. Molecular genetic technology now makes identifying such genes possible in both animals and humans. Characterization of the function of the gene products should facilitate understanding of the biochemical, physiologic, and neural basis for regulation of body weight and body fat, the resting metabolic rate, and metabolic efficiency. Interactions between genetic makeup and environment or environment alone during early childhood may influence the development of obesity. Understanding basic mechanisms elucidated by gene analysis also may provide important new insights into environmentally induced weight gain.

Physiologic research is helping define weight loss mechanisms that may be useful in therapy. Mechanisms identified include suppressing appetite, inhibiting gastric emptying, blocking carbohydrate or lipid digestion, stimulating lipid oxidation, and increasing thermogenesis. These mechanisms should be explored with pharmacotherapeutic research. Further efforts should be made to identify other mechanisms. Elucidating the physiologic basis for body fat distribution is important because of its relation to health.

The paucity of well-designed, long-term clinical trials evaluating various methods for voluntary weight loss is disturbing. Particularly lacking are data on minority populations and persons who are mildly to moderately overweight. Long-term clinical trials will provide the most convincing evidence about the longer term health effects of weight loss. Methods to improve compliance with weight loss regimens and methods for long-term maintenance of weight control should receive investigative priority. More must be known about the relationship of binge-eating, dieting, and weight loss. Commercial weight loss programs should routinely compile data on participant characteristics, attrition rates, degree and duration of weight loss, and adverse effects for all participants.

Because several observational studies found weight loss was associated with increased mortality, further analysis of existing data sets and survival studies of persons losing weight volun-

tarily are urgently needed. Better studies are needed to clarify long-term psychological effects of voluntary weight loss. Physical and psychological outcomes of weight cycling deserve additional investigation.

Population studies are needed to determine better the range of healthy weights by age, gender, and ethnicity. The effects of obesity in childhood, obesity treatment and prevention in children, and long-term consequences of childhood obesity are important research priorities.

Research on the prevention of obesity and unhealthy weight gain is an area of critical need. Of special importance are prevention of unhealthy weight gain in certain minority populations and prevention of unhealthy dieting among adolescent women. Weight and voluntary weight loss practices are closely tied to cultural and societal attitudes toward weight and body image. Interdisciplinary research involving all types of behavioral scientists is necessary to develop and evaluate prevention programs that encourage Americans to adopt healthy eating habits and lifestyles that will affect lifelong control of weight. Methods must be developed to deal effectively with such problems as an unrealistically thin ideal among some women and an uncritical acceptance of dangerous overweight in certain cultures.

### *Conclusions*

One quarter to one third of Americans are overweight; many have tried a variety of methods to lose weight, with limited success in retaining weight loss. In controlled settings, diets, behavior modification, exercise, and drugs produce short-term weight losses with reasonable safety. Unfortunately, most people who achieve weight loss with any of these programs regain weight. For many overweight persons, achieving and maintaining a healthy weight is a lifelong challenge.

Successful weight loss improves control of noninsulin-dependent diabetes mellitus and hypertension, reduces cardiovascular risk factors, and enhances self-image. Long-term health effects are much less clear. Several epidemiologic studies raise the possibility that weight loss is associated with increased mortality. The relevance of these findings to voluntary weight loss programs is not yet clear.

Survey evidence also confirms that many Americans who are not overweight, particularly young women, are trying to lose weight. This practice may have significant adverse physical and psychological health consequences.

Because of the importance of these issues, research on the biologic and social influences on weight and weight control and the health consequences of weight and weight loss should assume a high priority on the nation's health agenda.

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"Long-Term Benefits and Adverse Effects of Weight Loss: Long-Term Effects of Change in Body Weight on All-Cause Mortality"

Richard L. Atkinson, M.D.
"Setting Standards for Success"

George L. Blackburn, M.D., Ph.D.
"Comparison of Medically Supervised vs. Nonsupervised Approaches to Weight Loss and Control"

Steven N. Blair, P.E.D.
"Evidence for Success of Exercise in Weight Loss and Control"
"Long-Term Benefits and Adverse Effects of Weight Loss: Data From Two Prospective Epidemiological Studies"

George A. Bray, M.D.
"Evidence for Success of Drug Treatment in Weight Loss and Control"

John P. Foreyt, Ph.D.
"Evidence for Success of Behavior Modification in Weight Loss and Control"
"Attributes of Successful Approaches to Weight Loss and Control and Barriers to Success"

Walter H. Glinsmann, M.D.
"Evidence for Success of Caloric Restriction in Weight Loss and Control: Summary Data From Industry"

Millicent Higgins, M.D., D.P.H.
"Long-Term Benefits and Adverse Effects of Weight Loss: Observations From the Framingham Heart and CARDIA Studies"

James O. Hill, Ph.D.
"Evidence for Differential Success of Caloric Restriction Depending on Composition of Diet"

Jules Hirsch, M.D.
"Pathophysiology of Obesity"

John Horm, M.Sc.
"Who in America Is Trying to Lose Weight: National Health Interview Survey"

Robert W. Jeffery, Ph.D.
"Evaluation of Community-Based Approaches to Weight Loss and Control"

Shiriki K. Kumanyika, Ph.D., R.D., M.P.H.
"Special Issues Regarding Obesity in Minority Populations"

Alan S. Levy, Ph.D.
"Characteristics of Weight Loss Regimens: Weight Loss Practices Survey"

Elsie R. Pamuk, Ph.D.
"Long-Term Benefits and Adverse Effects of Weight Loss: Weight Loss and Mortality in a National Cohort of Adults, 1971-1987"

F. Xavier Pi-Sunyer, M.D., M.P.H.
"Medical Hazards of Obesity"
"Short-Term Medical Benefits and Adverse Effects of Weight Loss"

Judith Rodin, Ph.D.
"Cultural and Psychosocial Determinants of Weight Concerns"

Mary Serdula, M.D.
"Weight Control Practices in U.S. Adolescents and Adults: Youth Risk Behavior Survey and Behavioral Risk Factor Surveillance System"

Thomas A. Wadden, Ph.D.
"Evidence for Success of Caloric Restriction in Weight Loss and Control: Summary Data From Clinical Research Studies"

David F. Williamson, Ph.D., M.S.
"Descriptive Epidemiology of Body Weight and Weight Change in United States Adults
"Long-Term Benefits and Adverse Effects of Weight Loss: A Review of the Evidence That Weight Loss Is Associated With Increased Longevity"

G. Terence Wilson, Ph.D.
"Short-Term Psychological Benefits and Adverse Effects of Weight Loss"

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June 18, 1992

Mr. Graydon J. Forrer
Counsel
Subcommittee on Regulation, Business
Opportunities and Energy
Committee on Small Business
House of Representatives
Rayburn Building, Room B-363
Washington, DC 20515

Dear Mr. Forrer:

The following text is for insertion of page 66 of the transcript from the May 21 hearing on commercial diet programs and NIH diet research. This text is provided to answer the questions that Representative Wyden asked.

Please feel free to contact me (301-496-9281) for further information.

Sincerely,

Darla E. Danford, M.P.H., D.Sc., R.D.
Director
Division of Nutrition Research Coordination

Enclosure

cc: DLA/OD

Response to Questions from Mr. Wyden at May 21, 1992 Hearing
of the Subcommittee on Regulation, Business Opportunities and Energy

**QUESTION 1 - FUNDING FOR OBESITY AND WEIGHT LOSS RFAs AND PAs**

The Requests for Applications (RFAs) and Program Announcements (PAs) for which the current and projected status are described are part of the broader research portfolio on obesity supported by the institutes and centers at the National Institutes of Health. The funding levels follow:

**RFA - Genetic and Metabolic Factors in Obesity**

The RFA was released in February 1990 by the National Institute of Child Health and Human Development (NICHD) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

The NICHD funded four research projects in FY 1991 with total costs of $824,000. The estimated FY 1992 funding level for these projects is approximately $828,000. The estimated FY 1993 funding level is approximately $832,000.

The NIDDK funded four research projects at $875,443 in FY 1991. The estimated FY 1992 funding level for these projects is $899,577. The estimated FY 1993 funding level is approximately $900,000.

**PA - Studies on Obesity**

The PA was issued in September 1991 by the National Institute of Diabetes and Digestive and Kidney Diseases, National Heart, Lung, and Blood Institute, National Institute of Child Health and Human Development, National Cancer Institute, National Institute on Aging, National Center for Nursing Research, National Institute of Neurological Disorders and Stroke, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute on Deafness and Other Communication Disorders, and the National Institute of Mental Health.

Responses to this ongoing Program Announcement are just beginning to be tracked. Although support for projects responsive to a program announcement is not specifically earmarked, the institutes and centers issue a PA with the intent to support meritorious applications.

**RFA - Obesity/Nutrition Research Core Centers**

The RFA was released in November 1991 by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Child Health and Human Development (NICHD).

The NIDDK plans to fund three Obesity/Nutrition Research Centers in FY 1992 at a total cost of $2 million. The projected cost for FY 1993 for these Centers is $2 million.

The NICHD plans to fund one Obesity/Nutrition Research Center in FY 1993 at a cost not to exceed $700,000.

**PA - Nutrient Control of Gene Expression**

This Program Announcement was issued on May 8, 1992, by the National Institute of Diabetes and Digestive and Kidney Diseases.

Applicants will compete for available funds, but it is not possible to project at this time what the response will be.

**RFA - Obesity in Minority Women**

The initiative on obesity in minority women is still in the early planning phase at the National Institute of Diabetes and Digestive and Kidney Diseases.

**RFA - Obesity Prevention in American Indians/Alaska Natives**

The National Heart, Lung, and Blood Institute's research initiative "Request for Research Cooperative Agreement Applications: RFA (NIH-92-HA-01) Obesity Prevention in American Indians/Alaska Natives" invites applications for five Field Centers and one Coordinating Center. This solicitation is for a 3-year planning and feasibility study of a planned 9-year effort. A total of approximately $6.3 million (including direct and indirect costs) over a 3-year period beginning with FY 1993 will be awarded for the five Field Centers and the Coordinating Center. Awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

**QUESTION 2 - TOTAL FUNDING FOR OBESITY RESEARCH**

Actual expenditures by the NIH for obesity research were $48.9 million in FY 1990 and $54.6 million in FY 1991. Estimated expenditures for FY 1992 are $59.3 million, and the FY 1993 request is $62.1 million. From FY 1990 to FY 1991, expenditures for obesity research increased 12 percent; in the same period, the total NIH research expenditures increased 8 percent.

**TESTIMONY**
**BEFORE THE COMMITTEE ON SMALL BUSINESS**
**OF THE**
**UNITED STATES HOUSE OF REPRESENTATIVES**

**May 21, 1992**

Mr. Chairman, I am Jules Hirsch, a research physician at the Rockefeller University in New York City. My full curriculum vitae is appended to my written testimony, but the central items of my professional involvement, most important to the deliberations of this committee are that, for thirty-eight years I have been involved in research at the Rockefeller University and I now lead its clinical investigative group as Physician-in-Chief of the Rockefeller University Hospital. My major research interests have been in lipid or fat metabolism and most particularly the nature, composition and biochemical activity of adipose or fatty tissue. These interests have led me to become concerned with human obesity and related problems of human nutrition.

When I began my research, it was widely believed that obesity came about as a matter of careless behavior or a lack of nutritional information. It was thought that a combination of a special diet with will power and good common sense was all that was needed for the treatment of obesity and for its prevention. Over the years of my research, many types of diets have been recommended as rapid and effective treatments of obesity. At one time carbohydrate was thought to be a chief offender, hence diets high in fat, producing ketosis, a biochemical state related to carbohydrate restriction, were widely advocated. Diets high in protein or diets low in protein have been recommended. Diets utilizing specific food stuffs, such as grapefruit, have also had their avid proponents. What has become increasingly clear, is that no such special diets have been found to be the answer to the problem of obesity. Nevertheless, the public continues

its search for simple effective treatments.

Why the American public should be concerned about obesity was addressed in February, 1985, at a Consensus Conference of the National Institutes of Health. I was asked to chair that conference, at which a panel of experts addressed the definition of obesity, the evidence that obesity has adverse effects on health, and what these adverse effects might be. The conclusions are worth recalling. Convincing evidence was adduced that obesity, defined as excessive storage of energy in the form of fat, does have adverse effects on health and longevity. It was pointed out that using a conservative definition of obesity, as many as thirty-four million adult Americans were obese in 1985. Furthermore, it was established that obesity is associated with hypertension, hypercholesterolemia, diabetes, and excess prevalence of certain cancers. These findings have been central to the advice given to the public by many national groups. The Surgeon General's report, reports from the Heart Association and from the National Academy of Sciences, all place weight reduction or the prevention of obesity, high on their list of recommendations as to what the American public can do to promote health. The more recent report of the Department of Health and Human Services entitled, "Healthy People 2000," implicates dietary factors among the leading causes of death and obesity is again targeted as an important area for consideration.

If defining obesity and repeatedly reminding the American public of its hazards were all that it is needed, then surely we would be on the way to becoming a slimmer and healthier nation. We have had much better success in reducing cigarette smoking or in the use of seat belts in automobiles. But, in the matter of obesity, there is very little evidence that our concern has led to effective treatment or prevention.

In order to analyze this situation, the National Institutes of Health on March 30 - April 1, of this year, had a Technology Assessment Conference on the subject of Methods for Voluntary Weight Loss and Control. An expert panel examined the current status of weight reduction, as offered by various commercial groups, as well as by medical and scientific investigators. It was noted that:

"A health paradox exists in modern America. On the one hand, many people who do not need to loose weight are trying to do so. On the other hand, the percentage of Americans whose health is jeopardized by too much weight is growing. Most who need to loose weight are not succeeding."

As with the consensus conference in 1985, the recent meeting at NIH found that one-fourth to one-third of Americans are seriously overweight or obese. Furthermore, various surveys indicated that thirty-three to forty percent of adult women and twenty to twenty-four percent of men are currently trying to loose weight. Some ethnically or economically disadvantaged groups have a higher prevalence of obesity than the general public, and yet these groups are less likely to perceive themselves as being obese, and therefore, less likely to avail themselves of treatment programs. Those who are attempting weight loss do so to improve their self image, or because of their perception that overweight is unhealthy, and often, because of our society's lack of acceptance of overweight individuals. In general, the methods used for weight loss are eating fewer calories with or without efforts to increase physical activity. A variety of vitamin preparations, meal replacements, over the counter drug products and participation in weight loss programs, are regularly listed as the methods used for attempting to loose weight. These techniques for weight loss constitute a multi-billion dollar business. Some

estimates place the total cost for efforts at weight control or weight reduction, as high as thirty billion dollars per year.

The panelists at the technology assessment meeting were presented with an analysis of data on the efficacy, as well as potential harm of programs currently in use. It is generally agreed that individuals who enter any of the available commercial programs, may do so with high resolve and therefore, lose weight in the short run. There is, however, a high drop out rate. No statistically sound evidence was presented at the conference to indicate that commercial, non-medical programs have any enduring efficacy. When various programs with physician oversight and medical involvement were evaluated, it was found that approximately 50% of those who begin such programs, drop out within the first year. Of those who remain, a third to one-half will loose a significant amount of weight and maintain a majority of the weight loss for a one year period. Data for continued success beyond one year are very few. The consensus is that, by two years and surely by five years, the majority of subjects beginning any weight loss program will have returned to their starting weight. Probably fewer than 5% of those beginning the program will loose the weight and maintain it for as long as five years.

It is medically hazardous to be obese, but weight reduction has hazards as well. Very low calorie diets with less than 800 calories per day carry the risk of a variety of minor symptoms such as dizziness and hair loss, and more serious problems, such as the development or worsening of gall bladder disease and possibly cardiovascular risks.

It is clear to all, Mr. Chairman, that obesity is now our most prevalent nutritional disorder. Weight reduction is important for health and even a minor degree of weight reduction can improve co-existent diabetes or hypertension, yet it is extremely difficult for individuals to

maintain weight loss. Most experts feel that nothing short of a change in lifestyle, incorporating new patterns of food intake, physical activity, and methods of behavior modification are likely to effect lasting weight loss. When all of these techniques are combined in the best of treatment facilities, long term maintenance of reduced weight still remains a difficult goal to achieve.

How did this unfortunate situation come about? The development of obesity can only occur when there is an imbalance of food intake, such that the calories consumed exceed the calories expended by physical activity. There is no doubt that our society has a plenitude of attractive foods, widely available, and many aspects of modern life make it easier for us to expend fewer calories. In short, the "good life" is considered to be one in which highly attractive, deliciously flavored, foods are available and the need for strenuous activity is minimized. But, modern research also shows that there are fundamental cellular or biological mechanisms, which make some individuals particularly susceptible to the obesity producing factors in our society. Thus, genetic factors, as well as environmental factors acting during early development are important. The reasons for obesity, therefore, are to be found in a mixture of genetic, developmental and psycho-social factors. To attack this problem only at the psycho-social level, which is currently what we are doing, is simply not effective.

Almost every kind of dietary manipulation has been tried. Many commercial programs promise the obese individual that their particular approach to weight reduction is one in which weight loss is achieved rapidly and easily and when the weight is lost, the obesity will remain forever banished. This has not been the experience of those who treat obesity and is in fact, not a reasonable result to be expected with what we now know about the complex roots of this illness.

What is missing, is more fundamental understanding of energy metabolism in man. We know very little as to how calorie intake and calorie outgo are precisely equalized in the majority of the population, who never have a problem with obesity. By the same token, we have very little information as to why some individuals have a transient inequality of calorie intake and outgo, which leads to the production of obesity. In the obese state, the equation of calorie intake and outgo equalizes again. Although we as a nation expend billions in our search for a successful therapy, our expenditure is only in the millions for attempting to understand this illness in fundamental, scientific terms that will lead to successful treatment.

It is important at this point to remember that obesity is only one member of the list of nutritional concerns of the American public. It may head the list, but there are other concerns for which we also have no sure answers. Americans spend large sums on the purchase of vitamins and on attempts to regulate their diets in a variety of ways so as to prevent or ameliorate illness. In many instances, the scientific basis for or against such practices has not been established.

