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DIET, PHYSICAL ACTIVITY, DIETARY SUPPLEMENTS, LIFESTYLE AND HEALTH

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

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CONTENTS

Page

Hearing held on July 25, 2002 1

Statement of:

Coates, Paul M., Ph.D., Director, Office of Dietary Supplements, National Institutes of Health; and William Dietz, M.D., Director, Division of Nutrition and Physical Activity, Centers for Disease Control and Prevention 127

Ladd, Diane, actress, film director, certified nutritional consultant, Ojai, CA 32

Seckman, David, executive director and CEO, National Nutritional Foods Association; George Bray, M.D., Boyd professor, Pennington Biomedical Research Center, Louisiana State University; Larry Kushi, associate director for etiology and prevention research, division of research, Kaiser Permanente; Pamela Peeke, M.D., assistant clinical professor of medicine, University of Maryland School of Medicine, adjunct senior scientist, National Institutes of Health; Timothy S. Church, M.D., senior associate director, medical and laboratory director, division of epidemiology and clinical applications, the Cooper Institute; and David Heber, M.D., director, division of clinical nutrition, University of California at Los Angeles 59

Letters, statements, etc., submitted for the record by:

Bray, George, M.D., Boyd professor, Pennington Biomedical Research Center, Louisiana State University, prepared statement of 72

Burton, Hon. Dan, a Representative in Congress from the State of Indiana, prepared statement of 6

Church, Timothy S., M.D., senior associate director, medical and laboratory director, division of epidemiology and clinical applications, the Cooper Institute, prepared statement of 105

Coates, Paul M., Ph.D., Director, Office of Dietary Supplements, National Institutes of Health, prepared statement of 130

Dietz, William, M.D., Director, Division of Nutrition and Physical Activity, Centers for Disease Control and Prevention, prepared statement of 141

Heber, David, M.D., director, division of clinical nutrition, University of California at Los Angeles, prepared statement of 112

Kushi, Larry, associate director for etiology and prevention research, division of research, Kaiser Permanente, prepared statement of 84

Ladd, Diane, actress, film director, certified nutritional consultant, Ojai, CA, prepared statement of 38

Maloney, Hon. Carolyn B., a Representative in Congress from the State of New York, prepared statement of 63

Peeke, Pamela, M.D., assistant clinical professor of medicine, University of Maryland School of Medicine, adjunct senior scientist, National Institutes of Health, prepared statement of 99

Schrock, Edward L., a Representative in Congress from the State of Virginia, article entitled, "The Million Pound Challenge" 21

Seckman, David, executive director and CEO, National Nutritional Foods Association, prepared statement of 63

Towns, Hon. Edolphus, a Representative in Congress from the State of New York, prepared statement of 61

Waxman, Hon. Henry A., a Representative in Congress from the State of California, prepared statement of 158

DIET, PHYSICAL ACTIVITY, DIETARY SUPPLEMENTS, LIFESTYLE AND HEALTH

THURSDAY, JULY 25, 2002

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 10:29 a.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Morella, Schrock, Maloney, Norton, Cummings, Kucinich, and Tierney.

Staff present: Kevin Binger, staff director; James C. Wilson, chief counsel; David A. Kass, deputy chief counsel; S. Elizabeth Clay, professional staff member; Blaine Rethmeier, communications director; Allyson Blandford, staff assistant; Robert A. Briggs, chief clerk; Joshua E. Gillespie, deputy chief clerk; Robin Butler, office manager; Elizabeth Crane, deputy communications director; Corinne Zaccagnini, systems administrator; Sarah Despres, minority counsel; Ellen Rayner, minority chief clerk; and Jean Gosa and Earley Green, minority assistant clerks.

Mr. BURTON. Good morning.

A quorum being present, the Committee on Government Reform will come to order.

I ask unanimous consent that all Members' and witnesses' written and opening statements be included in the record. Without objection, so ordered.

I ask unanimous consent that all articles, exhibits and extraneous or tabular material referred to be included in the record, and without objection, so ordered.

Let me start by saying we will probably have Members wandering in with their shirttails hanging out and their ties not tied because we ran until 2:30 a.m. As a matter of fact, is there anybody in the audience? I can't see yet. In any event, this is going to be a very busy day. Members are trying to get their offices all squared away so they can head for the August recess and district work period. As a result, we will have people coming in and out. We may be interrupted for several votes on the floor. We will probably have votes coming in a series of two, three or four. Representative Schrock and others probably will take the chair from time to time because I will have to go down and speak probably this afternoon on the homeland security issue since our committee had primary jurisdiction over that when we were marking up the bill.

For those of you who will be wondering why we are running in and out and why we all look bloodshot eyed and tired, that is why.

Health care oversight activities have been a high priority for this committee during my tenure as chairman. I firmly believe that as we enter the 21st century we have the opportunity to change the landscape of health care and delivery of services.

Health care costs are skyrocketing. The national health expenditures are projected to reach $2.8 trillion in 2011. If we don't turn things around by 2011, we will be spending 17 percent of the Gross Domestic Product on health care, almost $1 out of every $5. One would think that because we spend more of our GDP on health care than any other country, that we would have the best health status. This, however, is not the case.

In June 2000, the World Health Organization announced their first ever analysis of the world's health systems. They compared 191 countries and found that the United States ranked 37th out of 191. Obviously, dramatically increasing our spending on health care is not the solution. I am attaching to this statement a list of guiding principles for health care renewal in the 21st century. These principles embody what we have been working on for the last 4 years, as we have looked at the role of complementary medicine in our health care system and the importance of preserving our rights as Americans to make our own health care choices.

One of the things we have noted is that doctors are taught how to deal with problems after they occur and not before they occur. That is why complementary and alternative medicine is a necessary adjunct to make sure that we do something that will prevent the onset of health care problems so that we can cut the health care costs.

I am pleased that Ms. Diane Ladd is here with us today. Ms. Ladd has been called 1 of the 10 leading actresses in the world. Her film credits include "Rambling Rose," "Wild at Heart," "Alice Doesn't Live Here Any More," and "Christmas Vacation." Ms. Ladd has also appeared in numerous television shows including "Dr. Quinn, Medicine Woman" with my friend, Jane Seymour, and a show that everyone loves, "Touched by An Angel." One of her most recent television movies was "Talking to Heaven." Ms. Ladd, in addition to acting and directing, is a certified nutritional consultant. She is here today to share her personal insights on the role of nutrition in healing.

It may seem like common sense that diet and exercise can improve our health. There is also an increasing body of scientific evidence that supports this. Experts tell us that about 85 percent of diseases and illnesses in this country result from lifestyle decisions. Conversely, the adoption of healthy lifestyle choices, including moderate physical activity, a sensible diet and the appropriate use of dietary supplements, can improve our health.

Unfortunately, the typical medical school student will spend less time in classes learning about nutrition than we will spend in our hearing today. My son-in-law is a doctor and when I start talking to him about this stuff, he says let's talk about golf. He is a real neat guy thought. If doctors have no training in nutrition, much less dietary supplements, how are they supposed to advise their patients?

One of our witnesses today is working to change that. Dr. Pamela Peeke is a Pew Scholar in nutrition and metabolism and an ad-

junct clinical professor at the University of Maryland. She is also the author of the book, "Fight Fat After Forty." Dr. Peeke devotes her energies to the education of medical professionals in nutrition, lifestyle and fitness. She presently is teaching and devising new medical curricula in nutrition and metabolism.

As part of our investigation, we have learned that naturopathic doctors who are trained at accredited naturopathic universities receive the training in nutrition that M.D.'s ought to receive. However, students may be discouraged from applying to these schools because there is an inequality in the loan programs at the Department of Education between M.D.s and N.D.s. The Department of Education needs to eliminate this discrepancy. The committee has been active in monitoring the implementation of the Dietary Supplement Health and Education Act of 1994. Previous hearings have focused primarily on the Food and Drug Administration's lack of full implementation. To date the American public has not been well served by the FDA in this respect. It has been 8 years, and still, we do not have good manufacturing practice guidelines published. There is negligible review of imported products. We must have the full implementation of DSHEA in order to assure the quality of products on the market and that information is readily available to consumers.

Yesterday, the National Academy of Sciences, under contract with the FDA, published for comment a Proposed Framework for Evaluating the Safety of Dietary Supplements. This is also an important issue that the FDA needs to understand in order to fully implement DSHEA. As we have learned previously, tracking adverse events for dietary supplements does not provide valid scientific data on which to develop policy.

Mr. David Seckman, the executive director and CEO of the National Nutritional Foods Association is here representing the manufacturers and retailers of dietary supplements. Mr. Seckman is appropriate to speak to these issues today not just in his role at the NNFA, but also because of his background as the former vice president for regulatory affairs of the American Health Care Association and former executive director of the Illinois Health Care Association.

In addition to traditional use, there is a scientific basis for the wise use of vitamins, minerals, and botanicals to improve health. Through research, we are learning which nutritional components are best obtained through diet and which are absorbed from supplements.

We already know from traditional use and research that drinking cranberry juice can help prevent certain infections. We also know the use of acidophilus, when taking antibiotics can help prevent the onset of yeast infections. Dr. Linus Pauling told me over 30 years ago that taking vitamin C every day would help prevent cancer. I am attaching a list of widely accepted nutritional connections to improving health.

In a February 1999 hearing, Dr. Dean Ornish testified about his research showing that heart disease could be reversed through a comprehensive lifestyle improvement program that includes a low-fat and plant-based diet, moderate physical activity, stress management, and dietary supplements. This approach has been shown to

reverse heart disease, a feat that drug and surgical approaches do not achieve. Currently the Ornish program is being evaluated in a Medicare demonstration program. Clinical trials are also under way evaluating the benefit of the Ornish program for preventing a recurrence of prostate cancer. The preliminary findings are promising.

In December, I introduced H.R. 3475, the Dietary Supplement Tax Fairness Act of 2001. This bill amends the Internal Revenue Code to treat amounts paid for foods for special dietary use, dietary supplements, and medical foods as medical expenses for purposes of the medical expense deduction. This bill has also been introduced as S. 1330 in the Senate.

Last month the Journal of the American Medical Association published research that recommended that all Americans take a multivitamin every day. With improved and expanded research we will learn more about how and when nutritional supplements will improve health and play a role in the healing process. It is also through research that we will learn more about safety, toxicity, and contraindications.

On June 20th, in outlining his health and fitness initiative, President Bush made the following remarks:

> Better health is an individual responsibility, and it is an important national goal. We are making great progress in preventing, detecting and treating many chronic diseases. That is good for America. We are living longer than any generation in history. Yet we can still improve. When America and Americans are healthier, our whole society benefits. If you are interested in improving America, you can do so by taking care of your own body. This year, heart disease will cost our country at least $183 billion. If just 10 percent of adults began walking regularly, we could save billions in dollars in costs related to heart disease. Research suggests that we can reduce cancer deaths in America by one-third simply by changing our diets and getting more exercise. The evidence is clear, a healthier America is a stronger America.

The President called for the adoption of four guideposts: No. 1, be physically active every day; No. 2, develop good eating habits; No. 3, take advantage of preventative screenings; and No. 4, don't smoke, don't do drugs, and don't drink excessively.

Dr. Timothy Church of the Cooper Research Institute will be testifying about the important role that physical activity plays in improving and maintaining health. The Cooper Research Institute, founded by Dr. Kenneth Cooper, has long promoted improved health through aerobic exercise.

Regular physical activity substantially reduces the risk of dying from coronary heart disease, the Nation's leading cause of death, and decreases the risk for colon cancer, which my wife succumbed to just recently, diabetes, and high blood pressure. It also helps to control weight; contributes to healthy bones, muscles, and joints; reduces falls among the elderly; helps to relieve the pain of arthritis; reduces symptoms of anxiety and depression; and is associated with fewer hospitalizations, physician visits, and medications. Moreover, physical activity need not be strenuous to be beneficial. People of all ages benefit from moderate physical activity, such as 30 minutes of brisk walking five or more times a week.

We have a lot of other people who will testify today and I am pleased that we will hear from a variety of these people, Dr. George Bray, Boyd professor of medicine, Louisiana State University is a

leading expert on obesity. Dr. Larry Kushi, associate director for etiology and prevention research, Kaiser Permanente, is an expert on macrobiotics and other plant-based diets and their role in preventing diseases such as cancer. Dr. David Heber, director, division of clinical nutrition, University of California at Los Angeles is one of the country's leading experts on the science of dietary supplements. I am also pleased that we will receive testimony from Dr. Paul Coates of the Office of Dietary Supplements at the National Institutes of Health and Dr. William Dietz, the Director of the Division of Nutrition and Physical Activity at the Centers for Disease Control and Prevention.

Improving our health through diet and lifestyle is low cost and effective, and will save the taxpayers a lot of money and the individual citizen a lot of money. We need to find ways to empower Americans to take charge of their lives and improve their health, and reduce the incidence and tragedy of chronic and life-threatening medical conditions.

The hearing record will remain open until August 8.

Other statements? Mr. Schrock.

[The prepared statement of Hon. Dan Burton follows:]

Opening Statement
Chairman Dan Burton
Committee on Government Reform

"Diet, Physical Activity, and Dietary Supplements - the Scientific Basis For Improving Health, Saving Money, and Preserving Personal Choice"

July 25, 2002
2154 Rayburn House Office Building
10:00 a.m.

Introduction

Health care oversight activities have been a high priority in the Committee during my tenure as Chairman. I firmly believe that as we enter the twenty-first century we have the opportunity to change the landscape of health care and delivery of services.

Health care costs are skyrocketing. National health expenditures are projected to reach $2.8 trillion in 2011. If we don't turn things around, by 2011 we will be spending 17 percent of the Gross Domestic Product (GDP) on health care. One would think that because we spend more of our GDP on health care than any other country, that we would have the best health status. This, however, is not the case.

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I am pleased that Ms. Diane Ladd is here with us today. Ms. Ladd has been called one of the ten leading actresses in the world. Her film credits include "Rambling Rose," "Wild at Heart," "Alice Doesn't Live Here Any More," and "Christmas Vacation." Ms. Ladd

has also appeared in numerous television shows including "Dr. Quinn, Medicine Woman" with my friend Jane Seymour, and a show that everyone loves, "Touched by An Angel." One of her most recent television movies was "Talking to Heaven." Ms. Ladd in addition to acting and directing is a certified nutritional consultant. She is here today to share her personal insights on the role of nutrition in healing.

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Dietary Supplements

The Committee has been active in monitoring the implementation of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Previous hearings have focused primarily on the Food and Drug Administration's (FDA) lack of full implementation. To date the American public has not been well served by the FDA in this respect. It has been eight years, and still, we do not have Good Manufacturing Practice Guidelines published. There is negligible review of imported products. We must have the full implementation of DSHEA in order to assure the quality of products on the market and that information is readily available to consumers.

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Physical Activity

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and decreases the risk for colon cancer, diabetes, and high blood pressure. It also helps to control weight; contributes to healthy bones, muscles, and joints; reduces falls among the elderly; helps to relieve the pain of arthritis; reduces symptoms of anxiety and depression; and is associated with fewer hospitalizations, physician visits, and medications. Moreover, physical activity need not be strenuous to be beneficial. People of all ages benefit from moderate physical activity, such as 30 minutes of brisk walking five or more times a week.

Unfortunately more than 60% of American adults do not get enough physical activity to provide health benefits. America's youth are increasingly less involved in physical activities as well.

I am pleased that we will hear from a variety of experts today. Dr. George Bray, Boyd Professor of Medicine, Louisiana State University is a leading expert on obesity. Dr. Larry Kushi, Associate Director for Etiology and Prevention Research, Kaiser Permanente, is an expert on macrobiotics and other plant-based diets and their role in preventing diseases such as cancer. And Dr. David Heber, Director, Division of Clinical Nutrition, University of California at Los Angeles is one of the country's leading experts on the science of dietary supplements. I am also pleased that we will receive testimony from Dr. Paul Coates of the Office of Dietary Supplements at the National Institutes of Health and Dr. William Dietz, the Director of the Division of Nutrition and Physical Activity at the Centers for Disease Control and Prevention.

Improving our health through diet and lifestyle is low cost and effective. We need to think outside the box and find ways to empower Americans to take charge of their lives, improve their health, and reduce the incidence and tragedy of chronic and life threatening medical conditions.

I now recognize the ranking minority member, Mr. Waxman for his opening statement.

Attachment 1

Design Principles of Healthcare
for Accelerating Personal and Health System Renewal

Preamble

Core principles drive the way healthcare operates and is experienced. Times of change and disturbance call us to examine, clarify and commit to renew our individual and community practices. The following set of principles emphasizes the integrative nature of optimal healthcare. Such care seeks to create health by engaging new and old approaches to health for the individual, system, community and environment. Integrative care is grounded in relationships, seeks sustainability, is energized by the unknown and crafted through continuous exploration of strategies for uniting the best of the world's evolving practices, outcomes and traditions.

These principles, based on the missions and visions of diverse stakeholders, are an initial expression of an effort to create a unifying view of a renewed system for healthcare delivery and payment. These principles are meant not as ideals, but as working tools of design, application, evaluation and alignment. They are offered here for community review, revision and amendment by the ad hoc Task Force on the Principles of Healthcare.

The design principles for accelerating health and well-being in individuals, and in the health system, are:

1. *Honor wholeness and interconnectedness in all actions.*

Body, mind, spirit, community, and environment are an integral whole that cannot be separated into isolated parts. All are involved in healing. Healthcare interventions, regardless of their focus, affect the whole.

2. *Enhance the capacity for self-repair and healing.*

The innate capacity for healing and the individual's personal empowerment in supporting these natural processes are fundamental considerations in all healthcare decisions.

3. *Prioritize care in accordance with a hierarchy of treatment.*

Care, and the leveraging of resources to affect care, are prioritized along diagnostic and therapeutic hierarchies which begin with education and empowerment in healthy choices, then move to the least invasive approaches and escalate, as necessary, to approaches linked to increased likelihood of adverse effects or higher costs. The starting point for intervention is established through clarifying, with the individual receiving care, the risks associated with foregoing, and with undertaking, more invasive approaches. Chronology and cause are fundamental aspects of this healing order.

4. *Improve care through continuously expanding the evidence base.*

Healthcare is a combined art and science in which personal practices and clinical choices and services are continuously evaluated and improved, by practitioners, users and organizations, based on diverse evidence. Included are the desires, perceptions and outcomes experienced by the individuals at the center of care, the clinical experience and understandings of all members of a provider team, and particularly, systematically gathered evidence of experience and outcomes. More stringent evidentiary standards are associated with higher risk or more costly interventions.

5. *Embrace the fullness of diverse health care systems.*

Conventional, traditional, indigenous, complementary and alternative models of care, and their bodies of knowledge, have contributions to make to the healthcare, which is culturally most appropriate and effective for individuals and communities. Best practices are discovered through exploring diverse structures for integration, including parallel, collaborative and assimilative models.

6. *Partner with patients, their families and other practitioners.*

Caregivers profoundly enhance healing and strengthen shared accountability through supporting the informed decision-making of the individuals/families/loved ones they serve, and through inclusive, respectful partnerships with other practitioners with whom they collaborate in care provision.

7. *Use illness and symptoms as opportunities for learning and growth.*

Illness represents an opportunity in which healing and balance are always possible even when curing is not. Symptoms are guides to health.

8. *Explore integration in one's own care.*

Practitioners, administrators and individuals are most effective in understanding and delivering integrative healthcare, and in embracing these design principles, when they follow these principles in their own care choices.

9. *Align resource investment with these healthcare principles.*

The renewal of our healthcare payment and delivery systems is fostered by aligning resource investment in the personal, public, philanthropic and private sectors, with these principles. Humble willingness to work to resolve the tensions between one's personal and professional interests, and those shared interests expressed in these principles, is required of all participants. The renewed healthcare system is a partnership between an expanded commitment to the public health and a thriving industry of health creation.

10. Respect the time required for personal and health system change.

Interventions may be swift, but healing, habit change, and transformation take time and ongoing commitment.

In a survey of a diverse group of 105 integrative medicine industry leaders, 85% of respondents strongly (52%) or mildly (33%) agree that the emerging Complementary and Alternative Medicine (CAM) industry "will benefit from a multi-stakeholder process of clarifying, generating endorsement for, and publicizing, a set of principles which announce a unified mission relative to the individual's healthcare experience and the reformation of the broader delivery and payment system."

The initial participants in the Task Force were Gary Sandman, Clement Bezold, PhD, Roger Jahnke, OMD, Len Wisneski, MD, Pam Snider, ND, Alan Dumoff, MSW, JD, John Weeks, Terry Schmidt, PhD (Cand.), Jery Whitworth, RN, CCP, and House Government Reform staff. The Task Force, which originally grew out of the Integrative Medicine Industry Leadership Summit 2000, is associated with the Collaboration for Healthcare Renewal and operates as a center within the Institute for Alternative Futures. (http://www.thecollaboration.org/public/)

Attachment 2

Examples of Nutritional Supplements and Foods That Are Widely Accepted to Promote General Health and Healing

- Fish oil, especially from cold water fish such as tuna and mackerel that are high in omega-3 fatty acids. It is beneficial in combating arthritis, asthma, inflammatory bowel disease, heart disease, high blood pressure, and several forms of cancer, including prostrate, breast, and colon cancer.
- Flaxseed and many kinds of nuts and seeds also are high in Omega 3 fatty acids.
- Coenzyme Q-10 is important to each cell's energy metabolism. It also can be extremely helpful in treating congestive heart failure, various forms of edema, periodontal disease, diabetes, and high cholesterol.
- Milk thistle protects liver from damage and helps stimulate the growth of healthy new liver cells.
- Flaxseed has omega-3 fatty acids, as indicated above, plus fiber that can relieve constipation, reduce high cholesterol levels, and balance an excess of hormones that lead to uncomfortable PMS symptoms.
- The B vitamins; especially B-6, B-12, and folic acid; help control homocysteine levels and therefore help prevent heart disease and peripheral vascular disease.
- Vitamin E is very important in preserving and restoring hearth health. It helps ward off myocardial infarctions and coronary artery disease, and it helps decrease angina and coronary spasm. It also is an antioxidant that inhibits tumor growth and it can enhance immune response.
- Vitamin C is another antioxidant that works synergistically with vitamin E. When taken together they can be both preventive and therapeutic factors in heart health and cancer prevention.
- Ginko biloba enhances circulation, which, in turn, improves cellular repair, reduces fatigue, and enhances memory.
- Cranberry and Bilberry sharpen night vision.
- Blueberries are excellent antioxidants and improve cognitive functions.
- Black Cohosh can be an important herb for every stage of a woman's reproductive life. Among other things, it can relieve PMS symptoms, regulate the menstrual cycle, and reduce menopausal hot flashes. This takes on increased importance in light of the recent report that post-menopausal hormone therapy likely does more harm than good!
- Saw palmetto promotes urinary tract health in both genders and is used to treat the enlarged prostrate in males.
- Echinacea helps combat colds, flu, viruses, and infections of all kinds.
- Ginger is as good a remedy as can be found anywhere for combating nausea.
- Green vegetables such as kale, collard greens, and spinach have Vitamin K, which increases blood platelet counts and enhances coagulation.
- The long list of beneficial nutraceuticals includes green tea, red wine extract, grape seed extract, pine bark extract, feverfew, glucosamine, bee pollen, kava, cherry juice, licorice, and many more.

Mr. SCHROCK. Thank you, Mr. Chairman.

Thank you for calling this meeting today to discuss what I feel is a critical issue that is facing our Nation. It is no secret that obesity is epidemic in the United States. According to this committee's background documents, there are currently over 45 million obese adults and about 8 million obese children. These numbers, I can assure you, are on the rise.

The effects of obesity in our population and on our economy is staggering. According to the Surgeon General, 300,000 Americans die prematurely each year due to their weight and obesity which costs Americans $100 billion per year. According to the RAND Corp., obesity contributes to higher cost increased for health care services and medications than do either smoking or drinking problems.

The July August 2002 edition of Men's Health Magazine, and I appear on the cover. [Laughter.]

Mr. BURTON. Something has happened to you. [Laughter.]

Mr. SCHROCK. There is a lot under this clothing, I can tell you.

The magazine had a series of articles on this topic and they have challenged American men to lose 1 million pounds collectively. This is a great challenge that will help men feel better, live longer and save them thousands of dollars over their lifetimes. Overweight men, according to this article, are 50 percent more likely to develop heart disease, 70 percent more likely to develop high blood pressure, 58 percent more likely to have total cholesterol of 250 or greater, 16 percent more likely to die from their first heart attack, 9 percent more likely to have a stroke, and 250 percent more likely to develop diabetes.

Overweight men spend 37 percent more a year at the pharmacy, make 12 percent more visits per year to their primary care doctor, spend 19 percent more days per year in the hospital, and pay $4,200 more over their lifetimes for medical care. Overweight men are 5 percent more likely to die of prostate cancer, 35 percent more likely to develop kidney cancer, 120 percent more likely to develop stomach cancer and 590 percent more likely to develop esophageal cancer. These statistics are staggering and though they are particularly for men, I am sure they could be translated to women as well.

The way I see it, the Federal Government should do all it can to encourage healthier living. After all, an ounce of prevention is worth a pound of cure. Last month, President Bush outlined his health and fitness initiative. Congress should take his lead and find ways to positively encourage our society toward healthier living. Our panel of experts today will provide us with valuable information that we should use to improve Federal policies with regards to diet, physical activity and dietary supplements. I look forward to their testimony.

I can tell you firsthand how important health is. On July 15, 1975, I was diagnosed with an incurable cancer and given 6 months to live. In 90 days, I lost 142 pounds and lived in a coma for 6 months and the doctors gave me absolutely no hope. During conversations the doctors had over me with my wife, they were convinced I would be dead anytime soon but I knew I was meant to be here to work on this issue. I think that is why I am here today.

I worked out heavily, I weighed 240, I drank and smoked more than I should have but that was my wake-up call. I no longer do any of that and I am the biggest health advocate in the world and I think when we come back in January I am going to challenge my colleagues on both sides of the aisle to take part in this million pound loss by challenging the Democrats to lose 5,000 pounds and the Republicans to lose 5,000 pounds because folks, some of the people I see walk into that chamber need to do it because they are going to die young and that is not a good thing. This is a very important issue and I wish every Member was here to hear it.

I am looking forward to hearing Ms. Ladd. Thank you for coming. I am delighted you are here and I am delighted the others are here as well.

Thank you, Mr. Chairman.

[The article referred to follows:]

MH

The Million-Pound Challenge

When we're finished with this country, you won't recognize it

WE *DARE* YOU TO DO IT.

According to the surgeon general, America will soon have a new number-one health problem: fat. Sixty-one percent of your countrymen—maybe even you—are now overweight or obese, compared with 47 percent in 1980.

We're doing something about it. As part of National Men's Health Week (June 10–16), we're challenging Americans to lose one million pounds in the next year. At the same time, 14 of our international editions are challenging *their* readers. It's a worldwide race to get lean.

To take part in the challenge, log on to our Web site: www.mhmillion.com. (Registration is free, and you can check back to report your progress.) Then read, and heed, the huge weight-loss package we've put together.

Some people will say this can't be done. Let's make them eat their words.

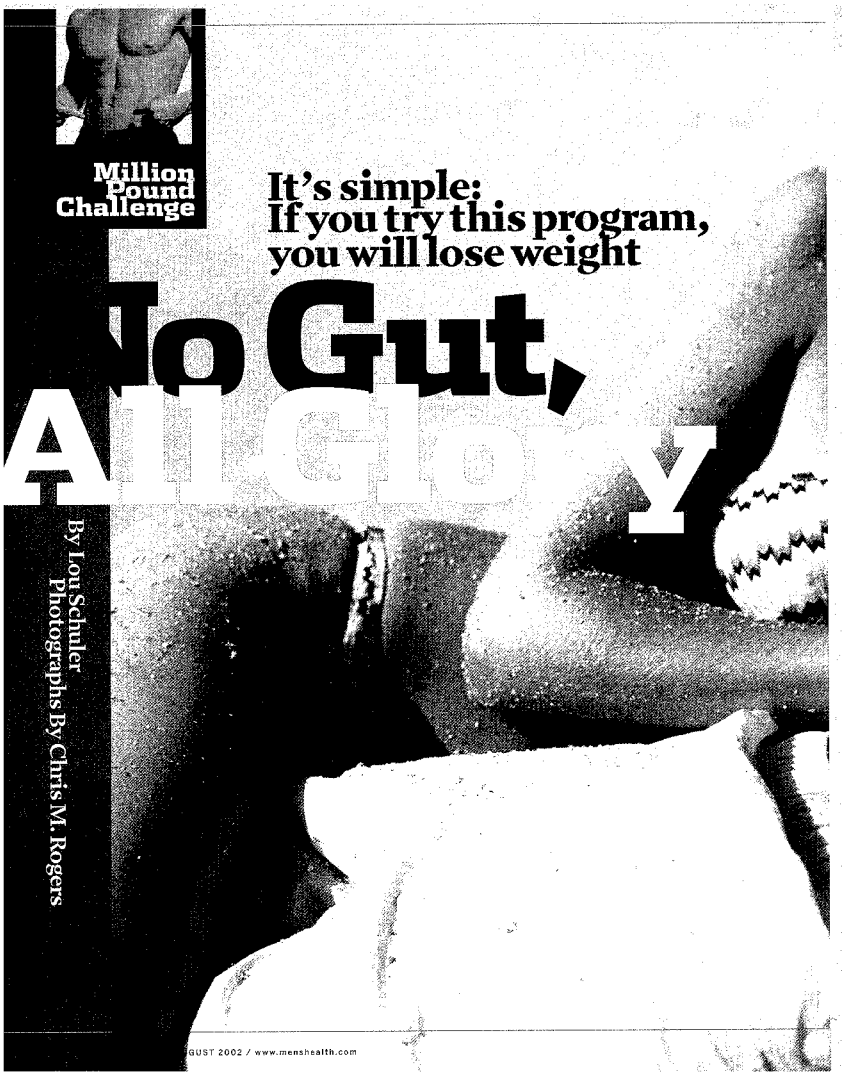
Fat's Dominos

Compared with normal-weight guys, overweight men are . . .

50% more likely to develop heart disease (obese men, 100%)

GROOMING AND MAKEUP: VALLERY HYTCH/BRUNK AND NICHOLE WING/BRUNK; STYLING: CHRISTINA SELLIN/NEET; PROP STYLING: ANNE CHUPNETT; FLASH BAL: MARBOUR SHORTS

PHOTOGRAPH BY CHRIS M. ROGERS



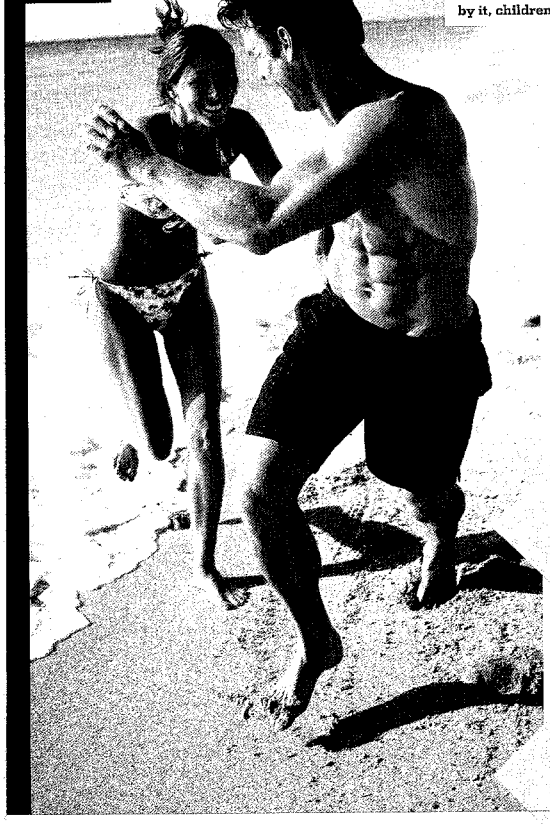
Million Pound Challenge

It's simple: If you try this program, you will lose weight

No Gut, All Glory

By Lou Schuler
Photographs By Chris M. Rogers

Million Pound Challenge



FRIEND, WE NEED TO TALK ABOUT THAT GUT of yours. We know you're not proud of it. You may crack jokes about how you're aiming for a gold medal in the splash-diving competition at Athens in 2004. But other than the impressive column of water you spew with each cannonball, you know that belly isn't doing you any good. You don't like looking at it in the mirror, women are turned off by it, children ask if you have a baby in there.

You have more trouble sleeping than you used to, your lower back hurts, and exercise makes your knees ache.

But the problem is actually worse than that. Much worse.

You see, the fat around your belly is different from fat elsewhere in your body. It's metabolically active tissue that actually functions like a separate organ, releasing substances into the rest of your body that, in excess, can increase your risk of disease.

Yeah, you got it: Your own belly could be poisoning you.

Gut-Check Time

The notion that abdominal obesity is the most dangerous kind isn't new. Back in the 1940s, the French physician Jean Vague observed that some obese patients had normal blood chemistry, while some moderately overweight patients showed serious abnormalities that predisposed them to heart disease or diabetes. Almost always, the latter patients carried their fat around their middles. And, almost always, they were men.

Multiple studies since then have shown that abdominal fat—the cause of the classic

The Monday Workout

▶ Do 10 repetitions of each exercise in a circuit—that is, do one set of every exercise before repeating any of them.

▶ Start with a warmup circuit, using one-half to two-thirds of the weight you'll use in your actual work circuits.

▶ Then do one, two, or three circuits, depending on your experience, fitness level, and time allotted. If you're a total beginner, aim for one circuit the first week or two, and gradually build up to three circuits.

GROOMING AND MAKEUP: VALLERY RIVERA/BLINK AND NATALIE KINGS/BLINK. STYLING: CHRISTINA COLLENNAVENT. PROP STYLING: ANNA CHUVAEVT. CLOTHING: OPENING SPREAD, ON HIM: OLD NAVY SHORTS; ON HER: MISSONI MARE SWIMSUIT. THIS PAGE, ON HIM: OLD NAVY SWIM TRUNKS; ON HER: BODY SWIMSUIT: BLAKE LITTLE (MAN'S TORSO).

Fat's Dominos

Overweight men are . . .

250% more likely to develop diabetes (obese men, 1,020%)

16% more likely to die of a first heart attack, or have another one (obese men, 49)

9% more likely to have a stroke (obese men, 17%)

apple-shaped body—is more than nature's way of telling you that you'll never become a soap-opera star, news anchor, rock legend, or *Men's Health* cover model. It's a sign that your body chemistry is seriously out of whack. There are a number of substances your bloated belly secretes to your heart, liver, and other vital organs. Among them:

Free fatty acids. Released directly to the liver, they impair your ability to break down insulin, which over time can lead to diabetes.

Cortisone. High levels of this hormone are associated with diabetes and heart disease.

PAI-1. This blood-clotting agent increases your risk of heart attacks and strokes.

CRP. This protein inflames blood vessels, making them more susceptible to artery-clogging plaque.

The upshot of all these chemicals floating around is big trouble for big-bellied guys. In a study at the University of Alabama at Birmingham, researchers took 137 men of all ages and sizes and used seven different measurements to determine their risks of cardiovascular disease. The single best sign of multiple heart-disease risks? No, it wasn't the guys' family histories or their cholesterol profiles. It was the amount of abdominal fat they carried.

By the way, heart disease and diabetes are only two of the ways belly fat can ruin your health. If you count them all up, you'll find at least 39 different diseases associated with abdominal obesity (40, if you include looking lousy with your shirt off).

This Way Out

When we set out to create the *Men's Health* Belly-Off Program, our mission was simple. We weren't looking for fancy dieting gimmicks. We weren't looking for amazing weight-loss theories. We weren't looking to invent electronic gizmos or miracle pills. We just wanted to create a simple, instinctive, and satisfying eating and exercise plan that would attack the fat around any man's middle.

You and your gut will be the judges of how well we did, but if you ask us, we think we hit it out of the park. The diet portion of the Belly-Off Program not only attacks belly fat specifically, but lets you eat regular food while you're at it. And our 8-week workout plan relies on the radical notion that you should do the kind of exercise you like to do.

So keep reading. Following our plan may kill your chances in the Olympic cannonball competition. But your odds of a gold-medal body just skyrocketed.

The Food Plan

Diets generally fail for one of two reasons: Either they're too restrictive about the kind of food you put in your belly, or they too frequently leave you feeling as if you haven't put any food in your belly. In either case, it's usually not long before you have chocolate cruller crumbs on the corners of your mouth.

You won't be sabotaged by either of those problems with the Belly-Off Program Diet, which was created for us by the trainer and nutritionist Thomas Incledon, Ph.D., R.D. Incledon built our program around three simple weight-loss principles:

If you want to shrink your gut, get enough protein in your diet. In this case, about 25

How Fat Are You?

FOR YEARS, OBESITY RESEARCHERS used a standard called the body-mass index to determine a person's chubbiness and health risk. It's a simple calculation of a person's weight-to-height ratio. A BMI between 25 and 30 indicates you're overweight; a BMI over 30 signifies obesity.

But BMI has one big drawback: It doesn't account for weight distribution. A 5'10", 220-pound couch potato has the same BMI as most NFL running backs.

That's why researchers have begun using waist size—more specifically, the ratio of your waist size to your hip size—to determine health risk. Here's why it's more useful than BMI: Fat that pushes your waist out in front is the most dangerous kind of fat you can have in your body. Exercise attacks abdominal fat, so the more you have, the less likely it is that you get a healthy amount of exercise.

▶ To figure your waist-hip ratio, measure your waist at the narrowest point and your hips at the widest (around your buttocks). Divide waist by hips. Your goal is to fall under 0.92.

▶ To calculate BMI, go to www.nhlbisupport.com/bmi.

Squat

▷ Stand holding a barbell across your upper back. Set your feet shoulder-width apart, toes pointed forward, lower back in its naturally arched position, and eyes focused straight ahead.

▷ Push your hips backward, as if you were sitting in a chair, and bend your knees until your thighs are slightly below parallel to the floor.

▷ Stand back up to the starting position.

Barbell Bench Press

▷ Lie on your back on a flat bench and grab a barbell with an overhand grip, your hands about shoulder-width apart (or as wide as they would be if you were doing a pushup). Hold the bar over your chest with your arms straight.

▷ Slowly lower the bar to your chest.

▷ Push back up to the starting position.

Farmer's Walk on Toes, with Dumbbells

▷ Grab a pair of dumbbells and hold them at your sides.

▷ Rise up on your toes and walk forward 10 steps with each leg. Stay on your toes the entire time.

▷ Turn and walk back 10 steps with each leg.

45-Degree Traveling Lunge with Dumbbells

▷ Hold a pair of dumbbells at your sides. With your left leg, take a large diagonal step forward and drop until your left thigh is parallel to the floor.

▷ Stand, bringing your right foot next to your left, and repeat with your right leg.

▷ Lunge five times with each leg, then turn and lunge back to your starting position.

Wide-Grip Seated Row

▷ Attach a straight bar to a low cable and sit so your feet are braced against the footrest and your knees are slightly bent. Grab the bar with a wide, overhand grip and sit upright so your torso is perpendicular to the floor and your lower back is in its natural alignment.

▷ Pull the bar to your lower abdomen.

▷ Slowly return the bar to the starting position.

Swiss-Ball Crunch

▷ Lie on your back on a Swiss ball, with both feet on the floor, just wider than shoulder-width apart. Your head should be slightly lower than your chest. Place your hands behind your ears and point your elbows out.

▷ Curl your rib cage toward your pelvis while keeping your head and neck still.

▷ Hold, then return to the starting position.

GROOMING: KEVIN ROLLINS/SERENE INC.

EXERCISE PHOTOGRAPHS BY BETH BISCHOFF

percent of calories. Why? For starters, protein makes you feel full and helps you build muscle (which increases metabolism, thereby making it easier to lose weight). Just as important, high-protein diets have been shown to be the best way of attacking belly fat. Consider a 1999 study published in the *International Journal of Obesity*. Danish researchers put 65 people on either a 12 percent protein diet or a 25 percent protein diet. The low-protein dieters lost an average of 11 pounds, which isn't bad. But the high-protein subjects lost an average of 20 pounds—including twice as much abdominal fat as the low-protein group.

Get enough fat. About 30 percent of your calories. First, fat helps you feel fuller longer between meals, slowing your appetite. Second, it provides essential fatty acids needed for optimal health. Above all, fat makes you feel that you're eating real food, not starving in the land of plenty. Deprivation? Hey, man, you don't need no stinkin' deprivation.