It is extremely important that the American public know the truth about these matters. Obesity is detrimental to health, but currently available treatments are not likely to be successful in the long run. This fact and the hazards of very low calorie or unusual diets, must be made clear to the consumer. Most importantly, however, the American public must realize that without further scientific information, this unfortunate situation is not likely to be rectified.

The National Institutes of Health are committed to the development of scientific programs to tackle these difficult issues. The consensus program of 1985 and the more recent Technology Assessment Conference sponsored by NIH are means of informing the public. Various institutes

of NIH have for more than ten years been attempting to bring the new sciences of molecular genetics and cell biology into clinical nutrition. Clinical Nutrition Research units, at which basic and clinical scientists work together to investigate problems of human nutrition, have been developed across the nation. I am pleased to note that the one clinical research unit emphasizing obesity research in this country will shortly be joined by others. The National Institute of Diabetes, Digestive and Kidney Diseases along with the National Institute of Child Health and Human Development are now considering proposals for new clinical nutrition research units emphasizing obesity research and it is likely that an additional three or four such units will be established shortly.

Mr. Chairman, this is a time when the fruits of modern biological science must be brought to bear on clinical issues. Clinical nutrition, which is of desperate importance to the American public and to those who wish to prevent illness, has not been accorded the urgency it deserves by biomedical scientists. To be sure, nutritional problems are difficult to attack, often requiring groups of investigators acting in concert over long periods of time, in studies utilizing human subjects. This makes for expensive, complex research, sometimes not leading to the same type of definitive results obtained from tissue cultures or simple systems, which can be more readily summarized and published in the basic scientific journals. But, with the advances of biomedical science, it is now possible to invigorate clinical nutrition with the fundamental biological sciences. To this end, an expansion of Clinical Nutrition Research Units, as well as specialized centers of research and nutrition, are very much needed. Too often these efforts have been scattered among the various institutes of the NIH and in other government agencies. As the NIH examines its strategic goals, it must, of course, emphasize support of the

basic biomedical sciences as it has done so well in the past. It has, however, the additional task of bridging the gap between basic information and clinical needs.

Programs to develop clinical investigators armed with the techniques of modern biomedical science, but committed to the study of energy metabolism in man, are the only sure way to develop effective techniques for the prevention and treatment of obesity. Lamenting the current inadequacy of treatment, warning the American public of the inefficacy of current treatment, and regulating those treatments which are unfairly presented to the public are all worthwhile endeavors. But, what most needs to be done is to develop the science of nutrition so that best scientists and physicians will utilize modern methods in behalf of understanding our nutritional disorders and then make programs of certain efficacy available to the American public.

Mr. Chairman, you have already indicated your deep concern with this matter. I urge you to assist me and my colleagues in the nutritional sciences and in clinical investigation, to enlarge our opportunities for fundamental research and to support the newly developed mechanisms within NIH which will foster collaboration between basic scientists and clinical nutritionists. Please join us as we speak for the need of a trans NIH commitment to Clinical Nutrition Research Units and to specialized centers of research in nutrition. These innovations are less costly than further surveys or clinical trials and at this stage of our understanding, are much more likely to yield the information we need to make nutritional science a mainstay of disease prevention and health maintenance.

- The upcoming National Heart, Lung, and Blood Institute Fourth National Minority Forum on Cardiovascular Health, Pulmonary Disorders, and Blood Resources, scheduled for June 26 and 27 in Washington DC, will include a workshop on Health Implications of Obesity in Minority Populations. This workshop will provide participants an update on the science in these areas since the National Heart, Lung, and Blood Institute-sponsored Conference on Obesity and Cardiovascular Disease in Minority Populations in August 1990.



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# CURRICULUM VITAE

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## EDUCATION

| | |
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| 1943-44 | Rutgers University, New Brunswick, New Jersey |
| 1945-48 | Southwestern Medical School, University of Texas - Dallas, Texas |

## PROFESSIONAL EXPERIENCE

| | |
|---|---|
| 1992- | Physician-in-Chief, Rockefeller University Hospital |
| 1988- | Sherman Fairchild Professor, Rockefeller University |
| 1985- | Senior Attending Physician, St. Luke's-Roosevelt Hospital |
| 1967- | Professor, Rockefeller University and Senior Physician to The Rockefeller University Hospital, New York |
| 1960-67 | Associate Professor, Rockefeller University and Physician to The Rockefeller University Hospital, New York |
| 1956-60 | Assistant Professor, Rockefeller University and Associate Physician to the Hospital, New York |
| 1955-56 | Assistant, Senior Assistant Physician, Rockefeller Institute for Medical Research, New York |
| 1954-55 | Assistant, Assistant Physician, Rockefeller Institute for Medical Research, New York |
| 1952 | Instructor in Medicine, Upstate Medical Center, Syracuse, N.Y. |
| 1951-52 | Resident in Medicine, Upstate Medical Center, Syracuse, N.Y. |
| 1950-51 | Assistant Resident in Medicine, Upstate Medical Center, Syracuse, New York |
| 1948-50 | Intern in Pathology and Medicine, Duke University Hospital, Durham, North Carolina |

Curriculum Vitae (continued)
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OTHER POSITIONS

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| 1991- | Fellow, Royal College of Physicians, Edinburgh |
| 1991- | Member, Committee on Med. in Society, N.Y. Academy of Medicine |
| 1990- | Chairman, Awards Committee, N.Y. Academy of Medicine |
| 1989- | Member, Advisory Council, NIDDK (NIH) |
| 1989-93 | Councillor, Society for Experimental Biology and Medicine |
| 1989-92 | Member, Public Affairs Committee, AIN/ASCN |
| 1989-90 | Chairman, Section N, Medical Sciences Committee, AAAS |
| 1988- | Director, The Pew Center for Excellence in Nutrition |
| 1988 | Fellow, The New York Academy of Medicine |
| 1987- | Member, Board of Directors, NutraSweet Company |
| 1986- | Adjunct Professor of Medicine, Columbia University |
| 1986- | Member, Mental Health and Behavioral Medicine Board, Institute of Medicine, National Academy of Sciences |
| 1986- | Member, Medical Advisory Board Hadassah Medical Organization |
| 4/86-4/87 | President, American Psychosomatic Society |
| 1985- | Scientific Consultant, Hoffman-La Roche Inc. |
| 2/84 | Chairman, NIH Consensus Development Conference on the Health Implications of Obesity |
| 1984- | Chairman, Institutional Reyiew Board, Rockefeller University |
| 1984-87 | Member-at-Large, American Association for the Advancement of Science, Section N, Medical Sciences Committee |

Curriculum Vitae (continued)
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OTHER POSITIONS

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| 1983-86 | Associate in the Columbia University Seminar on Appetitive Behavior |
| 1983- | Member, Subcommittee on Nutrition, The New York Academy of Medicine |
| 1983 | Co-Chairman, 4th International Congress on Obesity, New York |
| 1982-87 | Member, Clinical Sciences Panel, Institute of Medicine, National Academy of Sciences |
| 1982-85 | Chairman, Medical Advisory Board, Hadassah Medical Organization |
| 1978-79 | President, American Society for Clinical Nutrition |
| 1977-78 | Consultant, NIH Nutrition Coordinating Committee |
| 1975- | Adjunct Professor of Medicine, Cornell University Medical College |
| 1975- | Clinical Affiliate, The New York Hospital |
| 1972-74 | Councilor, American Society for Clinical Nutrition |
| 1972 | Councilor, Society for Experimental Biology and Medicine |
| 1971-75 | Advisory Board, Department of Mental Health and Mental Retardation Services, New York |
| 1968-72 | Member of Nutrition Study Section, NIH |
| 1968-71 | Member of the Council of the American Psychosomatic Society |
| 1967-70 | Advisory Board, Young Adult Institute |
| 1967 | Lecturer, New School for Social Research |
| 1966-68 | Executive Committee Member, Council on Arteriosclerosis, American Heart Association |

Curriculum Vitae (continued)
Jules Hirsch, M.D.

| | |
|---|---|
| 1965-66 | Member, Advisory Council, National Assoc. for Mental Health |
| 1963- | Member, Advisory Board, Vice President and President, Association for Mentally Ill Children of Manhattan |
| 1962-69 | Bd. of Directors, Scientists' Committee for Public Information |
| 1961 | Chairman, Gordon Conference on Lipid Metabolism |
| 1960-74 | Advisory Board, Journal of Lipid Research |
| 1957-67 | Vice Chairman, Scientists' Institute for Public Information |

FELLOWSHIP AND DIPLOMATE

| | |
|---|---|
| 1987 | Advanced Achievement in Internal Medicine, |
| 1982 | Fellow, American Assoc. for the Advancement of Science |
| 1971 | Fellow, American College of Physicians |
| 1967 | American Board of Nutrition |
| 1957 | American Board of Internal Medicine |

EDITORSHIP

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| 1992- | Section Editor, OBESITY RESEARCH |
| 1991- | Publications Committee, NAASO |
| 1991- | Editorial Board, The Weight Control Digest |
| 1989- | Editorial Board, Journal of Nutritional Biochemistry |
| 1989- | Associate Editor, Rx Nutrition, Health Learning Systems Inc. |
| 1989- | Advisory Board, Journal of Internal Medicine (Sweden) |
| 1977- | Editorial Board, International Journal of Obesity |
| 1968- | Editorial Board, Psychosomatic Medicine |
| 1967- | Editorial Board, Medical Letter |
| 1962-67 | Editorial Board, Journal of Nutrition |
| 1959-79 | Associate Editor, Journal of Lipid Research |

CURRICULUM VITAE (continued)
Jules Hirsch, M.D.

MEMBERSHIP
Alpha Omega alpha
Harvey Society
Sigma Xi
American Association for the Advancement of Science
American Federation for Clinical Research
American Institute of Nutrition
American Medical Association
American Oil Chemists Society
American Society for Clinical Investigation
American Society for Clinical Nutrition
Council on Arteriosclerosis of the American Heart Association
Society for Experimental Biology and Medicine
American Psychosomatic Society
Association of American Physicians
American College of Physicians
Academy of Behavioral Medicine Research
Royal College of Physicians, Edinburgh

HONORS/AWARDS
Distinguished Alumnmus Award, Southwestern Medical School
The McCollum Award of the American Society for Clinical Nutrition
Honorary Doctor of Science, State University of New York, May, 1988.

MILITARY SERVICE
SA Surgeon and Lieutenant Senior Grade with USPHS and U.S. Coast Guard on active duty: August, 1952-August, 1954. Present rank in USPHS - Medical Director. Active duty in 1983: 3 days as Captain, U.S. Coast Guard

PUBLICATIONS
Jules Hirsch, M.D.

Blankenhorn, D.H., J. Hirsch and E.H. Ahrens, Jr. Transintestinal intubation for measurement of gut length and physiologic sampling at known loci. Proc. Soc. Exp. Biol. Med. 88:356-362, 1955.

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Jules Hirsch, M.D.

Stern, J.S., J. Hirsch. Obesity and pancreatic function. In: N. Freinkel and D.F. Steiner, eds. The Handbook of Physiology, Vol 1, Section 7. Waverly Press, Baltimore, pp. 641-651, 1972.

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Publications (continued)
Jules Hirsch, M.D.

Czajka-Narins, D.M. and J. Hirsch. Supplementary feeding during the pre-weaning period. Biol. Neonate 25:176-185, 1974.

Stern, J.S., P.R., Johnson, B.R. Batchelor, L.M. Zucker and J. Hirsch. Pancreatic insulin release and peripheral tissue resistance in Zucker obese rats fed high and low carbohydrate diets. Am. J. Physiol. 228:543-548, 1975.

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Publications (continued)
Jules Hirsch, M.D.

Hirsch, J. A model for feeding behavior and obesity. In: D. Booth, ed. Hunger Models, Academic Press, London, pp. 61-70, 1978.

Hirsch, J., I.M. Faust and P.R. Johnson. What's new in obesity: Current understanding of adipose tissue morphology. In: Norbert Freinkel, ed. Contemporary Metabolism, Vol. 1, Plenum Press, pp. 385-399, 1978.

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Jules Hirsch, M.D.

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Testimony of
Arthur Frank, M.D.
before the
Subcommittee on Regulation,
Business Opportunities and Energy
of the
Committee on Small Business
of the
United States House of Representatives
May 21, 1992

Congressman Wyden and members of the Committee.

My name is Arthur Frank. I am a biochemist and a physician. For over thirty years I have been studying the physiology of fat metabolism. My medical specialty is internal medicine. Most of my practice deals with the medical problems of obese patients. I have talked to, cared for, struggled with, and shared the achievements and disappointments of over 4000 patients since 1977.

I am the medical director of the George Washington University Obesity Management Program, part of a consortium of medical school based obesity management programs. I work with a staff of physicians, dietitians, psychotherapists, counsellors and exercise therapists. We have as comprehensive a system for the management of obesity as can be devised.

Obese patients have a remarkably complex metabolic disease which is related to incompletely understood medical, psychological and environmental factors. It is difficult enough

to have this disease but at least three non-medical factors complicate its management.

First, almost everyone views obese patients and their disease with contempt. They are regarded as weak people out of control of their lives. Their eating patterns are thought to be willful misconduct.

Second, many health professionals to whom they turn for help hold the same contemptuous view and these professionals can provide very little effective care. What is provided by counsellors in commercial programs or by less than qualified professionals may be well intentioned, but is too often insufficient or incompetent. Too often also it is provided with a generous amount of exploitation and quackery.

Finally, the social and medical consequences of obesity are so substantial that patient care decisions are driven by desperation. Bad medical decisions are made when people are desperate.

This sounds dreadful, but what we have is a remarkable opportunity to make some improvements.

First, to soften the harshness of these comments, I would like to consider what is right about the management of obesity.

We now have a much better understanding of the metabolism of the disease. Given the meager resources devoted to research, a small group of dedicated scientists, including Jules Hirsh and Tom Wadden (who are here to speak to you today), have accomplished more in the past decade than has been known since the beginning of time about how humans eat and how body weight is regulated. We now recognize that obesity is a disease of metabolic regulation and we now understand some of the parts of the physiology and psychology of eating behavior.

What is right also is that we have made substantial progress in treating obesity although the system still fails adequately to provide this proper treatment. Thirty five years ago Albert Stunkard, another of the pioneering obesity experts, said in what surely was a moment of despair, "Most obese persons will not stay in treatment for obesity. Of those who stay in treatment, most will not lose weight and, of those who do lose weight, most will regain it."

In 1992 two of these three statements are no longer true. In a comprehensive treatment program, such as ours at George Washington University, most people will stay in treatment and most people will lose weight. It is clear that people who do well are people who are determined to do well, who can utilize the structure we create and who can sustain the enormous amount of effort required for control of this disease. Success for our

patients depends on the availability of a comprehensive program and the intensity of the patient's effort.

What is wrong is that we don't have enough comprehensive programs. Much like the treatment of cancer or of pain what is needed is a multidisciplinary approach with the skills of trained professionals. A high tech approach can work.

Can a simple low tech approach work? Sometimes it will, but for many it is a trivialization of a complex medical problem. It will often work for the uncomplicated patient, typically with small amounts of weight to lose who needs dietary information and support. It is a dangerous approach for the 250 lb., fifty year old diabetic who has complex family stress and overlying depression.

There is diffuse confusion about what is best for the management of obesity. Let me try to give you the perspective of a physician who has dealt with this problem every day for the past fifteen years. I would like then to suggest a format for a partial solution to the issues under consideration.

First the problems:

1. Patients don't know where to go. They bounce from one program to another, from one hope to another, and from one disappointment to the next. They tend to choose the current

fad program which is often the one with the most glitter and advertising hyperbole. Today's fad is most likely to be the program with the snake oil in the fanciest package.

2. Professionals are just as confused about how patients should be treated. The most conservative approach will be fine for some and a waste for others. The patient who has spent a lifetime struggling unsuccessfully with calorie counting and menu planning may need, and may do well, with a more aggressive program.

3. Obesity is not a single disease and it is not a curable disease. It is naive to think that any one program will solve the problem or will be suitable for all patients. Anything that will be helpful depends on the program's flexibility and ability to respond to the needs of each individual patient. We can not cure obesity any more than we can cure diabetes, but we can reasonably expect many patients to manage it with comfort and dignity.

4. Too few practitioners are well trained at any level of skill. Counsellors and those untrained managers of commercial weight loss programs can be helpful with caring and compassion, but they can do dreadful damage when they deal with those who are too sick or too complex for their skills.

5. Commercial weight loss programs often take on more than their personnel are trained to manage. They offer an elaborate pretense of substance and they almost always fail completely at maintenance. They offer treatment from people who are not sufficiently qualified to respond to the unique problems of each individual patient.

6. The cost is high. Prepackaged meal replacements are expensive and skilled professionals are expensive. But, the squandering of resources in the current system is also expensive. I suspect that good programs, properly run by skilled providers, will be less expensive than the fraud, waste and abuse in the chaos of modern mismanagement.

7. Most health insurance companies have elected not to pay for the treatment of this disease. Ironically, the obese patient, whose obesity complicates the management of his diabetes or hypertension, may get reimbursed if he goes to his family doctor for simple, but often inadequate treatment of obesity. But, he will receive no insurance benefits if he goes to the kind of comprehensive obesity management program that can control this disease. Insurance companies decline to pay for anything except perhaps the most extreme surgical treatment. Potentially qualified providers are reluctant to get involved and the vacuum is filled with an abundance of some of the sleaziest providers of care at all levels of care.

I would like to offer a simple proposal for starting to sort it all out. I am not convinced that any new government agency ought to be involved in the regulation of health care. I am convinced, however, that the provision of services in the weight loss industry can be regulated with a few relatively simple procedures that fall well short of what could be considered government meddling.

Let us establish a program for the voluntary accreditation of obesity treatment programs. Perhaps it could work in the following way:

1. A multidisciplinary commission of recognized experts should be convened to formulate reasonable standards of care, to characterize the types of services provided and to establish a non-governmental non-profit accrediting agency concerned with weight management programs. The commission itself will then go out of business.