If you get enough protein and fat, your total calorie intake should take care of itself. Because you feel full, you won't binge on a can of Pringles and blow your calorie count for the day. The remaining 45 percent of calories in our plan comes from carbohydrates—enough to give your palate a full range of tastes and your body a combination of fast- and slow-burning fuel.

Fat's Dominos

Overweight men are . . .

70% more likely to develop high blood pressure (obese men, 170%)

How to Use the Diet

The meals shown here are "templates" that you can vary any number of ways to please your tastebuds and avoid eating the same old thing every day. Follow them and you'll get between 2,400 and 2,800 calories per day. That should provide plenty of calories for all but the most severely obese, while allowing most guys to lose fat around their middles at a steady pace. (Don't worry about hitting the numbers on the nose every time. If you exceed your fat quota during lunch, for instance, just cut back a little during dinner.)

BREAKFAST

Whole grain cereal or oatmeal (1¼ c)

Fat-free milk (2 c)

Almonds or other nuts (4 Tbsp)

Raisins (2 Tbsp)

TOTAL: *591 calories, 29 grams (g) protein, 78 g carbohydrates, 18 g fat*

LUNCH

Sandwich made with whole grain bread (2 slices)

Lunchmeat or canned tuna (5 oz)

Reduced-fat cheese (1 slice)

Tomato (2 slices)

Mayonnaise (1 Tbsp)

Carrot (1)

Orange juice (1 cup)

TOTAL: *666 calories, 41 g protein, 71 g carbohydrates, 25 g fat*

DINNER

Meat (pork, chicken, or turkey breast, lean beef, seafood) (5 oz)

Salad (1 c)

Dressing (2 Tbsp)

Dark green vegetable (1 c)

Starch (bread, potato, pasta, rice) (1 slice or 1 c)

Fruit (¾ c)

TOTAL: *379–953 calories, 23–53 g protein, 33–109 g carbohydrates, 12–43 g fat*

FLOATER MEAL

(May be split into two snacks)

Whole grain bread (2 slices)

Peanut butter (2 Tbsp)

Fat free milk (2 c)

Apple (1 medium)

TOTAL: *629 calories, 31 g protein, 83 g carbohydrates, 20 g fat*

The Exercise Plan

Can diet alone help you lose belly fat? Probably. In a 2000 study in the *Annals of Internal Medicine*, a group who only dieted dropped just as much weight (16½ pounds) and just as much belly fat (about 2 pounds) as the group who simply exercised.

That said, the combination of diet and exercise is still the best ticket to permanent

The Wednesday Workout

▶ Do 15 repetitions of each exercise in a circuit.

▶ Start with a warmup circuit, using one-half to two-thirds of the weight you'll use in your work circuit.

▶ Then do one work circuit.

▶ Finish by doing the cardiovascular workout detailed on the next page.

Leg Press

▷ Position yourself in a leg-press machine with your feet slightly wider than shoulder-width apart and toward the top of the platform. (Use the position that's most comfortable for your knees.) Straighten your legs without locking your knees.

▷ Release the supports, then lower the platform until your legs are just past a 90-degree angle. Keep your lower back against the pad throughout the movement.

▷ Push the platform back to the starting position.

Good Morning

▷ Stand holding a barbell behind your neck so it rests evenly across your shoulders and upper-back muscles. Place your feet shoulder-width apart and bend your knees slightly. Keep your eyes focused forward and your lower back in its natural alignment.

▷ Slowly bend forward at the hips until your torso is parallel to the floor. Keep your lower back straight throughout.

▷ Raise your torso back to the starting position.

Wide-Grip Barbell Bench Press

▷ Lie on your back on a flat bench. Grab a barbell with an overhand grip, your hands a bit farther apart than for the barbell bench press, and lift it off the uprights. Hold it over your chin at arm's length.

▷ Slowly lower the bar to your chest.

▷ Pause, then push the bar back up until your arms are straight and the bar is over your chin again.

TOP: LAFT; ON HIM: OLD NAVY SWIM TRUNKS, ON HER: SWIMSUIT FREEDOM SWIMSUIT BY ROBERTO CAVALLI

Now You're Stuck

5 ways to stay with the program

IF YOU'RE LOOKING FOR A reason American men are fatter than ever, these stats might be enlightening: Fewer than one in five guys exercise long enough or consistently enough to produce any health-enhancing effects. Not that they don't know better—97 percent say they understand the benefits of exercise. Problem is, 50 percent of exercisers bail out within 6 months of starting an exercise program. After 21 months, the dropout rate reaches an astounding 75 percent.

Jim Annesi, Ph.D., an exercise psychologist with the YMCA of Metropolitan Atlanta, has done groundbreaking research on exercise adherence and identified three reasons people turn into quitters: lack of self-management skills (you always find an excuse not to work out); lack of social support (nobody's around to keep you pumped up); and physical discomfort (basically, you just think exercise sucks).

How can you beat those problems? Adopt these survival tactics:

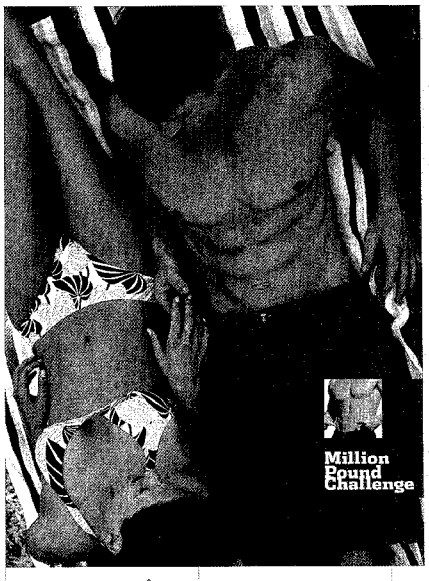
Tell your brain to shut its pie hole. When your brain tells you not to exercise ("The boss is on the warpath, and I'm too stressed to work out"), force a more rational, positive thought into your head: "Exercise will help me relieve stress. I'll feel worse if I don't exercise this week." For every negative thought your brain generates, we bet you can counter with three positive ones. Use 'em.

Mark off the days. After you complete a workout, mark down on your calendar what you did that day. If you perform a cardiovascular exercise such as running for 20 minutes, jot down "C-20." If you complete your weight-lifting program, write "WL." This gives you written proof of your accomplishments, which studies have shown is strong motivation and reinforcement.

Give yourself a reward. After an especially good workout, treat yourself to a whirlpool. After a week of consistent exercise, take your girlfriend out for dinner. After a month, buy yourself a CD boxed set. Or come up with your own plan. A long-term study of slightly overweight men showed that self-chosen rewards helped them reach their exercise goals.

Join a group or work out with friends. A review of 113 studies published in the Journal of Sport and Exercise Psychology shows you're more likely to make a lifetime commitment to exercise if you have some kind of social support.

Distract yourself from the pain. Psychologists call this "disassociation." You call it TV. Or music. Or Pilates hotties. No single distraction works for everyone, and studies suggest that multiple distractions may work best to improve exercise adherence. In one study, researchers assigned 56 exercisers to one of four groups: music only, television only, music and television, and no distractions. The music-and-television group had about half the dropout rate of the three other groups. (They also registered significantly higher in aerobic capacity after a 14-week period.)



Towel Pulldown

▷ Wrap a pair of towels around the bar of a lat-pulldown machine. Position yourself in the machine and grab a towel with each hand, keeping your hands just wider than shoulder-width apart.

▷ Pull the bar down to your chest as you lean backward slightly, keeping your back straight.

▷ Return to the starting position.

45-Degree Lying Dumbbell Row

▷ Set an incline bench to a 45-degree angle. Grab a pair of dumbbells and lie facedown on the bench, holding the weights straight down from your shoulders with your palms turned toward your feet.

▷ Lift the weights up and out to your sides so your elbows are bent about 90 degrees and your upper arms are nearly perpendicular to your torso.

▷ Slowly return to the starting position.

Towel Crunch

▷ Roll up a small towel and lie faceup on the floor with the towel in the arch of your lower back. Place your feet flat on the floor, put your hands behind your ears, and point your elbows out.

▷ Curl your rib cage toward your pelvis, lifting your head and shoulders off the floor.

▷ Return to the starting position.

Cardiovascular Workout

▷ Do any type of aerobic exercise you like, one to three times a week after lifting.

▷ Warm up for 5 minutes by going at a very easy pace, gradually increasing your effort until you're at 50 percent of your maximum.

▷ Go as hard as you can for 15 seconds.

▷ Recover for 2 minutes, returning to the pace at which you finished your warmup.

▷ Start the next interval and do a total of six to 10 of them.

▷ After your last 2-minute recovery, go at an even easier pace for 3 minutes to cool down.

CENTER RIGHT: ON HIGH, TUNNY VOTTIGER SYNAITIS; ON HERE: LAURA WRIGHT-SWINSETT; POTTERY: BARRY TOWEL

gut reduction. The diet-only group in the above study lost less total fat and more muscle than the exercise-only group. What's more, another, very scary study in *Obesity Research* looked at people who had each lost 14 pounds on a 28-day crash diet. Five years later, they had regained all the weight, with a twist: All the new weight was fat, whereas they'd originally lost a combination of fat and muscle. And their health had deteriorated in multiple ways, including increased insulin resistance and higher LDL cholesterol.

Fat's Dominos

Overweight men are . . .

more likely to have total cholesterol of 250 or greater (obese men, 122%)

So what's the best kind of exercise for losing your gut? The short answer is any kind that you'll actually do. But intriguing new research suggests that for many guys, particularly big guys with big bellies, weight lifting may be the best way to lose weight.

In a study published in *Preventive Medicine*, researchers separated a group of people by overall build—thinner or thicker—then put them on a 12-week weight-training program. More slender guys didn't get much benefit from weight lifting, but the guys who were big to begin with gained about 3½ pounds of muscle. The implication: Bigger guys benefit most from weight training.

(If you prefer to exercise on a bike or running trail—hey, you'll get no argument from us. Go to www.menshealth.com for "The Weights-Hater's Guide to Exercise," an 8-week beginner's guide to aerobic exercise.)

But if you're a weights guy, this is the plan for you. The goal of the program, designed by the Canadian strength-and-conditioning coach Craig Ballantyne, C.S.C.S., is to increase

The Friday Workout

▶ Do 10 repetitions of each exercise.

▶ Start with a warmup set, using one-half to two-thirds of the weight you'll use in your work sets.

▶ Then do three consecutive sets of each exercise before moving on to the next exercise.

Dumbbell Split Squat

▷ Grab a pair of dumbbells and hold them down at your sides as you stand with one foot about 3 feet in front of the other, as if you've just taken a long forward stride.

▷ Lower your body until the top of your forward thigh is parallel to the floor and your rear knee almost touches the floor.

▷ Return to the starting position. Finish the set, then repeat with your other leg forward.

Twisting Dumbbell Shoulder Press

▷ Stand holding a pair of dumbbells at the sides of your shoulders, palms turned toward each other, feet shoulder-width apart.

▷ Lift the right dumbbell straight over your shoulder as you twist your torso to the left.

▷ Lower the weight as you twist back to the starting position, then repeat with your left arm, twisting to your right.

Wide-Grip Stiff-Legged Deadlift

▷ Grab a barbell with an overhand grip that's about twice shoulder-width. Stand holding the bar down in front of you at arm's length and resting on your thighs. Set your feet shoulder-width apart and bend your knees slightly.

▷ Slowly bend at the waist as you lower the bar to just below your knees.

▷ Lift your torso back to the starting position. Keep the bar as close to your body as possible when raising and lowering.

Bridge

▷ Get into the pushup position on the floor, but rest your weight on your forearms and toes. Keep your back straight.

▷ Pull in your abdomen as far as you can—imagine you're trying to touch your belly button to your spine. Breathe as you hold in your abs for 10 seconds.

▷ Release and rest for a few seconds. Try to do six repetitions. One set is plenty.

TOP: ON HIM: HUNTER, SARAH TRUSSOS, ON HER: BOYD SWIMSUIT

energy expenditure while building muscle. Successful gut reduction through weight training combines these two elements. You need to burn calories to lose weight now, and you need to build muscle to increase metabolism and prevent future weight gain.

HOW TO USE THIS PROGRAM

Every week, do three workouts that each use different exercises and different systems of sets and repetitions. (The workouts start on the third page of this article.) Working three different ways each week ensures that your body takes longer to get used to the workouts and works harder to make adaptations. Hard work elevates metabolism, making you burn more calories between workouts.

Weight. If you've never lifted before, trial and error can determine the amount of weight you'll lift in each exercise. Try to increase the amount by about 10 percent each week.

Cardiovascular work. This program relies on what Ballantyne calls "the new cardio." Rather than long, slow, steady aerobic exercise, it calls for you to go hard for short periods, then easy for a minute or two. Do the cardiovascular workout one to three times a week.

Results. While muscle growth occurs after only one training session, it probably won't be visible for about 4 weeks. Fat loss, on the other hand, will be apparent much sooner. As soon as you start expending more calories than you take in, you'll start burning stored fat for energy. With the diet changes and this exercise program, you could lose a pound or two of fat each week for 8 weeks. MH

Adapted from The Men's Health Belly-Off Program, *by* Men's Health *editors. Copyright 2002 by Rodale, Inc. Available wherever books are sold.*

One-Arm Lat Pulldown

> Attach a stirrup handle to an overhead cable. Using an overhand grip, grab the handle with one hand (your left if you're right-handed) and position yourself in the machine with your working arm straight and the other down at your side.

> Pull the handle straight down until it's just outside your chest.

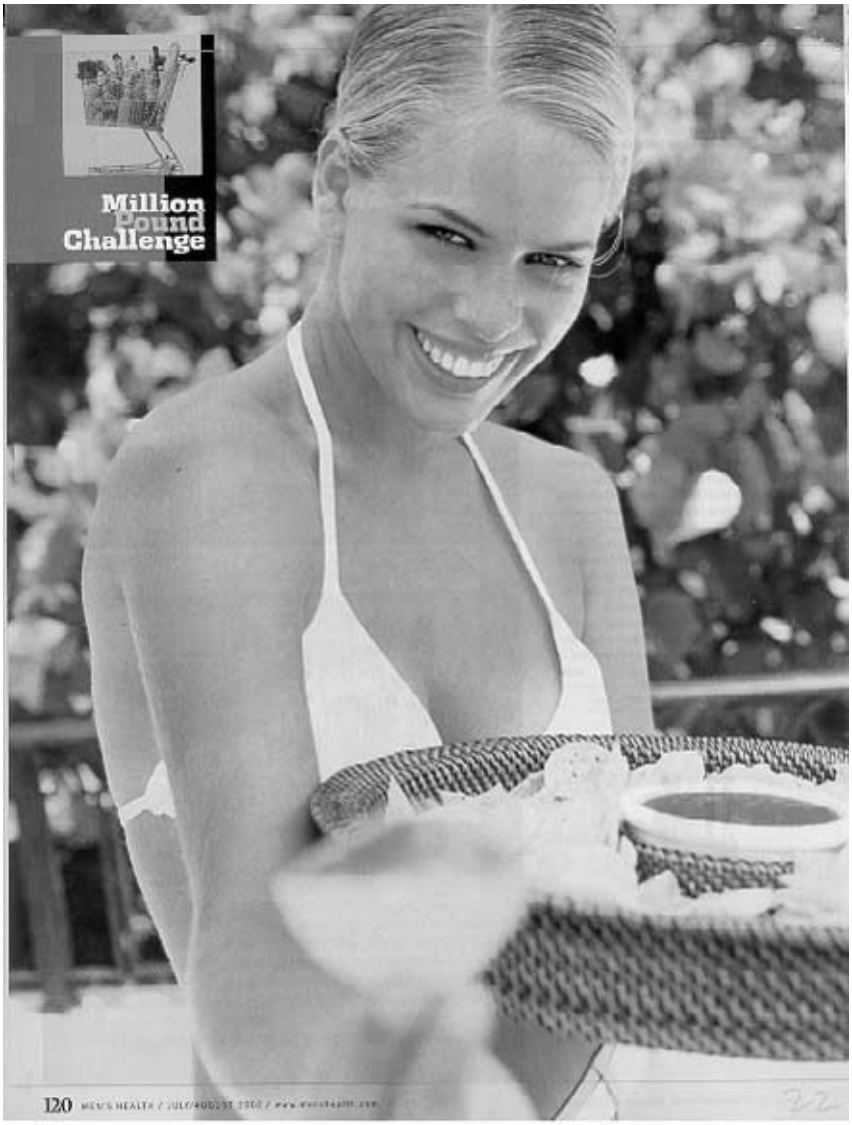
> Return to the starting position and repeat for the designated number of repetitions. Then, without resting, do the same number with the other arm.

Can Large Get Small?

Million Pound Challenge

THESE ARE THE MEN OF LARGE, PENNSYLVANIA, a small community just south of Pittsburgh on Highway 51. As you can see, it is indeed fitting that they live here. As in many cities across America, bellies are wide and obesity-related disease is high. But Large is finally going to get smaller. The men of this town and the surrounding community of Jefferson are the posterboys for The Million-Pound Challenge. With the help of *Men's Health*, they'll be trying to lose as many pounds as possible in the next 6 months through dieting and exercising. The men of Large are out to show the men of America what's possible. Follow their progress on our Web site (**www.mhmillion.com**) and in the magazine each month. Cheer them on. MH

LARGE, PA. PHOTOGRAPHS BY MICHAEL MCLAUGHLIN


Million
Pound
Challenge
120 MEN'S HEALTH

Mr. BURTON. Thank you, Mr. Schrock.

We do kid around a lot about some of these things, but it is very, very serious and I think you have illuminated that issue very well.

Now for our 29 year old colleague.

Mrs. MORELLA. Thank you, Mr. Chairman.

I didn't prepare any remarks but I am very interested in this hearing. I thank you very much for scheduling it.

I must say I was moved by my colleague, Mr. Schrock's comments and indeed, I would be very happy to help to partner with him as he pursues that tremendous goal.

This is a hearing where we might sometimes find ourselves in the situation where Robert Frost defined a poem. He said, "In the end, it tells me something I didn't know I knew" because some of the issues that will come up are really common sense issues like diet, to find out how important diet is; nutrition; the whole concept of supplements, how important are they; and the whole issue of exercise; and I would add another ingredient and that is attitude. I have always felt that attitude is altitude, how you look at things. We have seen that with you, Mr. Chairman, as well as with Mr. Schrock, in terms of how you handle situations.

Indeed, mention was made of obesity and you mentioned, Mr. Schrock, obesity in men in particular but we are going to have somebody testify today, someone who is a constituent of mine, Dr. Peeke who is going to be looking at the gender facet of that. Whereas 31 percent of men are obese, 34 percent of women are. Maybe in some way we can also look at gender nuances.

Above all, we can look at our role as policymakers and think of the money we would be saving. We are pouring a lot of money into the National Institutes of Health and I also note that Paul Coates, the Director of Dietary Supplements at the National Institutes of Health, is here. We know that some of the research is being reflected in our knowledge as well as our cures, including prevention of some of the major illnesses and the money we have saved, and the impact on families. We tend to forget sometimes that when you have these health crises, the impact on families, on caregivers, on every member of the family.

So I look forward to learning a great deal from the hearing today. I want to thank all the witnesses. You have assembled a very distinguished group of witnesses who will be able to share their experiences and knowledge with us. Dr. Peeke is accompanied by another constituent of mine, Irene Pollin. I am pleased she is here and Dr. Coates from NIH.

I yield back time served so we can commence the hearing.

Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Mrs. Morella, and you do look very young. You obviously take very good care of yourself.

Before we bring up Ms. Ladd, let me say that one of the things Katie Couric expressed when she lost her husband to colon cancer, and I lost my wife recently to colon cancer, and one of the things I try to say at every meeting, not on the subject at hand today, but anybody over 40 and surely over 50 should get a colonoscopy. My wife never was told that and because of that, when she started having stomach problems, they gave her stomach medicines and by the time we found out it was colon cancer, it had metastasized into

her liver and it was too late. So I would say anybody over 40 if you haven't had it, especially if you are over 50, remember what I am telling you. It is something that can save your life.

I gave a speech at a Republican get together in northern Indiana not long ago and I said this and the guy that was putting on the program wrote me a letter last week and said he had never even thought about that. He was a former State senator and they found 10 polyps in his colon and my bringing that to his attention probably saved his life because they think a couple of those were cancerous.

So all I am saying to you is that this is not on this subject but in addition to good health, good diet and good exercise and all that, you need to do these other things that are important as well.

With that, Ms. Ladd, you are a lovely lady. Would you please come forward so I can swear you in?

[Witness sworn.]

Mr. BURTON. I have admired your work as have my colleagues for many years. I don't know how many movies you have appeared in but it is well over 100. We are very happy to have you as we have had other celebrities here and we are anxious to hear what you have to say, so would you make your opening statement?

STATEMENT OF DIANE LADD, ACTRESS, FILM DIRECTOR, CERTIFIED NUTRITIONAL CONSULTANT, OJAI, CA

Ms. LADD. Mr. Chairman, Congressman Schrock, Congresswoman Morella, it is my privilege and pleasure to be here today. I not only talk to you as a fellow citizen and American, but as an actress, a species that lives between chance and oblivion. I am a resident of the State of California, previously a resident of New York. I have also at times in my life because of my work in the medical field been a resident of Texas and Florida but I was raised in the beautiful magnolia State of Mississippi.

My name is Ladd. My real name was Lanier or Ladner. My father sold medicine for poultry and livestock, wholesale and retail throughout five States. As a child at his knee, I witnessed my father encouraging human beings who did not have proper nutrition to go beyond the norm, to reach the extra mile to save their lives, the same with my great grandmother who was a doctor who studied with the Cherokee Indians, the healing arts and herbology.

As an actress, I am privileged to have represented my country and be a three time Oscar nominee and to have been honored with over 23 international awards and honors and sent telegrams by my Government, by Washington, by Mr. Jack Valenti representing my government.

My advocation is health. It is my love and it is a professional hobby. I am here with you today to share with you how important I feel vitamins and minerals are and how they can be involved in miracles. I am here to testify to the art of miracles and how they can be accomplished by making changes mentally, physically and spiritually. It takes a triad and in order to have a cure, one must know the cause.

As a young, young wife and mother, seems like eons ago, a young bride, my husband, actor Bruce Dern and I, two struggling actors, had a beautiful baby daughter 2 years old. Our child died in a very

tragic accident. Being an emotional actress, the pain is always with me because memory is always in you as a human being but the trick in life is to use the things that we go through not only to better ourselves but to better our fellow human beings. As Congressman Schrock said, maybe he is supposed to be here today to fight for these issues. I feel the same way.

After my daughter's death, my body screamed to replace that child, for God to give me another child. Indeed in a little over 8 weeks, I got pregnant again and I said, God taketh away, God giveth back but it was not to be so simple. It turned out it was a tubular pregnancy, a pregnancy in the fallopian tube. I almost died, it almost took my life. My right tube was completely removed and most of the left tube. They left me with just a little piece of a tube, probably for female functions. Five top doctors in our country told me that I, Diane Ladd, would never, never, impossible, have another child, no way.

I went on my own search in 1962 and there were no health stores, no health books except for Gaylord Houser's "Mirror, Mirror on the Wall." I took it to heart. I absorbed it. I spent my days not looking for acting jobs, but being in libraries, reading about the human body. What vitamins could help my body, what foods could help my body, avocado, the oils, bee pollens, the Vitamin B's, and so forth.

I flew to New York to a great semiscean pellor doctor who really cared about his fellow human beings who informed me that mud baths can prevent sterility. I went over massage, chiropractory, the doctors thought I was nuts. They wouldn't talk to me about it but I continued my search. Gentlemen, after 3½ years, I walked into the office of Dr. Charles Ledagurber, one of the top gynecologists in our country, one of the five doctors chosen by my government to go to China to do research on their traditional modalic medicine which is our alternative modalities in medicine.

I went in to Ledagurber, who had great empathy for me because he too had lost a child in his life but he had four other children, I had none. I had a smile and I said, Dr. Ledagurber, I think I am pregnant, go make your test. He looked at me with such a sad look and said, "Oh, Diane, honey, you cannot be pregnant. It is impossible. Go home and cry." I said, "Dr. Ledagurber, I have cried, now go make your test." He made the test and I was pregnant.

When my daughter, Laura Elizabeth Dern, was born, they took her caesarian to prevent any possibility of complications. While I was on that operating table, after they took my child from my womb, I remained on the table for 4 solid hours while they played in my gut and removed 16 major adhesions that had been caused by tubular pregnancy. They removed them from my body.

One of the other five doctors who said I could never have another child showed up to see it for himself. I was passed out on the table. They don't knock you out because the body bleeds more when it is knocked out but if you pass out, it is a little bit better. So I was passed out and they were in there doing their work when my subconscious heard the other doctor say, "My God, my God, it is impossible that this child got through that body and that tube. This is a miracle." I scared him, this blond head rose up off the table and

I said, "That is right. It is a miracle and it is a hell of a lot of hard work."

My daughter, Laura Elizabeth Dern, would not be on this planet today were it not for my own, individual vitamin and mineral program that gave my body the ability to assimilate those nutrients that I needed to rise above the negatives that had been created. Our body is a miracle machine, if we can follow our intuition. Or course actors have a seventh sense and they gave the medical profession psychodrama. Actors have been known to go into mental institutions and where doctors cannot get a patient to speak, actors have gotten a patient to speak, have opened them up to literally talk. As I said before, at one time in history in Egypt art and science was one profession.

My second medical miracle came when my daughter, Laura Dern, was 12½ years old. She was discovered to have scoliosis, a disease which is a crippler and a killer. I took her to a Dr. Jack Moshime, a very famous Beverly Hills orthopedic surgeon. He has done a lot of great work in this country. On x-ray, my daughter's spine was like an "S," very severe. I was pretty hysterical because having lost a child you can imagine how protective I was of this child, my little miracle. The fact that they hadn't discovered it before was unbelievable to me but it appeared that when she was 5 years old, she had been bitten by a black widow spider, and the poison from that bite had thrown the alignment of her spine out of balance so as she grew, the spine formed in a crooked manner.

I asked Dr. Moshime how long have I got before I have to put my child in that back brace you are telling me to put her in from her hips to her neck, her whole teenage livelihood? He said, I will give you 9 months, Diane, and you be back in here and we are going to put that brace on her. You go do whatever you think you are going to do and I will see you here in 9 months. In those 9 months, I took my daughter through several things. One of them was a Dr. Viola Framman in San Diego who today has the Osteopathic Promise for Children. Viola Framman had lost a child when she was a young medical student and she knew and testifies that she knew then and knows today that if the doctors treating her child had gone the extra mile, that her child would have lived. So she has devoted her whole lifetime to humanity, especially to children, with the art of cranial therapy. Her mentor was Dr. Magune who was one of President Eisenhower's private physicians. He is the grandfather of the art of cranial therapy. Dr. Magune taught Viola, Dr. Magune sent me to Viola and she worked on my daughter every 2 weeks and then every month for the next 9 months.

Through the art of adjustment, through cranial therapy, pictures were taken where you could see her body changing literally, photographs. I also took her to a chiropractor, I also took her to a laying on of hands healing arts, Doug Johnson, very famous all over the world. I also went on a vitamin, mineral regimen. I also rubbed peanut oil which is a healer on the bottom of her feet. I took the skin from potatoes and tied them at night on her eyes with a rag because I know it draws out poison from the body.

In 9 months, I went back in to Dr. Moshime. He takes one look at Laura and says, oh, my God, she has grown 2 inches. Diane, growth is a detriment. Scoliosis is a not only a crippler, it is a kill-

er. He was almost hysterical. I said, I don't know, go take your x-rays and tell me what to do now.

I sat in his waiting room among 16 other patients, my daughter and I, waiting for the verdict, the health verdict when suddenly this doctor comes racing through that room, waving his hands over his head, "My God, it is a miracle." I whispered, "Yes, Doctor, it is a miracle and a hell of a lot of hard work." On x-ray, in those 9 months, my daughter's spine instead of being like this, still had a little bit of problem, but ladies and gentlemen, it was like this, you could hardly see the curve. Laura Dern did not have to wear that prescribed brace for her whole teenage lifetime. Instead of being able to share her great talent that God gave her and make movies such as "Mask" and help influence our teenagers in the world to fight for morality and the good in their own lives, Laura would not have been able to do anything or fulfill her destiny had I not fought and used alternative modalities.

Third was allergies. I had gotten those from emotionalism, having gotten divorced and I had ragweed and pollens, dog hair and the actor's disease is dust because of our travels and old theaters. All of these, I had to get a staph shot once a month for the different cities, floating staph in the air and once a week, I had to get shots for the other allergies, and I had to give away my dogs.

Virginia Capers, a Tony winning, beautiful black actress came to me and said, "Diane Ladd, I am tired of you suffering like this, you take this book and make it your bible." It was a book on juices. It was a book that taught me that when the body gets uneasy, when the body gets too stressed, when it has disease, it begins to develop disease and the more it needs the vitamins and minerals, the body isn't capable of assimilating, of withdrawing from the nutrients what it needs. It must have supplementation.

I took the book and I supplemented my diet four times a day with natural juices, mixtures of carrot juice, cucumber, celery, spinach and very little parsley. Too much parsley is not good and beet. I mixed these juices and supplemented my diet four times a day and in 1 month all of my allergies were totally gone and I have never had to have a shot. That was in 1976. So that was the third thing.

The late Rock Hudson was a friend of mine, I had done a movie with him. They asked me to portray after his death his mother in a TV show. I hated the script, I thought it was completely a ripoff of this man's life. I took the script and threw it I was so angry. Then I said, Diane, if you don't do the movie, Hollywood is just going to do it and it is going to be terrible. At least if you get in there, you can fight, scream and try to make it better. Go do it and try to make it better and honor this man. So I did.

I told the producers that I would do it for very little money, minimum, if they would contribute $25,000 to research for immune related diseases at the hospital of my choice. I chose Scottsdale, AZ where Dr. Terry Friedman was doing his work. He was one of the seven doctors who founded one of the great organizations in our country, the American Holistic Medical Association. These are AMA doctors who believe in the oath they took and they believed when you say you are going to make a human being well, you help

them heal by using everything God gave you to help that person balance their body.

Dr. Friedman worked with the money they gave him on cancer victims and AIDS victims and one particular young man who came from Texas had been given 3 months to live, he was dying from AIDS. You could see this was a skeleton walking around. They gave him chelation, they gave him mineral programming, they gave him a diet of vitamins and minerals and as much proper foods as they could. They did alternative modalities, massage, manipulation, detoxification. Within 3 months, that man did not look like the same man. That young boy walked out of that hospital. Maybe he carried still some of the AIDS with him but life is precious, none of us knows who will walk out of here and be hit by a car. A minute is a minute to smell a rose. If God can give it to us, we have the right to fight for it.

There have been many other experiences. I have since worked with doctors, lectured all over the country. I am on the scientific board of advisors for Congressman Berkeley Bodel's organization here in Washington, the NFAM, the National Foundation for Alternative Modalities and when time permits, I work with doctors. I have a book I have written called, "Spiraling through the School of Life," which is coming out sharing all of the experiences I have had.

These experiences even included a sojourn to Central America where I picked up a parasite and St. John's Hospital didn't find it. Again, it was alternative modality doctor who is also an AMA medical doctor who in 2 weeks changed my body. In your packet today you have, which I asked for, approximately 20 letters from some of the top medical doctors in our country today who each has testified to the importance of vitamins and minerals. I as an actor testified that the actor's instrument is his body and today the arts are in as much trouble as medicine. There are those who would keep culture from shining and helping people. Culture is the mental part of health and if you don't believe me, go step in your Library of Congress. Take a minute and see what it does for your whole body, how it refurbishes your very soul. That is my primary way of healing through the arts.

In a profession where there is 120,000 actors today, and 87,000 of them didn't work last year, they made less than a poverty wage of $7,500, and in a world where 37,000 didn't work, in a world where we are losing $150 billion this decade to Canada alone which is $30 billion of your tax money, why should we give that money away? That can build medical centers, playgrounds. Why aren't we helping medicine and why aren't we helping the arts so that we can make good films which will make people feel better and be healthy?

I beg that the protection of vitamins and medicines, we have the right to choose our own vitamins. Medicines are food. Sure it can't be poisonous anymore than food should be poisonous but we have the right to choose. Nobody should give me a prescription for a vitamin or medicine. Don't they dare start to play that game. I want the right to choose my food in my country and the right to buy my own vitamins and medicines.

If my poor actors, 120,000 of them, 80,000 who are probably getting pretty depressed and pretty ill by now, don't have the right to buy a vitamin or a medicine, they are going to die. So let us keep some of your artists alive, let us keep humanity alive and by the way, just so you know, the cultural business is affecting men and women across the country. They are going belly up because of a lack of the right to do independent films in this country. They have no money and we need to get on board with France, Spain, Australia and everybody else and get some work in this country for these people.

We also need to have the educational committees work with Congressman Burton and you Congresspeople and let us get vitamins and minerals in the school lunches for our kids. If your own Surgeon General has said a proper diet can indeed prevent cancer, then let us help to get them a proper diet because when you go to dinner tonight, what is the proper diet? Sometimes food is like some of the people we know, pretty good on the outside, not much going on inside. So when you go to get your food tonight, I don't know what that food you eat has. Just to protect yourself, please let us get our kids some vitamins and minerals.

Thank you for allowing me to speak. Any questions, please.

[The prepared statement of Ms. Ladd follows:]

DIANE LADD'S TESTIMONY

Thank you, Mr. Chairman, committee members. I appreciate the opportunity to share my experience with you today and urge you to change the current system to enable citizens of our country to economically avail themselves of vitamins, minerals and supplements that can and do enhance health.

According to doctors, I have experienced three medical miracles in my life. I give thanks, primarily to alternative modalities, such as the practice of traditional medicine in China and the powerful impact of vitamins and minerals in that process.

Married very young, I was the mother of a treasured eighteen-month-old daughter, whom my husband and I lost in a tragic accident in 1962. My body *screamed* to replace this child! Amazingly, I became pregnant within eight weeks, but unfortunately, it was a tubal pregnancy and almost cost me my life. Surgery removed the right fallopian tube and more than three quarters of the left tube. I visited five renowned American doctors, one after another and all informed me that I would NEVER have another child.

It was an impossible dream. I feverishly began my own research. In 1963 there were no health stores and I could find only one health book in the marketplace – Gaylord Hauser's *Mirror Mirror on the Wall*, which I voraciously read and reread from cover to cover. There were no doctors that I could find involved in alternative modalities. Vitamins and minerals were subject matters hardly discussed – maybe Vitamin C for colds, but even that was considered bogus at the time.

My great grandmother Prudence was a midwife who became a doctor and was known as the "Mother of South Mississippi." She was legendary for her many cures, including typhoid fever and diphtheria before the advent of drugs for the prevention of these diseases. Her cures, based on her study of herbology among the Cherokee Indians, were the basis of her "alternative" education.

When I was a wee tot, our next-door neighbor's son contracted spinal meningitis. The Mobile, Alabama hospitals were filled to the brim – even beds in the halls! – due to the outbreak of this disease. The doctors told our neighbors to take their son home, he would be dead by morning, and nothing could be done!

I remember my Daddy standing in our doorway as the neighbor tearfully pleaded with him to save her son's life. He kept telling her he was a doctor for chickens and poultry while his eyes filled with tears, his chin quivering empathy. I heard him mutter, almost to himself, "You don't ever give up on life as long as you are *in* life." He went out and found a country doctor, a young man who just graduated from Harvard Medical School and took him to our neighbor's house. That doctor worked on that boy all night. The neighbors held the boy's arms and legs to restrain him so his head and neck wouldn't bend back and snap as it does in many cases. You could hear that child's screams all through the village that long night, but that boy LIVED!

So, in my own anguish at the loss of my daughter, I remembered my grandmother's spirit and my father's words as I embarked on my own search for a miracle. My days were spent not searching for acting jobs but in libraries seeking any tidbit of information that might enlighten me. I flew to New York and consulted with the famous Austrian doctor, S. Peller, M.D. who had served in the Army with T. E. Lawrence. He told me, among other advice, to take mud baths to prevent sterility. I flew as many places as my limited finances would allow in the hopes of obtaining more information.

As I sought answers, I learned much about the human body and the wonderful substances found in nature. When I told some doctors that cranberry juice was a natural antibiotic they laughed at me! Years later these same doctors would prescribe cranberry juice! When I told doctors that I knew Vitamin E, a high potency vitamin which should not be taken if you have high blood pressure, could help if you have scar tissue, they laughed at me. Years later these same doctors were prescribing Vitamin E to heal my own physical scars.

Three years later I zeroed in on a specific plan: for a whole month with diligence, I ate only foods and vitamins that would help detoxify my body, strengthen my circulation, minimize infections and inflammation, balance the yin and the yang, and in particular, nourish the female organs. I ate foods like avocado, took vitamins such as the various B's and used bee pollen.

After one month of my trial period, there was a smile on my face as I walked in to Dr. Charles Ledergerber, one of the most famous gynecologists in our country – a man later chosen by our government as one of five doctors to be sent to China to study their methods of traditional medicine, which is, of course, what we call alternative modalities.

I said, "I think I'm pregnant."

He shook his head and sadly replied, "Oh Diane, you can't be pregnant. It's impossible! Diane, go home and cry it out."

Dr. Ledergerber had great empathy for my pain because he, too, had lost a young child. However, he had four other children. I had none. I looked at him steady in the eye and stated firmly, "Dr. Ledergerber, I have cried. Now, go make your test!" The test was positive!

When Laura Dern was born on February 10, 1967, they took her Caesarian to make sure there would be no complications. However, after lifting my child from my womb, I remained on the operating table for FOUR HOURS while they removed sixteen major adhesions intertwined around my female organs and intestines. One of the other five doctors who had stated emphatically that I could never have another child came to the delivery to observe it for himself. I was not under general anesthetic because the patient will bleed more: they had only given me a spinal, so I was in a twilight state—in and out. So, while they were removing adhesions, the other doctor exclaimed loudly, "My God. It's impossible that this child got through that tube and this body! This is a miracle!"

Subconsciously, I heard him. This blonde head suddenly popped up off the table while they were still in the midst of the operation and I groggily exclaimed, "That's right doctor. It's a miracle – and a hell of a lot of hard work!"

The result was Laura Dern, a brilliant actress in her own right. My daughter and I made our country proud as we were hosted by Princess Diana and other notables for our work together in the film **Rambling Rose**, in which we made show business history as the first mother and daughter tandem to be nominated for Oscars in the same picture. Laura Dern would in fact NOT be on this planet if it were not for vitamins and minerals. No pharmaceutical drugs helped me conceive this child. Vitamins and minerals did!

My second miracle came as a result of Laura's scoliosis. She was just 12 years old. X-rays of her spine revealed two severe "S" curves. Dr Jack Moshein, renowned orthopedic surgeon in Beverly Hills wanted to put her in a back brace from her hip to her neck. I inquired, "How much time can I have before this HAS to be done?" He gave me nine months – enough time to have a baby – during which I birthed health! Nine months later when I walked into his office he screamed, "My God, Laura has grown 2 ½ inches! Growth is a detriment to scoliosis! Diane, scoliosis is not only a crippler, it's a killer. We *have* to get that back brace on her NOW!"

I told him to take his x-rays. I certainly had no way of knowing the final results. With fear and trepidation, my daughter and I sat in his waiting room among sixteen other people and waited for the results. Suddenly, he burst through the door, waving the x-rays over his head that showed her spine was very close to being completely straight and yelled "MY GOD THIS IS A MIRACLE!"

With a long awaited deep breath I smiled tentatively and whispered, "That's right doctor...a miracle...and a hell of a lot of hard work!" Dr. Moshein took me into his office and tape-recorded everything I had done. He enthusiastically stated that he was going before the medical board and share this tape. Unfortunately, I don't believe that happened. Sometimes fear of judgment among one's own peers is a devastating block to growth. Dr. Viola Frymann, D.O. was the crux of Laura's miraculous change. As a young medical student this doctor had also lost her only child. She felt that if the doctors involved had gone that extra mile in research her own child would have lived! Since then, she has dedicated her life to humanity, especially children, and established the flourishing *Osteopathic Promises For Children Clinic* in San Diego, CA. Dr. Magoon, one of President Eisenhower's private physician and the Grand-Daddy of Cranio-sacral therapy was Dr. Fryman's mentor. Today Doctors from all over the world travel to her clinic to study her methods. There were ***NO*** pharmaceuticals used in the amazing bone reformation in my daughter's spine. Part of Laura Dem's miraculous cure was an intensive vitamin and mineral therapy. If Laura had worn that prescribed brace from her hip to her neck, she probably would have never had the opportunity to share those magnificent performances with the world as she continues to do so today.

My third miracle had to do with emotional problems following a divorce. I needed a staph shot once a month, particularly if I was traveling from city to city. I also needed a weekly allergy shot for feathers, pollens, dust and dog hair – we even had to give our dogs away. But note this: when the body goes into any kind of dis-ease state, the physical body's ability to assimilate needed vitamins and minerals from the food we eat is acutely and rapidly diminished. From my research, I was led to embark on a one-month program of fresh squeezed vegetable juices 5 times a day that contained mega doses of certain vitamins and minerals as a supplement to my diet. In one month the allergies subsided, no shots were needed and I got my dogs back! It was a small miracle, but once again, a hell of a lot of hard work and boy did I feel good!

There are those in our country and in the world today who undermine forms of *Preventative Medicine*! We must supplement our body's nutrition with a healthy daily regimen of needed vitamins and minerals. Our Surgeon General stated that *a proper diet can help prevent cancer.* A healthy diet consists of the proper assimilation of needed vitamins and minerals. However, sometimes food can be like some people—attractive on the outside, not much goin' on...inside!

Food can only contain the vitamins and minerals that come, not only from its own seed but is extracted from the soil in which it grew. If the soil has not been chelated and/or nourished properly it may be barren of nutrients. Another concern is the large number and amounts of preservatives used in the United States which far exceeds those used in other countries. In addition, many of our foods today are poorly prepared. And with the accelleration of all manner of pollutants our health is in serious jeopardy. If one does not have somewhat of a nutritional balance to sustain themselves the body begins to dive into troubled water—and *dis-ease* begins. When one becomes ill you can only pray you find a doctor with wisdom, fortitude, and integrity who believes in his/her Hippocratic oath.

Over the years I've worked with doctors and medical clinics, time permitting. I've seen women come into a clinic with cancer. For example, some of them already had one breast removed and a diagnosis to lop off the other due to metastasized cancer. I've seen mental, physical, and spiritual applications that included positive reaffirmation – that's a way to help remove anger, most detrimental to all of us because anger sets off free radicals, in our bodies, one of the causes of cancer. I've seen the utilization of the other alternative methods such as hypnosis, which can help a patient get to the root of a problem. Therapy also helps patients communicate, discuss and release. Most of all, physical rehabilitation benefits from such therapeutic aids such as chelation, massage, oxygenation and most of all, **A VITAMIN AND MINERAL PROGRAM!** I saw with my own eyes *the cures* of these same women! No sign of cancer anywhere in their body and the devastating breast surgery no longer necessary.

In the late 80's, I agreed to star in Rock Hudson's life story for very little money if the producers would donate a sum of $25,000 to a hospital of my choice for the study of immune related diseases. The hospital was in Scottsdale, Arizona under the direction of Dr. Terry Friedman, Diplomat on the American Board of Family who had lectured at the Congress of Science and Religion in Italy and for Harvard University to name a few.. He was one of the seven founding doctors of *The American Holistic Medical Association*, an incredible organization of AMA doctors who believe in alternative modalities.

At this hospital, an AIDS patient had been given only three months to live when he arrived; he was literally at death's door. After two and a half months treatment, this patient looked to be a specimen of health and was released. A sobbing mother from Texas was very grateful. I don't know how long this patient lived, but as precious as life is, a day is a day, an hour is an hour and moments of smelling the roses a lifetime.

I was privileged to be in the room with five renowned medical doctors from this country when Dr. Friedman telephoned the Center for Disease and Control in Atlanta, Georgia and begged them to come and monitor what he and the other doctors were accomplishing. He didn't ask for money or support, he just requested they come observe and report. They inquired about the program and he mentioned vitamins and minerals, the guffaws were loud and clear. They literally laughed, "We don't believe in anything holistic!"

As a member of the Screen Actors Guild, I'm now faced with the fact that because my country is the only country that has not leveled the playing field for tax investments, we've lost major productions to other countries and our actors have little to no work in the U.S. Last year out of 120,000 actors, 87,000 could not buy milk for their babies, making less than the poverty wage. Moreover, 37,000 of these actors did not make *one dime*. Only 3000 out of 120,000 made $100,000 or better. Only 1500 made $200,000 or better. I know that people think Hollywood stars light cigars with hundred dollar bills, but it's just not true! That opinion is promulgated because we stars who live in the fish bowl have the ability to raise $10 billion a year for charities and other VIP groups. However, we can't seem to help ourselves and nobody seems to be helping us to help our own. When an actor makes $100,000 after he pays percentages to the at least five people who work for him and Uncle Sam, he takes home less than many plumbers or teachers!

Aside from the fact that this situation is creating a horrendous unemployment problem because "Mom and Pop" businesses and even larger companies who depended on film production are going belly up in state after state across our country. The actors' own immediate problem, aside from the fact that they're not making a decent living, is that they are becoming depressed and ill. It would help immensely if they could afford

the proper vitamins and minerals which might sustain them through these hard times. They could afford it if these much needed vitamins and minerals were tax deductible.

Therefore, I wholeheartedly endorse, not just for my fellow actors, but for every man, woman and child in our United States, Congressman Burton's insightful, amazingly wise initiative. Through this proposal, if we can further open avenues to preventive healthcare, might we not have more productive citizens in our society driving a more robust economy?

Among some of the great scientific minds who espouse the use of vitamins and minerals is Albert Einstein who said, "*If the doctors of today do not become involved in nutrition—then, the nutritionists will become the doctors of tomorrow.*"

Mr. Chairman, ladies and gentlemen, I appreciate your listening. Please use your hearts and minds to improve the lives of those you represent. Thank you!

WHITAKER WELLNESS INSTITUTE
MEDICAL CLINIC

July 31, 2002

Susie Schulte
Committee on Government Reform

Subject: HR 3475

To Whom It May Concern:

For over twenty-five years, I have used a sophisticated array of nutritional supplements in treating patients who come to me for help. Because I prescribe them, their cost is often tax deductible. However, the cost of nutritional supplements should be tax deductible for anyone who uses them to improve their health. The rationale for this is obvious.

Consider the following. If a mother gives birth to a child afflicted with a neural tube defect, a devastating occurrence, the child will often require hundreds of thousands of dollars of medical therapy throughout his life, all of which is tax deductible. It has been clearly shown that folic acid, taken as a nutritional supplement – not as a component of food - will prevent forty to eighty percent of neural tube defects. In fact, the United States Department of Public Health has looked upon supplemental folic acid as a preventive medicine opportunity comparable to the Salk vaccine.

Shouldn't the prevention of this devastating disease be tax deductible?

This is only one of dozens of examples that I could cite in support of the premise that the cost of nutritional supplementation should be tax deductible.

I hope this is helpful.

Sincerely,

Julian Whitaker MD

Julian M. Whitaker, M.D.

Cc: Diane Ladd

JMW/sw

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Statement of Dr. Douglas Markham
President, Total Health Care Partners
Founder, TotalHealthDoc.com

"Diet, Physical Activity, and Dietary Supplements – the Scientific Basis for Improving Health, Saving Money, and Preserving Personal Choice"

U.S. House of Representatives
Committee on Government Reform

July 25, 2002

Introduction

Chairman Burton, Mr. Waxman, and members of the Committee, thank you for the opportunity to provide a statement for the record of this very important hearing. It is encouraging to know that this committee ranks diet and nutrition high on the list of issues for Congressional exploration. I am honored to have been invited to help the committee think them through.

Mr. Chairman, if there is one key point that the committee should glean from my statement today, it is that the classic low-fat, high-carbohydrate diet that we have all been recommended to follow over the past 20 years simply does not work.

I grew up in the state of Wisconsin, and know from first-hand experience that we do not fatten the pigs and cows with fat, we fatten them with low-fat grain -- the same nutritional recommendations that the government and food industry have been telling us to eat over the past 20 years. It should come as no surprise that since these guidelines were issued, America has become 35 percent fatter.

Consider the following statistics from the U.S. Centers for Disease Control and Prevention (CDC):

- **The American public is 35% fatter than we were 20 years ago.**
- **1 out of 3 adults and 1 out of 8 children suffers from obesity.**
- **13% of children under 18, and 35% of adults in the U.S., are considered clinically obese.**
- **$100 billion is spent on obesity-related conditions (high blood pressure, high cholesterol, and adult onset diabetes) every year in the U.S.**
- **Obesity contributes to over 300,000 deaths per year, and is now surpassing smoking as the leading cause of preventable death in the U.S.**
- **53.6 million workdays are lost every year to obesity-related conditions.**
- **American businesses and companies are losing over $4 billion per year in lost productivity related to obesity.**

The way to fully understand why fat does not make us fat, and low-fat grains do, is to examine the dietary hormonal connection and how food acts as a drug.

Food Is A Drug: The Hormonal Connection

The kind of food we eat has a tremendous effect on our bodies, energy levels, mental alertness, and quality of life. Like a drug, the food we eat causes powerful biochemical reactions in our bodies. The kind of food we eat and when we eat it tells our bodies whether to burn fat or store fat.

Hormones are chemicals manufactured by special glands in our bodies and released into our bloodstreams. Our blood transports hormones to different parts of our bodies, where hormones influence the way organs and tissues work. Because hormones control and influence so many vital processes such as growth, sexual drive, aging and our metabolism, hormone research is one of the most exciting fields of medical science. Among the bodies of scientific research to emerge from these studies is the strong connection between food and hormones. Specifically, the kind of food we eat and how much we eat triggers the release of two powerful hormones, insulin and glucagon.

The difference? Insulin tells our bodies to store fat. Glucagon tells our bodies to burn fat.

The Dangers of Excess Insulin

When we eat foods that produce too much insulin, not only are we telling our bodies to store fat, but the excess insulin boosts production of triglycerides, or blood fats. What does blood fat do to our arteries? It clogs them, which makes us prime candidates for strokes or heart attacks. Excess insulin also stimulates the liver to produce cholesterol. This is why our cholesterol levels can still be high even if we cut all the fats out of our diet. The amount of fat we eat does not influence our blood cholesterol levels that much. The real culprit is excess insulin, which also contributes to high blood pressure.

When our bodies produce excess insulin on a regular basis, we are likely to develop insulin resistance. This is a vicious cycle where the body becomes less sensitive to insulin, and compensates by secreting more of it. Consequently, we store more fat and gain more weight. Ultimately, our pancreases, that produce insulin, cannot satisfy the demand. This is a precursor to acquiring the killer disease adult onset diabetes.

Adult onset diabetes, also known as type II diabetes, affects more than eight million Americans. It is a devastating disease characterized by loss of energy and weight gain. People afflicted with diabetes suffer from blindness, heart disease, kidney failure and circulatory problems that often lead to the amputation of fingers and toes. Diabetes is also a well-known cause of male impotency. It is estimated that an additional eight million Americans suffer from some form of diabetes and don't even know it.

Through many years of clinical practice, I have found an effective way to get our bodies to reduce the amount of fat-storing insulin and promote the release of fat-burning glucagon. The solution is to eat the right combination of everyday foods, in the right amount, at the right time.

The Hormonal Response to Food

The reason excess carbohydrate consumption leads to obesity has to do with our bodys' hormonal response to food. Consider what happens when we eat meals that are loaded with carbohydrates.

When we eat a high-carbohydrate meal, like pasta or French toast, those carbohydrates are rapidly converted into glucose or blood sugar. As a result, our blood sugar levels surge. The spike in blood sugar also triggers our pancreas to secrete insulin, and insulin's job is to reduce the amount of glucose in the bloodstream. It does this by storing excess glucose. First, a small amount is stored in our livers and muscles. The rest of the excess glucose is stored as body fat. When insulin does its job to reduce excess glucose, there is not enough glucose remaining for the brain to convert into energy. This is why we start to nod off after a big carbohydrate-heavy meal.

At this point, the brain sends a message: consume more carbohydrates. That is when we reach for the mid-morning or mid-afternoon carbohydrate snack, and that is how we end up taking a ride on the blood sugar roller coaster, cycling dramatically from high to low energy. That is how all those excess carbohydrates become excess pounds. It is a vicious cycle that leads to obesity, insulin resistance, and hypoglycemia.

The secret to breaking this cycle and taking control of our health is simple: increase the amount of protein we eat and decrease the amount of carbohydrates. Eating the right amount of protein stimulates the release of glucagon, a hormone that helps stabilize our energy levels by mobilizing the release of the sugars stored in your liver to satisfy our brains' need for glucose. Glucagon also helps our bodies to burn stored body fat.

So instead of eating French toast for breakfast, I tell my patients to have an omelet with fresh fruit. Instead of pasta for lunch, eat chicken, beef or fish with vegetables.

I am not suggesting that all carbohydrates are bad for us. Carbohydrates are an essential part of healthy nutrition, as long as we eat the right amount and the right kind.

Nutritional Education

Unfortunately, most medical doctors are not well informed on proper nutrition, but it is not their fault. The majority of their time in medical school is reserved for learning how to diagnose diseases and what types of medications or treatments to prescribe to combat them. Therefore, they must depend on the information they read in journals and publications outside of their normal education. No medical doctor would disagree with the fact that proper diet and exercise is good for you. Unfortunately, much of the information they are reading about proper diet is based on studies financed by the food industry. The food industry has made billions of dollars off the American public with this low-fat, no-fat diet craze. How many people do we know who have had high cholesterol and told by their physicians to cut out foods with fat? How many people do we know who have cut out the fat and have actually lowered their cholesterol levels? Not very many.

Physicians have been so busy diagnosing and treating disease, they do not have the time to consult on proper nutrition. This is why they refer their patients out to dieticians and nutritionists. In fact, about 30-40% of my patient referrals come from medical doctors.

Unfortunately, the majority of dieticians and nutritionists are still following the same misinformation of the high-carbohydrate, low-fat diet. Consequently, the results with most patients are poor, and the patients eventually get frustrated and abandon all hope of gaining control of their health through diet and exercise.

I have long recommended making nutritional education a part of the standard curriculum in medical schools. However, as much as we as a nation deserve more appropriately educated physicians, it is critical that the curriculum is based on proven methods of proper nutrition. If physicians are simply exposed to the nutritional guidelines that have been fostered over the past 20 years, we will have done nothing to combat the epidemic of obesity. In fact, the problem will get worse, and many more people will die from diseases that are almost entirely preventable.

Recommendations

According to the CDC, the solution to the obesity epidemic requires effective collaboration among the government, parents, schools, community organizations, and the media, as well as a commitment to action by individuals and communities across the country. Through a national public education campaign I will soon launch on the prevention of obesity-related diseases, I will be working with the private sector, but the government's role is equally as significant.

1) I urge this committee to put under intense scrutiny the nutritional guidelines developed by the US. Departments of Agriculture and Health and Human Services. What has become known as the "Food Pyramid" is among the most dangerously misleading documents ever to come out of the U.S. Government. This pyramid needs to be completely inverted, and the testimony I have given based on years of clinical practice and data underscores the favorable outcomes of such an inversion.

2) Further, I strongly suggest this committee to explore strategies to change the way the physicians are educated and trained. Medical students are in desperate need of reliable data on the basics of human nutrition and clinically proven methods of weight loss. They should not be forced to learn this critical information from the Internet or professional journals.

Thank you, Mr. Chairman, for the opportunity to provide this statement. I would welcome the opportunity to discuss these issues in greater detail with you and your staff.

Mr. Chairman,

I want to thank you for calling this meeting today to discuss what I feel to be a critical issue facing our nation.

It is no secret that obesity is epidemic in the United States. According to the Committee's background documents, there are currently over 45 million obese adults and about 8 million obese children. And these numbers are on the rise.

The effects of obesity on our population and our economy is staggering. According to the Surgeon General, 300,000 Americans die prematurely each year due to their weight and obesity costs Americans $100 billion per year. And according to the RAND Corporation, "obesity contributes to higher cost increases for health care services and medications than do either smoking or problem drinking."

The July/August 2002 edition of Men's Health magazine had a wonderful series of articles on this topic and they have challenged American men to lose one million pounds collectively. This is a great challenge that will help men feel better, live longer, and save themselves thousands of dollars over their lifetimes.

Overweight men, according to the article,:

Are 50% more likely to develop heart disease;
70% more likely to develop high blood pressure;
58% more likely to have total cholesterol of 250 or greater;
16% more likely to die of a first heart attack;
9% more likely to have a stroke; and,
250% more likely to develop diabetes.

Overweight men spend 37% more per year at the pharmacy; make 12% more visits per year to a primary care doctor; spend 19% more days per year in the hospital; and pay $4,200 more over their lifetimes for medical care.

And overweight men are 5% more likely to die of prostate cancer, 35% more likely to develop kidney cancer, 120% more likely to develop stomach cancer, and 590% more likely to develop esophageal cancer.

These statistics are staggering. And though they are particularly for men, I am sure they could be translated to women as well.

The way I see it, the Federal Government should do all it can to encourage healthier living. Our panel of experts today will provide us with valuable information that we should use to improve federal policies in regards to diet, physical activity and dietary supplements. It would be a shame that the federal government become complicit in encouraging behavior that is detrimental to the health of Americans.

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Opinion > Kerry Dougherty

Fat-o-meter of feds is one lightweight body of work

The Virginian-Pilot
© July 25, 2002

Kerry Dougherty

I feel better already.

Sure, I may look like a chunky monkey, but according to official height and weight charts, I'm in good company. Government-certified chubbies include Arnold Schwarzenegger, Mel Gibson, Sammy Sosa, Michael Jordan and, heck, the way things are going, maybe even Gwyneth Paltrow.

No one's safe from the accusatory finger of the federal fat force.

According to a front-page story (proof that this is, indeed, a horrifyingly slow news time) in yesterday's Pilot, someone finally noticed that the government's Bureau of Blubber forgot one thing when it created mathematical charts to tell us who should skip dessert: the difference between muscle and fat.

In other words, statisticians who have been shrieking about an American ``epidemic of obesity" don't distinguish between fitness fanatics who are bulked up with muscle mass and couch potatoes who are bulked up with M&Ms.

In fact, lean people with muscles often weigh more than people of the same height laden with cellulite.

Way more.

For example, a sedentary office worker who stands 6 feet 2 inches tall and tips the scales at about 235 pounds may look like a walrus with wingtips. Meanwhile, Schwarzenegger at about the same height and more weight looks lean and mean.

But appearances aside, both specimens are lumped into the 61 percent of Americans the government has declared seriously overweight.

Sheesh.

All of this goes to show that the only thing more bloated than the average American's waistline is the government itself.

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Why in the world are tax dollars going to tell us who's fat to begin with?

We have *eyes*, after all.

Yes, we all know obesity is bad. It can lead to heart attacks, diabetes and clandestine trips to Lane Bryant.

Still, since when did that become the business of government? Frankly, I'd prefer the feds stop fixating on my flab and focus instead on corporate fat cats who have left me with an alarmingly skinny stock portfolio.

Making matters worse, the federal fat watchers actually changed the official formula for pudginess in 1998. The Wall Street Journal reports one ``minor change" in government calculations four years ago produced an extra 30 million overweight Americans ``overnight."

Imagine that. You eat a salad for supper, pass up a piece of pie, and wake up in the morning with the government telling you you're a tub of lard anyhow.

Call me cynical, but it seems that researchers have a vested interest in plumping up the numbers of overweight Americans. By adjusting the scales so that more of us appear obese -- on paper -- they created a scary epidemic.

Then they marched to Congress to demand money to fix it.

In 1999 Congress dutifully appropriated funds for an annual nationwide Boy-Are-We-Ever-Fat survey.

This being a slow news day, I went to the official Body Mass Index site on the Internet and started plugging in vital statistics.

What I found was shocking. Arnold Schwarzenegger is not just plump, he's large enough to be declared a national monument.

And Shaquille O'Neal? Oh my. I plugged his eye-popping vital statistics into the BMI chart -- 7-foot-1, 315 pounds, by some accounts -- and he registered a whopping 30.7 on the government's chart.

Obese.

Frankly, if Shaq's obese, fat never looked better.

The next thing you know, airlines will want to use these government graphs at their ticket counters. Off-the-chart hunks like Arnold Schwarzenegger will be asked to buy two seats. One for each of his muscled buns.

I want to be there when *that* happens.

In the meantime, when it comes to body weight, a little common sense may be in order.

Instead of looking at a government chart to see who's overweight, why don't we all simply look in the mirror?

Reach Kerry at 446-2306 or at kerry.dougherty@att.net

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Mr. BURTON. Thank you, Ms. Ladd. You are very informative in your statement but you are also very interesting and I found it very entertaining as well.

You mentioned that your daughter, Laura Dern, wouldn't have been born if you hadn't had proper diet and vitamins and supplements. Are you aware of any research in our government that is looking at those issues?

Ms. LADD. I am aware of those letters from the doctors who are AMA doctors. I was privileged in Arizona, unfortunately, to be in a room with five top doctors from this country. A hospital is a terrible place to get your karma. You had better pray to God if you are ever in a hospital that you get a doctor who believes in his work because the chips are down then. I was in a hospital with doctors who believed in their work and they called the Center for Disease Control in Atlanta, GA. Dr. Friedman had them on the speaker and he begged them to please come monitor the work they were doing. They didn't want any work from them, they just wanted them to come and monitor it so they could maybe get a grant or something to continue their work for humanity sake. They asked them, please, in God's name, come monitor what we are doing. They said, well, what are you doing to save the lives? He said, chelation, which I personally have seen do wonders; Vitamin C drips, and I have seen that do wonders, miraculous wonders; vitamins, massage, and modalities and herbology, and mental programming. The Centers for Disease Control laughed in their face, roared with laughter and said, we don't believe in anything holistic and they slammed the phone down in these famous doctors' faces. I was there and witnessed it.

There is an organization called AHHA. She sent me a letter to thank me for coming to testify for you. She said she had heard me speak once in Scottsdale, AZ about 15 years ago and because of that she formed this organization to do research. She has a lot of research. You have a letter from her. Dr. Gladys McGary is one of the giants of the business and Dr. Bob Anderson. These doctors are the ones I put my faith in, the ones who working together to ask each other, tell me what you learned, I will tell you what I have learned, I will help you, you help me. We can't live alone, we are not isolated.

Mr. BURTON. Other cultures have embraced nutrition. I think China is a leading example of that. They have other methods of healing which are not generally recognized here in the United States. Here in America, it seems like we focus on after the fact, after the disease has taken place and trying to come up with the magic bullet. Can you tell us a bit about your experience with some of the methods used in other countries, the vitamins and supplements they use and how that might be effective?

Ms. LADD. When I mentioned my great grandmother, Prudence, she was a young doctor, had trained herself. First, she was a midwife and went to New Orleans with a horse and buggy and stole all the books from the library so she could help her patients. They didn't have any libraries in Mississippi at that time. She came back and finally got a medical degree, delivered over 3,000 babies. She was the kind of woman that once was thrown in a blizzard off a horse, broke her leg, got back on the horse and went and delivered

a baby, then had her leg set. There are records of her cures of typhoid fever and diphtheria before the advent of the drugs that would cure those diseases. She used the herbs the Cherokee Indians taught her.

I am also aware of an experience of my father when I was 5 years old. I was in Mobile, AL and there was an outbreak of spinal meningitis. The neighbor's son had been taken to the Mobile Infirmary and they even had beds in the halls. They told this poor farm couple take your son home, he was 17 years old, he will be dead by morning, there is nothing we can do. They came over to my daddy begging him, and my daddy said I am a doctor for chickens and cows and dogs. They said, oh, Mr. Ladd, please, you have to help us, we have nobody to turn to.

I remember seeing my father's chin quiver and I saw those tears in his eyes and I heard him mutter, you don't ever give up on life while you are in life. He went out that door and found a young country doctor who had just graduated from Harvard and was in this place Chickasaw, AL. He brought him to these people. This doctor rounded up the neighbors and the neighbors held the boy's body, the legs and hands down because in spinal meningitis the body will curl until the back will snap. They held the boy down so the body wouldn't snap and he worked on that boy all night. You could hear that boy screaming all through the neighborhood.

He also brought in an old man about 84 years old, a country doctor to advise him, tell me what to do, tell me what to use, what can we do. I don't know what all he used but I know he used alternative medicine just as fast as he could get his hands on it. Alternative medicine is herbs, perfecting the human body.

Yes, I believe in traditional medicine but today, we are overmedicated and there are many, many side effects. If a woman takes an antibiotic, she is going to get yeast unless she takes acidophilus. Lots of time men will get it too in their gut, all through their body. Like you said earlier, Shelley Winters' daughter graduated from Harvard, she had 7 years there, she only got 2 weeks nutrition. That is impossible. That doesn't make any sense today. How can that make sense when the Surgeon General says you need a proper diet? We must have nutritional training for our doctors. This must be demanded from the universities. We must protect the old and the young.

In answer to your question, I have seen with my own eyes miracles. I have seen women come into the wellness clinic there in Florida. I have seen them have breasts cutoff from cancer, and there is cancer in their body and I have seen the application of mental, physical and spiritual practices that then you couldn't find cancer in the body. This is without chemotherapy. I just lost another friend from chemotherapy. Two or three of my friends had cancer and it returned years later and took their lives.

My witness to these miracles of cancer tells me that we don't have to be so arrogant to think that we know what we don't know. Yes, I bless the people who have drugs that will cure my body, I also want to know if it can hurt my body. You had better warn me and tell me what else I do to get those toxics it is creating out of my body.

One of my experiences, and I am so sorry, Congressman, that you just lost your wife. Grief is an emotion that one cannot pretend does not exist. On May 23, I lost my beautiful 89 year old mother. She had a stroke 6 weeks earlier and I was in the hospital with her day and night. I know that I am still full of grief. I wake up and think, oh, I will make lamb tonight, it will be good for mother. Mother is not here, she won't eat the lamb, she is on the other side.

I know that in those 6 weeks, the little hospital I was at the nurses cried and said, you and your daughter have helped someone leave in death in a manner we have never seen before. We wish that every human being could have this kind of treatment and this kind of love as they were leaving. I know the doctor said, my God, your mother is a strong woman. My mother was a strong woman because of the vitamin/mineral regime I gave her.

My mother fell and broke her pelvis. She got up and healed. My mother fell and broke her arm. She got up and healed. My mother fell and cracked her hip but she got up and healed and she was looking forward to her 90th birthday, a beautiful party which she didn't get, but I know how vitamins and minerals helped her. I know many times the medicines they were giving her were the wrong medicines and they caused great side effects. We had to go back and talk to them and remove some of these medicines.

I talked to my own Motion Picture Academy and they have really been having a terrible time with some of the side effects from some of our drugs. Again, I repeat, we bless the people who got us the drugs but we really need to use all of the knowledge and wisdom of the medical doctors who care about their patients and believe in medicine alternative modalities. Let us not throw out the baby with the bath water. Let us embrace their wisdom and their experience, people like Berkley Bodell who went fishing 1 day, a tick bit him and he got lyme disease. He has set up this whole organization, NFAM.

My daughter did a picture one time where she played a blind girl. I remember Barbara Streisand saying to Peter Bogdanovich, where did you find a blind girl who could act? He said, that isn't a blind girl, that is Diane Ladd and Bruce Dern's daughter, she is an actress. She was 14 years old. Laura went to the Blind Institute to study, to find out. She was a method actress without even knowing it, to find out what do you need to know, what are the experiences she doesn't know because none of us knows what it is like when you are sick, none of us know what it is like when that person loses somebody they love. We forget what it is like to wear each other's shoes.

When my daughter went to the ball of the blind people, it was her graduation from high school year. She went to the party where the blind kids were having their party. She went into the bathroom and there was a little girl who could see but she couldn't hear and could hardly talk. It was just a little dark room with a little ball up there with lights and when Laura went back to dance, the child looked over her shoulder and looked at Laura, isn't it good? She experienced the greatest job whereas my daughter, who was at a private school, had a big shindig for graduation, Laura said, mother, none of those kids had as much joy as that child with the joy in her heart. Why is that? I said, Laura, it is a sad thing that man

has to go through hell to get to heaven, that only when his body is starving or dying does he realize his soul can starve too.

Like I said the arts have times when we are in great depression. Then we had men like FDR. Let us not do that with medicine, we will all be dead.

Mr. BURTON. Thank you, Ms. Ladd. Mr. Kucinich.

Mr. Kucinich. I just wanted to say your story is quite compelling. As someone who has a great deal of respect for complementary and alternative medicine, I think it is important that you have come before Congress to share your story and your understanding because I think a lot of Americans can identify with it.

Thank you for having the courage and the wisdom to pursue the path you have. Thank you.

Ms. LADD. You have just made my day. Thank you so much. It is my privilege and pleasure to have been here.

Mr. BURTON. Mr. Schrock.

Mr. SCHROCK. Thank you, Ms. Ladd. That was very interesting.

This really is all about prevention. If we did more prevention, then we wouldn't have to worry about the after effects of not taking care of yourself. I told you earlier years and years ago I used to think chiropractory was hocus pocus. Believe me it is not. It is absolutely right on. I work out heavily and I got to a chiropractor at least once a week and when I am home, twice a week. It has made all the difference in the world. My wife started going 5 years ago and she had a curvature of the spine and it is now ram-rod straight. It is absolutely amazing. I am a big fan of that.

Proper diet is right. Before I got sick, I would eat anything the traffic could bear and I realize now that is just not right. Diet will certainly prevent a lot of these problems. A lot of the diet problems occur right in the schools. My wife is a kindergarten teacher and you would see some of the junk these kids eat and that is provided by the school system, we are creating a generation of kids that will have all these problems. That has to stop. When they sell McDonald's in high schools, we are a junk food society. I like McDonald's like everybody else, but when I eat it I may as well get a can of Crisco and eat it. We have to stop that and that is what we are doing to our kids.

We are overmedicated. When I was going through my chemotherapy, they had me on more stuff and I was a different person when they did that. My wife's kids in kindergarten are on Ritalin, she has eight or nine kids on Ritalin in kindergarten and that is a terrible, terrible thing.

I think what you are doing is wonderful and everybody else's testimony will attribute to that, will agree with that and we just have to make sure we get this message out. It is very, very important because when you don't have your health, you don't have anything.

I appreciate what you do. Thank you.

Mr. BURTON. Mr. Tierney.

Mr. TIERNEY. I have no questions. I want to thank the witness for her testimony.

Ms. LADD. My privilege.

Mr. BURTON. Mrs. Maloney, any questions?

Mrs. MALONEY. First of all, I want to welcome you and thank you for your many contributions to New York culture, the Copacabana,

our theater and some of the movies that you starred in were filmed in our great city, so I appreciate very much your professional career and also speaking out on what is a very, very important subject and one that does not get enough attention.

You mentioned three miracles in your own life and I often hear miracles from others diagnosed with cancer, they are going to die, they go on a special diet, they cure themselves, they are fine now.

I would like to ask do you agree complementary and alternative treatment need to be proven safe and effective before patients decide not to take say traditional treatment but to follow a holistic item? I agree with my friend, Congressman Schrock, that we don't focus enough on prevention in our medicine. We don't focus on any treatment except coming up with a pill or a manufactured way to treat something. The whole focus from the NIH is not a holistic one; even environmental medicine or how the environment impacts us ignores it. I just don't think there is that much focus on it. What do you think we should be doing in government to advance this?

Second, expand on the idea of where do you recommend holistic or the traditional method?

Ms. LADD. I recommend both. I recommend respect for the medical profession so that the people get their sugar, their TLC which we all need today, that it is worthwhile for their lives. I see you Congresspeople getting up and running to that bell, I pray for your adrenalin. It is hard to be a Congressperson, it is hard to be a doctor, it is hard to be a human being and in today's society, we are all in a mechanized world. You would think the faster paced society and the mechanized world would pull us closer together. Unfortunately, it is not doing it. It is alienating us one from the other.

The high cost of living is accelerating greed in many areas in medicine and in culture and we are not always getting the quality of food, the quality of medicine, the quality of culture that we need. I think we need to look at all these issues. These issues have one goal, to make the world a more balanced, humane and harmonious place to live, especially our own country and for our kids.

I said quite often, and I mean this, if I win all the Oscars in the world and leave the planet as a sewer for my grandkids to roll around in, I haven't done a damned thing. When it comes to medicine, there is a threefold healing process. Many diseases are caused by free radicals and free radicals are anger. I think we have to help each other not to judge too harshly. We are all in a state of shock over being judged. At the same time, we have to apply wisdom. That means we have to have mental healing for people, physical healing for people and spiritual. Spiritual means a lack of judgment. Mental is culture.

I think many of the movies today are making people angrier. I think people are alienated and that is why they are looking at all these realism type TV shows to watch somebody eat bugs on TV. I don't want my kid watching this. I don't think this is a healthy thing. Where are the good shows where you could laugh and cry and respect human beings and get angry? I am not against even violence if violence teaches me something in a film or a story, the same way a medical doctor examines the waste from your body to try to heal your body but he doesn't recommend that you go out in the middle of the street to get rid of the waste.

I think we have already found safety methods. I think our alternative modalities today have as many safety methods as traditional medicine. I think traditional medicine in many instances is a lot more detrimental and harmful than our holistic methods. People are going after them. People are getting smart in some areas.

Ms. MALONEY. What can we do as a government to really educate people about the importance of a healthy lifestyle, good nutrition and alternative medicine?

Ms. LADD. I think as a government you need to give some support and grants to those qualified great physicians that have proven themselves in an organization so powerful like the AMA. This is not chopped liver. These are doctors who have spent their whole lifetime. I am not saying there might not be one bad apple in the barrel, but that is life, that is karma, wherever you go, whatever you are dealing with.

By and large we need to promote the best. Promoting the best gives a higher rate of involvement of understanding of wisdom. It is like that at the Library of Congress. That is the best. Just stand there and you will understand exactly what I mean. If you can see the best, if you hear a great singer hit a high note, if you hear that high note, something happens literally in your body. When you read a great book, how many are reading the great books today? When our children get the best, if we can help our children have the understanding and wisdom to select the best, they will have the brains to go after the best in medicine, after the best in culture.

Anytime through our history and any civilization that culture and medicine has been shot down because of greed and selfishness, the civilization has gone to decay. This has been proven. Right now, we have a tax in many areas on good medical modalities that could help our human beings. I think the government has to make sure that helpful aids to humanity, healthful aids, is not stopped. If you go to a restaurant, you get food. If you find out that somebody is selling you rotten meat, they get closed down. If there is a complaint about manufacturing vitamins, fine, if it is bad or rotten, close them down but I don't think ever in a billion years should this ever be put under pharmaceutical companies or prescriptions. That would be tantamount to greed on the highest level and that would be horrendous to those old people or poor people who can afford a vitamin, they wouldn't be able to afford it. It would be such a sin, nothing more than a mistake, to take something and miss the mark.

Help people not miss the mark. Help them fight for the best. You are all such intelligent people. My heart goes out to you as much as it does to my actors to try to do culture in a commercialized world, it is not easy to fight for truth and fair play. May God help you fight for proper, medical and proper alternative modalities. Insurance companies should cover alternative modalities. Detoxification of a human being, you get new cells every day. Everyday your body does 360 something billion cells tomorrow morning. How is that possible that you have that kind of machine?

If you are polluted in there when they do those billion cells, they have to fight that pollution. Alternative medicine isn't anything but good sense and detoxification and finding food and massage and things that detoxify. That is all it is. The poorest Indian of eons

ago knew that in his heart and soul. We know it in ours. We know it in our wisdom.

Health, wisdom. There is knowledge and there is wisdom. Knowledge changes everyday. We find out tomorrow we should have done this. Wisdom supersedes knowledge for all of us and there are those people who would keep us from using our wisdom. Don't ever let that happen to you. Please help me, don't ever let that happen to me.

Go talk to the AMA people, get a Gladys McGary and a Bob Anderson in here, get Christian Northrop who wrote those books, get Cynthia Watson from Beverly Hills who is doing it all, get Berkley Bedell in here. He has gone to 83 countries. You have the best out there fighting. Encourage that kind of caring and enthusiasm. If it is shot down, it may never come again in our kids' lifetime. Don't let it die. Fight for the good. That is all you can do is fight for the good and I beg of you to do that.

Mr. SCHROCK [presiding]. Mrs. Morella.

Mrs. MORELLA. Thank you, Ms. Ladd. I am not going to ask you any questions in the interest of time but we are very honored that you are here and gave us such a moving presentation of personal experiences.

I want to thank you for the nutrition that you provide through your acting. I think the arts do provide a tremendous amount of sustenance to life. I have a son who is an actor and I would agree with what you said about an actor lives between chance and oblivion, but it is so very necessary. I am pleased this year that on the House side we have increased the amount of money for the National Endowment for the Arts and Humanities.

I also note in you a personality trait that I think is part of what you exude in terms of health and that is you have a determination and an attitude which probably, as you said in your opening statement, is a kind of linchpin, a kind of spirituality. I commend you for that and I thank you very much.

Ms. LADD. Thank you. It has been my privilege and pleasure to be here today.

Mr. SCHROCK. Ms. Ladd, thank you very much for being here. I was privileged to be the Navy's liaison to the motion picture and television industry for 4 years. I probably should not admit that but I was, so I understand exactly where you are coming from.

Really, health is the most important thing we can deal with. When you say we are under pressures up here, you can't imagine sometimes and our health is impacted by that. So what you are doing is absolutely magnificent and I am really going to try to do my part up here because I know what good health is and I know what good health is not. There is no comparison.

Ms. LADD. I would like to respond to your comment about health through the arts, helping people. It is true, it is a proven fact that when you are watching actors, especially in a theater or a great show on television, which is very rare, when you cry it releases toxins and pains from your body and those who make you laugh actually release gas from your body and it is very good for your heart. Laughter is the most important commodity to have.

As I said, science and art was once one and you can look up my website, www.dianeladd.com and go to the bottom of the left side

where there is a group called ACT. It is an art and cultural task force of 160 professional actors who are fighting to try to create Stay Here Productions to help culture in our country. Congressman McCarthy of Missouri, who got that motto from Truman, "The Buck Stops Here," has taken over my ball and is going to run with it on behalf of art and culture to try to do something. I hope you will all give her your support while I am supporting medicine.

Mr. SCHROCK. Great. I think they say when you smile, you burn so many calories. Smile all the time and you can be slim and trim the rest of your life.

I thank you and Mr. Hunter for coming here today. We hope you will come back again soon.

Ms. LADD. Thank you.

Mr. SCHROCK. We are now ready for our second panel. Please rise and we will swear you in.

[Witnesses sworn.]

Mr. SCHROCK. Before we hear our speakers, let me yield to the ranking member, Mr. Kucinich.

Mr. KUCINICH. I want to thank the gentleman and welcome the witnesses. In particular, I want to welcome David Seckman. Thank you and I appreciate the opportunity to work with you in so many areas. And also, Dr. Larry Kushi. Dr. Kushi and I have known each other, our families have known each other a long time. His father and mother are the individuals most responsible in the world for promoting macrobiotics. I have learned much from both of them in following their writings and I have to say Larry Kushi has continued on the brilliant path of his parents in his own writings and his work. I just wanted to be here for a moment particularly to welcome you and to thank you and your family for your lifetime commitment to macrobiotics and to alternative health, and to peace.

Thank you.

Mr. SCHROCK. Mr. Seckman is the executive director and CEO, National Nutritional Foods Association of Newport Beach, CA. We are happy to have you here today. You are recognized to give your opening statement.

STATEMENTS OF DAVID SECKMAN, EXECUTIVE DIRECTOR AND CEO, NATIONAL NUTRITIONAL FOODS ASSOCIATION; GEORGE BRAY, M.D., BOYD PROFESSOR, PENNINGTON BIOMEDICAL RESEARCH CENTER, LOUISIANA STATE UNIVERSITY; LARRY KUSHI, ASSOCIATE DIRECTOR FOR ETIOLOGY AND PREVENTION RESEARCH, DIVISION OF RESEARCH, KAISER PERMANENTE; PAMELA PEEKE, M.D., ASSISTANT CLINICAL PROFESSOR OF MEDICINE, UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE, ADJUNCT SENIOR SCIENTIST, NATIONAL INSTITUTES OF HEALTH; TIMOTHY S. CHURCH, M.D., SENIOR ASSOCIATE DIRECTOR, MEDICAL AND LABORATORY DIRECTOR, DIVISION OF EPIDEMIOLOGY AND CLINICAL APPLICATIONS, THE COOPER INSTITUTE; AND DAVID HEBER, M.D., DIRECTOR, DIVISION OF CLINICAL NUTRITION, UNIVERSITY OF CALIFORNIA AT LOS ANGELES

Mr. SECKMAN. Thank you for the opportunity to address the committee with respect to the dietary supplement industry.