2. Programs and providers can elect to be certified by the accrediting agency at various levels of service character and intensity according to standards established by the agency. Obesity treatment, including the spectrum of self-help groups, non-professional counsellors, professional therapists and comprehensive multidisciplinary programs, can be accredited at their own level of skills and can be

classified according to the types of services they offer. The accrediting agency should not tolerate the mislabeling of professional skills or the promotion of exaggerated claims or the misrepresentation of services provided.

3. The treatment programs should pay for the certification process; very much like the program of hospital accreditation which has been in place for decades. The system will be financially self-sufficient and will not require any government funds.

4. The accrediting agency must provide education for consumers and guidelines about the kinds of services they might choose and how to select from those available. It is a waste of resources for a healthy young woman who is 15 lbs. overweight to undertake an intensive medical program with complex nutritional intervention and psychotherapy. But, it is a dangerous risk of human life for a 350 lb. patient with diabetes and cardiac disease to be managed by a counsellor who offers compassion but does not know how to interpret an electrocardiogram. Patients should be able to identify who is providing the care, the skills of those involved and the intensity and cost of the program. The public deserves this kind of protection.

5. Programs may elect not to be accredited and then take their chance against the marketplace of certification. Accredited

programs will be required to submit their data and will need regular recertification to sustain their credentials.

What do we accomplish with all this?

1. We provide a mechanism for public and professional education, guidance and direction.
2. We establish minimal and optimal standards at all levels of care.
3. We enable a larger fraction of patients to receive the kind of care that will do them the most good.
4. We will flush out and drive away the worst of the charlatans. They will be not be accredited. There will be fewer victims.
5. With a more direct approach to a serious medical problem perhaps we can get more capable and skilled professionals to participate in the process.
6. Perhaps we can even induce the cynical health insurance industry to develop some rational guidelines for reimbursing patients for the treatment of this disease.
7. Finally, perhaps we can lower the cost of the care. Surely we can avoid the waste that suffuses the $33 billion weight loss industry.

It is reasonable for our government to establish mechanisms to protect patients from being manipulated by this year's variety of consumer weight loss fraud. If we routinely condemn all

obesity management programs we will destroy the bad, but we will also destroy the good. The consumer will lose the opportunity to get competent care. A certification program will benefit health care professionals and the millions of obese people who want very much to establish some way of managing their disease.

PREPARED STATEMENT

OF

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DEPARTMENT OF PSYCHOLOGY, AND

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BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

OF THE

COMMITTEE ON SMALL BUSINESS

U.S. HOUSE OF REPRESENTATIVES

MAY 21, 1992

Mr. Chairman and members of the Committee: My name is Tom Wadden. I am Professor of Psychology at Syracuse University and Director of the university's Center for Health and Behavior. I have been engaged in full-time research on the treatment of obesity since 1981. My work in this area has been made possible by a Research Scientist Development Award from the National Institute of Mental Health, which I received in 1987.

Let me first express my admiration for the Committee's efforts to improve the commercial weight loss industry. The Committee has made remarkable strides in this area in the short period of two years, and its efforts will eventually benefit millions of Americans. I am honored to participate in this effort.

In this statement I will briefly examine three related issues:

1) the efficacy of current weight reduction therapies as determined in academic research trials;
2) the results of the first prospective, multicenter evaluation of a proprietary weight loss program; and
3) the need for all proprietary programs to disclose their results of treatment -- an objective clearly articulated by the Committee and one which I support fully.

## Efficacy of Current Dietary Treatment of Obesity: Findings from Academic Research Trials

One of the principal goals of these Congressional hearings has been to determine the effectiveness of commercial weight loss programs. When these programs disclose their results of treatment, as I anticipate they will, it will be important to have a "gold standard" by which to evaluate them. University research programs

have provided the most thorough findings on the treatment of obesity and, as such, they currently provide the best standard of comparison. I will briefly review the results of research studies in which participants have been treated by a program of lifestyle modification combined with either a 1) conventional 1000-1500 kcal/d diet or a 2) very-low-calorie diet. These are the two principal dietary interventions used with obese individuals, the latter of which is limited to persons 30% or more overweight.

Conventional Reducing Diets

In research trials, mildly obese individuals are usually prescribed a 1000-1500 kcal/d diet composed of conventional foods, low in fat (1,2). Participants typically also attend weekly group sessions in which they are taught to increase physical activity, modify inappropriate eating habits, and cope more effectively with food-related difficulties. Dr. Kelly Brownell (at Yale University) and I believe that this approach should be the first step of care with all obese individuals who require professional attention (1) (see Figure 1, at end of text). It is safe, requires no special foods, and can be delivered at a relatively low cost (i.e., $25 or less per week).

Attrition and weight loss. Table 1 provides a summary of research findings on this approach (3). The findings were abstracted from articles published from 1974 to 1990 in the following journals: Addictive Behaviors, Behavior Therapy, Behaviour Research and Therapy, and Journal of Consulting and Clinical Psychology. These are the top journals in our field.

The table shows that patients in studies published from 1985 to 1990 began treatment weighing approximately 200 lb (90 kg) and lost about 18 lb (8.4 kg) in 15 to 20 weeks. Thus, the average weekly weight loss was about 1 pound. Approximately 80-85% of persons who began treatment completed it. The results also show that the average weight loss more than doubled from 1974 to 1990 as the length of treatment also more than doubled. Recent efforts, however, to produce even greater weight losses by further extending the length of treatment have met with only partial success (4,5). Patients whom we treated weekly for 52 weeks lost only 32 lb, of which 26 lb were lost in the first 26 weeks. Thus, there appear to be limits on the size of the weight losses which can be achieved with conventional reducing diets.

Long-term weight loss. The studies published from 1985-1990 show that patients regained an average of one-third of their weight loss in the year following treatment (3). These findings clearly identify maintenance of weight loss as the critical problem confronting patients and their practitioners. Additional studies have shown that weight regain continues over time, such that a majority of individuals are likely to regain all of their lost weight within 5 years (6,7). Of equal concern is the fact that these results are probably among the best. They were obtained with what most would regard as our most conservative approach, and at research clinics which specialize in the treatment of obesity.

Maintenance of weight loss. Efforts to improve the maintenance of weight loss are in their infancy but have already yielded



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encouraging findings. Dr. Michael Perri (at the University of Florida) has shown in a series of studies that patients who, following weight loss, attend bi-weekly weight maintenance sessions achieve far better results 1 year after treatment than do persons without the benefit of such sessions (8). This model of treatment recognizes that, in the significantly overweight, obesity is a chronic disorder which requires on going care, similar to the life-long treatment of hypertension or type II diabetes. Increased physical activity (i.e., exercise) also significantly improves the maintenance of weight loss (9,10).

Very Low Calorie Diets

Very low calorie diets (VLCDs), providing less than 800 kcal/d, are frequently used with significantly obese individuals (30% or more overweight) who have failed to reduce using a conventional approach (11). These diets provide large amounts of high quality protein (> 50 grams daily), which is consumed either as lean meat, fish and fowl or in the form of a liquid diet (i.e., powdered protein mixed with water). Extensive research has shown that these diets are well tolerated (12) and are generally safe when administered for 16 or fewer weeks to carefully selected individuals under medical supervision (13). Recent reports, however, have indicated that the diets may increase the risk of gallstones (14), an issue which requires further investigation.

Attrition and weight loss. Large rapid weight losses account for the popularity of VLCDs. Women typically lose 40 lb in 12 weeks and men as much as 50 lb (11). Attrition, however, as great as 55%

to 68% of participants (in 15 weeks) has been observed (15). Persons who drop out of treatment tend to lose substantially less weight than treatment completers (16).

The large losses produced by VLCDs are usually ascribed to the diets' severe caloric restriction. A recent study, however, found that weight loss on an 800 kcal/d liquid diet was nearly as great as that on a 420 kcal/d (12). These findings raise the possibility that the success of VLCDs is attributable more to the form in which the diets are served than to the severity of their caloric restriction. The use of portion- and calorie- controlled servings, as with liquid diets, appears to facilitate excellent adherence and, thus, large weight losses. By contrast, studies have shown that obese individuals, when asked to consume a conventional diet, may underestimate their caloric intake by as much as 30% to 40% (17) (thus, eating more than the prescribed number of calories when dieting). The above findings for VLCDs need to be replicated but suggest that severe caloric restriction is not warranted and that equally robust losses would probably be obtained with liquid diets providing as many as 1000 kcal/d.

Long-term results. There are few controlled investigations of the short- and long-term results of VLCDs -- a disturbing finding in view of the hundreds of thousands of persons who have been treated by this approach. Table 2 presents the results of four randomized studies (7,18-20) in which patients were treated by a VLCD in combination with a program of lifestyle modification. Three of four studies agree in showing that patients regained substantial

amounts of weight in the first year or two after treatment. My own study with Dr. Albert Stunkard (at the University of Pennsylvania) showed that lifestyle modification limited weight regain the first year after treatment to one third of lost weight, as compared with two-thirds in patients treated by a VLCD alone (7). The superiority, however, of VLCD combined with lifestyle modification faded by a 3-year follow-up. At 5 years, patients treated by this combined approach had returned, on average, to their pre-treatment weight (as had patients treated by a 1200 kcal/d diet and lifestyle modification). We note that our Japanese colleagues, led by Dr. Miura (18), have achieved excellent long-term results using this same approach. We are unable to explain the discrepancy between the American and Japanese studies.

Interpretation of the Long-Term Results of Dieting

The preceding findings for both 1200 kcal/d diets and VLCDs confirm charges that "diets don't work," if is meant by this statement that a 15- to 25- week program of diet and lifestyle modification does not provide significant weight control 3 to 5 years after treatment. This finding is not surprising, however, in view of the treatment of other chronic disorders. Few physicians would expect to achieve long-term control of hypertension or type II diabetes after treating patients with these conditions for only 15 to 25 weeks. Similarly, a 6-month program of aerobic exercise would not be expected to confer cardiovascular fitness 3 to 5 years later. Continued efforts are required in all cases. Why would our expectations of weight reduction therapies differ?

We clearly have effective methods of inducing weight loss. The challenge which now confronts researchers is to improve the maintenance of weight loss by developing long-term models of care which employ dietary, behavioral, and/or pharmacological interventions. Further understanding of the genetic, metabolic, behavioral, and other factors which contribute to obesity is also critical to our successful management of this disorder.

Effects of Not Dieting

At the same time, we must determine whether weight loss, followed by the probable weight regain associated with our current therapies, poses greater or lesser threats to health than does remaining at an obese but perhaps more stable weight. Stated differently, is it better to have lost weight and regained or to have never lost at all? There is no shortage of opinions on this topic -- only a shortage of findings from which to draw sound conclusions and make appropriate recommendations.

To answer this question, we need studies which compare changes in weight and health status over a minimum of 5-years in groups of obese individuals who chose and do not chose to lose weight (21). At the end of 5 years, will individuals who chose not to diet weigh more or less than those who lost weight and regained it? Similarly, during a 5-year period, will nondieters as compared with dieters show better or worse control over weight-related complications such as hypertension or diabetes? Does remaining at an obese but possibly stable weight result in more favorable self-esteem than does losing weight and eventually regaining it?

Weight Cycling: Inconclusive Findings

We do not know the answers to these questions, although some would argue that studies have already demonstrated the ill effects of weight cycling (i.e., yo-yo dieting). It is important to note, that studies of the adverse effects of weight cycling are sharply divided (22-24). A majority of studies, in fact, indicate that cycles of weight loss and regain do not adversely affect resting metabolic rate or body composition (25). In summarizing this literature, Dr. Rena Wing (at the University of Pittsburgh) concluded that "weight cycling has no consistent effect on metabolic variables such as energy expenditure, ease of weight loss, or body fat" (25). Findings concerning the ill effects of weight cycling on psychological and physical health (26) are perhaps stronger, but still "need confirmation," as noted in National Institutes of Health Technology Assessment Statement on "Methods for Voluntary Weight Loss and Control." More and better studies are needed.

I fully support efforts to reduce the overriding preoccupation with weight and shape which afflicts females as young as 8 and as old as 80 and drives many to enroll in weight reduction programs in hopes of achieving weights which are unreasonable if not unhealthy. Research findings also suggest that individuals who are mildly overweight and carry their excess fat predominantly in their lower body, as women typically do, can perhaps relax their weight control efforts, if they are in good health (27,28). Current evidence, however, does not suggest that significantly obese persons whose

excess fat is carried predominantly in the upper body can forgo weight loss efforts (27,28). On the contrary, the health-related complications of upper body obesity, which is typically observed in men, are too well documented to relax attention to this problem. If anything, current evidence suggests that weight control efforts should be increased in men while relaxed in women (with lower body obesity).

Prospective Evaluation of a Proprietary Weight Loss Program

In contrast to our knowledge of the results of research-based programs for the treatment of obesity, little is known about the safety and efficacy of most commercial programs. Even with the initial demands that have resulted from these Congressional hearings for programs to provide relevant data, few have. In his review of commercial programs before the NIH Technology Assessment Conference (on March 31, 1992), Dr. Walter Glinsmann of the FDA noted that he had received over 75 lb of documents which, with a couple of exceptions, provided no sound information on treatment outcome. Consumers who wish to lose weight deserve and must have such information in order to make informed decisions in selecting a program.

Neither scientists nor dieters can assume that the results of the research studies previously cited are applicable to commercial weight loss programs. In most cases, research-based programs provide more intensive care than typically offered by commercial programs, and it is likely to produce better results. On the other hand, patients in research studies may have more severe and

refractory obesity than do persons who enter commercial programs. Thus, individuals who lose weight on their own or in commercial programs could obtain better long-term results as a result of their less serious obesity. We simply do not know the answer to this question given the lack of data from commercial programs.

A Research-Based Proprietary Program

With my colleagues Gary Foster, Kathleen Letizia, and Albert Stunkard (all at the University of Pennsylvania), I published a report in this months Archives of Internal Medicine (16) which we believe takes the first step in providing the kinds of data needed by consumers and researchers. It describes the short- and long-term results of the OPTIFAST® Program, marketed by the Sandoz Nutrition Corporation (Minneapolis, Minn).

I have been a consultant to Sandoz Nutrition since 1986, when I was asked to strengthen their behavioral treatment program by incorporating findings from Dr. Stunkard's and my research on the use of VLCDs combined with lifestyle modification. We assisted Sandoz in developing a 26-week program designed to modify eating, exercise, and thinking habits and which incorporated the use of a VLCD for 12 weeks. This approach was described in a 200-page manual which instructed dietitians and behavioral counselors in how to conduct weekly group treatment sessions. A similar manual was created for patients.

Having developed the program, the next step was to test its efficacy, its safety having been demonstrated in previous studies. I was interested to see whether a research-based program could be

successfully transferred to the real world of clinical practice. In particular, the program required that patients be treated by a multidisciplinary team which included a physician (to assess patients' health before and during treatment) and a behavioral counselor and registered dietitian to provide instruction in lifestyle modification during weekly 90-minute group sessions. In addition, the program required the use of closed treatment groups, in which patients remained in the same group of 10 to 15 persons throughout the 26-week program; no new members were added to the group after the first week. This format is used in research trials and is thought to facilitate patient retention and weight loss. It stands in contrast to the approach used in most commercial programs, in which participants are treated in either brief individual meetings or in open treatment groups in which the membership varies from week to week (29).

A Multicenter Trial

In September 1987, we began a multicenter trial to assess the OPTIFAST Core Program (as it came to be known). We initially studied 171 patients who were treated at 8 clinics nationwide. Changes in weight, blood pressure, and cholesterol were examined during the 26 weeks of treatment. After finding that such a study was feasible (as a result of excellent cooperation from the sites), Dr. Francis Peterson (at Sandoz) invited us in March 1988 to conduct a more extensive, long-term study of 346 patients treated at 14 sites (i.e., 4 sites from the first cohort plus 10 additional sites). These sites were not randomly selected, primarily because

only a minority of OPTIFAST programs at the time had fully adopted the Core Program, introduced in June 1987. Thus, we identified 21 sites nationwide which had adopted the program and had at least 100 patients in treatment (either in the Core Program or its predecessor). Clearly, if we had evaluated the effectiveness of an established program, we would have randomly selected sites, as well as patients from those sites.

Attrition and Weight Loss

Pretreatment characteristics of the 517 participants are shown in Table 3. The average weight loss for the 407 women who began treatment was 42 lb (19 kg), down from a starting weight of 225 lb (102 kg). This figure includes weight losses of all patients -- both treatment completers and noncompleters (i.e., drop outs). Fifty-six percent of women completed the full 26-week program and achieved an average weight loss approximately 50% greater than that of persons who dropped out (after an average of 12 sessions) (see Table 4).

The 110 men lost an average of 59 lb (27 kg) from a starting weight of 283 lb (129 kg). Fifty-four percent completed the full program and achieved an average loss approximately 50% greater than that of noncompleters (who attended an average of 11 sessions) (see Table 4). Both men and women with hypertension achieved large end-of-treatment reductions in blood pressure, as detailed in the published paper. Significant reductions in total serum cholesterol levels were also observed (16).

Long-term results. The 14 sites in the second cohort agreed at

the study's outset to conduct a 1-year follow-up evaluation of patients; however, three were unable to because of administrative changes. At the 11 remaining sites, the 160 patients who completed the full 26-week program were asked to return to the clinic to have their weight, blood pressure, and cholesterol measured; 118 (74%) did. Results for these 95 women and 23 men were combined because of the small number of men. These 118 patients began treatment with an average weight of 233 lb and lost 55 lb in 26 weeks. They regained a mean of 21 lb in the ensuing year, which resulted in a net weight loss from pretreatment of 34 lb. Patients on average maintained 60% of their weight loss in the year following treatment. Twenty-one percent maintained their full weight loss, whereas 11% regained all of their lost weight.

The 1-year results for these 118 persons may not accurately represent the mean weight loss of the full sample of 160 persons who completed treatment. They may be positively biased. Thus, the 42 persons (26%) who refused to participate in the follow-up (despite a minimum of three separate requests) may have done so because they regained large amounts of weight. Moreover, we have no information on the 45% of patients who did not complete the full program. Our previous research studies suggest that they were at high risk of regaining weight (7).