I am David Seckman, executive director and CEO of the National Nutritional Foods Association. NFA was founded in 1936 and is the oldest and largest trade association in the natural products industry. We represent the interests of more than 3,000 health food stores, thousands of manufacturer-suppliers and distributors of health foods, dietary supplements and related items.

The committee has asked that I address the economic opportunity for improving health through diet, physical activity and the use of dietary supplements. In addition, I will also address the importance of natural foods and diet as a tool for disease prevention and health maintenance.

First, let me say that I believe this hearing is occurring at a very fitting time, both in terms of some of the critical health issues we are facing today and emerging recent scientific research. There are probably few Americans who have not heard about our Nation's newest epidemic, obesity. Even our President has carved time from his own pressing schedule to personally address and champion physical activity and a healthy diet in combating this problem. Hopefully President Bush's involvement in this issue has served as a wake up call to all Americans. That call can't come soon enough.

This year, the Centers for Disease Control estimated that approximately 47 million Americans will suffer increased risk of a whole host of serious illnesses, including heart disease and cancer due to poor nutrition and physical inactivity. As if this news weren't bad enough, the CDC also estimates that the problem increases exponentially with age.

Having worked for many years in the long term care industry, I have witnessed firsthand how declining health in older Americans negatively impacts not only the patient but family members and society as well. One of the most devastating effects of a poor diet and inactivity is experienced by older Americans. This group is by no means the only population affected. The percentage of children and adolescents who are overweight has more than doubled since the 1970's. Today over 13 percent of our children and 14 percent of our teenagers are considered obese. These figures continue to rise each year, paving the way for increased health problems in adulthood.

Between the ages of 40 and 60, 1 in 3 will feel the effects of a lifestyle that favors fast food and inactivity. These are prime earning years for many adults whose professional and economic contributions to society will be severely or completely curtailed.

It is estimated that treating obesity related health problems in the United States exceeds $117 billion annually. Diabetes alone, which has a direct connection to obesity, accounts for more than $45 million each year.

The reason my organization was formed more than 65 years ago was to support the growing number of consumers looking to make healthier choices about the foods they eat. Much of what the followers of this trend believed based on empirical evidence and common sense has been borne out by science over the years.

For instance, whole, unprocessed and fortified foods has always been an important aspect of the natural or health food industry. Processing can eliminate some or all of a product's health qualities such as fiber and essential nutrients. Foods such as these that have retained their health benefits can be recognized by FDA au-

thorized claims on the label such as fiber from whole oats can reduce the risk of coronary heart disease.

It is important to keep in mind that whatever the health claim, the FDA requires substantial scientific proof that it is correct.

Since I am on the subject of vitamins and minerals, let me make a transition into the more generic topic of dietary supplements and their role in human health. The term dietary supplement encompasses a wide range of products that include essential nutrients, herbal remedies and what we call specialty supplement products comprised of natural ingredients like enzymes and amino acids.

When Congress unanimously passed the Dietary Self Help and Education Act in 1994, it acknowledged there may be a conection between dietary supplement use, reduced health care expenses, and disease prevention. In fact, current research is bearing out this very supposition.

For example, the American Medical Association recently reversed its position on the value of taking a daily multivitamin suggesting that every adult would benefit from a daily multivitamin. This study is particularly important because our research indicates that physicians often do not discuss supplementation with their older patients.

Other landmark studies include two published relating to the delay and lessening of symptoms of Alzheimer's disease by patients who took the herb ginko, Vitamin C and E. Not only has research demonstrated the health benefits of dietary supplements in foods, it has also shown they can reduce health care costs by billions of dollars.

For example, a major medical journal reported that increased intakes of Vitamin E, folic acid and zinc could save $20 billion annually in hospital costs by reducing heart disease, birth defects and premature death. Alzheimer's disease costs Americans $61 billion a year in lost productivity from absenteeism of employees who care for family members and businesses that share health and long term health care costs.

Even this modest reduction in symptoms and the delay of onset of this disease can save billions of dollars. Clearly dietary supplements as a whole, not just vitamins and minerals are beginning to get the research they deserve.

Stimulating a good deal of this research is funding from two groups under the National Institute of Health's umbrella, the Office of Dietary Supplements and the National Center for Complementary Alternative Medicine. Both play a vital role in providing consumers with accurate and reliable information about alternative treatments and therapies.

The recent questions raised about hormone replacement therapy which could affect an estimated 42 million American women underscores the need for more research and more information about safe and effective alternatives. More information about the qualities of dietary supplements is critical and so is access to them. Bills like Chairman Burton's Tax Fairness Act would allow taxpayers to deduct amounts paid for foods for dietary supplement uses, dietary supplements or medical foods as medical expenses.

We also agree with Chairman Burton that food stamp recipients should be allowed to use their benefits to purchase dietary supple-

ments. Although this amendment which was added to but ultimately removed from the most recent farm bill failed to become law, we hope this issue will be pursued in future legislation.

Without question, combining a nutritional diet and an appropriate supplementation with physical activity not only reduces the risk of contracting a host of ailments, it improves quality of life for every age group. The body of research about the health benefits of a nutrient rich diet is impressive but needs to be expanded, particularly in the area of dietary supplements.

While funding for research in this area has continued to grow, further investigation of the role of dietary supplements in maintaining optimum health is critical. Congressional hearings such as this one make strong impressions on the minds of Americans about the issues they cover. Often these issues are negative and the focus is on what went wrong and how can it be fixed.

I want to thank the chairman and members of the committee for taking time today to examine what is right about nutritional foods and dietary supplements.

[The prepared statement of Mr. Seckman follows:]

TESTIMONY OF DAVID R. SECKMAN

BEFORE

THE COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

July 25, 2002

Chairman Burton and Honorable Members of the Committee on Government Reform, thank you for the opportunity to address the Committee with respect to the dietary supplement industry. I am David Seckman, executive director and CEO of the National Nutritional Foods Association (NNFA). NNFA was founded in 1936 and is the oldest and largest trade association in the natural products industry. We represent the interests of more than 3,000 health food stores and 1,000 manufacturers, suppliers and distributors of health foods, dietary supplements and related items.

The Committee has asked that I address the economic opportunity for improving health through diet, physical activity, and the use of dietary supplements. In addition, I will also address the importance of natural foods in the diet as a tool for disease prevention and health maintenance.

First let me say that I believe this hearing is occurring at a very fitting time, both in terms of some of the critical health issues that we are facing today and emerging recent scientific research. There are probably few Americans who have not heard about our nation's newest epidemic: obesity. Even our President has carved time from his own pressing schedule to personally address and champion physical activity and a healthy diet in combating this scourge. Hopefully, President Bush's involvement in this issue has served as a wake-up call to all Americans.

And that call can't come too soon. This year, the Centers for Disease Control estimated that approximately 47 million Americans will suffer increased risk of a host of serious illnesses – including heart disease and cancer – due to poor nutrition and physical inactivity (1). As if this news weren't bad enough, the CDC also estimates that the problem increases exponentially with age. For instance, only 6.7 percent of people between the ages of 20 and 30 years experience the negative effects of a bad diet and inactivity. However, this percentage jumps to 43.5 percent for those between the ages of 60 and 69. Having worked for many years in the long-term care industry, I have witnessed first hand how declining health in older Americans negatively impacts not only the patient, but family members and society, as well.

While the most devastating effects of a poor diet and inactivity are experienced by older Americans, this group is by no means the only population affected. The percentage of children and adolescents who are overweight has more than doubled since the 1970s (2). Today, more than 13 percent of children and 14 percent of teenagers are considered obese. These figures continue to rise each year, paving the way for increased health problems in adulthood. Between the ages of 40 and 60, one in three will feel the effects of a lifestyle that favors fast food and inactivity. These are prime earning years for many adults whose professional and economic contributions to society will be severely or completely curtailed. It is estimated that treating obesity-related health problems in the U.S. exceeds $117 billion annually (3). Diabetes alone, which has a direct connection to obesity, accounts for more than $45 billion each year (4).

I read recently that our quest for convenience and immediate gratification has spawned a nation of couch potatoes and fast food junkies. While it may be true that a good many Americans fit this description, it is also true that many do not. The reason my organization was formed more than 65 years ago was to support the growing number of consumers looking to make healthier choices about the foods they ate. Much of what the followers of this trend believed based on empirical evidence and common sense has been borne out by science over the years.

For instance, whole or unprocessed foods have always been an important aspect of the natural or health food industry. Processing can eliminate some or all of a product's healthy qualities, such as fiber. A few years ago, the Food and Drug Administration recognized that soluble fiber from whole oats and can reduce the risk of coronary heart disease (5). Now products that qualify can make this claim on their labels. In allowing such a claim, the FDA requires a substantial amount of scientific proof. In recent years the FDA has authorized a number of health claims that can be made on food labels, including the following:

> 25 grams of soy protein a day may reduce the risk of heart disease
>
> Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke
>
> Foods containing soluble fiber from psyllium seed husk, such as certain breakfast cereals, may reduce the risk of coronary heart disease

Health claims are not limited to conventional food ingredients, however. They also can reference what are technically known as essential nutrients, but what most people would simply call vitamins and minerals. As an example, the FDA recognizes that calcium can reduce the risk of osteoporosis and maintain bone health. Another example is the daily consumption of folic acid in reducing birth defects. Again, in order to allow these claims the FDA required substantial scientific proof that they are correct.

Since I'm on the subject of vitamins and minerals, let me transition into to the more general topic of dietary supplements and their role in human health. The term "dietary

supplement" encompasses a wide range of products that include essential nutrients, herbal remedies, and what we call "specialty supplements," products comprised of natural ingredients like enzymes and amino acids.

National interest in and access to reliable information on safe and effective dietary supplements has grown steadily since the Dietary Supplement Health and Education Act (DSHEA) unanimously passed the House and Senate in 1994. In passing DSHEA Congress acknowledged that there may be a positive relationship between sound dietary practice and good health, and that, although further scientific research is needed, there may be a connection between dietary supplement use, reduced health-care expenses, and disease prevention. In fact, current research is bearing out this very supposition.

As examples, the American Medical Association recently reversed its position on the value of taking a daily multivitamin. In an article published in the association's journal this June, researchers concluded that every child and adult would benefit from taking vitamins daily (6). A report several months ago in the journal *Nutrition* also recommended a daily vitamin for older adults, who often don't get proper nutrition from food (7). These studies are particularly important because our research indicates that physicians often do not discuss supplementation with their older patients (8). Other landmark studies include two published in *JAMA* relating to the delay and lessening of symptoms of Alzheimer's disease by patients who took the herb ginkgo and vitamins C and E (9, 10).

Not only has research demonstrated the health benefits of dietary supplements and foods, it has also shown that they can reduce health-care costs by the billions of dollars. For instance, based on a computer model, researchers at the University of California in San Francisco estimate that 310,000 fewer people would die from heart disease over a ten-year period if they ate folate-fortified foods and supplemented with B vitamins vs. eating only fortified foods (11). Another study in a major medical journal reported that increased intakes of vitamin E, folic acid and zinc could save $20 billion annually in hospital costs by reducing heart disease, birth defects and premature death (12). Earlier I mentioned two studies showing the positive affect dietary supplements can have on Alzheimer's disease. This illness costs Americans $61 billion a year, in lost productivity from absenteeism of employees who care for family members with Alzheimer's and businesses that share health and long-term care costs (13). Even a modest reduction in symptoms and delay of onset of this destructive disease can save billions of dollars.

Clearly, dietary supplements as a whole – not just vitamins and minerals – are beginning to get the research attention they deserve. Each year, more and more studies are published in major medical journals that support the use of supplements for the treatment of specific conditions, prevention of diseases or for general nutritional enhancement. This is due, to an increasing extent, to funding from government agencies and offices. A good deal of this funding is coming from two groups under the National Institutes of Health's umbrella, the Office of Dietary Supplements (ODS) and National Center for Complementary and Alternative Medicine (NCCAM).

The Office of Dietary Supplements was established as a result of DSHEA to stimulate, coordinate and disseminate the results of research on the benefits and safety of dietary supplements in the treatment and prevention of chronic disease. NNFA agrees with the President's Commission on Dietary Supplement Labels that if fully-funded, "...ODS could play a valuable role in providing consumers with information about dietary supplements ...including [the] promotion of scientific studies on potential roles of dietary supplements in health promotion and disease prevention. Appropriations as authorized by DSHEA are essential if ODS is to meet [the] mandates of the Act."

The office, with NNFA's support, has begun funding research on botanical supplements through university-based research centers. Each of the ODS-funded centers will promote scientific discourse and provide the critical scientific mass necessary for sound studies on the efficacy and safety of botanical supplements. With the support of NNFA and other industry associations, the ODS's budget has grown from $69,000 when it was first created in the mid 1990s to $17 million in Fiscal Year 2002. For Fiscal Year 2003, NNFA not only supports the President's request for an increase in funding to $18.5 million, but would like to see it increased to $25 million.

In 1992 Congress directed the National Institutes of Health to establish the Office of Alternative Medicine with the express task of assuring objective, rigorous review of alternative therapies to provide consumers reliable information. In fiscal 1999 the Office of Alternative Medicine elevated to a Center with its own grant making capabilities. Funding for the Center has grown along with its increased authority from $2 million in fiscal 1992 to $100 million in 2002. NNFA supports increased funding of $113 million for NCCAM in fiscal 2003. We believe that NIH has the best infrastructure to clinically examine the science of dietary supplements.

We believe these additional funds will help to:

- Invest in additional scientific and clinically based research, coordinated within NIH
- Educate practitioners and consumers through continuing education and outreach programs
- Train additional investigators and invest in career development, and
- Publish scientifically peer-reviewed fact sheets and compile research literature.

The recent questions raised about Hormone Replacement Therapy, which could affect an estimated 42 million American women, underscores the need for more research and more information about safe and effective alternatives.

Although, as I mentioned earlier, funding continues to increase for supplement research, this funding should be treated as the precious resource that it is. Although the recently published NIH study comparing the botanical St. John's wort with placebo and a popular antidepressant drug for the treatment of depression may have been well intended, it evaluated the herbal remedy's effectiveness for a condition it was never intended to treat – major depression. Earlier European studies and popular usage have always been in regard to *mild* to *moderate* – not *major* - depression. More closely aligning the goals of a

study with how a product is to actually be used by consumers – perhaps through closer consultation with industry – would yield more useful results.

While information about the health promotion and disease prevention qualities of dietary supplements is crucial, so is access to them. Bills like the Congressman Burton's Tax Fairness Act would allow taxpayers to deduct amounts paid for foods for special dietary uses, dietary supplements, or medical foods as medical expenses. We also agree with Congressman Burton that food stamp recipients should be allowed to use their benefits to purchase dietary supplements. Although this amendment, which was added to but ultimately removed from the most recent Farm Bill, failed to become law, we hope this issue will be pursued in future legislation.

Without question, combining a nutritional diet and appropriate supplementation with physical activity not only reduces the risk of contracting a host of ailments; it improves quality of life for every age group. The body of research about the health benefits of a nutrient rich diet is impressive, but needs to be expanded, particularly in the area of dietary supplements. While funding for research in this area has continued to grow, further investigation of the role of dietary supplements in maintaining optimum health is critical.

* * * *

Congressional hearings, such as this one, make strong impressions on the minds of Americans about the issues they cover. Often, these issues are negative and the focus is on what went wrong and how it can be fixed. I want to thank Congressman Burton and the committee for taking the time to examine what's right with nutritional foods and dietary supplements. Thank you also for the opportunity to present these views.

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Mr. SCHROCK. Thank you, Mr. Seckman.

As you can hear, we have a vote. It is one vote. I think we will just recess for a few minutes. We will be back as quickly as we can and will continue then.

[Recess.]

Mr. SCHROCK. I want to recognize Dr. George Bray, a Boyd professor at the Pennington Biomedical Research Center at Louisiana State University in Baton Rouge. We are delighted to have you here and look forward to your opening statement.

Dr. BRAY. Thank you for the opportunity to participate in this hearing this morning. I won't read anything. I will make a few comments about the relationship of obesity and its treatment and the use of dietary supplements and over the counter products in that regard.

My interest has been peaked in this area by a man named Mr. Pennington who provided the money to LSU to build the Pennington Biomedical Research Center which I directed for a decade. Mr. Pennington was, he thinks, cured of his cancer very much like your story for 25 years from taking a group of vitamins. He believes it was B12, I am not sure which one it was, but because of his belief in this area, when he was making his donations, he provided $125 million to Louisiana State University in 1980 to develop a nutrition research institute. That is the basic work that our facility has been doing since the completion of those buildings.

Obesity, my area of interest, is an epidemic and I wanted to show you two figures. Dr. Dietz could do this but he said he wasn't, so I will. This is the behavioral risk factor survey data from 1989. I use it in color because it shows clearly the prevalence of obesity, less than 10 percent in yellow, 10 to 15 in green and there are no red States on this map. Ten years later, using the same survey techniques, you can see that only a handful of States are not now in this high risk category. So the epidemic as we all know, is a big and serious one.

It is also an expensive one with major risks. Data from a paper in 1989 looking at attributable risk for physical inactivity and obesity are causally related to diabetes, heart disease, hypertension, gall bladder disease and osteoarthritis. In those data, obesity can account for up to 70 percent of diabetes, 40 to 50 percent of gall bladder disease, hypertension and heart disease and 7 to 27 percent of cancers and osteoarthritis. Physical inactivity on the other hand is of the order of 5 to 20 percent. So obesity is a major epidemic with major health risks and high cost associated with it.

I was pleased to have Ms. Ladd's testimony earlier. She used at the end, the title of my testimony which is "Don't throw out the Baby with the Bathwater." Having a major epidemic we need things to do to overcome it, to provide American citizens with ways to deal with it when they are afflicted with the problem. The broader those options, the more likely we are to be effective.

When I was preparing for this testimony I went out to my health food stores to see what sorts of over the counter products there were and a number were available. I will have some suggestions about ways that might improve the public's ability to make decisions about using those supplements at the end.

Two additional points. Small weight losses can be highly beneficial in reducing the risk for the diseases I described earlier. In a study of which we are a part that is funded by the National Institutes of Health, called "The Diabetes Prevention Program," weight losses of 3 to 7 percent reduced by 58 percent and 31 percent the risk of people who are at high risk for diabetes from actually becoming diabetic.

If you translate that into a 3-year delay in the complications of this disease, it saves billions of dollars by reducing the risk for human dialysis, for renal failure, for amputations, for blindness and other complications associated with diabetes. So modest weight losses can be highly beneficial.

The dietary supplements that are available, particularly the ephedra-caffeine combinations have clear evidence from clinical trials of up to 6 months suggesting that the weight loss in the treating group is substantially larger than placebo and in the range that would be associated with these reductions in risk that were demonstrated in diabetes prevention programs.

If we could get small weight losses, we would have a major improvement in the health of the American public and that would be highly beneficial.

Let me read the three recommendations that came from my survey and I will finish. I want to read these so they are clear. First, provide clear and unambiguous labels on packages. All packages should be labeled so that consumers can find out what is in them. I found at least one that had no labeling information on it at all. Labeling should be improved to help consumers make choices. I found products with the same trade name having very different labeling of internal ingredients which can be confusing. It was confusing to me as a professional and certainly could be to the public. Having multiple packages with the same trade name but with different combinations makes selection difficult.

Second, standard dosing and use good manufacturing practices in preparing them, providing the public with assurance that the amount of active ingredients in each package is standardized by analytical testing and comparable from lot to lot would provide them with assurance that they are getting what they think they are purchasing.

Finally, encouraging research, providing financial incentives for manufacturers that conduct research to establish efficacy and safety of their products might be an important way to get this research done. Premarketing research should be particularly rewarded because knowing that the materials you are taking are safe and effective before they are available has real advantages to the public.

Thank you for the opportunity to testify and I would be happy to answer questions.

[The prepared statement of Dr. Bray follows:]

OBESITY: Don't Throw Out the Baby with the Bath Water

Statement of George A. Bray, M.D.

Credentials:

Thank you Congressman Burton for the opportunity to present my views to you on the epidemic of obesity that is sweeping the United States and much of the developed world. My message is simple. The public needs as many options as possible to help stem the tide of this epidemic. Herbal products can be one these options – I urge that we don't throw out the baby with the bath water by using less than rigorous methods in assessing risks and benefits for these products.

By way of background. My name is George A. Bray, M.D. I am a Boyd Professor and Professor of Medicine at the Louisiana State University. I was Executive Director of the Pennington Biomedical Research Center in Baton Rouge, LA from 1989 to 1999. I am now actively pursuing my research in endocrinology, diabetes, nutrition and obesity. I received my undergraduate education at Brown University where I graduated summa cum laude in 1953. I continued with my medical education at Harvard University, graduating magna cum laude in 1957. Following an internship at the Johns Hopkins Hospital I completed by medical residency and research training in endocrinology at the NIH, the National Institute for Medical Research in London, the University of Rochester in Rochester NY and the New England Medical Center in Boston Massachusetts.

Since 1965 I have been funded continuously by the National Institutes of Health for research work in the field of endocrinology, diabetes, nutrition and obesity. I have also done research funded by industry and have personal experience with sibutramine, orlistat, and ephedrine with caffeine among others. I have served on the NIDDK Advisory Council, and have been president of the American Society for Clinical Nutrition, the North American Association for the Study of Obesity and the International Association for the Study of Obesity. I was Nutrition Coordinator in the Office of the Secretary of Health at DHEW in 1977-78. As a result of my research on obesity I have contributed more than 1300 publications, chapters, reviews, and abstracts to the medical literature.

The central theme of my research program has been to understand the development of obesity and how it can be effectively treated.

Problem:

I am here today to argue for the continued availability of over-the-counter products as one tool to help combat this problem. Let us not throw out the baby with the bath water.

Obesity is a time bomb that needs to be defused. Although the relative weight of human beings had been increasing slowly for nearly a century, sometime in the late 1970's the rate of increase in obesity exploded. Obesity is now recognized as a chronic disease that is increasing in prevalence. Both the World Health Organization and the National Heart, Lung and Blood Institute have labeled obesity as an epidemic. More than 25% of adult Americans are now obese and the prevalence of obesity in children and adults has increased nearly 50% in the past decade. The progress of this epidemic in the United States is shown in the maps of the United States where the number of states that had more than 15% with a BMI > 30 in 1991 was 8% (4 of 50) and by 1998 it had increased to 40 of 50 or 80%.

Obesity is a stigmatized disease. The common view is that obese people are lazy and weak-willed. If fat people just had "will power" they would push themselves away from the table and not be obese. I reject this view, but it is widely held by the public and by health professionals alike. The stigma of obesity is supported by the clamoring of women to be lean. A recent report on more than 40,000 women from the Nurses Health Study highlights the negative quality of life associated with obesity. In this study 38% gained more than 5 pounds during the 4 years of follow-up. In these women, there was significant decrease in physical function, a decrease in vitality and an increase in bodily pain. These limitations on the quality of life were improved with weight loss.

Health Risks:

Obesity also poses a major risk to health. One indisputable consequence of obesity is an increase in mortality. It has been estimated that obesity is responsible for nearly 300,000 extra deaths each year. The relation of this excess mortality to obesity is best described by a "J" shaped curve. As body weight, usually expressed as BMI (Wt (kg)/[Ht(m)]^2) increases, there is a curvilinear increase in mortality. This relationship exists for men and women and for the ethnic groups that have been studied, but the steepness of the

increase with rising mortality varies from one group to another. Obesity also increases the risk for a number of diseases including diabetes mellitus, heart disease, hypertension, gall bladder disease and some forms of cancer. The relationship of obesity as a causative factor for other diseases is called the Population Attributable Risk, and it is expressed as a percent of the total contribution of all factors. This is shown in Table 1. The percentage of the risk for diabetes that can be attributed to obesity is nearly 70%. For other major diseases such as coronary heart disease, hypertension and gall bladder disease, obesity accounts for 40% to 50% of the risk. Cancer and osteoarthritis are caused to a significant but lesser degree by obesity. The contribution of physical inactivity to these various diseases is, in general, half or less of that attributed to obesity. The exception is osteoarthritis where physical inactivity is nearly as important as obesity.

Table 1. Effects of Obesity and Physical Inactivity on Health Costs

Condition	Obesity		Physical Inactivity	
	PAR %	Direct Cost	PAR %	Direct Cost
Diabetes Type 2	69%	$ 36.6	12%	$ 6.4
Heart Disease	40%	$ 16.2	22%	$ 8.9
Hypertension	40%	$ 7.6	12%	$ 2.3
Gallbladder Dis	50%	$ 4.3	22%	$ 1.9
Cancer – Breast	7%	$ 0.53	5%	$ 0.38
Endometrium	27%	$ 0.23		
Colon	10%	$ 0.89	22%	$ 2.0
Osteoarthritis	20%	$ 3.6	18%	$ 2.4

Adapted from Colditz, GA Med Sci Spt Exer 1999;11(Suppl):S663-S667

Benefits of Weight Loss

The ills that obesity brings, both social and physical, are reversible with weight loss. For most of the markers of ill health there is a proportional improvement with each unit of weight loss. To obtain significant benefits may require as little as a 5-10% weight reduction. The longer the weight loss lasts, the greater the benefits will be. In the large Diabetes Prevention Program, of which I was part, individuals who lost on average 7% of their body weight reduced their risk of developing diabetes over 2.8 years by 58%. By delaying the age at which diabetes becomes evident we can delay the onset of the many ill effects of diabetes such as kidney failure, blindness, heart attacks and death. "It can be estimated from the Framingham data that if everyone were at optimal weight we would have 25% less coronary heart disease and 35% less congestive failure and brain infarctions." If this is true, it seems worth spending considerable effort in prevention and treatment.

Causes of Obesity

The basic cause of obesity has been recognized for centuries. It results from an intake of energy as food that exceeds what the body needs. The excess is stored as fat. We reach our peak energy needs in our late teens or early 20s. Thereafter energy needs gradually decline about at 10 kcal/d per year. If our intake does not decline similarly we would anticipate a slow accretion of about 1 pound per year. The major dilemma is why the physiological controls of so many human beings are unable to recognize the gradual imbalance of energy intake until it is too late.

Treatment

The current backbone of therapy for this stigmatized and risky problem is diet, exercise and behavior therapy. The first popular diet was introduced nearly 150 years ago and new diets appear every month. It must be obvious to anyone who thinks about the problem, that if any of these diets lived up to its claims people would throng to them and there would no longer be a problem with obesity. Quite to the contrary, obesity is of epidemic proportions leading to the inescapable conclusion that none of these diets meets their claims.

Exercise is a second part of the troika of obesity treatment. As modern society has become ever more mechanized, few humans have been willing to maintain the activity levels of their forebears. We must conclude in part that there is something aversive about exercise. Few people want to do it, although those who do exercise can maintain a lower body weight. It is noteworthy that exercise that is effective increases heart rate, and this is indeed one of the ways to evaluate the effect on cardiovascular fitness. Exercise also increases blood pressure as needed for the movement of increased amounts of blood to peripheral tissues.

The third element of weight control is behavior therapy. Its principles were put into practice just over 30 years ago at the onset of the current epidemic of obesity. Although there are many reports of successful weight loss while behavior therapy is being actively pursued the long-term follow-up data make it clear that fewer than 5% maintain more than half of the weight they lost.

Given this epidemic of obesity, the fact that obesity is a stigmatized condition in a world that prizes thinness and youth rather than weight and age, it is no wonder that Americans spend more than $ 70 billion annually on diet related products and services. Since we can't yet prevent the epidemic of obesity, it is incumbent on us to offer what support we can give with therapy.

Medications

At present the pharmaceutical industry is actively working on new strategies for treatment. If they could, they would develop the ideal medication that would be effective, inexpensive, and have a safety profile that would favor its use. I would submit that many of the over the counter preparations when used judiciously and according to recommendations meet these criteria. This proposition has also been the result of a review of the literature recently published by Dr. Frank L. Greenway. A copy is attached to this testimony. A recent announcement from the Office of the Secretary of Health and Human Services indicates that the Rand Corporation is being commissioned to evaluate the ephedra containing products. We await this report with interest.

Available Over-the-Counter Products: On July 20, 2002 I took a short inventory of the products available in a local chain drug store in San Francisco. I found the following: There were 20 different product labels with some trademarks appearing on several different boxes that had different colors and modifications of the formula used. One product did not provide information on the package about what the product inside contained, but all of the others did. As I read the labels of various products from the same trade name I became confused. Doses of various ingredients varied from package to package. As a consumer it would be easy to be overwhelmed. From this visit, it was clear that there is a need to provide more information about what is in the packages to consumers. If I am confused think of the challenge to someone who doesn't work in this area. In addition to the various pills, there were diet bars from 3 manufacturers and liquid formulas from 2 manufacturers.

Standardization: Since most of the available products come from plant extracts, variability between one lot and the next could be high. The amount of active ingredients depends on the growing season, harvesting, processing methods, compounding procedures, and stability. Although labels provide "values" for what is in the preparation, many in the field are worried that these do not reflect lot-by-lot analyses. For protection of the consumer who follows the labels, it is important that the margin of error be as low as possible and that each individual lot be analyzed with serious penalties for failure to do so.

Efficacy: Demonstration of efficacy is important, but is only available for a few of the products on the market. The initial reports of an effective ephedrine-caffeine preparation for treatment of obesity came from a Danish pill, called the Elsinore pill, that was used to treat asthma but that also produced weight loss. It contained 40 mg ephedrine and 100 mg caffeine and was given 3 times daily. From this initial lead Astrup and his colleagues have pursued the use of ephedrine and caffeine as potential pharmacological agents for treatment of

obesity and showed that 20 mg ephedrine and 200 mg caffeine 3 times daily was more effective than 2 other combinations. The combination produced an acute 8% increase in energy expenditure and a small 9 mm Hg elevation in systolic BP and 7 beat/min increase in heart rate. It should be noted that exercise too increases heart rate and blood pressure. With continued treatment, there was a 4-11 mmHg drop in BP and a 1-2 beat/min drop in pulse rate by 12 weeks as the beta-1 and beta-2 receptors are down regulated. During the 24 weeks of the double-blind, placebo controlled trial the subjects treated with ephedrine and caffeine lost 17.5% of their body weight compared to a loss of about 14% for placebo. This reduction in weight continued for the 6 months of open-label follow-up.

The best randomized clinical trial of ephedra alkaloids and caffeine was only published within the last few months. This randomized clinical trial compared a generic herbal preparation of ephedra and caffeine against a placebo. It found that weight loss was twice as great in those receiving the herbal preparation as in the placebo group. Cardiovascular side effects were assessed with 3 periods of Holter monitoring during the first 4 weeks and with 3 24 hour intervals of ambulatory blood pressure measurement. The cardiac rhythm changes were the same in both groups. Blood pressure and pulse were slightly, but significantly higher in the herbal group, particularly when the subjects were sleeping. Other side effects included dry mouth, insomnia and constipation. The number of people completing the trial was similar in both groups. For individuals who are similar to those in this trial, the use of ephedra and caffeine combinations the risk-benefit profile appears to be similar to that published earlier by the Danish workers. All trials have contained only modest numbers of patients which limits their generalization.

In comparison with the background information available for ephedra alkaloids and for caffeine, the information available for other herbal products used for weight loss is limited or non-existent. From the public's perspective some type of information about efficacy and safety based on clinical information would facilitate their base for making informed choices.

In a survey in 1998, up to 70% of obese women and 60% of obese men were trying to lose weight. 7% of this sample had used over the counter diet aid, including 1% reporting using products containing ephedra. More than 3 billion doses of ephedra-containing products have been sold suggesting that they are meeting a need for the public. As this industry continues to expand, using good manufacturing practices for producing herbal products for weight loss and having information on efficacy and safety for the public to evaluate in making choices would, in my opinion, seem desirable.

Cost: The second need for a weight loss product is low cost. The over-the-counter route has real advantages here. By making products available directly to the consumer the costs will be substantially lower than if they must go through the prescription route. The herbal over the counter products meet this goal

Safety: For the sympathomimetic drugs, which include ephedra containing alkaloids, one would expect reports related to the central nervous system, to the autonomic nervous system, to the GI track (constipation) and the cardiovascular system. The problem with all of the available clinical trials is the limited number of patients to decide whether these reports are clinically significant. Events which occur at a rate of less than 1 in 500 would be difficult to detect reliably from the trials which have been reported to date.

The use of any weight loss product needs to be evaluate from a risk-benefit perspective. Obesity is associated with nearly 300,000 deaths per year, or nearly 800 each day. Thus showing that the use of any product was related to something this common could be difficult because of the frequency of the background event. This is a problem with interpreting the adverse events reported to the Food and Drug Administration.

A major focus for the press and the legal profession, with respect to the over-the-counter herbal products, has been the adverse events that have been reported to the FDA. Do these individual reports constitute a reliable basis for evaluating a product? If not, how do we establish safety? Adverse event reports have several serious limitations. First can be initiated by anybody regardless of their training and may or may not contain the needed information for evaluation. Second, there is no "control" population against which to compare them. As noted above, obese individuals have a significantly higher rate of sudden death than people of normal weight. How do we know when a death is reported that there is any cause and effect relationship? Usually we do not. I submit that adverse event reports where neither control data nor the frequency from which the sample is obtained are available are an inadequate basis for deciding whether a product is safe or not for general use. One approach to establishing toxicity is with animal experiments. This has been done for the ephedrine products, and they have a wide margin of safety. So, too, does caffeine. The second approach to evaluating safety is with clinical studies. The double-blind randomized clinical trial of 180 subjects by Astrup and his colleagues in Denmark showed the side effect profile expected from a sympathomimetic drug. This trial is of the size that would detect differences from placebo at 1% levels. The recent paper by Boozer et al, comparing herbal ephedra and caffeine against placebo showed only small degrees of cardiovascular effect. However, like other small studies, it would not have a sufficient power to detect less common events.

Because rare events will not be detected in clinical trials post-marketing follow-up is important. If a "cluster" of similar responses to a new medication is noted this may indicate a rare form of unexpected side effect. With the large amount of ephedra/caffeine preparations that have been sold no such clusters of cases of a similar nature have been identified suggesting that the smaller clinical trials have provided a fair estimate of its side effects profile.

I am old enough to have lived through a number of unwanted side effects with treatments for obesity including the "Rainbow pill problem" more than 30 years ago, the poor quality protein in very low calorie diets in the 1970's and the fen/phen problem in the 1990s. In all of these earlier cases there was a clear relation between the health problem and a product. With the logarithmic growth in the use of the herbal ephedra/caffeine preparations, and the few reports of adverse events, it was clear to me that none of the issues that surrounded the other problems when the FDA took action are in place now.

The experience with ephedrine and caffeine in Denmark provides additional reassurance about the side-effect profile of these proudcts. Astrup estimates that 2% of the population, or 60,000 people, have taken ephedrine and caffeine with no significant adverse events. This experience needs to be added to the data base the FDA is using in evaluating ephedra products.

Caffeinated beverages have been consumed by humans for centuries and there is nothing to suggest they need to be regulated. Ephedrine has been used in the treatment of asthma since I was a house officer more than 40 years ago. From the data I reviewed, I must conclude that the over the counter preparations of ephedra/caffeine are safe when used according to the directions.

Thus, in summary, I would argue that the balance of the risk-benefit fulcrum is clearly on the side of benefit. I would thus urge the panel to allow those people, particularly the individuals who would not qualify for the use of agents in the prescription category to continue to have access to these herbal preparations. It will improve their quality of life. Let us not throw out the baby with the bath water.

Recommendations:

1. Provide clear and unambiguous labels. All packages should be labeled so that consumers can find out what is in them. Labeling should be improved to help consumers make choices. Having multiple packages with the same trade name, but with different combinations of ingredients makes selection difficult.

2. Standardize dosing and use good manufacturing practices Providing the public with assurance that the amount of active ingredients in each package is standardized by analytical testing.

3. Encourage research. Providing financial incentives for manufacturers that conduct research to establish the efficacy and safety of their products might increase the amount of research. Pre-marketing research should be particularly rewarded.

Mr. SCHROCK. Thank you very much.

We are happy today to have from California, Dr. Larry Kushi, the associate director of etiology and prevention research, division of research, Kaiser Permanente in Oakland, CA. Thanks for coming all the way from the West Coast. We look forward to your opening statement.

Dr. KUSHI. Thank you for the opportunity to describe to you some of the strong and consistent scientific evidence that plant based eating patterns are perhaps the most helpful way of eating.

I am honored to be invited and thank the committee for its interest in how Americans can improve their health through diet and lifestyle choices.

I have a degree in nutrition and training in epidemiology from the Harvard School of Public Health. As mentioned, I now work at Kaiser Permanente.

As Representative Kucinich mentioned, my parents are credited with popularizing the macrobiotic way of life, the macrobiotic diet which is a central part of macrobiotics, a predominantly vegetarian diet emphasizing minimally processed whole foods. Among other things, it may be the most popular alternative comprehensive lifestyle approach to management of cancer.

The central role that macrobiotics and my parents has played as a catalyst for the natural foods industry and for inspiring many people in the complementary and alternative medicine field led the Smithsonian Institution to start a collection of works related to their work. As you may recall, my father actually testified before this committee in 1999.

Because of my personal and professional background, some say I have a unique perspective on what I can say on this topic. I am not sure how unique I am in that way but I will say my comments today are uniquely my own and don't necessarily reflect Kaiser Permanente's views or my parent's views.

As the committee members are aware, there is a tremendous interest in diet and health in the United States. For example, I will show you a couple of publications published 2 weeks ago, one from the New York Times, "What if fat doesn't make you fat?" and inside it says, "What if it has all been a big fat lie?" The same week, Time Magazine published this cover story, "Should you be a vegetarian?" Clearly there seems to be a bit of contradiction here. I am going to say the answer to both of these questions is probably yes and there isn't really a contradiction. There is a contradiction probably in the way Gary Taubes talked about fat and the Atkins diet in the New York Times article.

Let me make my views a little clearer. Basically, this article ignored certain fundamental truths about diet and health that can be gleaned from an epidemiologic perspective. We know, for example, there are tremendous variations in cancer and heart disease rates around the world. For example, with breast cancer, in which I have done a fair amount of work, there is a five to tenfold difference in breast cancer rates comparing countries in Asia versus the United States.

We know despite NIH's emphasis on molecular biology and genetics that most of these differences are not due to fundamental differences in biology but rather to the lifestyle choices we make,

the foods we eat, the physical activity we get, whether we smoke or not, the reproductive choices we make. And we know this because people who come from low incidence countries, such as Japan, and move to the United States, take on the disease experience of people in the United States rather than maintaining that in their home country.

Two areas of the world that attract considerable interest regarding diet and disease relationships are the Mediterranean area and East Asia because they have both good quality disease registries as well as good documentation of eating habits. There is tremendous variation in the amount of fat in these diets. The traditional Japanese diet has about 10 percent of calories from fat whereas the traditional Mediterranean diets can range up to 40 percent of calories from fat. So the overall question, does fat make you fat, or does fat intake make a difference in overall health, perhaps is not the appropriate focus of what public health policy should have been.

For comparison, in the United States our average fat intake is about 34 percent of calories and many of our recommendations have said we should be consuming 30 percent of calories from fat. This focus on fat may have been misguided public health policy.

Despite fat intake differences there are tremendous commonalities between the Mediterranean and East Asian dietary patterns. There is an emphasis on plant foods in terms of what people have eaten traditionally, and there is minimal use of animal food. There is a substantial literature on this topic. I have provided some copies of a few articles that I wrote on this topic to the committee.

I served as a member of the American Cancer Society's committees to develop dietary guidelines for the prevention of cancer in 1996 and again in 2001. In both cases, the committee, not just my view, but all committee members, agreed there was substantial evidence that the prevention of cancer can be helped through the adoption of plant based diets, deemphasizing meat and emphasizing whole grains, fruits and vegetables.

There have been a couple of good, randomized trials of plant based diets demonstrating they really are effective in promoting health and preventing cardiovascular disease. The Ornish trial mentioned by Congressman Burton in his introduction is one example, using a very low fat diet. The Lyon Diet Heart Study is another example, using a Mediterranean type diet with about 30 percent of calories. So you have two different studies, using different dietary patterns with emphasis on plant foods but differing in fat intake, that demonstrates that these types of dietary patterns can really help in promoting health.

As I mentioned, my parents have been leaders in macrobiotics. The macrobiotic diet is also characterized by an emphasis on whole, minimally processed foods. I also provided a copy of a paper to the committee we recently published last year about macrobiotics and cancer. Among the things in that paper was a picture of a pyramid which is sort of a takeoff of the USDA food guide pyramid. Unlike the USDA food guide pyramid, the macrobiotic pyramid my father drafted and promoted emphasizes plant foods and doesn't suggest that eating red meat on a regular basis is compatible with good health.

We also received funding from the NIH Office of Alternative Medicine to compile and document a series of cases of individuals who had used macrobiotics for cancer and appeared to benefit from this use. While the amount of funding was extremely small, we are still in the process of completing the best case series. I should mention some of my colleagues at the University of South Carolina are helping with that as well as the Kushi Institute, an organization my parents founded.

In that context, this past February 25, we presented six of these cases to the NIH Cancer Advisory Panel on Complementary and Alternative Medicine. While we are still waiting for the final report from the meeting, it did conclude that the cases we presented provided compelling rationale for further funding and research into macrobiotics and cancer care. I believe these cases we presented were quite remarkable, including a case of lung cancer which I detail in my written testimony, as well as several other cases of cancer.

In the meantime, the NIH has funded a couple of randomized trials of plant based diets on the recurrence of breast cancer. There is substantial literature growing related to diet and cancer treatment and breast cancer which I reviewed in this book, "Breast Cancer: Beyond Convention." I wrote one of the chapters, and it is edited by others.

Basically, I would like to emphasize that current scientific evidence really does point toward plant based whole food diets for the prevention and treatment of major chronic diseases, including heart disease and cancer. The macrobiotic diet that I am familiar with for personal reasons is one example of such a diet.

I thank the committee members for this opportunity.

[The prepared statement of Dr. Kushi follows:]

Congressional Testimony
Larry Kushi, Sc.D.
July 25, 2002
Committee on Government Reform
U.S. House of Representatives

The Honorable Dan Burton, Committee Members:

Thank you for this opportunity to describe to you some of the strong and consistent scientific evidence that plant-based eating patterns are perhaps the most healthful way of eating. I am honored to be invited, and thank the Committee for its interest in how Americans can improve their health through their diet and lifestyle choices.

I have a degree in nutrition and training in epidemiology from the Harvard School of Public Health, and am the Associate Director for Etiology and Prevention Research in the Division of Research, Kaiser Permanente of Northern California. I am also the son of Michio and Aveline Kushi, who are credited with popularizing the macrobiotic way of life. The macrobiotic diet, is predominantly vegetarian and emphasizes minimally processed, whole foods. It combines an ecologic perspective with a respect for tradition and the environment. It may be the most popular alternative, comprehensive lifestyle approach to the management of cancer. The central role that the macrobiotic movement has played as a catalyst for the organic and natural foods industry, and as an inspiration for the field of complementary and alternative medicine, led the Smithsonian Institution to begin a collection of materials related to my parents' work in 1999.

Some people have said that my personal and professional background provides me with a unique perspective on issues related to diet and disease. While I'm not certain if that is the case, I

should state that my comments today are uniquely my own, and do not necessarily reflect the official or unofficial views of my parents, Kaiser Permanente, or any other organizations with which I may have some affiliation.

As Committee Members are no doubt well aware, there continues to be great interest in whether the food we eat affects our health. Americans are interested in whether food choices can enhance our health, decrease the likelihood that we will develop cancer, or heart disease, or help us live longer and more fulfilling lives. It is often stated that one-third or more cancers could be prevented through dietary changes. Two weeks ago, two of our leading popular "medical" journals had major articles on just this topic. The New York Times Sunday Magazine (July 7) carried an article by Gary Taubes exploring the state of knowledge on dietary fat and obesity, with the headline, "What if It's All Been a Big Fat Lie?" The gist of the article was that perhaps the amount of fat we eat isn't really related to whether we become fat. Time Magazine, in its cover story by Richard Corliss of July 15th, asked "Should You Be A Vegetarian?" The answer to both of these questions, contradictory as it may seem, is probably "Yes."

Although the New York Times article by Taubes highlighted the popular interest in the Atkins diet, and focused almost exclusively on insulin resistance and obesity, it ignored certain fundamental truths that come from a voluminous epidemiologic literature related to nutrition and chronic disease risk. It has been known for decades that diseases such as cancer, heart disease, or diabetes vary tremendously from county to country. For example, U.S. breast cancer rates are seven- to ten-fold higher than in some regions in Asia. Despite the great interest by the National Institutes of Health (NIH) in genetics and molecular biology, we know that these differences are

driven primarily by external factors: the food we eat, the level of physical activity we get, whether we smoke, the reproductive choices we make, the environments we live in. This is clear from studies that demonstrate that people who move from an area with low disease rates to an area with high disease rates, e.g., Japanese from Japan to California, take on the disease experience of their adopted country rather than their home country.

Two areas of the world that have attracted considerable interest in determining how diet and lifestyle are related to differences in disease rates are the Mediterranean and East Asia. Both areas have low rates of cardiovascular disease and cancers such as breast, colon, or prostate that occur much more frequently in the US. Both regions are also characterized by dietary patterns that have traditionally focused on minimally-processed plant foods: grains as a staple food, vegetables, fruits, and beans, and smaller amounts of animal food. However, there are substantial differences in the amount of fat in these diets. The percentage of calories from fat in the traditional Japanese diet averaged less than 10 percent, while in traditional Mediterranean cuisines, it could be as high as 40 percent with the liberal use of olive oil. For comparison, the average fat intake in the U.S. is around 34 percent of calories, and many U.S. dietary guidelines suggest that population fat intake should be decreased to 30 percent of calories. What the Mediterranean and East Asian dietary experiences suggest, however, is that a wide range of fat intakes is compatible with low chronic disease rates. Therefore, decreasing total fat intake as a matter of public health policy has probably been misguided, and hence, to quote the New York Times, a "Big Fat Lie." Instead, the quality and types of fat, and more importantly, the quality and types of foods we select, are important.

This is underscored by the commonalities of these dietary patterns: an emphasis on a variety of plant foods, generally minimally processed and with a minimal use of animal food. There is a substantial scientific literature on this topic. I have provided copies of review articles I wrote a few years ago with colleagues at Harvard University on these and other aspects of Mediterranean dietary patterns (see Kushi, Lenart & Willett, 1995a and 1995b). While there have been numerous studies since on relevant topics, the general thrust of these articles, that plant-based diets carry substantially lower risk of heart disease and certain cancers, remains unchanged. I served as a member of the American Cancer Society's committees to develop dietary guidelines for the prevention of cancer in 1996 and again in 2001. These committees found that there is substantial evidence relating the prevention of cancer with plant-based diets that emphasize whole grains, fruits and vegetables, and minimizes red meat intake (American Cancer Society, 1996; Byers et al., 2002).

The importance of plant-based diets, regardless of fat intake, was demonstrated in two separate randomized trials, the Lifestyle Heart Trial, led by Dr. Dean Ornish of the Preventive Medicine Research Institute, Sausalito, CA (Ornish, et al., JAMA, 1998), and the Lyon Diet Heart Study, led by Dr. Michel de Lorgeril of Lyon, France (de Lorgeril et al., Circulation, 1999; de Lorgeril et al., Archives of Internal Medicine, 1998). In both these studies, the plant-based intervention diets resulted in substantially less coronary disease than the control "usual" diets. The Lifestyle Heart Trial used a vegetarian diet with 10 percent of calories from fat, similar to traditional Japanese diets, while the Lyon Diet-Heart Study used a Mediterranean diet with about 30 percent of calories from fat. What these two studies demonstrate is that dietary patterns that differ widely in amount of fat in the diet, but have feature a common emphasis on whole plant foods,

are compatible with improved cardiovascular and overall health. Both of these studies' results are entirely compatible with the bulk of the scientific literature on diet and chronic disease that I reviewed with my Harvard colleagues in the American Journal of Clinical Nutrition.

As I mentioned, my parents have been leaders in the popularization of macrobiotics. As I also mentioned, the macrobiotic diet is also characterized by an emphasis on whole, minimally-processed, plant foods. Another paper I have provided to you, published in the Journal of Nutrition last November (see Kushi et al., 2001), provides a picture of the "Great Life Pyramid," which illustrates macrobiotic dietary guidelines. This graphic can be compared to the USDA's Food Guide Pyramid. Unlike the USDA Food Guide Pyramid, and in common with the diets tested in the Lifestyle Heart Trial and the Lyon Diet-Heart Study, the macrobiotic diet emphasizes plant foods, and does not suggest that daily consumption of red meat is compatible with good health. This paper also outlines the few studies that have attempted to examine whether the macrobiotic diet may be helpful in the treatment of cancer, including describing progress on one study in which I am involved.

My colleagues and I received funding from the NIH's Office of Alternative Medicine to compile and document a series of cases of individuals who had used macrobiotics for their cancer, and appeared to benefit from this use. While the amount of funding was so small as to preclude quick review of these cases, we are currently completing this "best case series", with the leadership of the Kushi Institute and my colleagues, Drs. Jane Teas and Joan Cunningham of the University of South Carolina. Recently, this past February 25th, we presented a series of six cases to the NIH's Cancer Advisory Panel on Complementary and Alternative Medicine

(CAPCAM). Although we are still waiting for the final report from this meeting, I think it is safe to say that the CAPCAM concluded that the cases presented by us were compelling enough to warrant further funding and research into the effects of the macrobiotic diet on cancer care. This conclusion and recommendation was provided to the NIH's National Center on Complementary and Alternative Medicine (NCCAM) and to the National Cancer Institute's (NCI's) Office of Cancer and Complementary and Alternative Medicine (OCCAM).

Let me present just one example from the cases we presented to CAPCAM. This is the case of a nurse who was diagnosed in the spring of 1995 at age 45 with adenocarcinoma of the lung, with metastases to the peritoneum, liver, pancreas, and bones. The patient had surgery to remove the retroperitoneal mass four days after diagnosis, and had a limited course of chemotherapy for two days about one month later. About two weeks after the chemotherapy, the patient had a macrobiotic consultation and began macrobiotics. Because the patient was a nurse, the patient had access to regular radiological examination of the tumor and metastatic sites and progress over the course of several months from diagnosis. An x-ray taken about two months after beginning macrobiotics noted bony metastatic lesions on three ribs, and an accompanying CT Scan of the abdomen noted enlarged lymph nodes consistent with metastases. By the time the patient had been following macrobiotics for ten months, the radiological report from an x-ray noted that aside from some evidence of scarring, "The lung fields are otherwise clear" and "the bony structures are unremarkable. The previously noted destructive lesion involving the ... ribs .. are not appreciated or very difficult to appreciate." A follow-up abdominal CT scan also showed no evidence of enlargement or abnormal mass. This person has continued to follow

macrobiotics, has been living a fulfilling and normal life, and in fact attended the CAPCAM meeting in February.

While the cases we presented to CAPCAM were remarkable, including cases of long-term survival from metastatic malignant melanoma, pancreatic cancer, endometrial sarcoma, and inflammatory breast cancer, these are not the only cases of recovery from cancer using macrobiotics that have been reported. Unfortunately, at this time, there is little objective scientific evidence, such as through systematic intervention trials of macrobiotics, to determine the true value of macrobiotics in cancer therapy. It is certainly my hope that the recommendations of CAPCAM will be taken to heart and that funding for such studies will be forthcoming from the NIH.

In the meantime, I should probably mention that the NIH has funded at least one randomized trial of a plant-based diet and recurrence of breast cancer. The Women's Healthy Eating and Living (WHEL) Study, led by Dr. John Pierce at the University of California at San Diego, is studying the efficacy of a high fruit and vegetable diet in preventing recurrence and improving survival of women with breast cancer (Pierce et al., 1997). The NIH has also funded a randomized trial of a low-fat diet and recurrence of breast cancer, known as the Women's Intervention Nutrition Study (WINS) (Chlebowski et al., 1992). The results of both of these studies should be available in the next few years. There is, in fact, a limited but suggestive literature that indicates that plant-based, and perhaps lower fat, diets may indeed help prevent recurrence and mortality after a breast cancer diagnosis. I reviewed this literature in a chapter in the recently-published book, "Breast Cancer: Beyond Convention." (see Kushi, 2002).

The current scientific evidence points clearly toward plant-based, whole-foods diets for the prevention and treatment of major chronic diseases such as heart disease and certain cancers. The macrobiotic diet is one dietary pattern that embodies this approach, and is deserving of more systematic study. As noted previously, what is important are not the amounts of total dietary fat, but rather, the quality and types of the fat, and more importantly, the quality and types of foods we eat. That is why there is no contradiction with an affirmative answer to the question posed by those popular magazine articles, whether it has been a "big fat lie?" or whether we should "all be vegetarians?"

My comments have been focused mostly on plant-based dietary patterns, and the evidence that these dietary patterns can prevent heart disease and cancer. Physical activity often is forgotten in the overall equation when discussing lifestyle changes that may enhance health and prevent disease. Certainly, the evidence that physical activity helps prevent heart disease, osteoporosis, diabetes, and certain cancers, and improves overall survival, is substantial. I include just one example of this literature, which presents results that demonstrate that even a small amount of physical activity is better than none, and that more frequent regular activity is even better (see Kushi, et al., 1997).

Similarly, there is great interest in dietary supplements, and I know that this committee has been interested in the implementation of the Dietary Supplement Health and Education Act (DSHEA). While I won't comment specifically on this topic, I will make the general point that this evidence varies tremendously, from substantial evidence relating certain vitamin supplements such as

vitamin E or folic acid to certain diseases, to virtually no evidence for other supplements that are available to the general population. From an epidemiologic research perspective, the fact that there may be tremendous variation in the composition of supplements that nominally have the same active ingredients, and that new supplements are continously being introduced to the marketplace, is a source of great difficulty.

I would once again like to thank the Committee Members. I believe that there is strong and consistent evidence to support a role for whole-foods, plant-based, predominantly vegetarian diets in the prevention of cancer and heart disease. There is growing evidence that such diets may be beneficial in the treatment of these diseases as well, and the macrobiotic diet is one such diet that is worthy of further investigation.

I welcome any questions or comments.

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Mr. SCHROCK. We are glad to welcome Dr. Peeke here today. You have heard her mentioned a few times. Dr. Peeke is the assistant clinical professor of medicine, University of Maryland School of Medicine, and also an adjunct senior scientist, National Institutes of Health. We are delighted to have you here and look forward to your testimony.

Dr. PEEKE. It is an absolute delight to be here. I also wish to acknowledge my distinguished guest, Irene Pollin, who is the founder and executive director of a new national program called Sister to Sister which will acknowledge heart disease in women for education screening purposes.

You read an advertisement about nutrition or dietary supplements and what does it always end with? Before doing any of this, please consult your physician, the one person who knows less than you do. The ultimate nightmare for any physician in America today is during the 8 minutes allocated for a patient visit, a patient comes in with what we now refer to as the Internet printout under the armpit sign which means they have scanned the Internet, they have many questions, most of which we can't answer because they have to do with a topic, nutrition, that is now not taught actively or a required topic in the majority of medical schools in this country.

I am a bit of a mutation because after 11 years of critical care and trauma as an intensivist, I went back into academia as a Pugh scholar at the University of California at Davis where I had to, with a couple of colleagues, spend a couple of years learning nutrition and metabolism which is tough stuff, it is biochemistry. Then I came to the National Institutes of Health after that. What I found was that across America as I began to look at the medical curriculum in nutrition, there was none. As I teach at the University of Maryland, what I find is that the classes are standing room only, they are still voluntary not required and that interestingly who attends these classes are also the attendings, residents, interns and not just the medical students. There is an avid interest in this, if not just for our survival sake when our patients come in and ask these questions and we have so little information.

So I speak first to the salient point of a gap and the gap in the knowledge on the part of the medical professionals nationally, clearly anything that you can do to be able to help us with that would help all of us and the consumer in the end.

I will now speak to another gap, a gap that I had addressed in my testimony. What I was really trying to drive home was the issue of a brand new way of looking at this issue of obesity, nutritional deficiency, and that is looking at a new field of intellectual as well as academic concern. We now call it gender specific medicine after the work done by my colleague, Marianne Magado at Columbia University and others and clearly being put forth by the National Institutes of Health and the Office of Women's Research and Dr. Vivian Penn's excellent work as well as that of the HHS Division.

Here we are looking at a very interesting question. When you look at obesity, look at the unfitness of Americans, is there something that is gender specific about that per se? We have never really looked at that in a significant way until in 2001 we published

the findings of a milestone report by the Institute of Medicine, a Committee on Understanding the Biology of Sex and Gender Differences. It asked a provocative question, does sex matter? The answer? Yes.

We found that scientists were able to turn their attention to issues of everything from behavior and perception to lifestyle, the metabolism of drugs, to physical activity. Women and men do things differently, both of which need to be honored. It is no longer just about women's health and men's health. It is about gender specific medicine, one learning from the other's strengths and vulnerabilities.

What have we learned? During the endocrinological milestones of a woman's life which involve the onset of menstruation, pregnancy and her periomenopause, interesting things take place. What we have found in recent monographs is that during that time everything from depression to diabetes to asthma, epilepsy, migraine, are all worsened especially when a woman is unfit. We have been looking at this closer in the pre-menstrual period and now we are looking in the periomenstrual.

What does this mean? This means that during this period of time when a woman is trying desperately to maintain a healthy lifestyle, it is rather difficult. These are physiologic and biologic interferences that need to be honored. Interestingly, the herbal industry has been looking at this very closely, certainly with the current evidence-based medicine that has been generated, looking at black cohosh, for instance, but there is a paucity of data in this certainly with the new evidence that has emerged over the last couple of weeks with regard to hormonal replacement therapy and there issues thereof, we now turn our attention to again a woman's fitness, mind and body, during these endocrinological milestones and during the menopause.

We look at specific foods, for instance, phytoestrogens which were just mentioned. These are plant estrogens. Are they better for a woman, are they helpful? Absolutely. There is no question about that. We look at all kinds of new products like energy bars, this one in particular. What does it say? Soy, heart healthy. We never really looked at this before. Is this something that might be able to augment a woman's wellness during this time? Absolutely. No question.

We look at issues of obesity and fitness. One of the things we have never really looked at in a significant way before was the whole issue of diversity, ethnic diversity. Thirty-four percent of women, as Congresswoman Morella noted, are obese 31 percent of men. Among women there are important racial differences. Blacks, 48.6 percent, Mexican-American, 47.2 percent and these women are much heavier than the Caucasian women, 33 percent, there are real differences among these ethnic groups with regard to the kind of incidence of disease, for instance, diabetes.

For men, interestingly, White and Black men have almost identical numbers of incidence of obesity, 31.6 percent and 31.2 percent and yet 39.2 percent of Mexican-American men are overweight.

Have we spent enough time looking at this, not just in terms of gender differences but also in terms of ethnic diversity, absolutely not. We need much more information with regard to this.

Let us look at the psychological issues. You tell a man or you tell a woman, go ahead and get fit. Here is the template and you are going to hear excellent templates, everything from vegetarianism to physical fitness. What happens when a man and woman pursue this? What are the differences, the obstacles?

Interestingly, it is the mind in a lot of this. For instance, in a man's mind, he could be 105 percent of ideal body weight and still look in the mirror and see himself as thin and fit. Over 43 percent of women who are absolutely of normal weight and quite fit see themselves as overweight and go out of their way to torment themselves with more what I refer to as science fair projects or every diet fad that comes down the block, interfering with one of the most important things we need to look at, new avenues of science, not just weight, not about weight, it is about fitness, about body composition, about body fat.

If you look at a woman's body as she begins to evolve through her periomenopausal years after the age of 40, you will find there is a transformation. One of my female patients once told me, I am 45 years old, all of my life I have looked like an hour glass and I have looked at my body today and suddenly it is changed, I am not an hour glass anymore, I look more like a shot glass. In saying so, she noticed she was filling in. Was this more than just an aesthetic eyesore? Absolutely more. Why? Because she was adding weight to one of the most pieces of her body and that was the intra-abdominal area. We never knew this before.

By placing too much weight there, depositing there through a lack of physical activity in addition to abnormal eating patterns, clearly she is increasing her morbidity and mortality risk for everything from heart disease to diabetes to cancer. You do not have to be overweight significantly or even obese for this to happen. It is no longer just what you weigh, it is where you weigh it.

If you look at the current guidelines of the American Heart Association from this week, they are now asking that waist size now be looked at very closely as one of the greatest predictors and criterion for looking at disease morbidity and mortality, certainly for heart disease than just standing on a scale and looking at that specific number. Women are greatly affected by this. Women are more greatly affected by diabetes.

Going back to the mind for another moment, if you look at the mind, you look at the mind of a woman who needs to go out and take care of herself, what do you see? The No. 1 stressor of a woman, globally, is caregiving. Frankly, women will caregive anything that comes within 20 feet of them and usually defer anything in their own self-care to be able to accomplish this goal which is usually lethal for them because they never get to their self care.

Men are much smarter. They compartmentalize, they are highly focused, they are able to achieve that goal. Women's caregiving gets in the way. Clearly as they go through each decade of life, we just caregive different groups of people. So this must be understood.

Where are the easy to access parks for women to be able to walk with their strollers? How can we make it easier for women who have to caregive sick ones to be able to get that physical activity, to be able to access that healthy food vegetarian or otherwise? Are we making that possible?

Finally, in science itself, if you look at everything from a hormone called leptin and its concentrations in women, women have higher concentrations as they get more obese. Leptin is supposed to be able to regulate their appetite and ability to maintain more healthy body fat. What happens here? There is a difference.

Look at some of the findings of the Institute of Medicine's report which are really quite astounding. Cigarette for cigarette, if a woman smokes exactly the same number of cigarettes as a man, she has 50 to 72 percent greater risk of lung cancer. We metabolize things like nicotine very differently. We do not do heart attacks the same as men do. We don't clutch the chest and drop to the floor. We have epigastric distress, perhaps a little stomach aid as mentioned before might be able to help. It doesn't. Usually these women will come in now sicker because they didn't know they had heart disease all along.

What are we doing to be able to educate women nationally about this phenomenon? Most women don't know that. They are more terrified of breast cancer than heart disease, yet the No. 1 killer of women is heart disease.

In putting together programs and services nationally, I think now we are going to have to look at the issue of gender and also racial diversity as we have never done before to be effective and to be meaningful.

Thank you.

[The prepared statement of Dr. Peeke follows:]

July 25, 2002

Testimony before the Committee on Government Reform

"Diet, Physical Activity and Dietary Supplements: The Scientific Basis for Improving Health, Saving Money, and Preserving Personal Choice"

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A.E. Boycott once said "The difficulty in most scientific work lies in framing the questions rather than in finding the answers." Such was the challenge for the National Academy of Sciences when, in 2001, it published the findings of its milestone report of the Institute of Medicine's Committee on Understanding the Biology of Sex and Gender Differences. The title of the report was, at the very least, provocative, and asked the question: "Does Sex Matter?: Exploring the Biological Contributions to Human Health" The answer? In a word, yes.

For the first time in history, scientists turned their attention to examining how men and women may differ in every aspect of life, from behavior and perception, to the metabolism of drugs, to how differently men and women experience diseases such as heart attacks. Metabolism, lifestyle and physical performance were also considered. And the findings of this and other ongoing studies have clearly shown that when healthy lifestyle programs are developed for men and women, it is essential to gear such programs to address the unique needs of each gender to assure the success of such curricula. This is now what is referred as the new field of gender specific medicine. Men and women are wholly unique, demonstrate strengths and vulnerabilities, and we, as scientists and public policy makers, can learn much by comprehensively studying both genders and sharing that knowledge with the American public to benefit each gender's pursuit of health and wellness.

A baby girl born today is expected to live until at least age 86 and by 2015, 45% of American women will be forty-five or older. In other words, they will live over 1/3 of their lives after the child bearing years. Heart disease, diabetes, obesity, cancer and the dementias become of primary concern and therefore set the tone for health care reform and debate.

Let's look at obesity. 34% of American women and 31% of men are obese. Among women there are important racial differences: black (48.6%), Mexican American (47.2%) women are heavier than Caucasian women (33%). For men, white and black men have almost identical numbers (31.6% and 31.2%), and 39.2% of Mexican American men are overweight.

New research indicates that it's no longer just about how much you weigh, but where you weigh it. At the onset of puberty as well as menopause, the female's body composition changes such that her body fat percentage increases. And, during the perimenopause, a woman can accumulate more fat, lethal fat, deep inside her abdomen, below the abdominal muscle wall, increasing her risk for heart disease, diabetes and cancer, including breast cancer.

Psychology plays a significant role in the pursuit of healthy weight. Men perceive themselves as thin and fit when they are actually overweight, or up to 105% of normal weight. Of women who were of normal size, 43% perceived themselves as being overweight. Women will most frequently lose weight because they perceive that being thinner is its own reward. Men are functional and shed excess pounds for a reason---to enhance athletic performance or to prevent or treat a medical condition such as high blood pressure.

A 1994 National Academy of Sciences study noted that over two-thirds of all diseases that affect both men and women had been studied exclusively in men. Happily, due to the establishment of the Office of Women's Research at the National Institutes of Health as well as the work of HHS and its women's health division, researchers are now actively including women in clinical trials. Startling differences in how men and women experience disease have been discovered. For instance, in comparison to men, smoking in women is a more lethal habit. If a woman smokes the same number of cigarettes as a man, she has a 50-72% increased risk of developing lung cancer. Further, women secrete 52% less serotonin---a hormone which regulates mood and depression. Because of this, women are twice as likely to be depressed than men, interfering with their good intentions toward pursuing and maintaining a healthy lifestyle.

What have we learned that is pertinent to the issue of enhancing health and wellness as it relates to nutrition?

1) 180,000 women will develop breast cancer in a year, while almost one million will develop heart disease. Heart disease is the leading killer of American women, killing 1 in 4. Ongoing results from the Harvard University Nurse's Study have shown that supplementation with Vitamin B6 and folate, as well as Vitamin E appeared to lower the risk of heart disease. This study's investigators emphasized that if both men and women adopted healthier lifestyles of appropriate eating and exercise, the incidence of heart disease could be reduced by over 83%.
2) During every endocrinological milestone in a woman's life, including the menstrual cycle, pregnancy and the perimenopause, a woman's appetite can vary dramatically thus interfering with her pursuit of weight loss and a healthy lifestyle. In addition, asthma, arthritis, epilepsy, migraine, depression, and diabetes all worsen before the onset of the menstrual cycle. Ongoing research is being conducted to examine the

effect of herbal supplements such as black cohosh, chasteberry, hawthorn and St. John's wort and other related botanicals to help regulate these symptoms.

3) Phytoestrogen's are a group of compounds found mainly in legumes such as beans, peas, soybeans, lentils, soybean sprouts, podded plants and soy products such as tofu and soymilk. These plant estrogen-rich whole foods are being actively studied in women for their potential benefits in prevention of heart disease, high cholesterol, control of vasomotor problems such as hot flashes, changes in mood during hormonal fluctuations, as well as prevention of osteoporosis.
4) Women are more likely to develop diabetes than men and suffer complications such as heart disease. The presence of diabetes can eliminate any protection a woman would normally have from her premenopausal estrogen. 6% of women age 45-64 and 10% of women age 65 and over have been diagnosed with diabetes. Blacks and Latinos have twice the risk as whites, and Native American Indians have 10 times the risk of whites.

The gift of this gender specific research is to allow scientists, health providers and public policymakers the challenging new opportunity to correct and expand the traditional male models of human health and disease. This benefits both men and women, as we search for ways to enhance our nutrition, physical activity and mental health, drawing upon and honoring the unique qualities of each gender, and developing meaningful and effective healthy lifestyle programs.

Mr. SCHROCK. Dr. Church, welcome. Dr. Church is a senior associate director, medical and laboratory director, division of epidemiology and clinical applications, the Cooper Institute in Dallas. We are glad you are here today and look forward to your testimony.

Dr. CHURCH. I have some slides.

First, it is an honor and privilege to be here and be a part of such an esteemed panel.

The Cooper Institute was founded in 1970 by Dr. Cooper, as a non-profit research institution. Its original mission was to examine the role of exercise in the maintenance of health and function. Since that time, our mission has broadened considerably. To date there has been over 650 published works to come out of the Cooper Institute and the works have influenced major national policy initiatives from NIH, the American Heart Association, and the Centers for Disease Control and Prevention.

We are probably most famous for the Aerobics Center Longitudinal Data base, a data base consisting of over 70,000 Cooper Clinic patients, some of whom have been followed up to 30 years. This data base is so unique because of the fact that nearly every one of these individuals had a fitness test. They got on a treadmill and went to exhaustion. That is the max treadmill fitness test. No other data base in the world is greater than 10,000 which has max treadmill fitness test.

This is representative of some of the work that has come out of our group over the year. This slide shows CVD death rates across levels of fitness. On the left we have women and on the right we have men. You can see with increasing levels of fitness, you have dramatic dropoffs in CVD death rates. Often this is attributed to obesity. Individuals who are higher fit have lower rates of obesity.

We can see in this the left set of bars is lean, the middle set of bars is normal weight and the right set of bars is overweight. The pink bars are unfit, the yellow bars are fit and you can see at every single weight, there is a great benefit to being fit as compared to unfit. Even in obese individuals there is a tremendous advantage for risk of mortality for being fit compared to unfit.

We have a number of ongoing studies. We have an outstanding study going on now examining the role of exercise in the treatment of depression. We have an army looking at the role of exercise in weight loss and long term weight maintenance. We have a very exciting NIH funded study going now looking at different doses of exercise and risk factor reduction of post menopausal women.

I was specifically asked to spend some time commenting on the Cooper clinical trial which has just completed, so a lot of this data is literally right out of the computer. The trial ended last week. This was a placebo controlled, double blinded study consisting of over 200 participants with a 6-month trial period. Placebo controlled means that half of the study participants received a placebo and they didn't know they were. The other half received a vitamin and they didn't know they were receiving the vitamin. They don't know what they are getting, we don't know what they are getting. It is not until the end of the study when we break the code that we find out who got what. It is very important. This was a privately funded study and it cost approximately $300,000.

The primary outcomes of the study were homocystine, an amino acid found in the blood and a known risk factor for Alzheimer's disease and cardiovascular disease. Another primary outcome was oxidized LDL, a particularly bad type of cholesterol. The last primary outcome which was added during the course of the study was C reactive protein. C reactive protein is an inflammatory marker found in the blood. It has a risk factor for diabetes and cardiovascular disease.

I want you to look at the highlighted number at the top and the bottom of the screen. This shows how difficult it is to run these studies. We phone screened nearly 1,300 people at this time to complete 176. It takes quite a bit of work to run one of these studies.

These are the characteristics. You can see we have an even distribution of men and women, average age is 50 years, and BMI was 26.

You are always going to be looking at the vitamin group on the left two bars and on the right two bars, it is always going to be the control group. In this instance, we are looking at change in Vitamin C and change in betacarotene. This is change in the blood. As you can see there was a 60 percent increase in Vitamin C and a 60 percent increase in the betacarotene in the group that received the vitamin with no changes in the control group.

Same type of slide. There was a 100 percent increase in Vitamin E and a 50 percent increase in folic acid in the blood of the individuals who received the vitamins compared to the controls.

There was a 273 percent increase in Vitamin B6 and a 55 percent increase in Vitamin B12. Why is this important? This shows if you take a multivitamin, it gets into our blood, not just simply going out the way it came in.

Looking at our outcomes, there was a substantial decrease in homocystine in the vitamin group, nearly a 17 percent decrease. This is particularly interesting when you realize that folic acid is currently being supplemented in many of the grains we eat today.

Both these slides show the same thing, just measured differently. The individuals taking the multivitamin, there was a significant decrease in LDL oxidation meaning there was less of this bad cholesterol.

This is particularly provocative showing that a multivitamin lowers C reactive protein. This has never been examined before. We hope to submit this next week. C reactive protein is receiving a lot of attention because of its strong associated risk with diabetes and cardiovascular disease.

This is an important point. We saw no change in plasma glucose and it is important because in our pilot data, we saw a very large drop in plasma glucose in individuals who took a multivitamin but that was simply pilot data. These things need to be tested. When we rigorously tested it we saw no change in plasma glucose. It is important that these things be tested at the right study protocols.

In our findings we found that serum vitamin levels increased greatly with a multivitamin use. Individuals who took multivitamins had a decrease in homocystine, LDL oxidation and C reactive protein.

Thank you for this opportunity.

[The prepared statement of Dr. Church follows:]

Research At The Cooper Institute

In Dallas, Texas

Presented by Tim Church M.D., M.P.H., Ph.D.

Before setting up his Dallas-based medical practice, Kenneth H. Cooper, M.D., M.P.H., founded The Cooper Institute on June 22, 1970. The Cooper Institute, a non-profit organization, is an international leader in preventive medicine research and education. Areas of research include epidemiology, exercise physiology, behavior change, children's health, obesity, nutrition, aging, diabetes, neurological disorders, arthritis, hypertension, and other health issues. Researchers from The Cooper Institute have written more than 650 works published in leading medical journals and consumer publications. The majority of these reports have focused on the importance of physical activity on maintenance of health and function. Studies conducted at the Institute have influenced major national public policy initiatives from the National Institutes of Health, American Heart Association, and Centers for Disease Control and Prevention.

There are few research groups in the world with the specific mission to evaluate physical inactivity and levels of fitness as a major, global public health problem. The Cooper Institute has achieved international recognition as a leader in this area of epidemiological research and public health. The Aerobics Center Longitudinal Study (ACLS) is supported by the world's largest database both in numbers and qualitative/quantitative patient data.

Contains more than 70,000 patient histories, some of whom have been followed for 30 years.

Is the only database of this size that contains objective measures of cardiorespiratory fitness from the treadmill test, other clinical assessments, physical examination data and medical and health histories. No other database has even 10,000 patient histories with these measures.

Research from the Aerobics Center Longitudinal Study (ACLS) established that-

Death rates for low-fit individuals in the ACLS are two to three times higher than death rates in high-fit individuals. These results are seen in women and men, middle-aged and older persons, the fat and the thin, smokers and non-smokers, those with high levels of cholesterol or blood pressure and those who already have developed cardiovascular disease or diabetes.

In a report from the ACLS, more than 1,200 men with documented Type 2 diabetes were followed for an average of 12 years. High-fit men had an 80% lower risk of dying when compared with the low-fit men. Obese men had a 30% higher risk of dying when compared with men of normal weight. Thus, low fitness is a more powerful predictor of mortality than obesity.

> The proportion of deaths attributable to low fitness in many populations is higher than the proportion attributed to high cholesterol, high blood pressure, obesity, smoking, and even the presence of cardiovascular disease. The reason for this high population attribution risk is the strength of low fitness as a predictor of mortality coupled with the high prevalence of low fitness in the population.

The Cooper Institute investigators are at the forefront in research on how to help sedentary individuals become more physically active.

Our investigators were among the first to develop the concept of *"lifestyle physical activity interventions,"* and to evaluate these methods in rigorous, randomized clinical trials. We have now conducted three large-scale studies evaluating various interventions based on sound behavioral science theories and methods. These studies have included more than 900 initially sedentary women and men, with broad demographic representation, including the three major ethnic groups in Dallas. We are recognized throughout the world for our innovative work in this area.

Ongoing projects include the role of physical activity in the treatment of depression, the importance of physical activity in weight maintenance and weight loss and the dose-response relation between exercise and cardiovascular risk factors in post-menopausal women.

The Cooper Institute is also actively involved in research examining the role of proper diet in good health including the use of vitamins and supplements. We recently completed an exciting clinical trial examining the effect of a multivitamin on certain cardiovascular disease risk factors. This study involved over 200 individuals and cost approximately $300,000. Half the participants received placebo pills and the other half received a multivitamin. The study participants did not know if they received placebo or vitamin. All participants were tested at baseline and after six months and the primary outcomes of this study were:

1) Homocystiene- an amino acid found in the blood which is associated with increased risk for Alzheimer's disease and heart disease
2) Oxidized LDL cholesterol- A particularly bad form of cholesterol
3) C-reactive protein- an inflammatory marker found in the blood which is associated with increased risk for diabetes and heart disease

We found the vitamins to be heavily absorbed. For example, the blood levels of vitamin B_6 increased nearly 300 percent in the group taking vitamins with no increase in the group taking placebo. There was a large decrease in the homocysteine, oxidized LDL and C-reactive protein in the group taking the vitamins. We are very excited about the successful completion of this study and are currently

preparing the results for submission to scientific journals. Future supplement research includes examining the effect of omega-3 fatty acids (fish oil) on the heart rate and nervous system.

Mr. SCHROCK. Thank you very much.

Dr. Heber, welcome. Dr. Heber is the director of the division of clinical nutrition at the University of California at Los Angeles. We are glad to have you and look forward to your testimony.

Dr. HEBER. Health has no party line identification. I want to thank Congressman Burton for his leadership role and the many conversations I have had with Beth Clay over the last few months.

I want to confine my comments to a very few brief areas.

In the late 1970's, the State of California passed a law providing funding for a professor of nutrition at each of the University of California Medical School campuses. I was the first appointee at UCLA in 1983. Since 1985, we have had one of two National Cancer Institute funded Centers for Nutrition and Cancer Prevention. There are only two in the country and the other is Sloan Kettering and the American Health Foundation.

Those green boxes in the middle represent core laboratories of that Clinical Nutrition Research Unit. When I go back to California tomorrow, I will have my laboratory meeting with four assistant professors, two associate professors and seven research fellows, conducting research not only on nutrition and cancer prevention but also the box below the pink box is one of four nutrition obesity training programs in the United States funded by the NIDDK. This money was made specifically available in response to the earmarking by Congress of obesity as a national issue.

The top box represents an additional three core laboratories which we competed for in 1999 through the Office of Dietary Supplement Research represented today by Dr. Paul Coates whose testimony you will hear later. I wanted to indicate that UCLA as far as I know is the only university that has all three of these coordinated within a center for human nutrition in a dedicated facility.

The U.S. Government passed a law in 1977 called the Farm Bill, Public Law 95–113, which granted the USDA the responsibility for dietary advice as opposed to what was at that time called DHEW, now called DHHS. Many viewed this as a conflict of interest since the USDA is also dedicated to increasing food consumption, while it is clear that the over-consumption of some foods may be contributing to the health problems of obesity.

Many scientists in the community, including those who work in the health nutrition information service, such as Dr. Marian Nestle, have recently raised the issue of whether we ought to revisit and remodel the USDA pyramid which developed in 1992. This pyramid you see before you shows how Americans are eating. They are eating refined carbohydrates off the bottom of the pyramid and they are eating sweets, fats and oils at the top of the pyramid which appears to be almost toppling off.

The issue here with pyramids is that we recommended in 1997 that fruits and vegetables be placed at the bottom of the pyramid with whole grains above that. Dr. Alice Lichenstein at Tufts University and others, Dr. Walter Willet and others have asked that we revisit the pyramid. The USDA has held to the view we should have dietary guidelines. The difference between a dietary guideline and a pyramid is a pyramid creates a hierarchy of foods according to their health value whereas a dietary guideline allows you to talk in the abstract about fat, carbohydrate or protein. We know when

we had fat free foods in the 1980's, there was a 30 percent increase in obesity as sugars were put into foods.

We are having a lot of argument now which Dr. Kushi indicated and I think the answer is to go to a plant based diet. Man evolved on a plant based diet. If we look at this apple that has a red skin, there are 25,000 phytochemicals in that skin. If I take the Vitamin C from this apple and put it in with colon cancer cells, it will not inhibit their growth as well as if I take an extract of this whole apple. We have taken extracts of whole fruits and vegetables in our research and shown significant effects on cancer inhibition.

This is a simple picture of visualizing your plate. I think we can get advice to the American people through pyramids and also through looking at your dinner plate and making it colorful, two-thirds full of fruits and vegetables, berries for dessert and a nice dark green salad which is full of folic acid as mentioned in the last talk, and Dr. Kushi also mentioned. These are not impossible changes. I wanted to get that across to the committee, very simple things we can educate the public to do.

I wanted to indicate the botanical dietary supplements did not come from another planet. They are actually from our fruit and vegetable and traditional food sources. Chinese red yeast rice was classified by the USDA in 1920 as a food product. It was declassified as a dietary supplement in 2001 following the FDA's pursuit of a Federal Appeals Court decision in April 2001 declaring it an unapproved drug. The reason for this was that there is a part of the DSHEA legislation which says if a botanical dietary supplement contains something previously approved as a drug, it may not be classified as a dietary supplement.

This shows you nine chemicals and they look like little chicken wires up there. One of them is classified as a drug but the other eight all have activities in lowering cholesterol. This is one of the nine called monocolin K, made by the red yeast when it sits on top of the rice and the rice stimulates the yeast to make this family of nine compounds. One of these was selected and classified as a drug because it was purified and crystallized. The key difference between a dietary supplement and a drug is dietary supplements are combinations of multiple compounds whereas a drug is a single purified and crystallized compound.