Interpretation of Findings

We believe that our study demonstrates that the results of a proprietary weight loss program can be evaluated and reported in a manner consistent with academic research trials on the treatment of

obesity. The data on the short-term results of treatment are as strong as any of which we are aware, primarily because the mean weight loss reported is for all persons who entered treatment, not simply those who completed the program and did the best. The data presented in this study would provide consumers a very clear expectation of the size of the weight loss they could expect, both if they completed the full program or dropped out.

Long-term evaluation. It is always difficult in clinical research trials to obtain follow-up data at 1 year or later. The results of the present study suggest that follow-up evaluations of proprietary programs will be even more challenging. Despite the best efforts of clinic staff, they obtained 1-year weight losses on only 74% of patients who completed the full program. Thus, the present data would provide consumers who completed the full program a **reasonable** estimate of their weight losses 1 year after treatment, but not as **reliable** an estimate as the end-of-treatment results.

Long-term follow-up evaluations of proprietary weight loss programs will be difficult to conduct because patients in such studies will not feel obligated to participate. Persons in clinical research trials usually feel a commitment to participate in follow-up because they are provided treatment at nominal (or no) cost in exchange for agreeing to undergo testing during and after treatment. Persons in the present study paid full fees, consistent with usual practice. Although patients knew they were participating in a research investigation, we doubt that they were significantly

committed to the research goals of the study, which were secondary to the treatment for which they had paid.

Comparison with Other Findings

It is impossible to fully evaluate the significance of the short- and long-term weight losses reported here in the absence of comparable data from other proprietary programs. Three points are of note, however. First, the retention of 55% of patients at 26 weeks appears excellent when compared with retention of only 30% to 35% (after only 12 weeks) reported in commercial programs which used conventional 1000-1500 kcal/d diets (29,30). Second, the study's short-term weight losses are as strong as any from research trials (7,18-20) and are superior to those from programs in which patients were allowed to consume a VLCD for 16 or more weeks (15). Thus, time-limited treatment appears to be beneficial. Third, we do not think that the results reported here can be generalized to all proprietary programs which use a liquid VLCD. The present results are probably better than most and are limited to those programs in which 1) a multidisciplinary team provides 2) time-limited therapy to patients in 3) closed treatment groups.

Future Evaluation of Proprietary Weight Loss Programs

My co-authors and I hope that our report will encourage other commercial programs to evaluate their results of treatment and to publish findings which will allow consumers to make informed choices among programs. Consumers, for their part, must be taught how to inquire about a program's safety and efficacy and how to interpret the statistics that we hope they will be given.

Before selecting a program, prospective dieters should interview staff at commercial programs to obtain information which includes 1) the average starting weight of participants (of their sex), 2) the mean length of treatment, and 3) the average weight loss at the end of treatment and at least 1 year later. The full price of the program (including food) should be determined so that the approximate cost per pound of weight loss can be calculated for both the end of treatment and 1-year follow-up losses. The dieter should also inquire about potential psychological or physical complications that may be anticipated, as well as any expected improvements in health. Answers to these questions, as they pertain to the OPTIFAST® Core Program, are provided by our recent study (16) and related publications (12,13).

Prospective dieters should ask for written materials which address these questions, and may wish to review this information with their health care provider and family members. Moreover, persons who are significantly obese and have health complications should always consult with their physician to determine if the program that they have selected is appropriate, and to determine the frequency of medical monitoring they will require during weight loss.

Standardizing Program Evaluation

Commercial programs will need help in evaluating their results of treatment. It is difficult to design and conduct research studies, even when fully committed to such efforts. Thus, I think that a set of detailed guidelines should be prepared which describe

the kinds of data that are required to document a program's safety and short- and long-term results of treatment. In the absence of clear guidelines, many programs will fail to obtain all of the data needed or to employ what researchers would consider to be sound experimental designs. It is unrealistic to expect commercial programs to provide top quality research findings unless they are told precisely what information is desired and how it should be collected.

Obesity researchers undoubtedly will have different opinions concerning the types of information that should be collected and the experimental designs that should be used. I could offer my thoughts on these issues but think that it would be more useful to convene an expert panel to develop the needed guidelines. The panel could be composed of individuals who participated in the recent Technology Assessment conference, staff from the National Institutes of Health, and persons from the commercial weight loss industry (who would be more likely to embrace the guidelines if they participated in their development). Persons from this subcommittee, the FDA, and the FTC could also provide invaluable consultation to the panel. I think that a small working group of 10 to 12 persons would have the greatest likelihood of developing the desired guidelines in a timely fashion.

It should be noted that the development of these guidelines does not address the issue of whether disclosure of the results of commercial weight loss programs would be voluntary or mandatory. The resolution of such issues would be left to other agencies. The

proposed guidelines would be useful in either case and, for the present time, would allow those programs which so chose to conduct the best possible evaluations.

## Summary and Conclusions

Academic research trials have shown that we can successfully induce weight loss in significantly obese individuals by using a program of lifestyle modification combined with either a 1200 kcal/d diet or a very-low-calorie diet. Research is now needed on methods to improve the maintenance of weight loss, given findings that weight regain is the rule rather than the exception. Results should improve with further discovery of the causes of obesity and with recognition that significant obesity is a chronic disorder which requires long-term care. At the same time, research is needed to determine whether weight loss, followed by the probable weight regain associated with our current therapies, poses greater or lesser threats to health than does remaining at an obese but perhaps more stable weight. Stated differently, is it better to have lost weight and regained or to have never lost at all? We do not know the answer to this question.

The results of a recent study indicate that a proprietary weight loss program can evaluate its short- and long-term results of treatment and publish findings which would allow prospective dieters to make informed decisions in selecting treatment. My colleagues and I hope that this report will encourage other commercial programs to disclose their results of treatment but believe that commercial programs will need assistance in doing so.

**Therefore, we recommend that an expert panel be convened to develop a set of detailed guidelines which describe the kinds of data that are required to document a commercial program's safety and short- and long-term results of treatment.**

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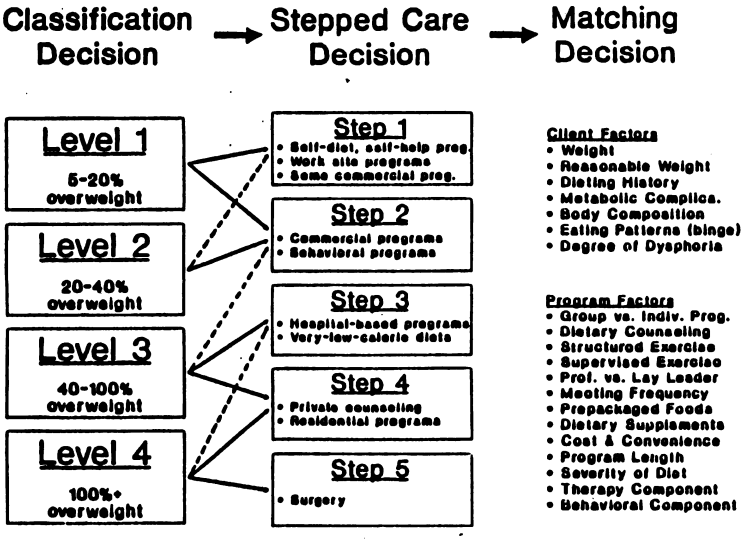


FIG. 1. A conceptual scheme showing the three-stage process in selecting a treatment for an individual. The first step, the Classification Decision, divides individuals according to percent overweight into four levels. This level dictates which of the five steps would be reasonable in the second stage, the Stepped Care Decision. This indicates that the least intensive, costly, and risky approach will be used from among alternative treatments. The third stage, the Matching Decision, is used to make the final selection of a program, and is based on a combination of client and program variables. The dashed lines with arrows between the Classification and Stepped Care stages show the lowest level of treatment that may be beneficial, but more intensive treatment is usually necessary for people at the specified weight level.

From reference #1.

TABLE 2.--Summary Analysis of Randomized Clinical Trials of Very-Low-Calorie Diets That Include Followup Data

| Reference | Subjects | Mean pretreatment weight (kg) | Mean age (yr) | Treatment regimen | Mean treatment duration (wk) | Mean weight loss (kg) | Mean weight loss at followup (kg) |
|---|---|---|---|---|---|---|---|
| Miura et al. (1989) | 46 F, 24 M | 148% of ideal weight | 35.4 | 1. VLCD for 4 to 8 wks followed by conventional diet | 16 | 8.6 | 1 yr: 5.0<br>2 yr: 4.1 |
| | | | | 2. BT + conventional diet | 16 | 4.5 | 1 yr: 5.5<br>2 yr: 5.8 |
| | | | | 3. BT + VLCD for 4 to 8 wk followed by conventional diet | 16 | 10.7 | 1 yr: 11.5<br>2 yr: 12.0 |
| Sikjaad et al. (1988) | 30 F (21;15) | 102.7 | 38.8 | 1. BT + VLCD for 16 wk | 16 | 17.5 | 2 yr: 0.8 |
| | | | | 2. BT + exercise + VLCD for 16 wk | 16 | 21.8 | 2 yr: 9.1 |
| Wadden et al. (1989) | 89 F (76;68;55) | 106.0 | 42.1 | 1. PSMF for 8 wk; 1,000 to 1,200 kcal/day for 8 wk | 16 | 13.1$_a$ | 1 yr: 4.7$_a$<br>5 yr: +1.0 |
| | | | | 2. BT + 1,200 kcal/day | 26 | 13.0$_a$ | 1 yr: 6.6$_a$<br>5 yr: 2.7 |
| | | | | 3. BT + PSMF for 8 wk; 1,000-1,200 kcal/day for 18 wk | 26 | 16.8$_b$ | 1 yr: 10.6$_b$<br>5 yr: +2.9 |
| Wing et al. (1991) | 26 F, 10 M (33;33) | 103.8 | 51.0 | 1. BT + 1,000 to 1,500 kcal/day | 20 | 10.1$_a$ | 1 yr: 6.8 |
| | | | | 2. BT + PSMF/VLCD for 8 wk; 1,000 to 1,500 kcal/day for 12 wk | 20 | 18.6$_b$ | 1 yr: 8.6 |

Note: Numbers in parentheses indicate the number of persons remaining at the end of treatment and at successive followup evaluations. VLCD, very-low-calorie diet; BT, behavior therapy; PSMF, protein-sparing modified fast. Dissimilar lowercase subscripts indicate significant differences.

From reference 3.

Tables 3 and 4 (from reference #16).

**Table 3—Baseline Characteristics of Women and Men Participating in the Study***

| Variable | Women (N=407) | Men (N=110) |
|---|---|---|
| Age, y | 40.9±0.6 | 42.3±1.0 |
| Weight, kg | 102.1±0.9 | 128.7±2.3† |
| Height, cm | 164.6±0.3 | 179.4±0.7† |
| BMI, kg/m² | 37.6±0.3 | 39.9±0.7† |

*BMI indicates body mass index.
†Difference between sexes are significant at $P<.0001$.

**Table 4—Mean Weight Losses and Number of Treatment Sessions Attended for Men and Women Who Completed and Did Not Complete Treatment***

| Patient Group | N | Weight Loss, kg | No. of Visits |
|---|---|---|---|
| Women | | | |
| **Total Sample** | **407** | 19.2±0.5 | 17.8±0.3 |
| Completing treatment | 226 | 22.0±0.6 | 21.8±0.4 |
| Not completing treatment | 181 | 14.3±0.7† | 11.7±0.5† |
| Men | | | |
| **Total Sample** | **110** | 27.0±1.2 | 17.0±0.7 |
| Completing treatment | 59 | 32.1±1.4 | 21.6±0.6 |
| Not completing treatment | 51 | 20.0±1.6† | 11.1±0.8† |

*Patients were considered to have completed treatment if they remained in the program through week 24. Women who completed treatment nevertheless missed an average of 4.2 of the 26 weekly sessions and men an average of 4.4.
†The difference between completing and not completing treatment is significant at $P.001$.

# A Multicenter Evaluation of a Proprietary Weight Reduction Program for the Treatment of Marked Obesity

Thomas A. Wadden, PhD; Gary D. Foster, MS; Kathleen A. Letizia; Albert J. Stunkard, MD

• *Background.*—Congressional hearings initiated in March 1990 revealed that America's $10 billion a year weight loss industry is subject to minimal regulation by federal agencies. Consumers are forced to rely on advertisements and testimonials when selecting treatment because no proprietary program has provided a prospective assessment of its short- and long-term results of treatment. This report describes such an assessment.

*Methods.*—A total of 517 obese patients (407 women and 110 men) participated in a proprietary program that included 12 weeks of treatment by very-low-calorie diet within a 26-week program of life-style modification. Patients were treated in two cohorts (6 months apart) according to a standardized protocol implemented at 18 hospital-based clinics across the nation.

*Results.*—Fifty-six percent of women and 54% of men completed treatment, at which time their weight losses (mean±SEM) were 22.0±0.6 and 32.1±1.4 kg, respectively. Weight losses of women and men who discontinued treatment averaged 14.3±0.7 and 20.0±1.6 kg, respectively. Weight loss was associated with significant improvements in blood pressure and total serum cholesterol levels. A 1-year follow-up evaluation of 74% of patients in the second cohort who completed treatment revealed that they maintained 15.3±1.2 of their 24.8±1.0-kg end-of-treatment weight loss; 59% of patients maintained a loss of 10 kg or more.

*Conclusion.*—We hope that this report will lead to the systematic evaluation of other proprietary weight loss programs and to the publication of findings that will permit consumers to make informed treatment decisions.

(*Arch Intern Med.* 1992;152:961-966)

America's weight loss industry is large and growing. In 1989, consumers spent approximately $10 billion dollars on weight loss programs and an additional $22 billion on slimming aids, such as diet sodas and health spa memberships.[1] Recent estimates project expenditure of more than $50 billion by 1995.[1]

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This vast industry is subject to no more than minimal regulation by federal and state agencies.[2] In striking contrast to the requirements for the introduction of new drugs, neither weight loss programs nor products need demonstrate any proof of safety or efficacy. It is therefore not surprising that serious problems have arisen. A mounting chorus of complaints led Congressman Ron Wyden of Oregon to conduct Congressional hearings in March 1990 on "Deception and Fraud in the Diet Industry."[3] False advertising was a particular target of the hearings. The Congressman's staff reported, "Unfortunately, we found advertising that should benefit consumers by offering them more choices had been clouded by blatant fraud and half truths. These ads sell false security about the safety of procedures and products."[3(p;35)] Congressman Wyden himself noted "a tidal wave of false and misleading advertising in a field already awash in gross overpromotion."[3] The Federal Trade Commission has initiated an intensive review of the advertising practices of commercial weight loss programs in response to the Congressional hearings (*FTC News*. October 16, 1991).

Clearly, regulation of the diet industry is needed, expensive as it will be.[4] A simpler measure, however, might achieve many of the goals of regulation and at a lower cost. Thus, voluntary *disclosure* of the results of commercial weight loss programs would permit consumers to make informed choices among programs and, in time, could create market pressures that would drive out unsound programs.[4] Regrettably, we are not aware of a single commercial program that has published the results of a large-scale, prospective evaluation of its short- and long-term results of treatment.

This report describes such an evaluation of a proprietary weight loss program for the markedly obese (30% or more overweight). It is based on a prospective, multicenter trial of 517 patients treated by a 26-week program that combined the use of a very-low-calorie diet (VLCD) with life-style modification. Extensive research has shown that these diets are generally safe when used under medical supervision by appropriate patients for no more than 16 weeks[5-15] and that they are associated with significant improvements in weight-related illnesses.[11-15] This report describes the effectiveness of this treatment approach and is designed to serve as an example of the kind of disclosure that, if generally practiced, would make possible informed choices among commercial programs.

## SUBJECTS AND METHODS

### Site Selection

Sites were selected from approximately 280 hospital-based clinics across the United States that offered the OPTIFAST Program (Sandoz Nutrition Co, Minneapolis, Minn). To be eligible, sites were required to have at least 100 patients in treatment at the time of the study and be willing to implement a standardized treatment protocol (referred to as the CORE Program). Twenty-one clinics were identified on the basis of geographic distribution, and 18 agreed to participate.

**Cohort 1.**—A first cohort participated in a pilot study to assess the feasibility of conducting a large multicenter trial. It included 132 women and 39 men (from eight sites) who entered treatment between September and November 1987. No follow-up data were collected on this cohort.

**Cohort 2.**—A second cohort consisted of 275 women and 71 men (from 14 sites) who entered treatment between February and April 1988. Four sites participated in both cohorts. All 14 sites in the second cohort agreed to conduct a 1-year follow-up evaluation of weight, blood pressure, and cholesterol level, but three were unable to do so because of administrative changes occurring in the clinics.

### Patients

Before treatment, all patients underwent a comprehensive medical evaluation that included a history, physical examination, electrocardiogram, and biochemical profile. Contraindications to treatment included the following: a recent myocardial infarction; history of cerebrovascular, hepatic, or renal disease; cancer; type I diabetes; pregnancy; and significant psychiatric illness. All patients gave their written informed consent to participate in the study. They received no inducements to participate and paid customary treatment fees.

### Treatment

All patients received the same 26-week program delivered by a multidisciplinary team. During the first week, women were prescribed a 5040-kJ/d balanced deficit diet (of their own choosing) and men a 6300-kJ/d diet. For the next 12 weeks, patients consumed either 1764 kJ/d (70 g of protein, <2 g of fat, 30 g of carbohydrate) or 3360 kJ/d (70 g of protein, 13 g of fat, 100 g of carbohydrate). Both diets provided 100% of the recommended daily allowance for essential vitamins and minerals; the 3360-kJ/d regimen was generally prescribed for men and patients with higher initial weights. Both diets consisted of a powdered supplement that was mixed with water and consumed five times daily (OPTIFAST 70 and OPTIFAST 800; Sandoz Nutrition Co).

During the next 6 weeks, conventional foods were reintroduced and the amount of liquid formula reduced so that, by week 19, patients consumed 4200 to 5040 kJ/d derived solely from conventional foods. During the last 7 weeks, women were prescribed 5040 to 6300 kJ/d and men 6300 to 7560 kJ/d.