We did the first trial of Chinese red yeast rice and published it in February 1999. In that trial, we showed that approximately 6 mg of monacolin K or lovastatin, the drug, when included in a matrix of an herb would actually lower cholesterol as effectively as 20 mg of mevacor. The yeast material cost $10 to $20 per month in your local drug store. This represents a potential significant cost savings, not just to the American public, but to the Federal Government through the Medicare and Medicaid programs who have to pay for expensive prescription drugs when these types of herbal products would do a similar job.

Over 57 million Americans today have high cholesterol. Only 13 million take expensive prescription lowering drugs. The affordability of botanical supplements could help save money as well as improve the public health. Both drugs and botanical supplements have a role to play in promoting health. It is not one versus the other but the DSHEA law should be fully implemented and not se-

lectively implemented. As I will point out in the next example, while FDA selectively implemented this provision I spoke about, they have not implemented the one you pointed out this morning, the issuance of good manufacturing practices which is almost 10 years overdue.

PC-SPES is a mixture of eight Chinese herbs, has a 50 percent response rate in advanced prostate cancer. We have recently done research to show this has a response in colon cancer and leukemias and lymphomas as well. Some of that work is going to be very shortly published. I have with me the July 15 issue of Cancer Research, one of our most prestigious journals in the United States in cancer research. There is an article in there by Dr. Peter Nelson at the University of Washington funded through CAP Cure, the Association for the Cure of Prostate Cancer where Mr. Michael Milken has raised almost $200 million for prostate cancer research.

This slide is fairly scientific but if you look at the line of identity in the upper two lines, that is comparing PC-SPES to itself and you get a 45 degree angle. If you look at it for a comparison for diethylstilbesterol which was said to be contaminated, you see there is no specific response comparing it. So it is totally different than diethylstilbestrol.

This slide shows a gene profile. The genes in red are the ones that are up regulated and that is taken from this article. The green genes are the ones that are down regulated. The PC-SPES is a mixture of eight well known Chinese herbs and specifically down regulates the androgen receptors, specifically down regulates tubulin genes and other genes involved in the carcinogenesis process.

Today using 21st century science, gene chips where we can monitor 80,000 genes from the prostate cancer cell, we see that the actions of PC-SPES which is prostate cancer has actions far beyond what can be explained by any of the putative contaminants which caused it to be removed from the market.

The California version of the FDA found warfarin contamination in PC-SPES and it was voluntarily withdrawn from the market so thousands of patients were deprived of this treatment. This is something that could have been avoided with good manufacturing practices. We are currently mobilizing research at UCLA to reactivate the science foundation for PC-SPES after it is appropriately manufactured with good manufacturing practices.

One of the problems here is that the FDA has not issued good manufacturing practices. The burden has been left to the industry in hard fiscal times to have to pay for these quality controls on their own rather than have this done as a government function which is how it should be done.

I would urge you to have full implementation of the DSHEA legislation by asking FDA not only to fully implement the good manufacturing practices to help us with that aspect but I would also ask you to increase support efforts to increase fruit and vegetable intake in the American diet because 93 percent of Americans say they want to change their diet, 78 percent want to increase fruit and vegetable intake, only 4.5 percent of the USDA budget is currently being spent on fruit and vegetable intake promotion. Secretary Veneman is supportive of this, so we have the public and

USDA both supportive. I think you could provide a very good catalytic action in moving this ahead.

We do have an IND pending before FDA to research the basic metabolism of Chinese red yeast rice. I would say to bring this public health benefit to the public, we do need to continue to have pressure for full implementation of DSHEA so that when we get nutrition breakthroughs as we have in the last 20 years, they are fully benefiting the American public by coordinating the activities of USDA, NIH, CDC, FDA and the Federal Trade Commission which has a role in clearing up the labeling problems that Professor Bray has noted.

Thank you for your time and your dedication. I look forward to working with you in the future.

[The prepared statement of Dr. Heber follows:]

Congressional Testimony of
David Heber, M.D., Ph.D., FACP, FACN
July 25, 2002
Committee on Government Reform
Dan Burton, Chairman

Mr. Chairman, Honorable Members of the Committee on Government Reform,

I am a Professor of Medicine and Public Health and the Founding Director of the UCLA Center for Human Nutrition and the Division of Clinical Nutrition at the David Geffen School of Medicine at UCLA with federal funding for centers and training of physicians and scientists from three NIH Institutes including the National Cancer Institute, the National Institute of Diabetes, Digestive and Kidney Diseases, and the Office of Dietary Supplements Research in cooperation with the National Center for Complementary and Alternative Medicine. Over the past 20 years, I have participated in and witnessed a revolutionary expansion of our knowledge of nutrition science and the benefits of fruits, vegetables and dietary supplements including botanical dietary supplements. When I attended medical school almost 30 years ago, I was taught that you get all the vitamins you need by eating the basic four food groups. Today, we know that is not true and that there is a great deal of evidence suggesting that four basic vitamins including multivitamins with folic acid, vitamin E, vitamin C and calcium can benefit all Americans by reducing the risk of chronic diseases (1). Unfortunately, scientific breakthroughs and insights such as these are not being translated into health benefits for our population as the jurisdiction for the regulation of nutrition information is divided among several different agencies with different primary missions including the USDA, the NIH, the CDC, the FDA, and the FTC. The discovery of hybrid corn in 1938 contributed to national security by helping this nation win World War II, and a grain

surplus continues to insure our national security. However, 70% of that grain is fed to domesticated animals for dairy and meat production. Refined sugars such as high fructose corn syrup (the cola sweetener) and vegetable oils increase hidden calories in popular snack foods marketed to our children. In fact, it is estimated that 1/3 of all Americans get 47% of their calories from so-called junk foods.

While nutrition experts often disagree on the solution to the obesity epidemic, they all agree eating more fruits and vegetables is healthy. Not only do fruits and vegetables provide fewer calories per bite than other foods in our overweight and obese society but they provide some 25,000 different chemicals called phytochemicals which can help prevent our most common diseases of aging including heart disease, diabetes and common forms of cancer. Evidence collected by the American Institute for Cancer Research finds that in countries where people eat over a pound of fruits and vegetables a day there is up to a 50% reduction in the incidence of certain common forms of cancer. The National Cancer Institute recommends that all Americans eat 5 to 9 servings per day of fruits and vegetables. My recent book ,"What Color Is Your Diet ?"(Harper Collins, 2001), recommends seven servings of different color grouping of fruits and vegetables each day so that individuals can obtain the benefits of a diverse group of phytochemicals for chronic disease prevention. For example, the red color in tomatoes is due to lycopene which concentrates in the human prostate gland and has been associated with reduced risks for prostate cancer. Lutein, a yellow/green pigment localizes in the retina where it has been associated with a reduced risk of age-related macular degeneration, the commonest preventable cause of blindness in Americans affecting over 13 million individuals. The anthocyanins which give blueberries, grape juice and red wine their

red/purple color have been shown to prevent age-related declines in mental function in animals. Despite this accumulating scientific evidence, US per capita consumption of fruits from 1990 to 1998 increased only 0.6% per year and consumption of vegetables increased only 1.1% per year. At this rate, Americans will reach recommended intake levels for fruits and vegetables in 128 years and 33 years respectively.

As you have heard we are facing a national and international epidemic of obesity, heart disease diabetes and common forms of cancer. Increasing fruit and vegetable intake will help to correct an imbalance of our genes and environment which has resulted from our great success in raising grains efficiently.

Modern humans evolved about 50,000 years ago in Africa in a veritable Garden of Eden where our genes were in equilibrium with a varied and colorful diet of plant foods as well as many minor species of herbs and spices that enriched our diet and provided health benefits. One result of our modernization of food production has been the loss of this diversity. Existing Hunter-Gatherers in the outback of Australia who live in equilibrium with nature eat over 800 varieties of colorful fruits, vegetables and other plant foods. The USDA spends only 4.5% of its budget promoting fruit and vegetable intake but recommends that fruits and vegetables make up 33% of the American diet. This discrepancy should be corrected, but the plant world has much more to offer us in terms of health that we have yet to discover. Botanical dietary supplements are at the growing edge of nutrition science, and represent the restoration of even greater diversity than can be accomplished with increased servings of fruits and vegetables. Spices such as garlic and curcumin have been known since ancient times to have health benefits. At UCLA, I directed the first U.S. clinical trial showing that Chinese Red Yeast Rice can be

as effective as prescription drugs for lowering cholesterol (2). This ancient spice is a distant relative of the red spice on Peking Duck and Pork Spare Ribs available at your local Chinese restaurant. The difference between that spice and the traditional spice is that modern spice is made by liquid fermentation and does not have the same phytochemicals contained in yeast fermented by the traditional Chinese method on a bed of premium rice. Red yeast rice made this way is a traditional food consumed throughout Asia for its food and medicinal value for over a thousand years with the first written documentation in 800 A.D.(3,4). The fungus Monascus isolated from red yeast rice first became known in Western society through the work of Dutch scientists who noted its use by local populations in Java as reported by Van Tieghem et al. in 1884 (5). A species isolated from red Koji or Honqu (as red rice yeast is known in East Asia) was named Monascus Purpureus Went in 1895 recognizing the purple coloration (6). Today there are more than 30 Monascus strains on deposit with the American Type Culture Collection (Bethesda, MD) and it was declared a food product by the USDA in the 1920's.

The traditional method of making red yeast rice is to ferment the yeast naturally on a bed of cooked non-glutinous whole rice kernels (7), and this method was industrialized in China to produce a dietary supplement which was imported and marketed in the United States until a Federal Appeals Court decision in favor of the FDA declared this an unapproved drug rather than a dietary supplement. The supplement contains only the rice and the Monascus fungus and the yeast in a capsule. There are a number of constituents in the natural product including pigments, fatty acids, and polyketides (monacolins) (8). The production of monacolins including Monacolin K by 124 strains of the genus Monascus including many strains of Monascus Purpureus was reported by Endo (9), and

these substances are believed to account for the majority of the cholesterol-lowering activity of the yeast. In animals fed diets designed to induce hypercholesterolemia, Chinese Red Yeast Rice has been shown to lower cholesterol (10). We believe that during the fermentation process chemicals on the rice surface send a signal to the yeast resulting in the production naturally of a family of compounds called Monacolins first discovered in the 1970's by Dr. Endo in Japan and now known to occur in 39 species of yeast and fungi including the oyster mushroom sold in the produce section of your local market. One of these compounds called Monacolin K was isolated by a drug manufacturer from a different species of fungus and purified and crystallized to purity. The drug, Mevacor (Merck) initiated a generation of medical research that has developed many drugs in the category called statins through novel chemical modifications. These drugs have been shown to reduce mortality from heart disease and may someday have benefits for bone disease and cancer. The key difference between drugs and herbs is that herbs are a combination of multiple compounds while drugs consist of a single purified crystallized compound. Our research shows that only 5 mg of Monacolin K in the matrix of this yeast has the same cholesterol-lowering effect as 20 mg of Mevacor demonstrating that the entire family of compounds has an effect not just the one species which became a drug. Furthermore in animals, the yeast has no side effects at 500 times the normal human dose, while it is well-known that some statins have muscle and liver toxicities.

There are 57 million Americans with high cholesterol and only 13 million take prescription drugs for cholesterol lowering. Mevacor at 20 mg to 40 mg per day has been shown to reduce heart disease deaths and heart attacks by 30% over 5 years in individuals with modestly high cholesterol levels. I suspect that Chinese Red Yeast Rice would

have the same public health benefit at lower cost, but the Federal Appeals Court decision has made this an unapproved drug based on its containing a substance previously approved as a drug. This phrase is included in the DSHEA law as a protection against companies simply marketing impure fractions of drugs, a situation that is not in my view pertinent here. I have an IND pending before FDA currently to allow me to study the differences in metabolism between mevacor and Chinese Red Yeast Rice, but there can be no large phase III trial of Red Yeast Rice in this country until we find a way to solve the procedural and legal barriers to its marketing. As it stands, Red Yeast Rice is sold legally in every country but the United States.

The use of botanical dietary supplements in the prevention and treatment of common forms of cancer has been dramatically rising in recent years in the United States (11-13), and our NIH-funded laboratories at UCLA have been studying such herbal products as green tea extract, Chinese Red Yeast Rice, and PC-SPES for their potent anti-cancer effects. PC-SPES was until recently being used by thousands of individuals with prostate cancer (14-17) . It contains a partially extracted mixture of eight different herbs: Dendrantherma morifolium, Tzvel; Ganoderma Lucidium, Karst; Glycyrrhiza glabra L; Isatis indigotica, Fort; Panax pseudo-ginseng, Wall; Robdosia rubescens; Scutellaria baicalensis, Georgi and Serenoa repens (15-19). In previous studies, we and others showed that PC-SPES mediated an antiproliferative effect on prostate cancer cells in vivo and in vitro (16-21). In addition, recent clinical studies showed that PC-SPES reduced prostate specific antigen (PSA) levels in more than 80 % of individuals with prostate cancer (22,23). CapCure, the Association for the Cure of Prostate Cancer, a non-profit foundation established by Michael Milken which has raised nearly 200 million dollars for

prostate cancer research supported much of the basic research on PC-SPES including a clinical trial conducted at Harvard University and UCSF. This trial comparing PC-SPES to DES, a hormonal treatment for prostate cancer was stopped when one laboratory in Boston found trace amounts of a hormone DES in one lot of PC-SPES. The preliminary results demonstrated a significant 50% response to PC-SPES at the time the trial was stopped. In another study (18), conducted at the University of Washington the actions of PC-SPES in terms of gene activation in prostate cancer were shown to be entirely different than DES. Subsequently the California equivalent of the FDA found trace amounts of warfarin in several lots of PC-SPES imported from China and PC-SPES was withdrawn from the market. The manufacturer has since gone out of business, and there are deliberations planned in the next month which will determine the future of research with this herbal mixture including an NIH-funded study at Johns Hopkins University. These eight herbs are well-known and we have the facilities at UCLA and other institutions to proceed to investigate this mixture. The strategies and details for manufacturing enough material for the ongoing scientific studies and clinical trials in a properly controlled manufacturing environment are being actively developed. Dr. Phillip Koeffler, who has directed several studies in collaboration with me at UCLA and is Chief of Medical Oncology at Cedars-Sinai Medical Center in Los Angeles is convinced that there is much more to PC-SPES than can be explained by any of the reported contaminants based on our findings of substances in these herbs that inhibit cancer cell growth in several forms of cancer. I share his view on this matter.

It is my view that we have the finest government in the world, the finest agriculture in the world and the finest medical research and drug development institutions

in the world. However, these complex institutions are not working in concert to optimize health in this country. Hippocrates said in 500 BC "let food be your medicine and let your medicine be food." Our 21st Century science has brought us full circle to realize that it is no accident that 2/3 of our drugs are derived from plants or that vitamin deficiency diseases only became evident when and where mankind doesn't have a varied intake of plant products. A single orange has 170% of the recommended dietary allowance of vitamin C but it also has in its skin a fatty substance the citrus fruits developed to fight off fungi (called limonoids) which also happen to inhibit cancer cell growth. Drugs have their place and so do botanical dietary supplements. As the DSHEA law is currently being interpreted, physicians and the public cannot appreciate the full benefits of the science we are attempting to carry out on botanical dietary supplements and in some cases that science is being impeded. In the future, I hope more attention will be given to funding efforts in schools, groceries and other institutions to increase fruit and vegetable intake. Some solutions to the current dilemmas facing botanical dietary supplements include:

1) Certification of contents and inspection 2) Standardization of preparations using markers 3) Clinical Testing through our finest medical research centers 4) Labeling and Marketing Standards and 5) Post-Marketing Surveillance. I appreciate the opportunity to testify before this committee and hope we can work together to improve the health of all Americans by implementing the full extent of the DSHEA legislation and making it possible to develop to their full potential the health benefits of fruits, vegetables, and botanical dietary supplements such as PC-SPES and Chinese Red Yeast Rice. I hope this committee will be successful in finding ways to enable the American people to continue

to have access to dietary supplements and for the scientific community through the National Center For Complementary And Alternative Medicine and the Office Of Dietary Supplement Research to build the science base for what I view not only as the medicines of the past but preventive formulas for the future utilized as self-care . As the late Dr. Ernst Wynder was fond of saying : " Nobody takes better care of you than you do." Self-care is part of the health care of tomorrow.

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Mr. SCHROCK. Thank you very much.

Your testimony has been fascinating and I appreciate everything you have said.

Mr. Seckman, you are right, our President is kind of taking a lead in this. His workout routine every morning is an inspiration to a lot of people and hopefully will get people on board. We do need to speak out up here and make sure that we are taking a lead in that. Some of us will certainly do that.

You talk about obese kids who eat chips and cokes all day long. It is no wonder we have that problem.

As a consumer decides what dietary supplements to use, not just the brand but specific substances like Vitamin C, ginseng, Vitamin E and others because you walk into these health food stores and there is this sea of things there and you think, what do I need and it is very, very difficult. The people behind the counter certainly don't know how to respond to you.

Mr. SECKMAN. That is an excellent question.

The local retailer is probably one of the best experts to direct you to certain areas. The NNFA has produced over the years and puts on our Web sites information for consumers written in language that consumers can understand about certain types of ingredients and products. We encourage them to go there. It is very difficult to go out to the mass market and have discussions with people in such and such a store but go to the local health food store where these people spend a vast majority of their lives, this is what they believe in, what they do. Talk to the retailers of those facilities about the different products and they can help guide you. Also look on the Internet at our Web site, www.nfa.org and get other information that is directed to consumers.

Mr. SCHROCK. Dr. Bray, you were talking about some of the health foods. In this magazine I held up earlier, there is one product that I have thought about using. It is called hydroxycut. I don't even know if you are familiar with that.

Dr. BRAY. I am.

Mr. SCHROCK. I have been advised by some not to use it because they say it makes you depressed and has other sorts of side effects. How does one know because on many of these bottles, you don't see that stuff and how much weight can one expect to lose from using some of these products?

Dr. BRAY. Let me take the second question first. Almost all of the data we have people will lose no matter what they do, sort of surgical approaches, less than 10 percent of where they started. The message I also delivered was that 3 to 7 percent is associated with reductions in risks for diabetes for people at high risk. So even small weight losses of 5 percent or less can be beneficial to people who are at risk for problems.

The issue of how you make selections is a very difficult one. It is where the educational forces from consumers unions, from Prevention Magazine, from the television, newspaper and magazine issues really come into play. I think we have to do the best we can to make sure the science writers are as well educated as possible in the broad issues and that they write it in a way in which it is informative.

The article that Dr. Kushi referred to a few moments ago in the New York Times has probably generated more letters and e-mails to them than any other thing they have had in a great while suggesting people read it, but there is controversy in this issue. This is a place where the press is particularly important where groups like yours are important but where it is difficult. Going in as I did on Saturday with my professional background but with nothing more than that, I found it a real challenge.

I think one area where improvement could be made would be in the labeling strategy that we use. Putting large numbers of things on a package can be more confusing than helpful. I think that our regulatory agencies could work to improve the labeling information that consumers have so that when they go in after reading the New York Times or Prevention Magazine, they can identify what they want in an easily readable and intelligent fashion.

Mr. SCHROCK. It seems every publication you read that each one tells you something different and that adds to the confusion when you try to decide what to take.

Dr. BRAY. The problem is some of the scientific articles shift back and forth. Sometimes fiber is good, sometimes it is not so good. That confuses even those of us who work in the field.

Mr. SCHROCK. If you will excuse me, we do have a vote. I assure you I will run over there, and run back here. We should be back in just a few minutes.

[Recess.]

Mr. SCHROCK. Thank you for waiting.

Dr. Kushi, thank you and your parents for what you do. You provide wonderful things for society and I really appreciate that a lot.

Fat in the diet, boy is that a big issue. The males had a screening in the Capitol not long ago and my communications director had his done and I had mine done. He had 11 percent body fat and mine was 15 and I was furious because he is younger than I am but I just don't understand. My doctor says for you, that is perfect, so I am trying to figure out what is the right amount of fat, what is not and is it OK for the average American to include plant products that contain fat such as avocadoes, nuts and olives because sometimes you hear there is too much in the nuts. From a personal standpoint, I would like to get your spin on that.

Dr. KUSHI. As far as fat in the diet, generally, one of the points I tried to make is that it is really the type of fat not the amount that is probably more important, although certainly the amount also plays some role. Plant-based products that have fat intake, for example, nuts, can be part of a healthful diet and probably should be.

We actually published a study that demonstrated that people who eat nuts on a regular basis have approximately 30 to 40 percent decreased risk of developing heart disease. So it is consumption of that type of plant-based quality, relatively high oleic acid, linoleic acid type fat.

Mr. SCHROCK. That is good because I thought if I liked it, it was not good for me.

Dr. KUSHI. I think the recommendations from the Heart Association will be changing partly as a result of these types of observations.

Mr. SCHROCK. Dr. Peeke, you made a lot of comments I want to comment on. You said nobody is teaching health anymore. When I was a kid, as I recall, we had a health class. It was Mr. Ridenhauer who was my health teacher. I don't think they have that sort of thing anymore but I remember it and I remember some of the things he taught me. I think that has carried me through to where I am right now. It seems like with budget cutbacks in school and such, they have gotten rid of that and I think that is a bad thing. I guess it is incumbent on us to try to do something about that. I certainly agree that is a problem.

You are the recognized expert in understanding the relationship between stress and weight gain and those of us who work here in Washington can certainly relate to that. How do you explain that, stress and the weight gain? In my case, when I am stressed, I don't eat but most people do and I wonder in the environment we have here how that impacts us?

Dr. PEEKE. We go back to the issue of men and women again. As it turns out, a number of studies have now been done over the last 2 years that have shown that it is women who are the primary stress overeaters, that it is men who tend to lean to alcohol in response to stress.

Your proclivity to undereating or overeating really depends on one, your genetic base upon which you usually deal with stress which is about 30 percent and also it depends on the level of stress. If you have a true tragedy, if you have something that is of monumental portions, it doesn't matter what the event was in your mind, by definition stress undereating tends to take place.

When we look at what happened with September 11th in town, as a Washingtonian, we studied this rather closely and what we found in both New York and Washington almost uniformly across the board, people were stress undereating for that first week, they were not stress overeating because of the incredible tragedy and the level of pain that was ensuing.

What was fascinating was there a rebound eating phenomenon that took place within the month. Once again, it was women who were the stress overeaters primarily and the men who interestingly coped with the stress much better. They tend to compartmentalize as I mentioned before, stay focused and just realize things would go on.

Women are womenators, women are ponderers and we have new research that has just been published by the proceedings of the National Academy of Sciences and others over the last 2 weeks that has shown there are real changes in the brain that you can actually follow using something called a MRI, a scan of your head which has been noted in at least two different university studies in the last month. Again, you see that gender difference.

The stress issue, very straightforward. We all have stress hormone and when stress hormone is utilized appropriately for your typical fight and flight, if I was running up those stairs and trying to not be late for the next meeting, that is normal. I am going to have a bit more functional elevation of that stress hormone, cortisol.

The problem ensues—something studied by my mentor, Dr. George Krusos at the National Institutes of Health in our lab—it

was found when you have chronic levels of stress, and you have chronic elevations of stress hormone for long periods of time, this is abnormal and unhealthy and it leads to a number of different ramifications, everything from depressed immune function, retarded growth, dysfunctional reproduction, and through the use of new technology in molecular biology and work of others, we have found that you can actually stimulate increased amounts of fat deposition in the worst place in the human body which is deep under your abdominal muscle wall. So if you get too much of that, that lovely little apple look or in a guy it is that big waist look, that fat is basically toxic to the human body. It is highly associated with what we now call the metabolic syndrome associated with an increased risk in incidence of heart disease, high blood pressure, blood clotting problems, diabetes and cancer.

If you look specifically at waist to hip ratios, rather than body mass index in women, the Iowa Women's Study, that is a greater predictor for morbidity, mortality than just scale weight alone. So you see we have come quite far.

Mr. SCHROCK. Obviously this guy has no stress is that what you are saying?

Dr. PEEKE. No, he has other things going on.

Mr. SCHROCK. Dr. Church, in some of the examples you gave, you had the two test groups and you said there was no change in the plasma glucose. My guess is that is what you were looking for and you didn't find it in those two groups. Why would that be because obviously one was better than the other?

Dr. CHURCH. It wasn't something I was looking for, it was something somebody told me to look for. I didn't believe the pilot data to start with. I thought it was just a sample size issue. Once again, that is why it is so important to always have placebo control, appropriately powered, double blinded studies to see if there really is an effect or not.

I think that glucose phenomenon we saw is an interesting issue because that is often what you see in those magazines you are holding. They will look at 10, 15 or 20 people and use a study that is a horrible study design and meant to show the results they are looking for. It is not a properly run study. If we were not who we are and don't do things the way we do, we could have made the claim that our research shows our vitamin lowers glucose but in fact now that we have done the appropriate research, it doesn't.

Mr. SCHROCK. We talk about obesity in kids and my wife teaches kindergarten and you cannot believe how many are so badly out of shape, you would think they were 30 year olds. How do we turn that around? PE programs? They try to teach some of that and feed the kids correctly in school but you have to be able to turn that around or these kids are going to be health nightmares all their lives.

Dr. CHURCH. I think PE is a great place to start. Look at Louisiana, a State that has gotten rid of PE and when I lived there, they were starting to get rid of recess. The studies show that kids who are not active in school will not be active when they go home. PE and laws that mandate PE is a great place to start.

Mr. SCHROCK. I agree.

Dr. Heber, your book is great. I am going to read this, "What color is your diet?" Explain why that is important.

Dr. HEBER. Humans and a few primates are the only ones who have red-green color discrimination. Dogs, cats and other animals are red-green color blind. It is believed we evolved that to be able to select our food supply. These colors are not random. They represent specific families of chemicals that have been implicated in disease prevention.

The red group would be tomato juice, tomatoes, tomato sauce, tomato soup and pink watermelon and pink grapefruit all have lycopene. The green-yellow group would be spinach, kale and avocado which have lutein in them. We were the ones at UCLA that showed that avocado is the richest source of lutein among fruits. These are concentrated in the back of the retina where they help prevent age related macular degeneration, the primary preventable cause of blindness in people over 65.

The orange group is alpha and betacarotene, it is a cancer preventive and also contributes to night vision. Around the world most people get their Vitamin A from plant products. Here in the United States, we get it from Vitamin A and D fortified milk and from meat products. There may be biological differences of getting it in that way versus getting it from the fruits and vegetables.

Garlic, onion and chives have Allyl sulfides in them which were used as antibiotics before World War II and these also inhibit cancer growth.

The red-purple group are raspberries, blueberries and strawberries. If you feed blueberries to mice as they age, they don't go through a maze as quickly but if you put blueberries in their feed and change it from that brown, beige color to a purple color, they do better in performance tests.

There is the green group which is broccoli, brussels sprouts, bok choy and cabbage that has isothiocanates which goes to your liver and stimulates enzymes to help you fight off pesticides and carcinogens in the environment.

The yellow-orange group is citrus, pineapple, banana. Citrus fruits have preventive substances on their surface. If you squeeze an orange peel, a little bit of fluid comes out that has liminoids in it and these have also been shown to be cancer preventive. The oranges and lemons develop this to fight off fungi that would land on their surface and by an accident of nature, these substances are cancer preventive in humans.

These and many other compounds are being studied by the National Cancer Institute for Cancer Prevention and seven servings a day of these different colors not only give you the diversity but there is 475 calories there, a lot of fiber and it is easier to diet when you fill up. Barbara Rolls wrote a book on that called "Volumetrics."

Nutrition authorities disagree a lot but we all agree that more fruits and vegetables are healthy. That is my push with this book. We are going to meet with grocers to see if we can get increased emphasis on produce sales throughout the country. The National Cancer Institute has an Office of Five a Day for Better Health that we initiated in California that is working on this in partnership with us.

Mr. SCHROCK. All of what you said is in here?

Dr. HEBER. Absolutely.

Mr. SCHROCK. I had a boss a few years ago who used to eat garlic all the time. He looked great, smelled like the dickens but he said it was a very healthy thing for him. I understand that now.

Dr. HEBER. There is a lot of science on that and on green tea and other things.

Mr. SCHROCK. I thank you all. You have been wonderful. We have learned a lot and I hope we can continue this discussion. This Member wants to get involved in this subject and if there is anything I can do to help you on Capital Hill, I want to be the person to do that. I probably have a better feel for good health than most Members. I want to be a part of that to make sure nobody else has to go through what I went through. If there is anything I can do to help you all, that is what I am here for.

Again, thank you for being here.

We have Dr. Coates and Dr. Dietz next. We have to do the obligatory swearing.

[Witnesses sworn.]

Mr. SCHROCK. Let the record reflect the witnesses responded in the affirmative. Thank you for being here.

Our first speaker is Dr. Paul Coates, Director, Office of Dietary Supplements, National Institutes of Health. We are delighted to have you here. Our second speaker is Dr. William Dietz, Director, Division of Nutrition and Physical Activity, Centers for Disease Control and Prevention.

STATEMENTS OF PAUL M. COATES, Ph.D., DIRECTOR, OFFICE OF DIETARY SUPPLEMENTS, NATIONAL INSTITUTES OF HEALTH; AND WILLIAM DIETZ, M.D., DIRECTOR, DIVISION OF NUTRITION AND PHYSICAL ACTIVITY, CENTERS FOR DISEASE CONTROL AND PREVENTION

Dr. COATES. I appreciate the opportunity to discuss with you the activities of the Office of Dietary Supplements and to highlight the directions we have taken in developing good science in the field of dietary supplements.

At the end of my testimony, I will also provide some comments about issues related to diet and chronic diseases as requested by the committee.

Dietary supplements are widely used by American consumers often in combination with other lifestyle measures such as diet and physical activity for their potential benefits in health promotion and disease prevention. This potential has been realized when some supplement ingredients have been put to a true scientific test. I have provided examples of these in my written testimony. I will give one example here, folic acid in the prevention of neural tube defects.

The positive effects of other ingredients, while promising and subjected to early scientific testing, have yet to be fully proven. Some of these are under active investigation in studies funded by the National Institutes of Health such as a study of Gingko biloba to prevent decline in cognitive function in older individuals.

I want to remind folks that the Office of Dietary Supplements was authorized by DSHEA in 1994 and its mission is to identify

and foster research on the health benefits and the risks of supplements based on the merit of the underlying scientific evidence.

To meet this goal, ODS uses a number of mechanisms. A major one is that we fund a network of multidisciplinary botanical research centers around the country. These centers at the University of Illinois, Chicago; UCLA; University of Arizona; and Purdue University are jointly funded with the National Center for Complementary and Alternative Medicine or NCCAM with additional support coming from other components of the NIH.

The National Institute of Environmental Health Sciences supports the activities of a related center at the University of Missouri. I am pleased to announce that as of yesterday, we added a new center at Iowa State University funded in collaboration with the NIEHS.

Examples of other ongoing activities of the ODS are research training and career development, an important component in establishing new careers in the area of dietary supplement research. We also cofund grants and conferences with other NIH institutes and among our educational activities, we create fact sheets for consumers.

The budget for ODS has grown substantially from approximately $3.5 million in 1999 to $17 million this year. This has permitted us to expand our research agenda into new and important areas including evidence-based reviews of dietary supplement efficacy and safety, development of improved tools to evaluate dietary supplement use in the population, a research agenda focused on ephedra and analytical science tools relevant to botanical ingredients.

We have worked with partners in both the public and the private sectors to meet these goals. In my view, these collaborations within and outside the NIH demonstrate the strength of forging partnerships and in my opinion have been crucial to the advancement of science in this area of dietary supplements.

You asked me to comment on our efforts related to ephedra. ODS and NCCAM recently funded an evidence report on the efficacy and safety of ephedra containing dietary supplements for weight loss and athletic performance. Our specific goal in sponsoring this report was to help us with the appropriate next research steps on this topic, a mandate called for in recent congressional report language supporting the ODS budget.

This evidence report, still in draft form and under review by content experts, was developed by the RAND Southern California Evidence Based Practice Center, one of a network of such centers supported by the Agency for Health Care Research and Quality, a sister agency in HHS.

This report systematically and objective assesses and analyzes the world's literature relevant to this topic, both published and unpublished. The final version of this report is expected to be released later this year but in the meantime, ODS has already begun to develop research initiatives for ephedra including the development and validation of analytical methods and standard reference materials and the evaluation of potential ephedra toxicity using animal models.

In the last part of my testimony, I wanted to comment briefly on some issues related to the role of dietary and lifestyle interventions

that may be involved in the prevention of or contribution to chronic disease. While this is somewhat outside the purview of the Office of Dietary Supplements, here are some comments I was able to gather from my colleagues at the National Institutes of Health. More details are given in my written testimony.

The Dietary Guidelines for Americans, issued by the Departments of Agriculture and Health and Human Services in 2000, recommend a diet low in saturated fat and cholesterol and moderate in total fat as part of an overall healthy eating pattern. This healthy eating pattern needs to consist of a variety of foods including grains, fruits and vegetables. The Guidelines also point to the critical importance of maintaining a healthy weight and a physically active lifestyle.

Balancing dietary intake with energy expenditure is crucial, given concerns about the rising epidemic of obesity and the increase in sedentary lifestyles in the United States. A large body of evidence, alluded to more than once in previous testimony, indicates that avoiding overweight, obesity, and adult weight gain is linked with reduced risk of several cancers as well as heart disease, hypertension, and Type II diabetes.

Finally, I wanted to comment that the Departments of Health and Human Services and Agriculture have contracted with the Institute of Medicine to prepare a report on dietary reference intakes of macronutrients, specifically carbohydrates, proteins, and fats. This report, due to be released within the next several weeks, is expected to contain recommendations regarding adequate levels of intake, levels that may exert positive health benefits, as well as levels that may be associated with adverse health outcomes.

I thank you again for inviting me and I would be happy to answer questions.

[The prepared statement of Dr. Coates follows:]

Testimony
Before the Committee on Government Reform
United States House of Representatives

NIH's Role in the Field of Dietary Supplements: Opportunities and Challenges in Developing Good Science

Statement of
Paul M. Coates, Ph.D.
Director,
Office of Dietary Supplements,
National Institutes of Health,
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 AM
on Thursday, July 25, 2002

Mr. Chairman and Members of the Committee,

Thank you for the opportunity to appear before you today representing the Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH). This document describes in some detail the activities of ODS, and it highlights both the opportunities and the challenges associated with developing good science in the field of dietary supplements. At the end of this testimony, I also provide some comments requested by the Committee on the role of diet and lifestyle intervention in the prevention of (or contribution to) chronic diseases.

Health Effects of Dietary Supplement Ingredients

Dietary supplements are widely used by American consumers, often in combination with other lifestyle measures such as diet and physical activity, for their potential benefits in health promotion and disease prevention. Surveys show that 40% or more of American adults use supplements, primarily vitamins and minerals, but herbal and other supplements as well. There are many hopes pinned on dietary supplements to improve health and prevent disease, hopes that have been realized when some of them have been put to a true scientific test. Some examples of these include:

- Folic acid for the prevention of neural tube defects, one of the most common birth defects. As a result of this research, the Centers for Disease Control and Prevention (CDC) and other partners in the National Folic Acid Campaign aim to educate all women of childbearing age to consume 400 micrograms of synthetic folic acid daily from vitamin supplements and/or fortified foods in addition to eating food folate in a healthful diet;

- Calcium to reduce the risk of osteoporosis. The NIH Consensus Development Conference in 1997 concluded that while the preferred source of calcium is through calcium-rich foods, both calcium supplements and calcium-fortified foods are other means by which optimal calcium intake can be reached in those who cannot meet this need by eating conventional foods;

- Iron supplementation during pregnancy to prevent maternal anemia and delivery of premature infants;

- Vitamin B-12 supplementation for those (particularly among the elderly) who cannot readily absorb food-bound B-12;

- Vitamin and antioxidant supplementation to prevent progression of macular degeneration; and

- Supplements promoting antioxidant activity generally to reduce risk of oxidative stress damage from exposure to environmental agents.

By contrast, the positive effects of other products have not yet been proven and need further exploration. A prime example of this is the finding that, instead of reducing cancer risk, beta-carotene may actually increase lung cancer incidence and mortality in a sub-population of cigarette smokers. Furthermore, a recently completed NIH-funded study showed that St. John's wort was no better than a placebo in improving symptoms in patients with major depression of moderate severity.

Many ingredients have yet to be tested in a rigorous, scientifically sound manner. Some are under active investigation at the NIH, including:

- Ginkgo biloba: does it prevent decline of cognitive function in older individuals?
- Dietary phytoestrogens: do they prevent bone loss in postmenopausal women?
- Selenium and vitamin E: alone or in combination, do they prevent prostate cancer?
- Echinacea: does it shorten the duration or lessen the severity of colds in children?
- Glucosamine and chondroitin: alone or in combination, do they diminish the pain associated with knee osteoarthritis?

The Emerging Role of ODS in Dietary Supplement Research

ODS was authorized by the Dietary Supplement Health and Education Act of 1994 (DSHEA) and was formally installed in the Office of the NIH Director in 1995. Its mission, based on a comprehensive strategic planning process, is to "identify and foster research on the health benefits and risks of these substances based on the merit of the underlying scientific evidence, regardless of how they might be currently incorporated into the different categories of commercial products or their regulatory status in the commercial marketplace."

This strategic planning process helped considerably in guiding ODS activities by identifying the research and education goals that ODS would meet. ODS has been able to embark on a number of important activities, including:

- Co-funding of dietary supplement research grants with other Institutes and Centers (ICs) at NIH;
- Sponsoring conferences and workshops, again most often in collaboration with other ICs;

- Developing a series of fact sheets on vitamins and minerals, in collaboration with the Clinical Center at NIH; and

- Initiating two important database efforts: the International Bibliographic Information on Dietary Supplements (IBIDS), developed jointly with the National Agricultural Library of the US Department of Agriculture (USDA) and citing more than 600,000 references to the world's literature; Computer Access to Research on Dietary Supplements (CARDS) to track the Federal investment in dietary supplement research; the current data set describes the FY 1999 NIH investment as 354 grants, totaling $206 million.

I became Director of ODS towards the end of 1999. By that time, ODS started the development of a program of comprehensive Dietary Supplement Research Centers around the country. By the end of 2000, the program had four of these multidisciplinary Centers. The Centers are jointly funded with the National Center for Complementary and Alternative Medicine (NCCAM) and are administered by NCCAM. The National Institute of General Medical Sciences (NIGMS) and the Office of Research on Women's Health (ORWH) also participate in funding these Centers. The National Institute of Environmental Health Sciences (NIEHS) supports the activities of another related Center.

Let me pause for a moment to stress a theme that runs through all of the activities that I have just mentioned. All of them have been developed in collaboration with other agencies, both within and outside the NIH. They could not have been accomplished otherwise. To me, this is the strength of forging partnerships and exploring common research goals. Our position in the Office of the Director, NIH, has permitted us to do just that.

More recently, the budget for ODS has grown, from approximately $3.5 million in FY 1999 to $17 million in FY 2002. This has permitted expansion of our research agenda into new and important areas:

- Evidence-based reviews of dietary supplement efficacy and safety;

- The development of an ephedra research agenda;

- Surveys of dietary supplement use, e.g., the National Health and Nutrition Examination Survey (NHANES) directed by the CDC;

- Training and career development;

- Participation in international research efforts; and

- Development, validation, and dissemination of analytical methods and reference materials for dietary supplements.

In partnership with other Institutes and Centers at NIH, ODS funds research grants in areas such as:

- The role of B-vitamins in atherosclerosis;
- The interaction between St. John's wort and drug metabolizing systems in men and women;
- Clinical study of the effect of chromium on insulin action;
- Isolation, identification, and quantification of phenolic compounds in botanicals;
- Zinc therapy in HIV-positive drug users;
- Homocysteine lowering in renal transplant patients;
- Conjugated linoleic acid effects on lipid synthesis;
- Folate receptors in craniofacial malformations;
- Dietary supplement use by participants in the International Population Study of Macronutrients and Blood Pressure (INTERMAP) study;
- Dietary supplement knowledge and use in youth; and
- The role of St. John's wort in the management of minor depression.