During the first 19 weeks, patients were examined weekly by a physician trained in the use of VLEDs, and every other week a biochemical profile was obtained. A final visit was scheduled during the last 7 weeks.

### Life-style Modification

Patients were treated weekly for 75 to 90 minutes in groups that typically included 10 to 12 persons. Patients remained in the same group throughout treatment, and no new members were admitted after the second week (ie, closed-enrollment groups). Group sessions were led by master- or doctoral-level counselors who instructed patients in such behavioral measures as keeping a diet diary, adhering to the VLCD, reducing unwanted eating, assertiveness training, and relapse prevention. Treatment followed detailed protocols (*The OPTIFAST CORE Program Group Leader Guide: Volumes I and II*; Minneapolis, Minn, Sandoz Nutrition; 1987) and patients received a 200-page manual that summarized all materials (*The OPTIFAST CORE Program Patient Manual*. Sandoz Nutrition, 1987). The behavioral counselor was joined at weeks 13 to 22 by a registered dietitian who instructed patients in the refeeding protocol, meal planning, the use of exchange lists, and related topics in the patient manual just mentioned. Five times during the program, an exercise specialist instructed patients in methods of increasing their physical activity, which for most consisted of walking. At week 8, patients were instructed to exercise two to three times weekly for 8 to 12 minutes per session at 40% to 60% of estimated maximum heart rate.[16] Physical activity was increased over time so that, by week 26, patients were to exercise three to five times weekly for 20 to 40 minutes at 60% to 80% of estimated maximum heart rate.

Table 1.—Baseline Characteristics of Women and Men Participating in the Study*

| Variable | Women (N = 407) | Men (N = 110) |
|---|---|---|
| Age, y | 40.9 ± 0.6 | 42.3 ± 1.0 |
| Weight, kg | 102.1 ± 0.9 | 128.7 ± 2.3† |
| Height, cm | 164.6 ± 0.3 | 179.4 ± 0.7† |
| BMI, kg/m² | 37.6 ± 0.3 | 39.9 ± 0.7† |

*BMI indicates body mass index.
†Difference between sexes are significant at $P<.0001$.

Treatment delivery was standardized by requiring at least one staff member from each clinic to attend a national meeting at which protocol implementation was reviewed. In addition, one of us (G.D.F.) visited 17 of the 18 sites to discuss the treatment protocol with staff and to observe its implementation in a group session. We also had frequent telephone contact with staff at all clinics.

### Dependent Measures

**Retention.**—Patients were considered to have discontinued treatment if they formally withdrew from therapy or were absent for 4 consecutive weeks. The week of discontinuation was defined as the week after the last clinic visit. Patients were classified as completers if they remained in treatment through week 24; noncompleters discontinued before this time.

**Weight, Blood Pressure, and Serum Cholesterol Levels.**—Weight was measured weekly on a balance-beam scale. Blood pressure and total serum cholesterol levels were measured throughout treatment in patients in both cohorts; however, only measurements obtained on patients in the second cohort were sufficiently standardized to meet research criteria. In these patients, blood pressure was assessed weekly in the seated position after patients had rested for at least 5 minutes on arriving at the clinic. Fasting serum cholesterol level was measured at baseline, weeks 10 and 20, and follow-up.

This study was initiated before the publication of findings (from controlled investigations) of gallstone formation occurring with VLCDs.[17,18] Thus, patients were not rigorously assessed for this complication (including by ultrasound). Staff members were asked, however, to record medical complications on the patients' data cards (described below) and to note, when appropriate, the reasons for a patient's terminating treatment prematurely.

**Data Collection.**—Results of each patient's weekly clinic visit were recorded on a data card by the study coordinator and mailed to us. Study coordinators at each site were contacted regularly to discuss the data, which were coded and analyzed by us.

### Statistical Analyses

A preliminary multiple analysis of variance showed that there were no statistically significant differences between patients in the two cohorts (or among the 18 sites) on baseline variables or end-of-treatment changes in weight. Thus, the two cohorts were combined for all analyses except the 1-year follow-up evaluation. Patients' baseline characteristics are summarized in Table 1.

Data are presented as mean±SEM. Analysis of covariance[19]

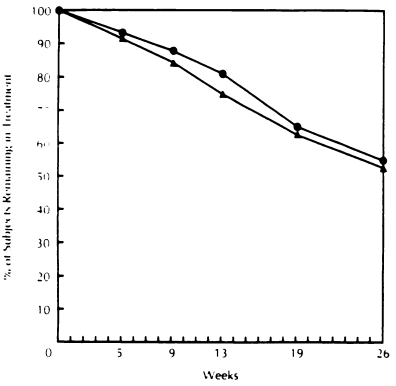


**Fig 1.**—*Percentage of women (circles) and men (triangles) remaining in treatment at five assessment periods. Patients consumed a very-low-calorie diet (1757 to 3348 kJ/d [420 to 800 kcal/d]) during weeks 2 through 13, a refeeding diet during weeks 14 through 19, and a 5021- to 6276-kJ/d (1200-to 1500-kcal/d) diet for the remainder of treatment.*

was used to assess differences in weight loss between men and women and between treatment completers and noncompleters. Correlation analyses were used to identify predictors of change in the dependent variables.

## RESULTS

### Retention

Figure 1 shows the retention rates for women and men. Eighty-two percent of the 407 women completed the first 13 weeks of treatment (during which the VLCD was consumed), falling to 66% at the end of the refeeding period, and 56% at the end of the 26-week program. The mean number of treatment sessions attended by women (and men) is shown in Table 2.

Retention rates for men were similar to those for women. Seventy-five percent (of the 110 men) completed the 13 weeks of the VLCD, falling to 64% by the end of refeeding, and to 54% at the conclusion of the program. The $\chi^2$ tests revealed that there were no statistically significant differences between the retention rates for men and women at any time during treatment.

### Weight Loss

Women who completed treatment lost an average of 22.0±0.6 kg (mean±SEM) and men lost 32.1±1.2 kg, equal to reductions in initial weight of 21%±0.5% and 25%±0.8%, respectively. Among women, 95.1% lost 10 kg or more and 54.4% lost 20 kg or more. Comparable statistics for men were 100% and 86.4%, respectively.

Figure 2 shows that most of the weight loss occurred during consumption of the VLCD. Men's cumulative weight losses at the end of the VLCD and the conclusion of the refeeding period were significantly greater than women's (both $P<.02$). Differences in weight losses at the end of treatment were not statistically significant, however ($P>.1$). Men lost 10 kg more than women at this time, but the relative weight losses of men and women were roughly comparable when the higher initial weights of men were taken into account (Table 1).

Women and men who discontinued treatment prematurely lost an average of 14.3±0.7 and 20.0±1.6 kg, respectively (Table 2). These losses were significantly smaller than those of persons who completed the full program (both $P<.001$). Among women who did not complete treatment, 78.0% lost 10 kg or more and 26.8% lost 20 kg or more. Comparable statistics for men were 85.7% and 49.0%, respectively.

Baseline weight correlated highly with weight loss at weeks 13, 19, and 26 in both women ($r=.68$, .66, and .69, respectively) and men ($r=.56$, .58, and .58, respectively) (all $P<.0001$). Thus, heavier patients tended to lose more

**Table 2.—Mean Weight Losses and Number of Treatment Sessions Attended for Men and Women Who Completed and Did Not Complete Treatment***

| Patient Group | N | Weight Loss, kg | No. of Visits |
|---|---|---|---|
| Women | | | |
| **Total Sample** | 407 | 19.2±0.5 | 17.8±0.3 |
| Completing treatment | 226 | 22.0±0.6 | 21.8±0.4 |
| Not completing treatment | 181 | 14.3±0.7† | 11.7±0.5† |
| Men | | | |
| **Total Sample** | 110 | 27.0±1.2 | 17.0±0.7 |
| Completing treatment | 59 | 32.1±1.4 | 21.6±0.6 |
| Not completing treatment | 51 | 20.0±1.6† | 11.1±0.8† |

*Patients were considered to have completed treatment if they remained in the program through week 24. Women who completed treatment nevertheless missed an average of 4.2 of the 26 weekly sessions and men an average of 4.4.

†The difference between completing and not completing treatment is significant at $P.001$.

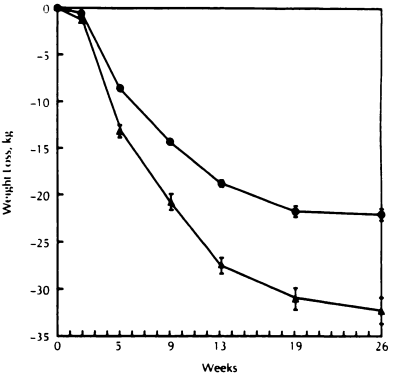


**Fig 2.**—*Weight losses of women (circles) and men (triangles) during 26 weeks of treatment. Patients consumed a very-low-energy diet (1757 to 3348 kJ/d [420 to 800 kcal/d]) during weeks 2 through 13, a refeeding diet during weeks 14 through 19, and a 5021- to 6276-kJ/d (1200- to 1494.3 kcal/d) diet for the remainder of treatment. Weight losses are for all patients in treatment at the time of assessment. Values are mean±SEM.*

Table 3.—Weight Loss and Percentage Reduction in Initial Weight in 226 Women and 59 Men Who Completed Treatment*

| Initial BMI, kg/m² | N | Change at the End of Treatment: Weight, kg | Change at the End of Treatment: % Reduction in Weight |
|---|---|---|---|
| **Women** | | | |
| 30.7 ± 0.2 | 56 | −16.1 ± 0.7 | −19.2 ± 0.8 |
| 34.9 ± 0.1 | 57 | −21.0 ± 1.0 | −22.2 ± 0.9 |
| 38.8 ± 0.2 | 57 | −22.1 ± 1.1 | −21.0 ± 1.0 |
| 46.3 ± 0.6 | 56 | −29.0 ± 1.2 | −23.2 ± 0.8 |
| **Men** | | | |
| 32.8 ± 0.3 | 15 | −22.4 ± 1.2 | −21.9 ± 1.1 |
| 36.8 ± 0.3 | 15 | −31.0 ± 1.8 | −25.2 ± 1.4 |
| 41.8 ± 0.5 | 14 | −37.3 ± 2.0 | −28.2 ± 1.4 |
| 49.9 ± 1.4 | 15 | −38.2 ± 3.6 | −23.6 ± 2.0 |

*Patients were divided into quartiles on the basis of initial body mass index (BMI). For women, the initial weights associated with each weight class were 83.7 ± 1.1, 94.0 ± 0.9, 105.2 ± 1.3, and 125.5 ± 2.2 kg, respectively, while those for men were 102.5 ± 2.9, 122.9 ± 2.7, 132.4 ± 2.9, and 161.9 ± 5.1 kg, respectively.

weight. This relationship is demonstrated more clearly by the data presented in Table 3, which shows weight changes of patients divided into quartiles on the basis of initial body mass index (weight in kilograms/height in meters squared). Differences in weight losses of patients in the lightest and heaviest quartiles were as great as 13 kg for women and 16 kg for men. The percentage reduction in weight in the four classes was very similar, however, ranging only from 19% to 23% in women and 22% to 28% in men.

### Blood Pressure and Cholesterol

Table 4 shows changes in systolic and diastolic blood pressure for four groups of patients, based on magnitude of initial blood pressure and medication usage. Data for men and women are presented together (as they are for cholesterol levels). All groups showed significant reductions in blood pressure during treatment, with normotensive patients showing the smallest and unmedicated hypertensive patients the largest reductions (Table 4). Significant reductions occurred in the 13 patients who discontinued all antihypertensive medication on their physician's advice.

Total serum cholesterol levels fell sharply (from 5.64 ± 0.10 mmol/L [218.2 ± 4 mg/dL] to 4.24 ± 0.08 mmol/L [163.8 ± 3 mg/dL]) during the first 10 weeks in which patients consumed the VLCD ($P < .0001$). It rose to 4.85 ± 0.08 mmol/L (187.6 ± 3 mg/dL) at week 20, when patients resumed consumption of a balanced deficit diet (but remained significantly below baseline; $P < .001$). At this time, 59.2% of patients showed reductions in cholesterol level of 0.52 mmol/L (20 mg/dL) or more, and 49.2% had reductions of 0.78 mmol/L (30 mg/dL) or more.

Symptomatic gallstones were detected the 15th week of treatment in a 22-year-old woman with an initial weight of 116.4 kg and serum cholesterol level of 6.03 mmol/L (233 mg/dL). She had lost 14.6 kg at the time of complications. A 47-year-old woman who completed the program and lost 28.4 kg underwent a cholecystectomy in the year after treatment. Before treatment, she weighed 102.1 kg and had a serum cholesterol level of 5.25 mmol/L (203 mg/dL). No other cases of symptomatic gallstones were reported, although we reiterate that this complication was not a primary focus of the study.

Table 4.—Changes in Systolic and Diastolic Blood Pressure During 26 Weeks of Treatment*

| Classification | N | Variable | Baseline, mm Hg | Week 13, mm Hg | Week 26, mm Hg |
|---|---|---|---|---|---|
| Normotensive | 230 | SBP | 118 ± 0.7 | 112 ± 0.9† | 113 ± 1.4† |
| | | DBP | 76 ± 0.5 | 71 ± 0.7† | 72 ± 1.0† |
| Hypertensive, no medication | 26 | SBP | 147 ± 2.6 | 125 ± 2.3† | 127 ± 5.0† |
| | | DBP | 93 ± 1.7 | 80 ± 1.6† | 79 ± 2.0† |
| Hypertensive, medication | 28 | SBP | 149 ± 2.5 | 126 ± 2.3† | 131 ± 4.5† |
| | | DBP | 93 ± 1.8 | 80 ± 1.6† | 79 ± 1.6† |
| Hypertensive, medication discontinued | 13 | SBP | 153 ± 4.5 | 130 ± 5.1† | 133 ± 2.7‡ |
| | | DBP | 92 ± 1.8 | 77 ± 1.9† | 83 ± 3.4‡ |

*SBP indicates systolic blood pressure; DBP, diastolic blood pressure. Data are for men and women in the second cohort.
†$P < .005$ vs baseline (paired $t$ test).
‡$P < .05$ vs baseline (paired $t$ test).

### One-Year Follow-up Evaluation

Eleven of 14 clinics in the second cohort participated in the 1-year follow-up evaluation, which was completed a mean of 12.9 months after treatment. In these 11 clinics, 160 patients completed the full course of treatment and were asked to participate in the follow-up; 118 (74%) did. One hundred eleven patients were assessed at clinic visits, while seven reported their weights by telephone; 2.3 kg was added to these self-reported weights to correct for the likelihood of underreporting.[20] Forty-two patients declined to participate in the follow-up evaluation despite a minimum of three contacts by letter and/or telephone. Other than being younger (37.5 ± 1 vs 43.6 ± 1 years, respectively), these patients did not differ significantly on any other baseline variables, or on end-of-treatment weight losses, from patients who participated in the follow-up.

Data for the 95 women and 23 men who completed the follow-up were combined for analysis because of the small number of men. These 118 patients began therapy with a mean weight of 106.1 ± 1.9 kg and lost 24.8 ± 1.0 kg at the end of treatment. They regained a mean of 9.5 ± 0.9 kg in the 13 months after therapy, equal to a net weight loss from baseline of 15.3 ± 1.2 kg. Twenty-four patients (21%) maintained their full end-of-treatment weight loss (within 3 kg) at follow-up, while 13 (11%) regained to or exceeded their baseline weight. At the end of treatment, 96% of these patients had achieved a loss of 10 kg or more and 64% a loss of 20 kg or more. At the 1-year follow-up, 59% maintained a loss of 10 kg or more and 33% a loss of 20 kg or more.

### Blood Pressure and Cholesterol at One-Year Follow-up

Changes in blood pressure were examined at the 1-year follow-up in 64 patients who began the study without hypertension (120/76 mm Hg) and who showed significant reductions of 6/4 mm Hg at the end of treatment. No statistically significant changes were observed in these

patients at the 1-year follow-up (ie, blood pressure had returned to baseline levels). Data for the three groups of hypertensive patients shown in Table 4 were not statistically analyzed because the sample sizes were less than 10 in all three groups.

Total serum cholesterol levels were obtained at follow-up in 74 patients, who began the study with a mean value of 5.73±0.13 mmol/L (221.7±5 mg/dL) and achieved a reduction of 0.88±0.03 mmol/L (34.0±1 mg/dL) at the end of treatment (with a mean weight loss of 25.9±1 kg). One year later, cholesterol levels remained 0.28±0.03 mmol/L (10.7±1 mg/dL) below baseline in these patients ($P<.01$), despite their having regained approximately 34% of their weight loss during the year. At the end of treatment, 62.2% of these patients showed reductions in total serum cholesterol levels of 0.52 mmol/L (20 mg/dL) or more, and 54.1% had reductions of 0.78 mmol/L (30 mg/dL) or more. Comparable statistics at the 1-year follow-up were 35.1% and 25.7%, respectively.

## COMMENT

This study's most significant contribution is its demonstration that the treatment results of a proprietary weight loss program can be evaluated and described in a scientifically acceptable manner. If followed by other commercial programs, such reports could replace the "tidal wave of false and misleading advertising" with information that would permit patients, in consultation with their physicians, to make informed choices among programs.

Women in the present study who completed treatment lost 22.0 kg (21% of body weight) and men lost 32.1 kg (25% of body weight)—far more than the 5 to 10 kg associated with the use of conventional 5021-kJ/d (1200-kcal/d) reducing diets.[21-25] Moreover, the weight losses in this study are comparable to those reported for the use of VLCDs in research programs that specialize in the treatment of obesity.[7,8,26-30] Findings that weight loss was accompanied by reductions in blood pressure (in hypertensive patients) and in serum cholesterol levels have been reported previously[7,8,12] and are critically important to this population, which experiences at least a threefold increase in the risk of cardiovascular morbidity and mortality.[31]

Fifty-six percent of women and 54% of men completed the full 26 weeks of treatment. These retention rates are lower than those reported in research clinics[21,26,29,30] but are better than the rates of 30% to 40% after only 12 to 15 weeks of treatment in commercial programs employing 4184- to 6276-kJ/d (1000- to 1500-kcal/d) diets.[32-34] The present results are also superior to those reported in studies that used the identical VLCD but failed to use a structured, time-limited program. Thus, retention of only 32% was observed after approximately 11 weeks of treatment in a study conducted at a single site.[15] In a more comparable investigation, Blackburn[35] conducted a retrospective survey of 15 sites and found that only 24% of patients remained in treatment at 26 weeks—less than half the percentage observed in this study.

Retention of patients in treatment is critical to their losing weight and is associated with improved maintenance of weight loss.[36,37] We believe that the favorable retention in the present study is attributable, in part, to treatment by time-limited therapy in closed-enrollment group sessions, common to the behavioral treatment of obesity as practiced in research programs.[21,25] The vast majority of proprietary programs employ open-ended therapy often combined with open-enrollment therapy groups. Although intuitively appealing, open-ended therapy may not maximize motivation and may prove discouraging to some patients because it does not provide a clear end to treatment and to the significant effort that patients must expend. Similarly, the use of open-enrollment groups in which new patients are entered into ongoing group behavioral counseling at any point in time, is likely to prevent group cohesiveness, critical to the successful outcome of therapy.[38] It is also likely to preclude the development of an integrated curriculum because new patients are poised to begin the first week of treatment while other individuals in the same group may be in their sixth week or sixth month of therapy. Ultimately, a controlled randomized trial will be needed to determine which method of delivering treatment is the most effective.

Patients in the second cohort who completed treatment regained a mean of 9.5 kg of their 24.9-kg weight loss in the year after treatment. This regain—of approximately 40%—is comparable to that reported in research programs that have used either VLCDs[29,30] or conventional 5021-kJ (1200-kcal) diets.[21,22,25] Even with weight regain, nearly 60% of patients maintained a weight loss of 10 kg at the 1-year follow-up and 33% a loss of 20 kg or more. These losses continued to be associated with significant reductions in total serum cholesterol levels.

The end-of-treatment weight losses of patients who failed to participate in the follow-up evaluation did not differ significantly from those of participants. Thus, our follow-up sample was not biased in this regard, but patients who failed to participate in follow-up may well have been less successful in maintaining their weight losses. Moreover, we have no information on the long-term outcome of women and men who discontinued treatment prematurely after having lost an average of 14.3 and 20.0 kg, respectively. We suspect, however, that these individuals regained a greater percentage of their weight loss than did those who completed the full program.[29] Thus, the present findings leave little doubt that once they have lost weight, the great majority of patients require subsequent instruction in the maintenance of weight loss.[25] Maintenance therapy has proved beneficial after weight loss by a 5021-kJ/d (1200-kcal/d) diet[39] and should improve the results after treatment by a VLCD.

This study would have been improved by the inclusion of a no-treatment control condition, which would have allowed us to assess the health benefits of weight loss followed by partial regain (at the 1-year follow-up), as compared with weight stability at an obese weight. There is growing concern that cycles of weight loss and regain may be associated with an increased risk of cardiovascular morbidity and mortality.[40] The study also would have been improved by the rigorous assessment of the incidence of gallstone complications. Patients treated by VLEDs (as well as by some 4200- to 6300-kJ/d diets) appear to experience an increased risk of gallstone formation.[17,18] Further research is needed to identify methods of preventing this complication during weight loss.

We hope that this report will lead to the systematic evaluation of the safety and efficacy of other proprietary weight loss programs and to the publication of findings that will enable patients (and their practitioners) to make informed treatment decisions. Such evaluation and reporting should become mandatory for this industry. Moreover, we urge commercial providers to take full ad-

vantage of their opportunities to contribute to research on the cause and treatment of obesity. There is great potential for contribution by an industry that treats more than 2 million Americans a year. The pharmaceutical industry has demonstrated that outstanding health care research can be conducted by proprietary organizations. For the diet industry, the first step in this direction is the full disclosure of the results of treatment.

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**STATEMENT OF ROBERT HOERR, M.D., Ph.D.**
**DIRECTOR, MEDICAL AFFAIRS**
**SANDOZ NUTRITION CORPORATION**
**TO THE SUBCOMMITTEE**
**ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY**

**May 21, 1992**

Sandoz Nutrition appreciates the opportunity to submit a statement for the Record of this hearing of the Subcommittee on Regulation, Business Opportunities, and Energy.

This hearing follows the April NIH Technology Assessment Conference on Methods of Voluntary Weight Loss and Control and the continuing Federal Trade Commission inquiries into advertising practices. In the years since Congressman Wyden and the Committee initiated its oversight process, Sandoz Nutrition has worked actively with government to promote standards and share data of the quality needed to affect one of the nation's worst public health problems. Regrettably, few voices have joined that of Sandoz Nutrition to call for a shift in the way weight management companies conceive, judge and promote their services. At the same time, anti-diet and fat-is-fine groups have loudly shared their opinions without supporting data of the caliber called for by NIH, FTC and this Committee and supplied by Sandoz Nutrition.

Our position is that weight management companies willing to adopt and conform to the exacting standards of the healthcare community could provide a service of real benefit to the nation's 34 million obese people. By and large, industry has not responded to this challenge.

It may be helpful to summarize what Sandoz Nutrition has done to adopt and uphold such standards since this Committee last met.

**NIH Technology Assessment Conference**

In response to the NIH Technology Assessment Conference on Methods of Voluntary Weight Loss and Control, Sandoz Nutrition was one of 10 companies active in the weight loss field that was asked to provide information on treatments, health benefits and weight maintenance to the Food and Drug Administration. Dr. Walter Glinsmann, Associate Director for Nutrition, assessed and presented this data to the NIH Panel.

Of the 10 companies, 6 provided clinical data. Industry also submitted 60 published references from the medical literature. Fifty-five of these were provided by Sandoz Nutrition. Reviewing these studies, Dr. Glinsmann found them to be of generally solid quality. At the conclusion of his report, he stated that the FDA would shortly establish a petition process for health claims for products used in weight control. His final statement was, "Except for data on products that are managed under a physician's care, information supplied by industry to date have failed to provide a sufficient base to consider claims in this area." We must believe that Sandoz Nutrition constitutes Dr. Glinsmann's exception, and has more than adequately pioneered the clinical field to provide a base for consideration of claims.

The Panel did a commendable job surfacing the most needed reform in the weight management industry: outcome research -- as the Panel stated, "preferably in the form of peer-reviewed published studies." Just a week ago, the ARCHIVES OF INTERNAL MEDICINE published the first long-term scientific evaluation of an entire commercial weight-loss program -- the OPTIFAST Program from Sandoz Nutrition. This study had been underway since 1987. Even before the Panel had identified the issue, we had done so, and had acted on it.

The Panel also underscored that "maintenance of a stable weight, or of a newly lowered weight, is the most important feature of a successful weight loss program." In the ARCHIVES study, of 118 persons who were followed up one year after completion of the 26-week OPTIFAST treatment protocol, 21 percent maintained their full end-of-treatment weight loss, while 11 percent regained all their weight. Participants, on average, kept off 60 percent of their weight loss.

The Study also showed that 55 percent of patients who completed the full 26 weeks of treatment lost approximately one-third more weight than persons who dropped out. Weight losses were associated with improvements in blood pressure and cholesterol levels.

Sandoz Nutrition is pleased that the study confirms it is possible to maintain a significant weight loss over time in the population studied -- the medically-at-risk patient 50

pounds or 30 percent or more over ideal body weight. This study and others in progress or in-press will influence improvements now underway in our core weight-loss and weight management programs. The latter currently include the 26-week ENCORE Maintenance Support Program and the intensive 8-week Staying on Track Relapse Intervention Program. Moreover, we will continue to improve our understanding of predictors of longer-term success through our OPTILINK® National Database that now contains data on more than 11,000 patient records.

**Federal Trade Commission and Advertising Practices**

While obesity, we are learning, can be managed, it cannot yet be cured. Studies such as that in the ARCHIVES are encouraging for showing that maintaining a weight loss is possible. Researchers, however, must rethink the notion of "maintenance" of weight loss in favor of a chronic disease management model positing long-term, possibly lifelong, management of a healthier weight with periods of normal weight fluctuations. Longer time periods for measuring "success" must at the same time, be integrated into the clinical evaluation process.

Unfortunately, the weight loss industry, by and large, has not been interested in health or weight management. This may be because the weight loss industry tends to be made up of business people, not health professionals. The worst offenders get in and out of fat people's lives -- and pockets -- as quickly as possible. Little money appears to have been

spent on obtaining clinical data deemed acceptable by NIH despite substantiation concerns voiced by FTC. Overall, the last two years have seen few changes, despite the well-intentioned efforts of the FTC.

With respect to our involvement in the FTC effort, Sandoz Nutrition signed a consent decree in July 1991 acknowledging that we would henceforth provide greater detail when making claims of safety or efficacy, but not admitting that prior safety or efficacy claims had been false and misleading. In coming to a prompt and amicable agreement with the FTC, we were assured that our leadership position would help lead to a speedy clean-up of egregious advertising practices by others in the industry. We remain confident that this will occur.

In addition to supporting FTC efforts, in March 1991 we joined with the Commissioner of Consumer Affairs in New York City to recommend that weight loss providers collect and share outcome data. Sandoz Nutrition voluntarily adopted the New York "Truth-in-Dieting" regulations, recommending they be used by OPTIFAST Programs nationwide. We also suggested that the commission incorporate a "Weight Loss Consumer's Bill Of Rights" in the regulations. This was formally adopted, and the law became effective in May 1992. We believe that many of our independent OPTIFAST Programs have, at our recommendation, adopted the regulations as well.

In contrast, the marketing practices and claims of many other major weight loss companies have changed little.

-o-

Testimonial images of individuals achieving massive weight loss and shrinking clothing sizes still abound. One company has gone so far as to present an abstract at a scientific meeting claiming that participation in such testimonial advertising was beneficial to maintaining a lower body weight.

**Basic Research**

Absent from much of the public debate about weight loss claims, treatments, and effectiveness is attention to basic metabolic and behavioral research. With the technological tools available today, such research holds the promise to radically expand our understanding of obesity and how treat it in the future.

What we call obesity today may in fact be a number of conditions presenting with the same symptoms, and there may be a number of therapeutic paths to each of those conditions.

For example, in metabolic research there are a number of possible causes to evaluate, from hormonal abnormalities involving insulin and steroids, to autonomic nervous system malfunction and its interaction with hormonal control systems, to what researcher Gerald R. Reaven called, in his 1988 Banting Lecture, "Syndrome X."

This last area of research is especially germane to the future of obesity treatment. Syndrome X is a process which can be traced to the resistance of insulin-stimulated glucose uptake. Dr. Reaven's and others' primary observation is that co-morbidities of obesity -- i.e., related health problems

such as high blood pressure and diabetes -- develop in a systematic, predictable order over time. This order is, typically, elevated insulin levels, then elevated cholesterol levels, followed by elevated blood pressure levels, and finally the frank presentation of Type II diabetes. A preliminary analysis of 11,000 OPTIFAST Program participants has shown a similar progression. The implications for treatment are elementary but profound: intervene at an earlier stage with a non-pharmacologic dietary regimen, and many of these co-morbidities could be reduced or prevented. Our experience in the OPTIFAST Program has shown that in most cases, dietary intervention results in these physiological parameters returning to normal. It is not uncommon to have patients, under the guidance of their physicians, either drastically reduce or even eliminate their medications within the first few weeks of treatment, long before any dramatic cosmetic changes have occurred.

Within the field of behavioral research, there are equally promising developments. One is studying the prevalence and nature of binge-eating disorder among some obese people. Another is an examination of the cardiovascular benefits of physical activity that challenges the long-held notion that, to be effective, exercise must occur in continuous chunks 3-4 times a week. Given the known positive effect of physical activity on adherence to a weight management regimen, this type of research could benefit millions of sedentary and overweight individuals not currently doing "exercise."

**Recommendations and Predictions**

In conclusion, Sandoz Nutrition urges the Subcommittee to consider the following recommendations and predictions.

- FTC and NIH should continue their efforts. In addition, they should immediately 1) apply the healthcare-based standards they have advocated evenly to all members of the weight loss industry, and 2) recommend measures to make clear to the public the differences among mild, moderate and severe overweight and the distinction that treatments may vary accordingly. Individuals 40 pounds or 20 percent or more over ideal body weight -- by definition obese and at risk to their health -- should be encouraged to see their physician for advice on an effective treatment regimen.
- More dollars must be found for basic research into what causes the complex, resistant condition of obesity. Any disease that has the potential to harm the health of more than 1 in 5 Americans -- half of whom may be fat because of their genes -- must be researched as thoroughly as heart disease or cancer. Still, a "magic bullet" cure for obesity is probably decades away. In the short term, this country must:
- Embrace prevention.

Healthcare reform will be a reality -- possibly this year.

37 million Americans -- just a few million more than the number of obese citizens -- may be added to insurers' rolls. These bill-payers, most likely led by the taxpayer-supported U.S. government, will finally use the carrot of prevention instead of the stick of utilization review.

The need for prevention of major, chronic health problems in an aging population leads me to a number of predictions. Among U.S. physicians, we will see, as have the Canadians, a shift away from the costlier procedural specialties to less costly preventive care delivered by the family physician or general practitioner.

Among these physicians, obesity will finally be seen for what it is -- an independent health risk factor amenable to improvement and in which the physician can play a vital role.

According to the 1988 Surgeon General's Report on Nutrition and Health, for 2 out of 3 Americans who do not smoke or drink, eating patterns may determine their long-term health more than any other factor.

The other half of the equation -- exercise -- will come to be seen in light of exciting new research alluded to earlier that may make physical activity more accessible for more overweight people.

What physicians lack that industry can help provide are skills and tools they can use to integrate health risk factor management into their practices. With respect to obesity,

the combination of readily available outcome data and new research on causation could turn physicians' current mood of frustration in treating their obese patients into cautious optimism.

As a physician, I must add a personal note. I have seen the misery that brings people to treatment, the hope of initial weight loss, the fatalism of prior failures, the joy of regaining mobility, and the panic of relapse. I have seen individuals who are embarrassed to take off their shoes for a physical exam because they know they cannot put them back on again, and who weep when I must help them. It also goes, perhaps without saying, that I have seen the most profound manifestation of obesity too often: death at an early age.

In response to the disturbing mortality and morbidity rates associated with obesity, the U.S. Public Health Service's national consortium Healthy People 2000 made a modest proposal: reduce overweight to a prevalence of no more than 20% of the American people by the year 2000. This worthy goal will not be met until:

- Government funds basic and applied research on obesity's causes and treatments, and...
- Industry accepts the charge from government and the public to evaluate weight management programs by healthcare community standards and make changes as necessary.

Then we might see less of the hype and more of the help we as a nation must provide to improve the health of millions of overweight Americans.

# # #

TESTIMONY PRESENTED TO

SMALL BUSINESS SUBCOMMITTEE ON REGULATION,
BUSINESS OPPORTUNITIES AND ENERGY

JULY 15, 1992

BY

BARBARA J. YODER

PRESIDENT, NATIONAL ASSOCIATION
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My name is Barbara Yoder, and I am president of the National Association of Weight Loss Counselors (NAWLC). I welcome the opportunity to present testimony to Rep. Wyden and the Small Business-Subcommittee on Regulation, Business Opportunities and Energy.

The NAWLC is a very new non-profit corporation. Counselors from several different commercial weight loss companies met in January of this year to set standards and establish credentialing for our profession. The NAWLC is governed by its Board of Directors, which consists of the elected officers and a Professional Advisory Board. The Professional Advisory Board is made up of five professionals who have achieved a masters degree or above in one of the following areas: Nursing, Exercise Physiology, Counseling, Nutrition and Education. We organized ourselves because we want to become more effective in our work.

I have read the testimony that has been presented to this committee, and I want to assure you, the public and the professional people who have testified here, that we, the NAWLC members, understand the problem. We understand about false and deceptive advertising, false hopes, failure, gimmicks and fads. We understand that some clients belong in therapy rather than a weight loss program. We applaud your efforts to correct these problems. We understand the complexities of obesity and know there are no simple solutions. We understand that unless we are a part of the solution, we are a part of the problem. We also understand we have something important to contribute--that our experience, compassion and common sense are valuable assets and we can collaborate effectively with the scientific community.

I would like to define for you the problems identified by the NAWLC specific to weight loss counselors as a group, outline our plan to solve those problems and report our progress so far.

THE PROBLEMS

1. We don't have any credentials and therefore no credibility. It is embarrassing to us that all workers in the weight loss field are lumped together as being ill trained and uneducated, regardless of background, length of service or knowledge.

We have no means of providing clients, the legislature or professionals with proof of our competency.

2. There are no weight loss counseling training schools. Weight loss companies provide training, but the focus is primarily sales training and proprietary information rather than specific nutrition knowledge or counseling training.

3. There are no standards of practice or definitions of success. We don't know our limitations nor does anyone else. No one has offered us any kind of structured entry level training program or curriculum.

4. There is no career mobility. It is not unusual for a person to work at a company for a year or two, not be able to improve their status or pay and end up leaving the industry entirely. As a result, their experience and training is lost.

5. It is difficult for owners/managers to find qualified people to work in weight loss clinics. There is certainly no glamour or status involved that would attract workers into the field. The pay is low and there is not much chance of advancement. And of course, there are no training schools churning out eager graduates.

## THE SOLUTION

1. Offer a certification program designed for entry level workers in the field. Require a pre-certification class, competency testing and a professional designation. We agree with Dr. Frank: let those who don't want to be certified take their chances in this competitive field among those who are certified. Make the industry self- regulating and self supporting to avoid government involvement and expense.

2. Provide mandatory continuing education courses for certified counselors. Make certification renewal contingent upon compliance with continuing education requirements.

3. Write definitions and determine standards of practice for certified weight loss counselors, being specific enough that there will be no question about qualifications, limitations or defining characteristics.