ODS sponsors workshops and conferences, again in collaboration with other organizations both within and outside NIH. These meetings are valuable sources of information in assisting us to shape upcoming research activities. Some recent workshops include:

- The Role of S-Adenosylmethionine (SAMe) in Treatment of Alcoholic Liver Disease. This led to issuing a Request for Applications (RFA) earlier this year with the National Institute on Alcohol Abuse and Alcoholism and NCCAM; applications submitted in response to this RFA are currently being reviewed;
- The Role of Antioxidants in the Prevention of Diabetic Complications. This led to a Program Announcement (PA) jointly sponsored with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Eye Institute, the National Institute on Aging, and the National Institute of Neurological Disorders and Stroke;

- Diet, DNA Methylation Processes and Health, sponsored by the National Cancer Institute (NCI) with participation by ODS, NIEHS, NIDDK, the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Child Health and Human Development (NICHD), and the Food and Drug Administration (FDA). This is expected to lead to a substantial research initiative;

- Chromium as Adjuvant Therapy for Type 2 Diabetes and Impaired Glucose Tolerance. This led to a PA jointly sponsored with NIDDK and NCCAM;

- Metals in Medicine. This led to a PA jointly sponsored with NIGMS, NIEHS and NIDDK;

- Two conferences on Dietary Supplement Use in Children and in Women (with NICHD, NCCAM, ORWH and others); and

- Science and Policy of Performance-Enhancing Products (with the Council for Responsible Nutrition).

The development of other new areas of investigation relies on forging strategic partnerships with other agencies as well. A few current examples include Interagency Agreements with:

- The National Center for Health Statistics at CDC to support improvements in the ability of NHANES to more accurately assess dietary supplement intake in the US;

- The Agency for Healthcare Research and Quality (AHRQ) to develop evidence reports of dietary supplement efficacy and safety. The first of these, on ephedra efficacy and safety in weight management and athletic performance enhancement is currently under review in draft form and is planned for release in final form later this year. ODS, NCCAM, and other agencies will use this report as the basis for further discussion about an appropriate research agenda;

- The FDA to support the development and validation of analytical methods, beginning with validation of analytical methods for ephedra by the Association of Official Analytical Chemists (AOAC) International; and

- The National Institute of Standards and Technology (NIST) in the Department of Commerce to support botanical reference standard development, also beginning with ephedra.

We have worked with partners in the private sector in a number of areas:

- Publication of an annual bibliography of outstanding research in dietary supplements with the Consumer Healthcare Products Association;

- Co-sponsorship of a conference on the science and policy of performance-enhancing products with the Council for Responsible Nutrition; a summary of this conference is in press in the journal, *Medicine and Science in Sports and Exercise;* and

- Engaging with industry – as well as other federal agencies, non-governmental organizations and academia – to develop, validate, and disseminate analytical methods and reference materials for dietary supplements.

In my view, these collaborations – within and outside the NIH – are crucial to the advancement of science in the area of dietary supplements. Further details of these and other interactions can be found on the ODS website (http://ods.od.nih.gov).

Development of a Research Agenda for Ephedra

I noted earlier that ODS and NCCAM jointly funded an evidence report on the efficacy and safety of ephedra-containing dietary supplement products for weight loss and for athletic performance. This report, still in draft form and under review by content experts, has been developed by the RAND/Southern California Evidence-Based Practice Center, one of a network of such Centers supported by AHRQ. This is the first step for us in determining whether – and what – further research is necessary to understand the potential health benefits and risks of ephedra.

Among the studies to be included in the RAND report is a recently published clinical trial (Boozer CN et al, International Journal of Obesity 26:593-604, 2002) of a product containing ephedra and kola (a source of caffeine). The authors concluded that it was both effective and safe for weight loss over a 6-month period in a population of well-characterized, carefully monitored subjects. This is important information, but it must be remembered that this is a single study conducted under careful medical supervision and it is not yet clear whether a similar profile of benefit and safety would be seen in more typical settings with more prolonged use.

CANTOX Health Sciences International conducted a risk assessment study of ephedra under contract to the Council for Responsible Nutrition ("Safety Assessment and Determination of a Tolerable Upper Limit for Ephedra"). Its approach and conclusions will be considered in the RAND report as well. We will await the results of the full evidence report before determining what future clinical research strategies are necessary.

In the meantime, ODS has begun to develop other components of a research agenda for ephedra. We have funded the validation of several methods for the analysis of ephedra and the development of standard reference materials for ephedra. We initiated an evaluation of potential

ephedra toxicity by the National Toxicology Program of the NIEHS.

Dietary Interventions to Prevent Chronic Disease

You have asked me to address some issues related to the role of dietary interventions that may be involved in the prevention of, or contribution to, chronic diseases. While this is somewhat outside the purview of ODS, I did have the benefit of comments from colleagues in some of the NIH ICs, which I present below.

The Dietary Guidelines for Americans issued by the Departments of Agriculture and Health and Human Services in 2000 recommend a diet low in saturated fat and cholesterol and moderate in total fat as part of an overall healthy eating pattern. There is strong evidence that saturated fat raises blood cholesterol levels and increases the risk of heart disease. Clinical trials have shown that blood cholesterol lowering reduces the risk of heart disease, and the composite results of the diet trials are entirely consistent with drug trials that have shown comparable blood cholesterol reductions. The critical importance of maintaining a healthy weight and a physically active lifestyle is emphasized in the 2000 Guidelines. Balancing dietary intake with energy expenditure to maintain a healthy weight and avoid weight gain during adult life was given increased attention because of the concern for the rising epidemic of obesity and the increase in sedentary lifestyles in the US. The 2000 Guidelines emphasize that a healthy eating pattern consists of a variety of foods, with several recommendations related to eating a variety of grains, fruits and vegetable, including whole grain foods and eating at least 5 servings of fruits and vegetables a day. Other aspects of a healthy eating pattern consist of eating a variety of other foods including lean meat, fish, poultry, low-fat dairy products, and foods rich in unsaturated fats (such as olive oil and canola oil). Fresh fruits and vegetables, which are low in saturated fat and rich in folic acid and other vitamins, antioxidants, and fiber, are encouraged because in population studies their consumption is associated with a reduction in heart disease and its risk factors.

A large body of evidence on the adverse effect of overweight, obesity and adult weight gain and physical inactivity has been recently summarized in a February 2002 International Agency for Research on Cancer (IARC) report on Weight Control and Physical Activity. This research indicates that avoiding overweight, obesity and adult weight gain is linked with reduced risk of colon, postmenopausal breast, endometrial cancer, adenocarcinoma of the esophagus, and renal cell cancer. In addition, increasing physical activity is linked with reduced risk for colon and breast cancer. The evidence is also strong to support weight control by increasing physical activity and decreasing caloric intake for reducing the risk for heart disease, hypertension, and type 2 diabetes mellitus.

There is limited research on the specific effect of weight control diets, including plant-based diets, on cancer outcomes. Recent meta-analyses of cohort studies and randomized controlled trials on the effect of fruits and vegetables on selected cancers, such as colon cancer, have not found strong protective effects of such diets on colon cancer incidence. Therefore, these new data are inconsistent with prior research on the protective effect of high intakes of fruits and

vegetables on colon cancer incidence. Extensive research is ongoing on the effects of specific dietary components, including individual nutrients such as calcium, folate, and various carotenoids, as well on types of fatty acids and how these are influenced by the genetic characteristics of the individual. In addition, research is ongoing on the effect of specific food groups and dietary patterns on cancer outcomes.

At the present time, there are not major clinical trials directly investigating the specific comparative effects of plant-based versus animal-based or high protein diets in the prevention of chronic diseases, such as cancer, diabetes, and heart disease. With careful attention and good diet design, either of these approaches can contribute to the prevention of chronic disease, but in general, a variety of food choices are suggested. Advantages of plant-based foods include their low levels of saturated fat and lack of cholesterol and their high content of folic acid and other vitamins, beneficial antioxidants, and fiber. As has been described in the literature and lay media, a vegetarian diet can be considered healthful; however, individuals choosing a vegetarian diet must be careful of their selections in order to obtain adequate amounts of all nutrients (i.e., vitamin B-12 and iron). Animal-based diets, comprising most high-protein diets, tend to be high in saturated fat and cholesterol; on the other hand, they are excellent sources of many micronutrients and trace elements.

Currently, the Department of Health and Human Services and the US Department of Agriculture, along with the Canadian government, have contracted with the Food and Nutrition Board of the Institute of Medicine to prepare a report on Dietary Reference Intakes with a focus on macronutrients (carbohydrates, proteins, and fats). This report is being prepared by a committee of experts and, after undertaking a review of all available scientific studies in this area, is to make recommendations related to various macronutrient intakes to the health of the public. It is anticipated that recommendations will be made related to adequate levels of intake, levels that may exert positive health benefit, and levels that may be associated with adverse health events. The committee has also been requested to identify research needs and opportunities related to this topic. The report is due to be released within the next several weeks.

Closing Remarks

Mr. Chairman and Members of the Committee, I thank you again for inviting me to review the accomplishments of the Office of Dietary Supplements at NIH, and to highlight some of its ongoing research opportunities and challenges. I would be happy to answer questions from the Committee.

Mr. SCHROCK. Last but certainly not least is Dr. William Dietz, the Director, Division of Nutrition and Physical Activity, Centers for Disease Control and Prevention. We are delighted to have you here and would love to hear your testimony as well.

Dr. DIETZ. It is a pleasure to be here and I am grateful for the opportunity to address the risks of obesity and the scientific basis for diet and physical activity.

You are already very familiar with the topic which I was invited to address, the burden and the costs of this disease. With your permission, I would like to abbreviate my comments and focus on a few points which I think deserve greater emphasis.

You mentioned already the prevalence of obesity has increased substantially but the increases have been even greater in children and adolescents than they have been in adults. Between 1980 and 1994, the prevalence of obesity in children doubled and in adolescents it tripled. Over that same time period it only increased by about 50 percent in adults.

Second, you mentioned the burden of disease attributable to obesity. I think diabetes which has been mentioned is a very pertinent example. This used to be a disease which was limited to adults and now we are seeing it in children and adolescents for the first time and in some communities, Type II diabetes accounts for almost half of all new cases of diabetes. This is in effect a new disease and there has been a recent report which suggests the morbidity associated with Type II diabetes in adolescents is worse than we previously have seen and is associated with early death, early blindness, early kidney failure.

The other point I think is worth emphasizing is the contribution of childhood onset obesity which you have been very concerned about and I think appropriately so. We know from some data we published that over 60 percent of overweight 5 to 10 year olds already have one additional complication of obesity like elevated blood pressure, elevated lipid levels or elevated insulin levels and 25 percent of those 5 to 10 year old children have two or more. This is a disaster waiting to happen.

We published data last month showing that hospitalization rates for obesity and its associated diagnoses in children tripled over a 20 year period. The costs from obesity in childhood also tripled.

To me the gravest concern is that although childhood onset obesity only contributes about 25 percent of adult obesity, children who are overweight in early childhood tend to be the heaviest of adults. The mean BMI for a child who is overweight before 8 years of age is over 40 which means that as an adult they are 100 pounds or more overweight and therefore, more susceptible to the complications of adult disease.

You are very familiar with the deaths and disabilities attributable to this, so I won't emphasize that except to say that State Medicaid costs already account for 20 percent of the average State's budget and the epidemic of obesity and its associated illnesses are going to drive those costs further. So in an era of shrinking State budgets and increased Medicaid costs, we are going to be confronting a very serious financial crisis.

Paul mentioned the collaboration of NIH with other groups and we have been pleased to assist the Office of Dietary Supplements

with a survey of non-prescription weight loss products by adults in five States. According to our data, 7 percent of adults reported they used an over the counter weight loss product in the past 2 years and 2 percent reported the use of phenylproponolimine and 1 percent the use of an ephedra product. I think this reflects the high level of concern on the part of the population about the need for effective weight control strategies and emphasizes the need to provide the public with very effective and safe weight loss strategies.

However, the rapidity with which obesity has increased can only be explained by substantial changes in the environment that have served to modify calorie intake and energy expenditure. Effective control of this epidemic will require more information about the opportunities and barriers to physical activity and good nutrition and most importantly, the development of effective interventions.

The size of the population that we are attempting to reach, 25 percent of the adult population, 15 percent of the pediatric population, indicate that we can't rely on individual behavior changes alone, that those must be augmented with broader, coordinated policy and environmental changes across multiple sectors that affect large numbers of people.

We have made efforts to develop effective prevention and treatment strategies through our State obesity programs, the State coordinated school health programs, the youth media campaign, partnerships with other organizations and applied research agenda to develop and refine new approaches.

We believe there are four strategies which can be implemented today to address the epidemic of obesity and its associated chronic diseases. These include physical activity, which includes physical education programs in schools, increased fruit and vegetable intake, control of TV time watched by children and breast feeding for all infants. There is recent data which suggests that breast fed infants have a lower risk of the subsequent development of obesity.

In summary, as you pointed out, obesity in the United States is epidemic. The diseases caused by obesity are already increasing and are already contributing to increased health care costs. Our programs have begun to address the problem of obesity but are small and just beginning. Nonetheless, comprehensive nutrition and physical activity programs to prevent and treat obesity appear the most logical course for us to address this widespread problem.

Thank you very much for the opportunity to talk with you about it.

[The prepared statement of Dr. Dietz follows:]

Testimony
Before the Committee on Government Reform
United States House of Representatives

CDC's Role in Combating Obesity and the Scientific Basis of Diet and Physical Activity

Statement of
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Good morning. I am Dr. William Dietz, Director of the Division of Nutrition and Physical Activity at Centers for Disease Control and Prevention (CDC). I am pleased to be here today to participate in this important discussion on the risk of obesity and the scientific basis of diet and physical activity.

Burden of Obesity

The burden placed on our society by obesity and related chronic diseases is enormous. In the last 20 years, obesity rates have increased by more than 60 percent in adults. Since 1980, rates have doubled in children and tripled in adolescents. More than 25 percent of the adult population in the United States is obese, or approximately 50 million adults. Almost 15 percent of our children and adolescents are overweight, or approximately eight million youth. Rates of obesity and severe obesity are greater among African Americans and Mexican American women. Obesity in the United States is truly epidemic.

We have already begun to see the impact of the obesity epidemic on other diseases. For example, type 2 diabetes, a major consequence of obesity, also has increased rapidly over the last 10 years. Although type 2 diabetes in children and adolescents was virtually unknown 10 years ago, it now accounts for almost 50 percent of new cases of diabetes in some communities. Obesity is also a major contributor to heart disease, arthritis, and some types of cancer. Recent estimates suggest that obesity accounts for 300,000 deaths in the country annually, second only to tobacco related deaths.

The contribution of childhood onset obesity to adult disease is even more worrisome. Although onset of obesity in childhood only accounts for 25 percent of adult obesity, obese adults who were overweight children have much more severe obesity than adults who became obese in adulthood. Sixty percent of overweight children have at least one additional cardiovascular disease risk factor, and 25 percent have two or more. Hospitalization rates for the complications of obesity in children and adolescents have tripled.

The combination of chronic disease death and disability accounts for roughly 75 percent of the $1.3 trillion spent on health care each year in the United States. Last year, *The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity* suggested that obesity and its complications were already costing the nation $117 billion annually. By way of comparison, obesity has roughly the same association with chronic health conditions as does 20 years of aging, and the costs of obesity were recently estimated to exceed the health care costs of smoking and problem drinking.

The recent increases in the prevalence of obesity indicate that obesity-associated diseases and the costs associated with them will also increase. For example, the prevalence of diabetes increased 49 percent between 1990 and 2000 (95 percent of all diagnosed diabetes cases are type 2). Type 2 diabetes was previously a disease of older adults, but now accounts for a substantial proportion of new cases of diabetes in children and adolescents. State Medicaid costs already account for 20 percent of an average state's budget. The epidemic of obesity and its associated

diseases will likely increase these costs further. According to an American Diabetes Association cost study, the estimated economic cost of diabetes in 1997 was $98 billion. Of this amount, $44 billion was due to direct medical costs and $54 billion to lost productivity.

The rapid increases in obesity across the population and the burden of costly diseases that accompany obesity indicate we cannot afford to ignore this epidemic. The rapidity with which obesity has increased can only be explained by changes in the environment that have modified calorie intake and energy expenditure. Fast food consumption now accounts for more than 40 percent of a family's budget spent on food. Soft drink consumption supplies the average teenager with over 10 percent of their daily caloric intake. The variety of foods available has multiplied, and portion size has increased dramatically. Fewer children walk to school, and the lack of central shopping areas in our communities means that we make fewer trips on foot than we did 20 years ago. Hectic work and family schedules allow little time for physical activity. Schools struggling to improve academic achievement are dropping physical education and assigning more homework, which leaves less time for sports and physical activity. Television viewing has increased. Neighborhoods can be unsafe for walking, and parks may be unsafe for playing. Many office buildings tend to have inaccessible and uninviting stairwells that are seldom used, and many communities are built without sidewalks or bike trails to support physical activity.

Public Health Approach

The population that we are trying to reach is too large for us to rely solely upon individual interventions, which target one person at a time. Instead, the prevention of obesity will require coordinated policy and environmental changes that affect large populations simultaneously. The Secretary has identified obesity prevention as a priority within the Department of Health and Human Services. Many related activities are currently taking place within the Department and necessitate collaboration among agencies as well as the creation of public-private partnerships. The CDC has tried to develop effective prevention and treatment strategies through our state obesity programs, state coordinated school health programs, partnerships with other organizations, and an applied research agenda.

A Coordinated Strategy to Address the Obesity Epidemic

Currently CDC funds 12 states to prevent and reduce obesity and its chronic related diseases. Our support permits states to develop and test nutrition and physical activity interventions to prevent obesity through strategies that focus on policy-level changes (e.g., States assess and rate childcare centers for nutrition and active play) or a supportive environment (e.g., competitive pricing of fruits and vegetables in school cafeterias). For example, in Massachusetts, The National Institutes of Health (NIH) funded a school-based obesity curriculum known as Planet Health. This curriculum, which integrated reduced fat, increased fruit and vegetable intake, increased physical activity, and reduced television; with messages in science, math, language and social

studies classes significantly reduced obesity in adolescent girls. The CDC is now supporting the expansion of this program into public, charter, and parochial school systems in Boston.

Another example is the North Carolina Healthy Weight Initiative, which involves communities and an energetic statewide task force comprised of community leaders and health professionals. The group has developed a curriculum known as "Color Me Healthy" for 4 and 5 year olds that focuses on interactive, innovative learning opportunities on eating healthy and being active. Through an innovative collaboration with the U.S. Department of Agriculture (USDA), implementation of "Color Me Healthy" is underway in 71 counties through cooperative extension and the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). These programs help illustrate how CDC-funded programs translate research findings into practice, and integrate Department of Health and Human Services (DHHS) activities with those of other government agencies.

In addition to the collaboration with state health departments, CDC also funds 20 state educational agencies through the Coordinated School Health Program. This program reaches students in elementary and secondary schools and strives to increase physical activity and improve the nutrition among our nation's young people. Through this program, the CDC awards competitive grants to state, tribal, and territorial educational agencies to:

- Plan, implement, and evaluate programs, including curricula, to promote a healthy lifestyle, including programs that increase physical activity and improve the nutrition of the students at elementary and secondary schools;

- Provide education and training to education professionals, including physical education, health education, and food service professionals, in State and local educational agencies;

- Monitor youth lifestyle behaviors and/or programs to influence them;

- Develop and implement policies to support effective implementation of school health programs at the local level; and

- Build effective partnerships with other government agencies and non-governmental organizations to support effective implementation of school health programs.

As part of this program, many states have begun to implement their own strategies. For example, West Virginia has adopted one of the strongest standards for school nutrition in the nation. The West Virginia Board of Education prohibits the sale or serving of the following foods at school: chewing gum, flavored ice bars, and candy

bars; foods or drinks containing 40 percent or more, by weight, of sugar or other sweeteners; juice or juice products containing less than 20 percent real fruit or vegetable juice; and food(s) with more than eight grams of fat per one-ounce serving. At West Virginia elementary and middle schools, soft drinks are prohibited. In addition to implementing these policies, the West Virginia Department of Education Office of Healthy Schools collaborated with the Office of Child Nutrition and the West Virginia Nutrition Coalition plan and delivered a week-long nutrition symposium for school food service, health education, and school health services professionals. These programs impact more than 300,000 students in a state where over 25 percent of the children ages 5–17 live in poverty.

CDC's coordinated school health program enables state departments of education and health to work together efficiently, respond to changing health priorities, and effectively use limited resources to meet a wide range of health needs among the state's school-aged population.

Partnerships

National or state programs alone will not succeed unless they are supported by a wide array of partnerships. Nutrition and physical activity programs must be integrated across other CDC-funded state programs aimed at cancer, diabetes, and cardiovascular disease. In addition, as the North Carolina program emphasizes, nutrition and physical activity programs must be linked to other departments, such as the USDA. Groups that share concerns about the impact of obesity on other diseases, such as the American Heart Association and the American Cancer Society, are natural allies in obesity prevention efforts. For example, the CDC is exploring joint training activities with the American Cancer Society around nutrition and physical activity strategies within states.

Priority Strategies

At least four behavior change strategies appear justified by the current state of our knowledge. These include the development of sophisticated marketing messages designed to increase health behaviors among youth, reduced television viewing in children and adolescents, increased physical activity for the population, and the promotion of breast feeding and efforts to increase its duration.

The prevalence of obesity has been directly related to the amount of time children and adolescents watch television, and therefore reducing television time appears to be an effective strategy to treat and prevent obesity. Nonetheless, incentives for parents to reduce the amount of time their children watch television must still be identified. Some research suggests that parental concerns about televised violence or sexuality may be more persuasive reasons than obesity prevention to control children's television time.

Physical activity represents our most effective strategy for obesity and the one for which the most substantial body of evidence exists. Increased physical activity for overweight patients reduces many of the co-morbidities associated with obesity such as

hypertension, hyperlipidemia, and glucose intolerance. The chapter on Physical Activity in the Guide for Community Preventive Services lists six evidence-based strategies that can be used to increase physical activity. These include large-scale, intense, highly visible, community-wide campaigns; point-of-decision prompts that encourage people to use the stairs instead of the elevators; physical education programs in schools; providing social support for increasing physical activity; individually adapted health behavior change programs; and enhanced access to places for physical activity.

Large-scale, intense, highly visible, community-wide campaigns are effective in both rural and urban communities and among different ethnic and socioeconomic groups. Such campaigns direct their messages to large audiences through different types of media, including television, radio, newspapers, movie theaters, billboards, and mailings. They promote activities such as support or self-help groups, physical activity counseling, risk factor screening and education, health fairs, and environmental changes such as the creation of walking trails.

Point-of-decision prompts that encourage people to use the stairs instead of elevators or escalators are effective in getting people to be more physically active. Point-of-decision prompts are signs that encourage people to use nearby stairs for health benefits or weight loss. These signs tell people about the health benefits from taking the stairs, and they remind people who already want to be more active that an opportunity to be physically active is at hand. These type of interventions are effective in a variety of settings including train, subway and bus stations, shopping malls and university libraries. They are also effective among different population subgroups - both men and women, both obese and not obese individuals.

Physical education programs in schools provide a safe supervised opportunity for physical activity for children and adolescents. Daily participation in physical education among high schools students has declined from 42 percent in 1991 to 29 percent in 1999. Physical activity may improve class room behavior and performance.

Efforts made in community settings to provide social support for increasing physical activity are effective. These interventions focus on changing physical activity behavior through building, strengthening, and maintaining social networks that provide supportive relationships for behavior change (e.g., setting up a buddy system, making contracts with others to complete specified levels of physical activity, and setting up walking groups to provide friendship and support). Interventions involve either creating new social networks or working within existing networks, such as in the workplace. These interventions are effective in various settings including communities, worksites, and universities, men and women, among adults of different ages, and among both sedentary people and those who are already active.

Also effective are individually adapted health behavior change programs, which teach behavioral skills to help participants incorporate physical activity into their daily routines. Programs should be tailored to each individual's specific interests, preferences, and readiness for change. These programs teach behavioral skills such as: goal-setting and self-monitoring of progress toward those goals; building social support for new behaviors; behavioral reinforcement through self-reward and positive

self-talk; structured problem solving to maintain the behavior change; and, prevention of relapse into sedentary behavior. These interventions may be delivered to people either in-group settings or by mail, telephone, directed media or by health care providers and are effective among both men and women.

Access to places for physical activity provides opportunities for those who are motivated to utilize such facilities. Promotion of trails or park use enhances the likelihood that recreational facilities will be utilized. The Department of Health and Human Services, the National Park Service, U.S. Department of Agriculture, and the Army Corps of Engineers recently signed a Memorandum of Understanding to promote outdoor lands for physical activity.

Breast feeding is unquestionably the most appropriate form of feeding for most infants, and clearly reduces the incidence of acute diseases of infancy and early childhood. Recent studies of breast-feeding indicate that children who are breast-fed appear to have a reduced risk of obesity later in life. Nonetheless, only 64 percent of new mothers initiate breast feeding, and only about 29 percent have continued breast feeding six months after birth. A major research objective is to understand how to increase breast feeding rates and duration through strategies such as spouse support or worksite modifications that permit mothers to continue to feed their children breast milk after they return to work.

Other Approaches

Medical approaches are an integral part of weight control. When 25 percent of adults are affected with obesity, the effective translation of proven strategies into approaches that can be used in primary care settings must become a high priority. We recently calculated what it would cost if all obese Americans were started on one of the two available drugs for the treatment of obesity. The costs of drug therapy were approximately the same as the direct costs of obesity. This observation indicates that conventional medical therapy for the treatment of obesity is extremely expensive. However, last year an NIH clinical trial demonstrated that diet, exercise, and modest weight loss decreased the incidence of diabetes by almost 60 percent - a far greater improvement than the pharmaceutical therapy in the comparison group. These results emphasize the importance of lifestyle modification in the treatment of prediabetes. We are currently working with several managed care organizations to begin the process of translating these approaches into strategies that can be used in primary care. In a meeting to be held this summer, we will begin the process of identifying simple and effective counseling techniques that can be used by physicians, nurse practitioners and nutritionists to help obese patients. Evaluation of these approaches will be critical.

Dietary Supplement Use

Investigators at CDC recently examined the usage of nonprescription weight loss products by adults in five states, including Florida, Iowa, Michigan, West Virginia, and Wisconsin. Seven percent of adults reported that they had used an over-the-counter (OTC) weight loss product in the past two years. Two percent reported the use of

phenylpropanolamine, and one percent reported the use of an ephedra product. As expected, use of OTC products was increased among obese women. Almost 30 percent of obese women and 14 percent of obese men reported use of an OTC drug in the past two years. An important limitation of these surveys was the relatively limited number of questions that could be asked and the small sample size. Therefore, we have been pleased to help the Office of Dietary Supplements at NIH collect data from a greater number of adults in South Carolina. These data will help clarify the frequency and duration associated with the use of these products, as well as whether information about OTC drug use was discussed with their physicians.

In summary, obesity in the United States is epidemic and it is adversely affecting the health and well-being of Americans. The diseases associated with obesity like diabetes have also begun to increase, and are already adding to health care costs. CDC programs have begun to address the problem of obesity, but are small and just beginning. Nonetheless, comprehensive nutrition and physical activity approaches to prevent and treat obesity appear the most cost-effective strategy to reduce obesity and its complications.

Thank you for the opportunity to talk about this very critical issue. I would be happy to answer any questions the Committee may have.

Mr. SCHROCK. Thank you very much. Fascinating.

Dr. Coates, first of all, thank you for what you do at NIH. I think this Federal Government is finally realizing we need to do more there and I know the budget increased last year. We need to continue doing that because what you do there has such an impact on every other segment of society that we need to continue funding that.

I am not going to ask you for name brands but everybody is on a weight loss program. What is the best kind of weight loss program? My wife, who is gorgeous anyhow, is now 32 pounds lighter because she has lost 32 pounds on her way to 35 on Weight Watchers. It really does the trick but is that a permanent solution or what? How do people get it off and keep it off?

Dr. COATES. I can make a couple of brief comments and perhaps Dr. Dietz would be able to expand on it.

Thank you for your comments about the NIH. I wish I could take credit for the broad swath of advances made there but I am very pleased to be a part of an organization that has this kind of reputation. It is a very exciting place to work, I assure you.

In terms of weight loss programs, I think it was alluded to a little earlier that a great many weight loss programs can work in the early phases. The trick is to be able to sustain the weight management and if necessary the continued weight loss, whether it is possible to continue to take off weight.

There are a lot of programs out there. There are some that have been well designed, well tested. Sometimes you cannot distinguish between the ones that have been well designed and tested from the ones that might not have.

I think it is fair to say that consumers are in a position where they have to make choices among a great many things. It is not always easy to do that.

Do you have any further wisdom on that?

Dr. DIETZ. I completely agree there are a lot of approaches to taking off weight but the key is sustaining those losses. There is an interesting weight loss registry that exists in Pittsburgh, a national registry, that consists of people who have lost 60 pounds and kept it off for a year.

There are four strategies that appear to be successful in maintaining weight loss. The first is eating breakfast; the second is monitoring weight at least on a weekly basis; third is a reduced fat diet; and fourth is physical activity, about a hour of moderate physical activity daily. Those strategies appear to be uniform across the people who have lost substantial amounts of weight and sustained it.

Mr. SCHROCK. I am not so sure my wife would be happy about me talking about that but those are the four things she has done and it really does work.

Dr. Coates, as I get closer to being a senior citizen, it is said that they often absorb less nutrition from their food and you kind of wonder why it wouldn't be important for seniors to do more supplemental food type things. Every time I am in one of those food supplement stores, I am the oldest guy there. They are usually young ladies trying to keep thin and guys who want to bulk up, and the

young but not senior citizens. Wouldn't that be a good thing for them?

Dr. COATES. I agree with you on that. Indeed, one of the items I referred in my written testimony was that supplementation with Vitamin B12 is an effective strategy, particularly among the elderly because of the decreased ability to absorb B12 from food. I think we are really just beginning to understand some of those issues. B12 is a signal example.

Our colleagues in the National Institute on Aging and we are sponsoring a conference on this issue about dietary supplement use in the elderly to be held at the NIH early next year. In part, this was driven by the good sense at the NIH that this was an area that needed developing, but you probably also remember that Senator Breaux from Louisiana held a hearing last year I believe on September 10 on the issue of dietary supplement use in the elderly. So there is clearly a lot of concern and enthusiasm at the same time for the potential for dietary supplement use in the elderly. We just don't understand enough of the need there.

Mr. SCHROCK. Isn't a lot of it genetics? My dad will be 89 in a couple of weeks and honestly I go out to California and I come back exhausted just trying to keep up with him and others half his age look like they are twice his age.

Dr. COATES. You can argue if it were that genetic that you would be the same but I think there are differences among people. There is an unknown proportion of this sort of thing that is under genetic control and it is probably true for all of these issues. Maybe there are some common themes that run through them. I don't actually know that is true but we would be always looking for those interactions between genes and the environment, where in this case the environment would be nutrition or dietary supplements.

Mr. SCHROCK. Dr. Dietz, you made a comment that was interesting. All of a sudden we are really concerned about the increase in childhood diabetes. Why? When I was a kid, I don't remember it at all. Now, it is a big deal. We have friends who have kids that have it. I never heard about that when I was growing up.

Dr. DIETZ. It is driven by obesity, 80 to 90 percent of the Type II diabetes in children and adolescents is attributable directly to obesity. There is a strong family history in those kids that it is the obesity which brings it on.

Mr. SCHROCK. I never would have thought that.

What role is the CDC playing in the President's new initiative on physical fitness? Are you integrally involved?

Dr. DIETZ. Yes, we very much are. We helped write the document that came out and in my division there is a Physical Activity and Health Branch which in the last administration helped put together the President's report on physical fitness or I think it was entitled, "Physical Activity in Youth."

We are part of the co-lead with the President's Council on Physical Fitness and Sports for drafting the Healthy People 2010 Guidelines and are actively pursuing revisions in the recommendations around physical activity. For example, our questions and surveillance only ask about leisuretime physical activity and neglecting the potential for physical activity at work. So we are involved both in terms of assessing the problem, developing recommendations

and implementing those both within communities and within States.

Mr. SCHROCK. It is not a bad thing to see the President in a workout environment, working with weights and things. I think that sends a strong message.

Dr. DIETZ. Yes. He is a wonderful model. In some respects though I think what the President is doing may have exactly the opposite effect because I think a lot of people see the President running and doing 7 minute miles which is extraordinary and just dismiss it, they say I can't do that. The message we try to send is you don't have to be a marathoner to have an improvement in your health as a result of physical fitness.

Mr. SCHROCK. That is right. Schools, can they have an impact on this and how?

Dr. DIETZ. Absolutely. We recently published a chapter for a document known as the Guide to Community Preventive Services which is an evidence based document much the same type of analysis that physicians rely on when they prescribe a specific drug for a specific problem. One of the recommendations in that chapter was the importance of physical education as a documented way to increase physical activity in children and adolescents.

In an era when parents are increasingly concerned about safety and neighborhoods are increasingly less safe for children and adolescents, schools represent one of the last safe places for children to be physically active, not only within school but one of the programs we are working on which is turning out to be quite popular in communities is the Kids Walk to School Program. When I was young, I walked to school regularly. In fact, 80 to 90 percent of adults today walked regularly to school. Today, less than one-third of children walk to school. In part, that is because they lack safe routes and in part, it is because communities lack sidewalks and part is the absence of neighborhood schools.

Walking to school is one of the ways that children could build physical activity routinely into their day because they have to get to school. If they have a safe route to walk to school, that is a ready made opportunity for physical activity.

Mr. SCHROCK. I walked to school. I would grouse about it and my dad would say, when I was your age I used to walk 5 miles uphill to get to school and 5 miles uphill to get home and I bought that for a long time but that is true. That is one thing my wife does, she walks several miles every day and she wears a thing on her hip and that is an incentive to see how high she can get that thing.

Faith based initiatives and issues have kind of taken hold in the last few years. I am wondering if there is a role for those kinds of organizations in promoting physical fitness in communities and if there are funds available for that sort of thing?

Dr. DIETZ. It is a very important opportunity and churches have played a major role and there are well documented studies. For example, in North Carolina church based initiatives can change fruit and vegetable consumption and change physical activity levels. I think with appropriate funding that is an important opportunity.

Mr. SCHROCK. Let me recognize the real chairman, Chairman Burton.

Mr. BURTON. I want to apologize for not being here. As I said earlier, this is the last day, today and tomorrow, of the session before the break and we have been working on homeland security. We have been down there fighting over that and what kind of amendments are going to be and so forth. I have a couple of amendments for the floor tomorrow, so I apologize for not being here.

One of the things that concerns me about the first panel, Ms. Ladd, she mentioned the Food and Drug Administration about some alternative and complementary therapies that were used involving supplements and she said they literally laughed at them and said, we don't buy that supplement theory and that sort of thing, words to that effect.

Do you find there is a mindset in any of our agencies, FDA, HHS, or CDC, that would indicate that complementary and alternative therapies and dietary supplements are not worth a darned?

Dr. DIETZ. That is certainly not true at the CDC. She mentioned the CDC as the place she called and was greeted with guffaws and laughter. I was embarrassed to hear that, first, because I think that certainly is not the way my division treats callers and second, because it is the agency I work for and I am quite proud of it.

We think there is a very important role for dietary supplements and weight loss supplements. As I mentioned earlier, we have been pleased to assist the NIH in transferring funds to South Carolina to explore the frequency of usage of these products.

Mr. BURTON. Have any of the agencies, including CDC, had any extensive studies on how supplements affect different diseases? Have there been any double blind studies you know of that would say large amounts of Vitamin C reduce the risk of heart attack or cancer or stroke or any of those things? Have there been double blind studies you know of that deal with that?

Dr. COATES. On behalf of the NIH—because it is generally more likely that those kind of clinical trial studies would emerge from the National Institutes of Health—while I didn't go into any detail in my oral testimony, I did provide some examples in my written testimony of ongoing and some finished studies that have looked at these sorts of things where people are randomized to a treatment group and to a placebo group and the questions asked are how effective is it, how safe is it?

So examples of ongoing trials using NIH funds are on Gingko biloba for the prevention of cognitive decline in older individuals, Echinacea to look at the possibility of prevention of colds in children, either prevention or the severity of colds. So there are a number of these studies. We think this is the right way to do this kind of evaluation so that we can send good messages to consumers about issues related to efficacy.

Mr. BURTON. Have you done any studies on any of the approaches to medicine that are age old like in China where you use acupuncture and other things? Are they doing studies on that?

Dr. COATES. I won't speak for my colleagues in NCCAM or the other Institutes, but I do know because we have some areas of common interest with NCCAM that they are actively pursuing these kinds of things, addressing frontier kinds of medicine or age-old traditional medical approaches and trying to evaluate them in the

context in which they are being used in the United States, which in some instances is quite different from the traditional ones.

Mr. BURTON. We have had a number of hearings on the health care industry and our government agencies, as well as supplements and alternative therapies and that sort of thing. One feels sometimes that the pharmaceutical industry has a tremendous amount of influence because of the grants they help with and other things they do in conjunction with our health agencies.

Do you ever feel like sometimes our health agencies are in some way being manipulated or controlled by the pharmaceutical industry?

Dr. COATES. I don't have an opinion on that. I don't observe it as part of my regular work. I don't know.

Mr. BURTON. But you do know that sometimes people come from the pharmaceutical industry and come into government work and work in the various health agencies and vice versa, people that work in the health agencies will leave and go to work for the pharmaceutical companies with very lucrative jobs.

Dr. COATES. I certainly have seen people moving back and forth, yes.

Mr. BURTON. And that would have some influence I think on some people?

Dr. COATES. It might, I don't have an opinion on that.

Mr. BURTON. OK. You are being very political.

There was a letter published in the Journal of American Medical Association last week from Dr. Wayne Jonas about a St. John's Wort study. Are you familiar with that letter?

Dr. COATES. I saw the letter, yes, I did.

Mr. BURTON. What did you think of that?

Dr. COATES. It is a very reasoned approach. There are issues about trial design that always come up. I think he alluded in his letter to the fact that the recent funded St. John's Wort study in the population that was studied did not demonstrate any effectiveness of either St. John's Wort or the active drug in reducing the impact of depression in this population.

Part of his comment was that the placebo effect is increasingly a complexity of depression oriented trials. I don't know how much weight that has but it was certainly something that others commented on.

Mr. BURTON. Was that study flawed, do you think?

Dr. COATES. Studies, if they don't come up with the answer that a person wants, that person could think it is flawed. If they don't come up with an answer at all, you do begin to question whether there was something about the design or the followup that may have complicated the interpretation of those results. At this point, I can't say.

Mr. BURTON. The staff says they studied major depression when St. John's Wort was never supposed to have been used for that, only mild and minor depression. Can you explain why they did that? I think right on the bottle it says it is not for major depression and yet they did include that in the study.

Dr. COATES. The study population was called major depression of moderate severity. These are terms that I am not aware everybody can agree on. As an example, this is my understanding, I am some-

what peripheral to this argument, but in some European studies of St. John's Wort, the criteria that were used to enter patients into studies were similar to or maybe not very dissimilar from the criteria used to enter patients to this recently completed St. John's Wort study.

That the populations might be called something different could be a function of how we define depressive disorders in the United States as opposed to their definition somewhere else. I am not trying to take the fifth on this, I am trying to help to understand why there might be some differences.

I think it is true that this population had some measures of depression that would be considered more severe than people would have been interested in seeing. Just as an aside, we in the Office of Dietary Supplements along with NCCAM and the National Institute of Mental Health are mounting a follow-on study in a population that will be defined in a somewhat different way but will carry the diagnosis of minor depression. It is a tricky diagnosis to make and I think that may have also contributed some to the final results.

Mr. BURTON. You know what the DSHEA law is?

Mr. COATES. Yes.

Mr. BURTON. What do you think about that?

Dr. COATES. The law was passed in 1994, enacting among other things the Office of Dietary Supplements. It asked for us to provide a scientific basis, scientific support to better inform the American people about the benefits and the risks of dietary supplements, to give people the best information possible. That is my interpretation of DSHEA. It is how it affects me directly and my office.

Mr. BURTON. Do you think that the people at our health agencies, HHS and CDC and FDA, feel Congress overstepped its bounds in passing the DSHEA law?

Dr. COATES. I can't speak for others.

Mr. BURTON. How about you?

Dr. COATES. I think this is a law that presented a very worthy opportunity and in 1994, it was an excellent piece of legislation to try to deal with an emerging area of use in the population. I think—this is a personal opinion for which nobody else should take blame or credit—that it is not a bad idea periodically to reexamine where we are with a piece of legislation. I am not a legislator so I can say that.

Mr. BURTON. What do you think about today, 8 years later?

Dr. COATES. I think we have demonstrated that there is plenty of room for the use of dietary supplements in a host of different conditions. I also think that people in some sectors have used it as an opportunity to be able to market in an area that was beyond what was intended by DSHEA. If DSHEA was intended to provide products that people could use for health promotion, then it is perhaps a stretch to market products for disease treatment.