4. Educate the public and other professionals to appreciate these standards and definitions.

## PROGRESS SO FAR

The NAWLC has written its By-laws, mission statement, and code of ethics. We have outlined the responsibilities of a Certified Weight Loss Counselor. We have written a definition of success. We have acquired approximately 50 members in several states.

The Professional Advisory Board will be teaching the first ever pre-certification class for weight loss counselors in September, 1992. Those who pass the test will become the first Certified Weight Loss Counselors in the country. We are planning our next Conference in September as well. At that time specific definitions, continuing education criteria and standards and scope of practice will be written.

We are also the accrediting agency for weight loss counseling schools and curriculums. Guidelines have been written to provide for the development of weight loss counseling schools in various states, so that certification will soon be available in all areas of the country.

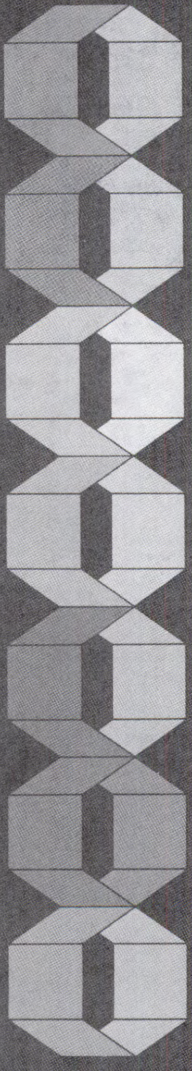
We are inviting comments, criticism, or encouragement from all interested parties regarding our organization. You are all welcome to examine our credentials and character.

Progress in promoting health in our country through weight loss can only be achieved through constant evaluation, education, communication and constructive criticism. It is the desire of the NAWLC to contribute to that progress.

Thank you for the opportunity to present this testimony.

Nutrition and Your Health:

# Dietary Guidelines for Americans



**Eat a variety of foods** page 5

**Maintain healthy weight** page 8

**Choose a diet low in fat, saturated fat, and cholesterol** page 13

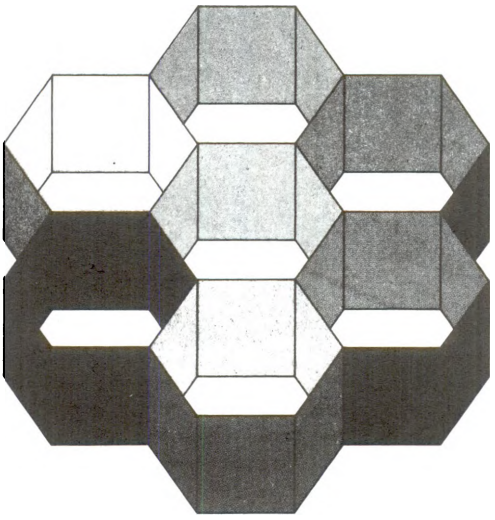
**Choose a diet with plenty of vegetables, fruits, and grain products** page 18

**Use sugars only in moderation** page 21

**Use salt and sodium only in moderation** page 23

**If you drink alcoholic beverages, do so in moderation** page 25

Third Edition, 1990
U.S. Department of Agriculture
U.S. Department of Health and Human Services



Revised November 1990

2

Nutrition and Your Health:

# Dietary Guidelines for Americans

What should Americans eat to stay healthy?

These guidelines help answer this question. They are advice for healthy Americans ages 2 years and over—not for younger children and infants, whose dietary needs differ. The guidelines reflect recommendations of nutrition authorities who agree that enough is known about diet's effect on health to encourage certain dietary practices by Americans (see page 27).

Many American diets have too many calories and too much fat (especially saturated fat), cholesterol, and sodium. They also have too little complex carbohydrates and fiber. Such diets are one cause of America's high rates of obesity and of certain diseases—heart disease, high blood pressure, stroke, diabetes, and some forms of cancer. The exact role of diet in some of these is still being studied.

Diseases caused by vitamin and mineral deficiencies are rare in this country. But some people do not get recommended amounts of a few nutrients, especially calcium and iron.

Food alone cannot make you healthy. Good health also depends on your heredity, your environment, and the health care you get. Your lifestyle is also important to your health—how much you exercise and whether you smoke, drink alcoholic beverages to excess, or abuse drugs, for example. But a diet based on these guidelines can help you keep healthy and may improve your health.

The first two guidelines form the framework for the diet: "Eat a variety of foods" for the nutrients you need and for energy (calories) to "Maintain healthy weight." The next two guidelines stress the need for many Americans to change their diets to be lower in fat, especially saturated fat, and higher in complex carbohydrates and fiber. Other guidelines suggest only moderate use of sugars, salt, and, if used at all, alcoholic beverages.

## DIETARY GUIDELINES FOR AMERICANS

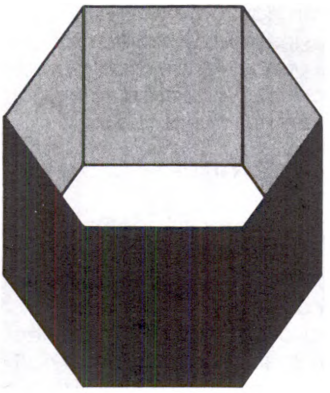
- **Eat a variety of foods**
- **Maintain healthy weight**
- **Choose a diet low in fat, saturated fat, and cholesterol**
- **Choose a diet with plenty of vegetables, fruits, and grain products**
- **Use sugars only in moderation**
- **Use salt and sodium only in moderation**
- **If you drink alcoholic beverages, do so in moderation.**

These guidelines call for moderation—avoiding extremes in diet. Both eating too much and eating too little can be harmful. Also, be cautious of diets based on the belief that a food or supplement alone can cure or prevent disease.

Your good health may depend on your learning more about yourself. Are you at your healthy weight? Are your blood pressure and your blood cholesterol levels too high? If so, diet or medicine your doctor prescribes may help reduce them. Generally, the sooner a problem is found, the easier it is to treat.

The foods Americans have to choose from are varied, plentiful, and safe to eat. These guidelines can help you choose a diet that is both healthful and enjoyable.

Read on for more about each guideline—what it means, how it is important to health, brief "advice for today," and some tips on using the guideline. See page 27 for how to get more help.



# Eat a Variety of Foods

You need more than 40 different nutrients for good health. Essential nutrients include vitamins, minerals, amino acids from protein, certain fatty acids from fat, and sources of calories (protein, carbohydrates, and fat).

These nutrients should come from a variety of foods, not from a few highly fortified foods or supplements. Any food that supplies calories and nutrients can be part of a nutritious diet. The content of the total diet over a day or more is what counts.

Many foods are good sources of several nutrients. For example, vegetables and fruits are important for vitamins A and C, folic acid, minerals, and fiber. Breads and cereals supply B vitamins, iron, and protein; whole-grain types are also good sources of fiber. Milk provides protein, B vitamins, vitamins A and D, calcium, and phosphorus. Meat, poultry, and fish provide protein, B vitamins, iron, and zinc.

No single food can supply all nutrients in the amounts you need. For example, milk supplies calcium but little iron; meat supplies iron but little calcium. To have a nutritious diet, you must eat a variety of foods.

One way to assure variety—and with it, an enjoyable and nutritious diet—is to choose

foods each day from five major food groups (see box). Individuals who do not eat foods from one or more of the food groups may want to contact a dietitian for help in planning how to meet nutritional needs.

**A DAILY FOOD GUIDE**

Eat a variety of foods daily, choosing different foods from each group. Most people should have at least the lower number of servings suggested from each food group. Some people may need more because of their body size and activity level. Young children should have a variety of foods but may need small servings.

| Food group | Suggested servings |
|---|---|
| Vegetables | 3-5 servings (see p. 20)[1] |
| Fruits | 2-4 servings (see p. 20) |
| Breads, cereals, rice, and pasta | 6-11 servings (see p. 20) |
| Milk, yogurt, and cheese | 2-3 servings (see p. 17) |
| Meats, poultry, fish, dry beans and peas, eggs, and nuts | 2-3 servings (see p. 17) |

[1]See pages noted for help on how to choose foods to follow the other guidelines and on what counts as a serving.

Source: USDA's Food Guide (see page 27).

People who are inactive or are trying to lose weight may eat little food. They need to take special care to choose lower calorie, nutrient-rich foods from the five major food groups. They also need to eat less of foods high in calories and low in essential nutrients, such as fats and oils, sugars, and alcoholic beverages.

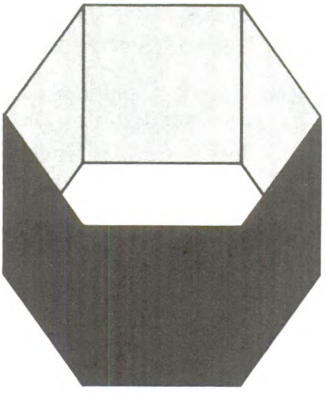
Diets of some groups of people are notably low in some nutrients. Many women and adolescent girls need to eat more calcium-rich foods, such as milk and milk products, to get the calcium they need for healthy bones throughout life. Young children, teenage girls, and women of childbearing age must take care to eat enough iron-rich foods such as

lean meats; dry beans; and whole-grain and iron-enriched breads, cereals, and other grain products.

Supplements of some nutrients taken regularly in large amounts can be harmful. Vitamin and mineral supplements at or below the Recommended Dietary Allowances (RDA) are safe, but are rarely needed if you eat a variety of foods. Here are exceptions in which your doctor may recommend a supplement:

- Pregnant women often need an iron supplement. Some other women in their childbearing years may also need an iron supplement to help replace iron lost in menstrual bleeding.
- Certain women who are pregnant or breast-feeding may need a supplement to meet their increased requirements for some nutrients.
- People who are unable to be active and eat little food may need supplements.
- People, especially older people, who take medicines that interact with nutrients may need supplements.

**Advice for today:** Get the many nutrients your body needs by choosing different foods you enjoy eating from these five groups daily: vegetables, fruits, grain products, milk and milk products, and meats and meat alternatives.



# Maintain Healthy Weight

If you are too fat or too thin, your chances of developing health problems are increased.

Being too fat is common in the United States. It is linked with high blood pressure, heart disease, stroke, the most common type of diabetes, certain cancers, and other types of illness.

Being too thin is a less common problem. It occurs with anorexia nervosa and is linked with osteoporosis in women and greater risk of early death in both women and men.

Whether your weight is "healthy" depends on how much of your weight is fat, where in your body the fat is located, and whether you have weight-related medical problems, such as high blood pressure, or a family history of such problems.

What is a healthy weight for you? There is no exact answer right now. Researchers are trying to develop more precise ways to describe healthy weight. In the meantime, you can use the guidelines suggested below to help judge if your weight is healthy.

See if your weight is within the range suggested in the table for persons of your age and height. The table shows higher weights for people 35 years and above than for younger adults. This is because recent research suggests

**Table. Suggested Weights for Adults**

| Height[1] | Weight in pounds[2] | |
|---|---|---|
| | 19 to 34 years | 35 years and over |
| 5'0" | [3]97-128 | 108-138 |
| 5'1" | 101-132 | 111-143 |
| 5'2" | 104-137 | 115-148 |
| 5'3" | 107-141 | 119-152 |
| 5'4" | 111-146 | 122-157 |
| 5'5" | 114-150 | 126-162 |
| 5'6" | 118-155 | 130-167 |
| 5'7" | 121-160 | 134-172 |
| 5'8" | 125-164 | 138-178 |
| 5'9" | 129-169 | 142-183 |
| 5'10" | 132-174 | 146-188 |
| 5'11" | 136-179 | 151-194 |
| 6' 0" | 140-184 | 155-199 |
| 6' 1" | 144-189 | 159-205 |
| 6' 2" | 148-195 | 164-210 |
| 6' 3" | 152-200 | 168-216 |
| 6' 4" | 156-205 | 173-222 |
| 6' 5" | 160-211 | 177-228 |
| 6' 6" | 164-216 | 182-234 |

[1]Without shoes.

[2]Without clothes.

[3]The higher weights in the ranges generally apply to men, who tend to have more muscle and bone; the lower weights more often apply to women, who have less muscle and bone.

Source: Derived from National Research Council, 1989 (see page 27).

that people can be a little heavier as they grow older without added risk to health. Just how much heavier is not yet clear. The weight ranges given in the table are likely to change based on research under way.

Ranges of weights are given in the table because people of the same height may have equal amounts of body fat but differ in muscle and bone. The higher weights in the ranges are suggested for people with more muscle and bone.

Weights above the range are believed to be unhealthy for most people. Weights slightly below the range may be healthy for some small-boned people but are sometimes linked to health problems, especially if sudden weight loss has occurred.

Research also suggests that, for adults, body shape as well as weight is important to health. Excess fat in the abdomen is believed to be of greater health risk than that in the hips and thighs. There are several ways to check body shape. Some require the help of a doctor; others you can do yourself.

A look at your profile in the mirror may be enough to make it clear that you have too much fat in the abdomen. Or you can check your body shape this way:

- Measure around your waist near your navel while you stand relaxed, not pulling in your stomach.
- Measure around your hips, over the buttocks, where they are largest.
- Divide the waist measure by the hips measure to get your waist-to-hip ratio. Research in adults suggests that ratios close to or above one are linked with greater risk for several diseases. However, ratios have not been defined for all populations or age groups.

If your weight is within the range in the table, if your waist-to-hip ratio does not place you at risk, and if you have no medical problem for which your doctor advises you to gain or lose weight, there appears to be no health advantage to changing your weight. If you do not meet all of these conditions, or if you are not sure, you may want to talk to your doctor about how your weight might affect your health and what you should do about it.

Heredity plays a role in body size and shape as do exercise and what you eat. Some people seem to be able to eat more than others and still maintain a good body size and shape.

No one plan for losing weight is best for everyone. If you are not physically active, regular exercise may help you lose weight and keep it off. See page 12 for the calories expended in some activities. If you eat too much, decreasing your calorie intake as advised on page 12 may help. However, getting enough of some nutrients is difficult in diets of 1,200 calories or less. Long-term success usually depends upon new and better lifelong habits of both exercise and eating.

Do not try to lose weight too fast. A steady loss of 1/2 to 1 pound a week until you reach your goal is generally safe. Avoid crash weight-loss diets that severely restrict the variety of foods or the calories you can have.

Avoid other extreme approaches to losing weight. These include inducing vomiting and using medications such as laxatives, amphetamines, and diuretics. Such approaches are not appropriate for losing weight and can be dangerous.

You probably do not need to try to lose weight if your weight is already below the suggested range in the table and if you are otherwise healthy. If you lose weight suddenly or for unknown reasons, see a doctor. Unexplained weight loss may be an early clue to a health problem.

Children need calories to grow and develop normally; weight-reducing diets are usually not recommended for them. Overweight children may need special help in choosing physical activities they enjoy and nutritious diets with adequate but not excessive calories.

**Advice for today:** Check to see if you are at a healthy weight. If not, set reasonable weight goals and try for long-term success through better habits of eating and exercise. Have children's heights and weights checked regularly by a doctor.

**TO INCREASE CALORIE EXPENDITURE—**
be more physically active.

| Activity | Calories expended per hour[1] | |
|---|---|---|
| | Man[2] | Woman[2] |
| Sitting quietly | 100 | 80 |
| Standing quietly | 120 | 95 |
| Light activity: | 300 | 240 |
| Cleaning house | | |
| Office work | | |
| Playing baseball | | |
| Playing golf | | |
| Moderate activity: | 460 | 370 |
| Walking briskly (3.5 mph) | | |
| Gardening | | |
| Cycling (5.5 mph) | | |
| Dancing | | |
| Playing basketball | | |
| Strenuous activity: | 730 | 580 |
| Jogging (9 min./mile) | | |
| Playing football | | |
| Swimming | | |
| Very strenuous activity: | 920 | 740 |
| Running (7 min./mile) | | |
| Racquetball | | |
| Skiing | | |

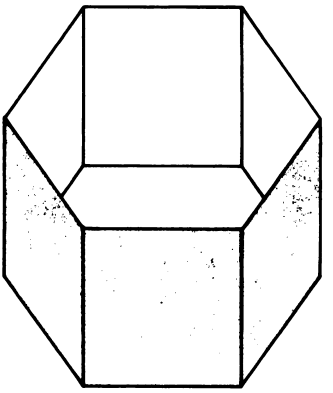
[1]May vary depending on environmental conditions.
[2]Healthy man, 175 lbs; healthy woman, 140 lbs

Source: Derived from McArdle, et al., **Exercise Physiology**, 1986.

**TO DECREASE CALORIE INTAKE—**
Eat a variety of foods that is low in calories and high in nutrients:

- Eat less fat and fatty foods.
- Eat more fruits, vegetables, and breads and cereals—without fats and sugars added in preparation and at the table.
- Eat less sugars and sweets.
- Drink little or no alcoholic beverages.

Eat smaller portions; limit second helpings.



# Choose a Diet Low in Fat, Saturated Fat, and Cholesterol

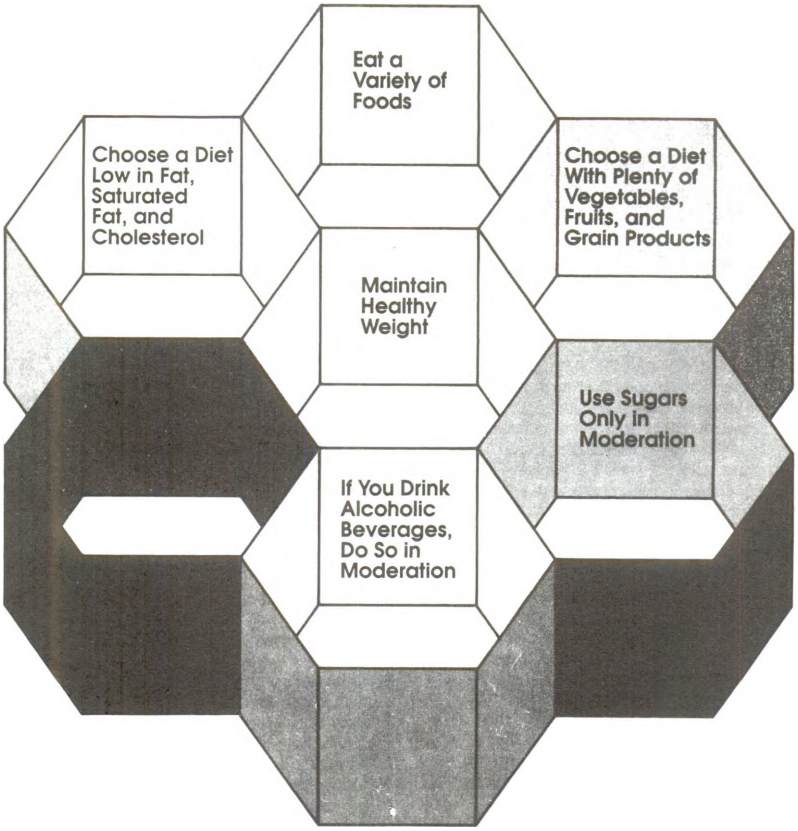
Most health authorities recommend an American diet with less fat, saturated fat, and cholesterol. Populations like ours with diets high in fat have more obesity and certain types of cancer. The higher levels of saturated fat and cholesterol in our diets are linked to our increased risk for heart disease.

A diet low in fat makes it easier for you to include the variety of foods you need for nutrients without exceeding your calorie needs because fat contains over twice the calories of an equal amount of carbohydrates or protein.

A diet low in saturated fat and cholesterol can help maintain a desirable level of blood cholesterol. For adults this level is below 200 mg/dl. As blood cholesterol increases above this level, greater risk for heart disease occurs. Risk can also be increased by high blood pressure, cigarette smoking, diabetes, a family history of premature heart disease, obesity, and being a male.

The way diet affects blood cholesterol varies among individuals. However, blood cholesterol does increase in most people when they eat a

(continued on page 16)




**Use the seven guidelines together as you choose a healthful and enjoyable diet.**

diet high in saturated fat and cholesterol and excessive in calories. Of these, dietary saturated fat has the greatest effect; dietary cholesterol has less.

Suggested goals for fats in American diets are as follows:

**Total fat.** An amount that provides 30 percent or less of calories is suggested. Thus, the upper limit on the grams of fat in your diet depends on the calories you need. For example, at 2,000 calories per day, your suggested upper limit is 600 calories from fat (2,000 x .30). This is equal to 67 grams of fat (600 ÷ 9, the number of calories each gram of fat provides). The grams of fat in some foods are shown in the box.

**Saturated fat.** An amount that provides less than 10 percent of calories (less than 22 grams at 2,000 calories per day) is suggested. All fats contain both saturated and unsaturated fat (fatty acids). The fats in animal products are the main sources of saturated fat in most diets, with tropical oils (coconut, palm kernel, and palm oils) and hydrogenated fats providing smaller amounts.

**Cholesterol.** Animal products are the source of all dietary cholesterol. Eating less fat from animal sources will help lower cholesterol as well as total fat and saturated fat in your diet.

These goals for fats are not for children under 2 years, who have special dietary needs. As children begin to eat with the family, usually at about 2 years of age or older, they should be encouraged to choose diets that are lower in fat and saturated fat and that provide the calories and nutrients they need for normal growth. Older children and adults with established food habits may need to change their diets gradually toward the goals.

These goals for fats apply to the diet over several days, not to a single meal or food. Some foods that contain fat, saturated fat, and cholesterol, such as meats, milk, cheese, and eggs, also contain high-quality protein and are our best sources of certain vitamins and minerals. Lowfat choices of these foods are lean meat and lowfat milk and cheeses.

**Advice for today:** Have your blood cholesterol level checked, preferably by a doctor. If it is high, follow the doctor's advice about diet and, if necessary, medication. If it is at the desirable level, help keep it that way with a diet low in fat, saturated fat, and cholesterol: Eat plenty of vegetables, fruits, and grain products; choose lean meats, fish, poultry without skin, and lowfat dairy products most of the time; and use fats and oils sparingly.

**FOR A DIET LOW IN FAT, SATURATED FAT, AND CHOLESTEROL**

**Fats and oils**

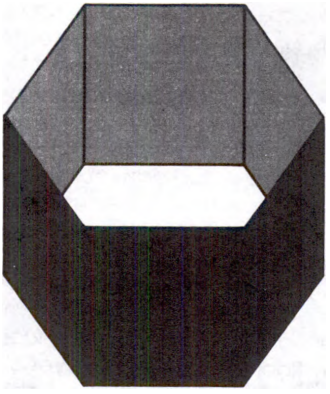
- Use fats and oils sparingly in cooking.
- Use small amounts of salad dressings and spreads, such as butter, margarine, and mayonnaise. One tablespoon of most of these spreads provides 10 to 11 grams of fat.
- Choose liquid vegetable oils most often because they are lower in saturated fat.
- Check labels on foods to see how much fat and saturated fat are in a serving.

**Meat, poultry, fish, dry beans, and eggs**

- Have two or three servings, with a daily total of about 6 ounces. Three ounces of cooked lean beef or chicken without skin—the size of a deck of cards—provides about 6 grams of fat.
- Trim fat from meat; take skin off poultry.
- Have cooked dry beans and peas instead of meat occasionally.
- Moderate the use of egg yolks and organ meats.

**Milk and milk products**

- Have two or three servings daily. (Count as a serving: 1 cup of milk or yogurt or about 1 1/2 ounces of cheese.)
- Choose skim or lowfat milk and fat-free or lowfat yogurt and cheese most of the time. One cup of skim milk has only a trace of fat, 1 cup of 2-percent-fat milk has 5 grams of fat, and 1 cup of whole milk has 8 grams of fat.



# Choose a Diet with Plenty of Vegetables, Fruits, and Grain Products

This guideline recommends that adults eat at least three servings of vegetables and two servings of fruits daily. It recommends at least six servings of grain products, such as breads, cereals, pasta, and rice, with an emphasis on whole grains. (See box on page 20 for what to count as a serving.) Children should also be encouraged to eat plenty of these foods.

Vegetables, fruits, and grain products are important parts of the varied diet discussed in the first guideline. They are emphasized in this guideline especially for their complex carbohydrates, dietary fiber, and other food components linked to good health.

These foods are generally low in fats. By choosing the suggested amounts of them, you are likely to increase carbohydrates and decrease fats in your diet, as health authorities suggest. You will also get more dietary fiber.

Complex carbohydrates, such as starches, are in breads, cereals, pasta, rice, dry beans and peas, and other vegetables, such as potatoes and corn. Dietary fiber—a part of

plant foods—is in whole-grain breads and cereals, dry beans and peas, vegetables, and fruits. It is best to eat a variety of these fiber-rich foods because they differ in the kinds of fiber they contain.

Eating foods with fiber is important for proper bowel function and can reduce symptoms of chronic constipation, diverticular disease, and hemorrhoids. Populations like ours with diets low in dietary fiber and complex carbohydrates and high in fat, especially saturated fat, tend to have more heart disease, obesity, and some cancers. Just how dietary fiber is involved is not yet clear.

Some of the benefit from a higher fiber diet may be from the food that provides the fiber, not from fiber alone. For this reason, it's best to get fiber from foods rather than from supplements. In addition, excessive use of fiber supplements is associated with greater risk for intestinal problems and lower absorption of some minerals.

**Advice for today:** Eat more vegetables, including dry beans and peas; fruits; and breads, cereals, pasta, and rice. Increase your fiber intake by eating more of a variety of foods that contain fiber naturally.

**FOR A DIET WITH PLENTY OF VEGETABLES, FRUITS, AND GRAIN PRODUCTS, HAVE DAILY—**

**Three or more servings of various vegetables.**
(Count as a serving: 1 cup of raw leafy greens, 1/2 cup of other kinds)

- Have dark-green leafy and deep-yellow vegetables often.
- Eat dry beans and peas often. (Count 1/2 cup of cooked dry beans or peas as a serving of vegetables or as 1 ounce of the meat group.)
- Also eat starchy vegetables, such as potatoes and corn.

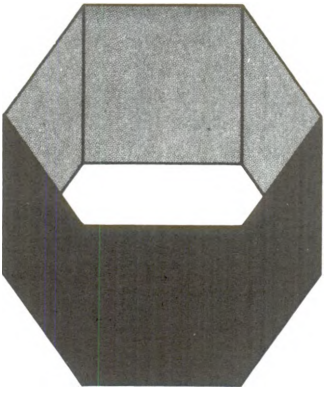
**Two or more servings of various fruits.**
(Count as a serving: 1 medium apple, orange, or banana; 1/2 cup of small or diced fruit; 3/4 cup of juice)

- Have citrus fruits or juices, melons, or berries regularly.
- Choose fruits as desserts and fruit juices as beverages.

**Six or more servings of grain products (breads, cereals, pasta, and rice)**
(Count as a serving: 1 slice of bread; 1/2 bun, bagel, or english muffin; 1 ounce of dry ready-to-eat cereal; 1/2 cup of cooked cereal, rice, or pasta)

- Eat products from a variety of grains, such as wheat, rice, oats, and corn.
- Have several servings of whole-grain breads and cereals daily.

Vegetables, fruits, and grain products are generally low in calories if fats and sugars are used sparingly in their preparation and at the table.



# Use Sugars Only in Moderation

Americans eat sugars in many forms (see box on page 22). Sugars provide calories and most people like their taste. Some serve as natural preservatives, thickeners, and baking aids in foods. This guideline cautions about eating sugars in large amounts and about frequent snacks of foods containing sugars and starches.

Sugars and many foods that contain them in large amounts supply calories but are limited in nutrients. Thus, they should be used in moderation by most healthy people and sparingly by people with low calorie needs. For very active people with high calorie needs, sugars can be an additional source of calories.

Both sugars and starches—which break down into sugars—can contribute to tooth decay. Sugars and starches are in many foods that also supply nutrients—milk; fruits; some vegetables; and breads, cereals, and other foods with sugars and starches as ingredients. The more often these foods—even small amounts—are eaten and the longer they are in the mouth before teeth are brushed, the greater the risk for tooth decay. Thus, eating such foods as frequent between-meal snacks may be more harmful to teeth than having them at meals.

Regular daily brushing with a fluoride toothpaste helps reduce tooth decay by getting fluoride to the teeth. Fluoridated water or other sources of fluoride that a doctor or dentist suggests are especially important for children whose unerupted teeth are forming and growing.

Diets high in sugars have not been shown to cause diabetes. The most common type of diabetes occurs in overweight adults, and avoiding sugars alone will not correct overweight.

**Advice for today:** Use sugars in moderate amounts—sparingly if your calorie needs are low. Avoid excessive snacking and brush and floss your teeth regularly.

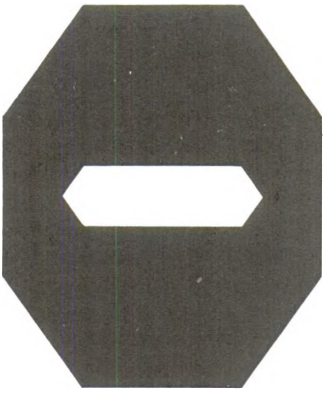
**WHAT IS MEANT BY "SUGARS"?**

| | |
|---|---|
| table sugar (sucrose) | honey |
| brown sugar | syrup |
| raw sugar | corn sweetener |
| glucose (dextrose) | high-fructose corn syrup |
| fructose | molasses |
| maltose | fruit juice concentrate |
| lactose | |

Read food labels. A food is likely to be high in sugars if its ingredient list shows one of the above first or second or if it shows several of them.

**FOR HEALTHIER TEETH AND GUMS—**

- Moderate the use of foods containing sugars and starches between meals.
- Brush and floss teeth regularly.
- Use a fluoride toothpaste.
- Ask your dentist or doctor about the need for supplemental fluoride, especially for children.
- Do not use a nursing bottle with any beverage other than water as a pacifier.



# Use Salt and Sodium Only in Moderation

Table salt contains sodium and chloride—both are essential in the diet. However, most Americans eat more salt and sodium than they need. Food and beverages containing salt provide most of the sodium in our diets, much of it added during processing and manufacturing.

In populations with diets low in salt, high blood pressure is less common than in populations with diets high in salt. Other factors that affect blood pressure are heredity, obesity, and excessive drinking of alcoholic beverages.

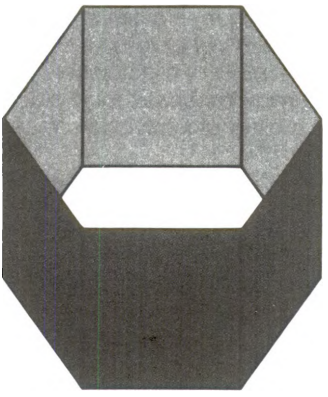
In the United States, about one in three adults has high blood pressure. If these people restrict their salt and sodium, usually their blood pressure will fall.

Some people who do not have high blood pressure may reduce their risk of getting it by eating a diet with less salt and other sources of sodium. At present there is no way to predict who might develop high blood pressure and who will benefit from reducing dietary salt and sodium. However, it is wise for most people to eat less salt and sodium because they need much less than they eat and reduction will benefit those people whose blood pressure rises with salt intake.

**Advice for today:** Have your blood pressure checked. If it is high, consult a doctor about diet and medication. If it is normal, help keep it that way: maintain a healthy weight, exercise regularly, and try to use less salt and sodium. (Normal blood pressure for adults: systolic less than 140 mmHg and diastolic less than 85 mmHg.)

**TO MODERATE USE OF SALT AND SODIUM—**

- Use salt sparingly, if at all, in cooking and at the table.
- When planning meals, consider that—
  - —fresh and plain frozen vegetables prepared without salt are lower in sodium than canned ones.
  - —cereals, pasta, and rice cooked without salt are lower in sodium than ready-to-eat cereals.
  - —milk and yogurt are lower in sodium than most cheeses.
  - —fresh meat, poultry, and fish are lower in sodium than most canned and processed ones.
  - —most frozen dinners and combination dishes, packaged mixes, canned soups, and salad dressings contain a considerable amount of sodium. So do condiments, such as soy and other sauces, pickles, olives, catsup, and mustard.
- Use salted snacks, such as chips, crackers, pretzels, and nuts, sparingly.
- Check labels for the amount of sodium in foods. Choose those lower in sodium most of the time.



# If You Drink Alcoholic Beverages, Do So in Moderation

Alcoholic beverages supply calories but little or no nutrients. Drinking them has no net health benefit, is linked with many health problems, is the cause of many accidents, and can lead to addiction. Their consumption is not recommended. If adults elect to drink alcoholic beverages, they should consume them in moderate amounts (see box on page 26).

Some people should **not** drink alcoholic beverages:

- **Women who are pregnant or trying to conceive.** Major birth defects have been attributed to heavy drinking by the mother while pregnant. Women who are pregnant or trying to conceive should not drink alcoholic beverages. However, there is no conclusive evidence that an occasional drink is harmful.
- **Individuals who plan to drive or engage in other activities that require attention or skill.** Most people retain some alcohol in the blood 3 to 5 hours after even moderate drinking.

- **Individuals using medicines, even over-the-counter kinds.** Alcohol may affect the benefits or toxicity of medicines. Also, some medicines may increase blood alcohol levels or increase alcohol's adverse effect on the brain.
- **Individuals who cannot keep their drinking moderate.** This is a special concern for recovering alcoholics and people whose family members have alcohol problems.
- **Children and adolescents.** Use of alcoholic beverages by children and adolescents involves risks to health and other serious problems.

Heavy drinkers are often malnourished because of low food intake and poor absorption of nutrients by the body. Too much alcohol may cause cirrhosis of the liver, inflammation of the pancreas, damage to the brain and heart, and increased risk for many cancers.

Some studies have suggested that moderate drinking is linked to lower risk for heart attacks. However, drinking is also linked to higher risk for high blood pressure and hemorrhagic stroke.

**Advice for today:** If you drink alcoholic beverages, do so in moderation; and don't drive.

**WHAT'S MODERATE DRINKING?**

**Women:** No more than 1 drink a day
**Men:** No more than 2 drinks a day

Count as a drink:
- 12 ounces of regular beer
- 5 ounces of wine
- 1 1/2 ounces of distilled spirits (80 proof)

**Acknowledgments:** The U.S. Department of Agriculture and the U.S. Department of Health and Human Services acknowledge the recommendations of the Dietary Guidelines Advisory Committee—the basis for this edition. The Committee consisted of Malden C. Nesheim, Ph.D. (chairman); Lewis A. Barness, M.D.; Peggy R. Borum, Ph.D.; C. Wayne Callaway, M.D.; John C. LaRosa, M.D.; Charles S. Lieber, M.D.; John A. Milner, Ph.D.; Rebecca M. Mullis, Ph.D., and Barbara O. Schneeman, Ph.D.

**Some of the scientific basis for these guidelines:**

—The Surgeon General's Report on Nutrition and Health. 1988. Public Health Service, U.S. Department of Health and Human Services.

—Diet and Health: Implications for Reducing Chronic Disease Risk. 1989. National Research Council, National Academy of Sciences.

—Recommended Dietary Allowances, 10th Ed. 1989. National Research Council, National Academy of Sciences.

**Information on how to put the guidelines into practice:**

- Contact the Human Nutrition Information Service, USDA, Room 325-A, 6505 Belcrest Road, Hyattsville, MD 20782, for how to order:

—The USDA Food Guide in "Preparing Foods and Planning Menus Using the Dietary Guidelines." HG- 232-8, 1989.

—"Dietary Guidelines and Your Diet." HG-232-1 through -11, 1986 and 1989. Bulletins on eating right the Dietary Guidelines way.

—"Nutritive Value of Foods," HG-72. 1985.

- Contact the National Institutes of Health, Room 10 A 24, Building 31, Bethesda, MD 20892, for this and other bulletins:

—"Eating for Life." NIH Publication No. 88-3000, 1988.

- Contact your county extension home economist (Cooperative Extension System) or a nutrition professional in your local Public Health Department, hospital, American Red Cross, dietetic association, diabetes association, heart association, or cancer society.

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