Mr. BURTON. Such as obesity, like ephedra?

Dr. COATES. That is a tricky one, sir.

Mr. BURTON. The reason I bring up ephedra is because the ephedra issue, we have had some discussions with people in our health agencies and a lot of companies have used synthetic ephedra and it has caused severe problems. Non-synthetic ephedra when

used in proper doses as shown on the bottle and the inserts has minimal side effects.

There was a study done by Harvard and Columbia Universities which I believe has been published now in the International Journal of Obesity and they tried to get it published in some others but they ran into some problems. That study which we have looked at pretty thoroughly showed it wasn't a big problem.

I know that our health agencies are doing another study on that right now. You are managing that study now?

Dr. COATES. The Office of Dietary Supplements and the National Center for Complementary and Alternative Medicine sponsored the development of an evidence report by the RAND Corp. They do that under contract to AHRQ.

Mr. BURTON. That is going on right now.

Dr. COATES. That is going on now.

Mr. BURTON. Do you think the study that was done and published that came out of Columbia and Harvard was flawed? Why are we seeing another study being done? I am just curious.

Dr. COATES. This was one of the very first randomized, clinical control trials of an ephedra-containing and caffeine-containing product used for weight management or weight loss, one of the very first randomized placebo-controlled trials. So it is significant that it was.

As is true of most studies like this, it was done in a population of very-well defined and characterized subjects in whom potential risk factors for the development of some side effects were excluded. That is a good thing. You don't wish to embark on a clinical trial for weight loss where you put subjects at increased risk. So what I would say is, on the basis of that study, the results are promising but the results of that trial relate to a population so described, monitored carefully over 6 months. Over 6 months they experienced weight loss that was comparable to weight loss that could have been obtained through other pharmacologic means. That is encouraging. It was also encouraging that there were no evidence safety problems.

I have to keep reminding myself that in the context of a randomized control trial, your job is to do the very best you can to monitor and prevent potential side effects in a population like that. Therefore, I think we have to limit our enthusiasm. I limit my enthusiasm for the results of the study to a similarly described population and would need to have more information in order to be certain that people who are using this in the context of weight loss in their communities, walk into a store and buy it, they are not being monitored by a physician.

Remember this randomized control trial was done under the control of a number of physicians. It is a somewhat different circumstance. We should be encouraged but I also maintain some caution.

Mr. BURTON. Individuals buy aspirin and all kinds of products and if they don't read the label, and I have been guilty of that from time to time, taking more things than I should have or less and finding out they didn't work. I am talking about pharmacological products.

Dr. COATES. I agree with you.

Mr. BURTON. So we can't control everything a human being does. They have to be responsible themselves and if there is a dietary supplement or a prescription drug, they have to read what they are supposed to do or else they put themselves at risk. That study, as you said, didn't appear to be flawed and we hope when the results of the study you are doing come out, it isn't skewed in such a way that it is designed to change the outcome specifically because they want to see us move toward pharmacological products instead of natural products like natural ephedra.

Dr. COATES. I will make one reminder, sir. We commissioned that report because we wanted to determine what the next research steps needed to be in terms of ephedra.

Mr. BURTON. Not to discredit the other report?

Dr. COATES. Not at all. In fact, the Boozer study to which you referred and published in the International Journal of Obesity is one of the studies being systematically reviewed in the report that is being developed by the RAND Corp.

To clarify one thing, this is not a brand new clinical study, this is a meta-analysis of existing studies that relate to ephedra efficacy and safety.

Mr. BURTON. Let me end by saying I hope the health agencies continue to look at alternative and complementary therapies as well as dietary supplements as a help to people to help cut down the overall cost of medical care and the cost to the government for medical care.

I hope there is not an attempt to circumvent or change the DSHEA law. If there is need to change the law, people like you who have expertise I hope will come to the U.S. Congress and talk to laymen like me who have been interested in the subject for a long time and explain why there is a need to change that so we can try to work together to get that done in a way that is very responsible.

We have an awful lot of jobs and people who make their living in the private sector through the supplement industry. I believe the supplement industry has helped a great deal as far as health is concerned. So I hope we have a good working relationship and that if there is need for change, it is done in the proper way and not with our health agencies trying to circumvent what Congress decided.

Dr. COATES. I would be pleased to talk with you in more detail about that at your request. We have also found that the dietary supplement industry has been a valuable partner in trying to move forward research activities, that they have not interfered with our activities, they try to be effective partners with us in some aspects of those things where they really do have expertise.

Mr. BURTON. Beth just told me that we have not yet fully implemented or health agencies have not yet fully implemented the DSHEA law and until that is done, we probably wouldn't be of a mind to change it anyhow but once it is completely implemented, if there is flaws, we will try to get those corrected.

Mr. SCHROCK. Thank you, Mr. Chairman.

Thank you for your testimony and the discussion. It has been very helpful. I think this whole day has been helpful because this is an issue that should be important to every single Member of

Congress, every single staff member because it impacts so much of what we do up here.

Mr. BURTON. I don't know if you were here earlier. My wife died of metastatic colon cancer on May 10. One of the things I hope our health agencies will do has nothing to do with the present subject, is to illuminate the need for people above 40 or 50 to have colonoscopies and other preventative measures to prevent death or severe health problems.

Had my wife's doctor told her to get a colonoscopy, she would be here today. I am convinced of that. They didn't. When she started having some minor symptoms, they just gave her pills. I am not so sure the medical profession, all of them, are aware of how important things like colonoscopies are. So if our health agencies could send out a circular when you do a mailing or whatever you do to inform the AMA or doctors, tell them how important some of these preventive measures are, it would be appreciated by not only me but I am sure thousands across the country that might be saved because of that.

You guys can do a lot in addition to making sure we get the right prescriptions and the right drugs to make sure people are informed about how important preventive measures like colonoscopy are.

Mr. SCHROCK. I agree with that. I wish we could somehow legislate people to get physicals every year. I hate to say it, but the male is worse than anybody else. We need to make sure we do that. You heard his story. Mine was caught early. I am blessed it was but so many times it gets so far down the pike, there is nothing you can do about it.

Thank you very much for your testimony. Thank you for being here.

This hearing is now adjourned.

[Whereupon, at 3:09 p.m., the committee was adjourned, to reconvene at the call of the Chair.]

[The prepared statements of Hon. Henry A. Waxman, Hon. Edolphus Towns, and Hon. Carolyn B. Maloney, and additional information submitted for the hearing record follow:]

STATEMENT OF REP. HENRY A. WAXMAN
RANKING MINORITY MEMBER
COMMITTEE ON GOVERNMENT REFORM
HEARING ON
"DIET, PHYSICAL ACTIVITY, AND DIETARY SUPPLEMENTS"

July 26, 2002 - 10:00 a.m. - 2154 Rayburn House Building

Mr. Chairman, thank you for holding this hearing on the relationship between diet, exercise, lifestyle, and dietary supplements on health.

It seems that every day there is new information coming out about the effect of diet and exercise on health.

In terms of diet, for instance, it is now clear that there is a link between how much saturated fat you eat and your cholesterol level. Increased cholesterol levels are associated with increased risk of heart disease. Trans fats appear to be particularly bad. The Institute of Medicine recently released a report concluding that there is a clear relationship between eating foods high in trans fat, such as crackers and donuts, and increased cholesterol, which leads to a higher risk of heart disease. In fact, the IOM recommends that people eat as little trans fat as possible. This report highlights the need for FDA to finally issue regulations requiring labels to report on the amount of trans fat in a

product. FDA proposed such regulations in 1999, nearly three years ago. Despite the known health risk of trans fat, this regulation has yet to be finalized.

Numerous studies have shown that exercise can reduce the incidence of many preventable diseases. Researchers recently reported that regular aerobic exercise, even when it does not result in weight loss, drives down blood pressure, regardless of age or weight or initial blood pressure. Exercise has even been found to reduce, and even reverse, the impact of aging. New research has shown that many of the physical changes that are associated with getting old – insulin resistance, decreased lung function, and elevated blood pressure – are not due so much to aging, but to inactivity.

I am pleased that the committee will receive testimony from government witnesses about what research the government is conducting on the relationship between diet and exercise and health and what steps the government is taking to educate Americans about the benefits of a healthy diet and an active lifestyle. I am also pleased the committee will receive testimony from private witnesses, who will tell us about their research in these important areas.

I would like to comment on the way that the witness list has been

put together, however. One issue we will discuss today is the role of dietary supplements and health. Clearly, there are some supplement products that are important for maintaining health. Calcium, for example, has been demonstrated to help prevent osteoporosis. Pregnant women should make sure that they have adequate intake of folic acid to help protect against certain birth defects. However, experts have raised some safety concerns about some supplements and safety is an issue that needs to be considered when understanding the implementation of the Dietary Supplement Health and Education Act.

To that end, I requested that the majority include one witness at today's hearing, Mr. Todd Weger. Todd Weger was an Army Ranger who suffered a series of strokes after taking a dietary supplement containing ephedra. He successfully sued the manufacturer of the product. As part of the settlement, the manufacturer agreed to strengthen the consumer warning. Todd Weger could have brought an important consumer perspective to this hearing. However, Chairman Burton denied this request. I am disturbed that we are not allowed even one witness at this hearing.

Thank you.

Statement of Congressman Ed Towns
Government Reform Full Committee Hearing
"Diet, Physical Activity, Dietary Supplements, Lifestyle and Health – the Scientific Basis for Improving Health, Saving Money, and Preserving Personal Choice"
July 25, 2002

Thank you Mr. Chairman for holding this important hearing today. I welcome the panelists and thank you for appearing before this committee to provide your expert testimony.

With over 300,000 deaths a year caused by overweight or obesity it is imperative that we take the necessary steps to increase public awareness and offer whatever other assistance that we can to combat this increasingly deadly disease. Last year, I introduced legislation, H.R. 1641, the 'Medicaid Obesity Treatment Act of 2001' to provide Medicaid coverage for overweight and obesity medications. I introduced this legislation because I recognized that there is a problem in this country when it comes to weight. Chairman Burton has introduced H.R. 3475, the Dietary Supplement Tax Fairness Act. This bill would allow dietary foods and supplements to be treated as medical expenses and could be deducted on your taxes. Both steps aim to increase access to overweight and obesity treatments that can be cost prohibitive. Both steps would be important tools in the effort to fight this disease.

The National Center for Health Statistics reports that 60 percent of Americans more than 20 years of age are overweight or clinically obese. In addition, weight-related conditions are the second leading cause of death in the United States. Earlier this year I went to the House Floor to raise awareness about this disease and former Surgeon General David Satcher's "call to action" to prevent and decrease overweight and obesity. According to Dr. Satcher, the prevalence of overweight and obesity has almost doubled among America's children and adolescents since 1980, and it is estimated that one out of every five children is obese. The epidemic growth in obesity in childhood or adolescence is particularly threatening to the national health because it often persists into adulthood and increases the risk for some chronic diseases later in life. Overweight and obesity are public health problems because they substantially increase the risk of illnesses, including breast cancer, colon cancer, ovarian cancer, prostate cancer, cardiovascular disease, high blood pressure, high cholesterol, type 2 diabetes, heart disease, stroke, gallbladder disease, arthritis, sleep disturbances, and respiratory problems. In addition to the human costs of this disease there is also an economic toll. In 1995, the total cost, both in terms of health care and lost productivity, of obesity alone was estimated at $99 billion. In fact, the President himself recently joined with his Secretary of Health and Human Services, Tommy Thompson, to increase public awareness of the importance of healthier living. On June 20, 2002, the President launched a National Health and Fitness Initiative called "Healthier Us" – this initiative calls for moderate daily exercise, developing good eating habits, preventative screenings, and the three don'ts – "don't do drugs, don't smoke, and don't drink excessively". At the kick-off of this initiative President Bush pointed out, "This year, heart disease will cost our country $183 billion. If just 10 percent of adults

began walking regularly, we could save billions of dollars in costs related to heart disease."

There is no doubt that having public figures at all levels of public life is an important tool in getting the message out that there is a problem and you can solve it. In fact, the response to overweight and obesity issues continues to grow – at all levels of government. Recently, Marty Markowitz, the Borough President of my home borough of Brooklyn, concluded a diet challenge in which Brooklyn lost 82,655 thousand pounds during an 8-week weight loss campaign, called "Lighten Up Brooklyn". Now other elected officials are trying to match or surpass this achievement.

Weight loss competitions are not exclusive to government and elected officials. The Today Show recently held a diet challenge pitting teams from cities across the country to promote healthier living. While we increase awareness and offer remedies we must also be careful not to confuse our message. Sound science must lead us through debates which currently rage questioning the potential value of fat vs. carbohydrates. This is an important debate because thousands of people follow diet regimens, such as "the Atkins diet" because it seems like a painless way to lose weight. The real question is, is it safe ? Would you rather eat an egg while dieting or cottage cheese? Does a steak sound better than dry salad? I will be interested in hearing from today's panelists who can speak to the effectiveness of various "pop-diets". Is there science backing them up or are they dangerous fads ? Also, I look forward to hearing from the panelists on the effectiveness of the Dietary Supplement Education Health and Education Act of 1994 (DSHEA). I thank Chairman Burton for recognizing overweight and obesity for the critical health crisis that it is.

Statement of Congresswoman Carolyn B. Maloney
for the Committee on Government Reform
Hearing on Diet, Physical Activity,
Dietary Supplements, Lifestyle and Health

Mr. Chairman,

We are here today to talk about the health of the American people. There can be no greater consideration for government to consider than the health of its citizens. We must remain committed to doing its utmost to promote long, healthy lives for their citizens.

One important aspect of a healthy lifestyle is regular exercise. There are many different ways to exercise,

and everybody should be able to find an exercise that will keep them healthy. Some like to play competitive sports, others work out at the gym, and still others dance or practice some form of martial arts. I am a member of the Tae Kwon Do club of Senators and Representatives. Our rich society provides ample opportunity for each and every individual to find a type of exercise that he or she enjoys in order to live an active, healthy, life.

Diet is another crucial component of healthy living. Congress is currently funding, and must continue to fund, studies that refine our knowledge about what constitutes a healthy diet. Americans must alter their eating habits to conform more closely with those recommended by doctors and nutritionists.

officials, to start paying more attention to their health. We should be looking for preventative measures, not only reacting after unhealthy lifestyles bring diseases upon us. I hope that the witnesses who will testify today will be able to help point us in the right direction.

obesity reviews

The safety and efficacy of pharmaceutical and herbal caffeine and ephedrine use as a weight loss agent

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Summary

Since passage of the Dietary Supplement Health and Education Act of 1994, the sale of herbal dietary supplements containing caffeine and ephedrine for weight loss has become widespread in the United States. Reports of adverse events associated with the use of these non-prescription supplements have raised concerns in the United States regulatory community. Restricting the use of these products is now being considered. Such restriction should be based upon controlled clinical trials. This review of the literature in Medline relative to the use of caffeine and ephedrine in the treatment of obesity concludes that caffeine and ephedrine are effective in causing weight loss. Caffeine and ephedrine give equivalent weight loss to Diethylpropion and superior weight loss compared to dexfenfluramine. Caffeine and ephedrine have a long history of safe, non-prescription use. The adverse events accompanying acute dosing are mild and transient. Adverse events with caffeine and ephedrine reach and remain at placebo levels after 4–12 weeks of continuous treatment, but data from randomized trials up to 6 months only are available. Obesity is chronic, requires chronic treatment, its incidence is increasing and it has few effective treatments. The benefits of caffeine and ephedrine in treating obesity appear to outweigh the small associated risks. Restriction of dietary herbal supplements containing caffeine and ephedrine, often with other ingredients, should be based on controlled clinical trials of these products.

Keywords: Caffeine, Ephedrine, Obesity.

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Introduction

Herbal forms of caffeine and ephedrine fall under the Dietary Supplement Health and Education Act of 1994. Selling caffeine and ephedrine, in herbal form, for weight loss, is now a large industry. The widespread use of this herbal combination has lead to reports of serious adverse events and raised safety concerns in the regulatory community (1). The United States Food and Drug Administration (FDA) published a proposed ruling in 1997 to restrict the use of herbal caffeine and ephedrine products. The Government Accounting Office's review of that ruling prompted the FDA to withdraw portions of its proposal.

Reports of serious adverse events associated with the use of herbal caffeine and ephedrine have continued, however, and the FDA is re-exploring the need to intervene to protect the public. This need to protect the public should be based upon the determination of the relative risks and benefits of taking herbal caffeine and ephedrine for weight loss. Such a determination requires knowledge of the incidence of these serious adverse events and the efficacy of caffeine and ephedrine for weight loss, things that cannot be determined from a voluntary reporting system. Prospective studies with appropriate controls can make this determination and such studies do exist in the peer-reviewed scientific literature. A review of this scientific literature is therefore the best resource upon which to make these regulatory decisions.

This review of the peer-reviewed literature was compiled by reviewing the articles in the Medline database published in English from 1966 through to 2000 using the terms

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caffeine and ephedrine, each cross-referenced to the term obesity as a search criteria. In reviewing this literature, particular emphasis has been given to the efficacy of caffeine and ephedrine in causing weight loss, the benefits that can be expected from that weight loss and the incidence of adverse events placed in the context of an appropriate control group.

Since the concern of the FDA has been relative to herbal products and the literature deals almost exclusively with pharmaceutical grade caffeine or other methylxanthines with ephedrine, one might question the applicability of this literature review. Caffeine in the herbal products is the same chemical contained in pharmaceutical caffeine. Herbal ephedrine has 4 isomers, but the pharmaceutical grade product contains the most potent of these (2). Therefore, the herbal form of ephedrine should be even safer than equivalent doses of the pharmaceutical grade product, because it contains less of the most potent isomer.

Background

In 1972, Dr Erikson, a Danish general practitioner in Elsinore, Denmark noted unintentional weight loss when he prescribed a compound containing ephedrine, caffeine and Phenobarbital to patients he was treating for asthma. As he pursued his observation, rumour spread from his patients to the rest of the country. By 1977, over 70 000 patients were taking the 'Elsinore Pill', and one Danish pharmaceutical house was producing one million tablets a week.

During the time that the 'Elsinore Pill' was used for the treatment of obesity, there were skin rashes, some serious, reported. These were most likely due to the Phenobarbital in the 'Elsinore Pill'. In 1977, the Danish Institute of Health issued a warning to doctors not to prescribe the compound due to the increased incidence of skin rashes, and Dr Erikson was pilloried in the public and scientific press.

On that background the 'Elsinore Pill' without phenobarbital was compared with the appetite suppressant diethylpropion and to a placebo in 132 subjects in a 12-week double-blind trial. In subjects given 25 mg of diethylpropion three-times-a-day (tid) and the 'Elsinore Pill' without Phenobarbital (100 mg of caffeine and 40 mg of ephedrine tid) weight loss of 8.4 kg and 8.1 kg was noted, respectively, which was not significantly different from each other, but which was greater than the placebo weight loss of 4.1 kg ($P < 0.01$). Tremor and agitation were more frequently noted with subjects on the 'Elsinore Pill', but were transient and the withdrawal for side-effects was equal in the diethylpropion and 'Elsinore Pill' groups. There was no increase in blood pressure, pulse rate or laboratory parameters. The authors concluded that ephedrine and caffeine had the advantage over diethylpropion because of its lower cost with equivalent safety and efficacy (3).

Other early studies of ephedrine and caffeine also used commercial asthma preparations. Theophylline and caffeine are both methylxanthines and have the same pharmacologic actions. One mg of theophylline is equivalent to 2 mg of caffeine (4). Miller used the 'Do-Do' pill manufactured by Ciba-Geigy in the United Kingdom that contains 22 mg of ephedrine, 30 mg of caffeine and 50 mg of theophylline per pill. Each pill therefore contains the equivalent of 22 mg of ephedrine and 130 mg of caffeine (5).

ephedrine with theophylline was the primary treatment for asthma in the 1960s and 1970s and ephedrine is still sold in the United States without a prescription for the treatment of asthma (6). Ephedrine with caffeine is still the most widely sold prescription weight loss medication in Denmark and has held 80% of the market share even, when dexfenfluramine has been available.

This long history using ephedrine in combination with methylxanthines, both for the treatment of asthma and obesity, makes the present concern over the safety of herbal products using lower doses seem somewhat surprising. This review will consider the animal studies and human trials of caffeine, ephedrine and their combinations in treating obesity.

Caffeine

Animal studies

Obesity can be associated with low sympathetic activity (7). Based upon this association, caffeine was evaluated in genetically obese ob/ob mice. Caffeine decreased body fat and improved sympathetic activity in that animal model, suggesting a possible role in the treatment of human obesity (8).

Human studies

Caffeine in an oral dose of 250 mg increased free fatty acids and glucose, but not cortisol levels, in obese and lean humans compared with a water placebo with each subject acting as his own control (9). Oxygen consumption, fat oxidation and serum free fatty acids were increased in six normal subjects given caffeine 8 mg kg^{-1} orally compared with 0.5 gm glucose. Oxygen consumption and fat oxidation were also increased in seven normal and six obese subjects after 4 mg kg^{-1} of caffeinated coffee compared with a decaffeinated control after fasting and after a mixed meal (10).

Six obese, six lean and four post-obese women were evaluated after 4 mg kg^{-1} oral caffeine. Caffeine levels were higher in the lean compared with the obese and post-obese subjects, and the rise in oxygen consumption and free fatty acids was lower in the post-obese compared with the obese and lean subjects. These changes were felt to be due to dif-

ferences in lipolysis (11). Increases in oxygen consumption and fat oxidation suggest a potential role for caffeine in the induction of weight loss.

Since the initial studies evaluating the effect of caffeine on oxygen consumption, further investigations have been undertaken. Caffeine 100 mg was shown to increase resting oxygen consumption 3–4% in nine lean and nine post-obese subjects. Caffeine (100 mg) also improved the defective diet induced thermogenesis over 150 min that was present in the post-obese. Five lean and six post-obese subjects were given 100 mg caffeine every 2 h for 6 h. Daily energy expenditure increased 150 kcal d^{-1} in the lean subjects and 79 kcal d^{-1} in the post-obese subjects (12).

Ten lean and 10 obese women were evaluated for 24 h in a metabolic chamber on two occasions, one with 4 mg kg^{-1} caffeine 5 times a day and the other with placebo. Caffeine increased energy expenditure and lipid oxidation, but less in the obese than in the lean (13). The response of serum catecholamines to 4 mg kg^{-1} caffeine was evaluated in 12 pre-pubertal lean, 15 pre-pubertal obese, 12 pubertal lean and 24 pubertal obese subjects. The rise in serum catecholamines was less in the pubertal obese group (14). Caffeine administration significantly elevated systolic blood pressure 4.5–6.6 mm Hg, but there was no change in diastolic blood pressure or pulse rate. Subjects reported no symptoms or side-effects.

The caffeine-induced increase in thermogenesis is dissipated through an increase in skin temperature (15). The increase in resting metabolic rate induced by 4 mg kg^{-1} of caffeine predicts the amount of weight lost in response to a diet and exercise programme (16).

Pharmacology

The changes in levels of caffeine following an acute dose in the lean compared with the obese subjects prompted more elaborate pharmakinetic studies. The volume of distribution of caffeine was found to be proportional to body weight with caffeine having the same clearance in the obese as in the lean subjects (17). Therefore, for metabolic studies one might justify a loading dose, but for chronic treatment no change in dosage is necessary for the obese (18,19).

Epidemiology studies

Several epidemiologic studies have addressed the safety of caffeine. The positive correlation found between heavy coffee drinking and elevated cholesterol is felt to be due to factors other than caffeine in coffee, since caffeine consumption in the form of tea or cola has no effect on cholesterol (20,21). Heavy caffeine use is associated with resistant hypertension and snoring. Resistant hypertension is defined as high blood pressure not controlled by three blood pressure medications at full doses. Heavy caffeine use is also associated with cigarette smoking. Since cigarette smoking is associated with hypertension and snoring, it may be the smoking that is responsible for the association with these conditions rather than the caffeine (22,23).

On a chronic basis, caffeine consumption has been correlated in epidemiologic studies with a decreased risk of hospitalization for coronary heart disease (24). It has also been associated with lower blood pressure (25,26). Therefore, caffeine consumption on a chronic basis appears to reduce the risk of cardiovascular disease, the opposite suggested by caffeine's acute cardiovascular response. Although the intake of more than 2 cups of coffee per day is associated with osteoporosis, this association has only been demonstrated in women between 50 and 98 years of age and only when they consume less than one glass of milk per day, far below the intake recommended by nutritional guidelines (27). As noted before, coffee contains more than caffeine and any negative effect on bone could as easily be related to one of the other components of coffee.

Clinical trials

A clinical trial with 288 healthy subjects evaluated the effects of a single 200 mg d^{-1} dose of caffeine compared with the placebo. Caffeine gave a 2.2 mm Hg in diastolic blood pressure which was felt to be clinically insignificant. There was no change in pulse rate or systolic blood pressure (28).

caffeine not only has a long history of safe use in food, but has also been used for many medicinal purposes. It is used in headache preparations, to treat fatigue, to treat intracranial hypertension and to treat respiratory distress in the neonate (29,30). The US FDA approves caffeine for sale without a prescription for use as a stimulant by persons 12 years of age or older at a dose up to 200 mg every 3 h (1600 mg d^{-1}) and as an ingredient in pain medications which gives further support to its safety.

Ephedrine

Animal studies

Ephedrine was proposed as a potential treatment for obesity on the basis of a study comparing it to triiodothyronine in six animal models of obesity and lean controls. Triiodothyronine increased both oxygen consumption and food intake, causing death in genetically obese animals. Ephedrine elevated oxygen consumption without increasing food intake while causing weight and fat loss (31). There were no deaths in the ephedrine group. Two other animal models of obesity were treated with ephedrine. Increased energy expenditure, decreased food intake and fat loss were demonstrated (32,33).

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In an effort to discover a potential drug to treat obesity, 33 compounds known to stimulate oxygen consumption were screened in several animal models of obesity. In general, these compounds gave selective fat loss without loss of body protein by increasing energy expenditure without increasing food intake. Ephedrine was one of the two most efficient compounds and a case was made for its use in the treatment of obesity (34,35).

Mechanisms

Ephedrine stimulates brown adipose tissue thermogenesis through the activation of β-receptors. It has been estimated that 40% of the acute rise in oxygen consumption to ephedrine is due to activation of the β-3 adrenergic receptor (36). The isomer of ephedrine in pharmaceutical preparations is the most active of the four existing isomers (37). As one would expect for a drug that acts on beta-receptors, the beta blocking drug atenolol prevents the weight loss induced in ob/ob mice by ephedrine (38).

Aspirin has been shown to increase ephedrine-induced thermogenesis. Mice made obese by monosodium glutamate (MSG) and treated with aspirin had no change in their energy expenditure, body fat or body weight. Mice made obese with MSG, and treated with ephedrine increased their energy expenditure by 9%, reduced their body fat by 50% and reduced their body weight by 18%. The combination of aspirin and ephedrine increased energy expenditure by 18%, reduced body fat by 75% and reversed obesity (39).

Ephedrine was proposed as a possible obesity treatment in humans as early as 1974, but was felt to give side-effects in doses adequate to suppress appetite (40). Ephedrine, however, was shown to improve its ability to increase oxygen consumption and enhance peripheral conversion of thyroxine to triiodothyronine with time. Ephedrine 20 mg tid increased oxygen consumption by 1.3 L over 3 h at baseline. This figure rose to 7 L over 3 h at week 4 and 12 of treatment accompanied by weight losses of 2.5 kg and 5.5 kg, respectively (41). Chronic treatment with ephedrine increased metabolic rate by 10% and increased fat oxidation (42).

Human studies

Clinical trials have been conducted with ephedrine for the treatment of obesity. A 3-month trial comparing 25 mg of ephedrine tid (13 subjects) and 50 mg tid (17 subjects) with placebo (16 subjects) showed similar weight losses in all groups with significantly more side-effects (blood pressure elevation, pulse elevation, agitation, insommia, headache, weakness, palpitations, giddiness, euphoria, tremor and diarrhoea) in the ephedrine 50 mg tid group compared with placebo (43). There was more weight loss in the ephedrine groups, however, at the end of the first and second months, a difference that was lost by the end of the third month (44). A second trial compared 50 mg of ephedrine tid with placebo over 8 weeks in 10 low-energy adapted women who had already lost weight. The study used a crossover design. Weight loss was greater during the 2-month period on ephedrine (2.4 kg) than on placebo (0.6 kg). Side-effects were uncommon; agitation (2 subjects), insomnia (3 subjects), giddiness (2 subjects), and palpitations (2 subjects), and none required withdrawal of medication (45).

Ephedrine has also been evaluated in conjunction with a very low calorie diet. Ephedrine decreased urinary nitrogen and blunted the fall in resting metabolic rate (46). The rise in oxygen consumption to ephedrine 1 mg kg^{-1} was increased by 5 weeks of exercise training 1 h per day on a bicycle at a heart rate of 140–160 beats per min. (47).

Mechanisms

Attempts have been made to explore the mechanisms by which ephedrine exerts it effects in humans. Although ephedrine stimulates brown adipose tissue in rodents, ephedrine-induced thermogenesis in humans takes place primarily in skeletal muscle, since humans have little brown adipose tissue (48). Ephedrine has also been shown to decrease gastric emptying which may contribute to its effect on food intake (49). As one might expect from a compound that stimulates β-1, β-2 and β-3 receptors, intravenous ephedrine acutely increases oxygen consumption, serum glucose, insulin and c-peptide (50). β-1 receptors stimulate heart rate, and β-2 receptors increase glucose in addition to stimulating oxygen consumption along with the β-3 receptors.

Post-prandial thermogenesis measured for 160 min following a liquid meal was greater in 10 obese women to an acute dose of ephedrine 30 mg and aspirin 300 mg than to an acute dose of ephedrine 30 mg alone. Aspirin did not have this additional effect on thermogenesis in 10 lean women (51). Ephedrine and aspirin normalized the post-prandial thermogenesis in obese women to levels equal to the lean (52).

Adverse events

Side-effects with ephedrine were agitation, insomnia, headache, weakness, palpitations, giddiness, tremor and constipation, but were only seen with the 50 mg tid dose and dissipated with time. No significant changes were seen in pulse or blood pressure (53). Ephedrine has been reported to cause urinary difficulty in subjects with prostatic hypertrophy and can exacerbate angle-closure glaucoma (54).

Ephedrine with methylxanthines (caffeine, theophylline, and aminophylline)

Animal studies

Caffeine and methylxanthines have been demonstrated to be synergistic in animals. Caffeine or theophylline given alone to mice with MSG-induced obesity caused no change in weight, fat or energy expenditure. Ephedrine decreased weight by 14%, fat by 42% and increased energy expenditure by 10%. When caffeine or theophylline was added to ephedrine, weight decreased by 25%, fat decreased by 75%, energy expenditure increased by 20% and body composition was normalized to that of lean control animals (55).

Caffeine with ephedrine and theophylline also normalized obesity in fa/fa Zucker fatty rats by decreasing food intake by 40% and increasing energy expenditure from 25 to 33% (56). Oxygen consumption was increased by 32% with ephedrine, 48% with caffeine and 47% with caffeine and ephedrine in the LA-corpulent rat, another rodent obesity model. These rats lost three times the weight with the caffeine and ephedrine than with ephedrine alone (57). Not only can rodent obesity be effectively treated with ephedrine and methylxanthines, but caffeine, ephedrine and theophylline also prevent obesity in fa/fa rats by normalizing energetic efficiency to that of lean animals (58).

Although most of the animal studies with caffeine and ephedrine have been done in rodents, the effect of this drug combination was also evaluated in primates. Caffeine and ephedrine gave fat loss in both lean and obese monkeys, but weight loss and decreased food intake was only seen in obese animals. Nocturnal energy expenditure increased by 21% and 24% in the lean and obese monkeys, respectively. There was no change in the glucose tolerance test, but leptin levels decreased (59).

Adipsin

Adipsin is a serine protease with complement factor D activity that is synthesized in fat cells and secreted into the blood stream. Genetically obese mice (ob/ob and db/db) and mice with MSG induced obesity have low adipsin levels that precede the obesity, and the obesity in these animals is associated with low levels of sympathetic activity. Since caffeine and ephedrine correct both the obesity and the adipsin levels, it was postulated that adipsin is under sympathetic control (60). Since it was later demonstrated that BRL 26830 A, a selective beta-3 adrenergic stimulator, depressed adipsin levels, it was suggested that adipsin was inversely related to body fat (61). It now appears that adipsin levels are controlled by food intake, since both ephedrine with caffeine and food restriction increase adipsin levels (62).

Mechanisms

The mechanism by which methylxanthinines potentiate ephedrine-induced thermogenesis was assumed to be inhibition of the adenosine receptor, a known effect of methylxanthines. Using an *in vitro* assay of brown fat cell respiration, it was shown that the adenosine receptor plays only a minor role, and most of the methylxanthine effect is due to phosphodiesterase inhibition (63). Ephedrine and theophylline also increase hepatic lipase activity, the enzyme that degrades atherogenic intermediate density lipoproteins (64). Lower intermediate density lipoproteins should, in turn, protect from atherosclerotic vascular disease.

Herbal caffeine and ephedrine

Herbal forms of caffeine and ephedrine have also been evaluated in rodents. Bofu-tsusho-san containing ephedrine and a phosphodiesterase inhibitor when fed to mice with MSG-induced obesity decreased both fat and body weight by activating brown fat thermogenesis (65). Oolong tea prevented the obesity and fatty liver induced by a high fat diet, stimulated noradrenaline-induced lipolysis, stimulated hormone sensitive lipase and inhibited pancreatic lipase activity in rodents (66). This effect was attributed to caffeine, but more recent studies demonstrate that green tea contains not only caffeine, but also catechin polyphenols that inhibit catechol-O-methyl transferase, the enzyme that breaks down noradrenalineephrine. Just as caffeine and ephedrine are synergistic in their effect on the respiration of brown fat cells *in vitro*, so are the catechins in green tea synergistic with caffeine, ephedrine and the combination of caffeine with ephedrine (67).

Human studies

Initial human studies with caffeine and ephedrine were with the 'Elsinore Pill' which contained 40 mg of ephedrine and 100 mg of caffeine given three times a day. Although this combination increased metabolism, thyroid hormone did not seem to be responsible for this increase. Diet, diethylpropion and the 'Elsinore Pill' all significantly decreased levels of T_3 by a mean of 9% during weight loss (68). Extrapolating from animal studies, the increase in energy expenditure was postulated to come from stimulation of brown adipose tissue. Further studies with ephedrine demonstrated that, at maximum, 15% of the increase in human thermogenesis could come from brown adipose tissue, the majority being due to thermogenesis in muscle (48).

The next published study of ephedrine and methylxanthines used Do-Do pills, a non-prescription asthma medication containing 22 mg of ephedrine, 30 mg of caffeine

and 50 mg of theophylline made by Ciba-Geigy, UK. The ephedrine-methylxanthine combination was twice as effective in raising resting metabolic rate in lean and post-obese subjects than ephedrine alone. Although there was no change in 24-h energy expenditure in lean subjects measured in a metabolic chamber, the post-obese increased their energy expenditure by 8%. The ephedrine-methylxanthine combination normalized the defective thermogenic response to a meal in the post-obese (69).

Since aspirin and methylxanthines both potentiate ephedrine-induced thermogenesis, 100 mg of aspirin with 50 mg of ephedrine and 50 mg of caffeine was given three times a day for 8 weeks in a double blind clinical trial. Weight loss was faster in the aspirin-ephedrine-caffeine group compared to placebo, and there were no significant differences in pulse rate, blood pressure, fasting glucose or symptoms (70).

In an effort to evaluate the best combination of caffeine and ephedrine, single doses of ephedrine (10 mg and 20 mg) and caffeine (100 mg and 200 mg) were compared with three combinations of caffeine with ephedrine (10 mg/200 mg, 20 mg/100 mg, and 20 mg/200 mg). Ephedrine (20 mg) with 200 mg of caffeine gave increases in oxygen consumption that were greater than the sum of the increase seen with 20 mg of ephedrine and 200 mg of caffeine separately. The other two doses of caffeine and ephedrine were equivalent to the additive effect of their component doses of caffeine and ephedrine separately on oxygen consumption. The acute dose of caffeine and ephedrine elevated systolic blood pressure 9 mm Hg and pulse rate 7 beats per minute (bpm). Plasma glucose, insulin and c-peptide were also elevated (71). This acute effect of caffeine and ephedrine in raising blood pressure, pulse, and glucose is lost with chronic treatment (66).

The dose of caffeine with synergism, 20 mg of ephedrine with 200 mg of caffeine given three times a day, was chosen for a clinical trial. One hundred and eighty obese subjects were randomized to 20 mg of ephedrine tid, 200 mg of caffeine tid, 20 mg of ephedrine with 200 mg of caffeine tid or placebo for a 24-week double blind trial. Weight loss with caffeine and ephedrine was greater than placebo from 8 weeks to the end of the trial. Ephedrine alone and caffeine alone were not different than placebo. The caffeine with ephedrine group lost 17.5% of their body weight in the 24-week trial. Side-effects of tremor, insomnia and dizziness reached the levels of placebo by 8 weeks, and blood pressure fell similarly in all four groups. Heart rate rose in a statistically significant manner in the ephedrine group compared with placebo, but fell below the baseline value in the caffeine and ephedrine group (72).

Two weeks after cessation of the 24-week trial, headache and tiredness were more frequent in the group that had taken caffeine with ephedrine. At the end of the 2-week washout period, all subjects were given the opportunity to participate in an additional 24-week open-label trial using caffeine with ephedrine. Those subjects remaining on caffeine with ephedrine maintained their weight loss to the end of trial at week 50 (73). Seventy-five percent of the weight loss was explained by anorexia and 25% was explained by increased thermogenesis (74).

Since acute treatment with 200 mg of caffeine and 20 mg of ephedrine three times a day had cardiovascular and metabolic effects, the chronic effects were evaluated in the 24-week trial. By week 12 the blood pressure had dropped 4–11 mm Hg below baseline and remained similar to the placebo group. The pulse rate dropped 1–2 bpm from baseline during the trial, and reductions in plasma glucose, cholesterol and triglycerides were not different between the groups at the end of the 24-week double-blind trial (75). These findings were confirmed in an 8-week trial using 50 mg of ephedrine, 50 mg of caffeine and aspirin 110 mg given three times a day that was double-blinded and placebo-controlled trial. There was no significant change in heart rate, blood pressure, blood glucose, insulin, cholesterol or side-effects relative to placebo, but weight loss was greater in the ephedrine, caffeine and aspirin group (76).

The effect of 200 mg of caffeine with 20 mg of ephedrine three times a day on body composition has been studied with bio-impedance. At the end of 8 weeks, weight loss was not different, but the group on caffeine and ephedrine lost 4.5 kg more fat and 2.5 kg less lean tissue than the placebo group, a significant difference. As one might expect, the fall in energy expenditure was 13% in the placebo group and only 8% in the group treated with caffeine and ephedrine (77). Treatment with caffeine and ephedrine over 8 weeks also prevented the expected drop in high density lipoprotein (HDL) cholesterol. Since HDL cholesterol protects from atherogenesis, this finding suggests that caffeine and ephedrine may have the potential to reduce atherosclerotic cardiovascular disease. The placebo group experienced the drop in HDL cholesterol routinely reported with diet-induced weight loss (78).

Ephedrine with or without a methylxanthine was evaluated in adolescents. The effect of ephedrine in stimulating thermogenesis was lost after 1 week of treatment, but was restored by combining it with aminophylline for one week (79). This would explain why the trials with ephedrine alone give more weight loss than placebo early in trials that decreases with time unless combined with a methylxanthine.

The same group reported a 20-week, double-blind, placebo controlled and randomized clinical trial of caffeine and ephedrine in 32 adolescents age of 16 ± 1 years and Tanner stage III-V (80). Subjects less than 80 kg were given one tablet containing 100 mg of caffeine and 10 mg of ephedrine three times a day and subjects more than 80 kg were given two pills three times a day. The loss of initial body weight was 14.4% and 2.2% in the caffeine with

ephedrine and placebo groups, respectively ($P < 0.01$). All three dropouts were in the placebo group and adverse events were described as negligible. After the first 4 weeks the adverse events in the caffeine group were not different than placebo.

The most successful weight loss drug combinations have been phentermine with fenfluramine and caffeine with ephedrine. Both combinations give weight losses in the range of 15–20% of initial body weight in 6 months (81). Caffeine (200 mg) with 20 mg of ephedrine given three times a day was compared with dexfenfluramine 15 mg twice a day in a double-blind trial. In subjects with a BMI greater than 30 kg m^{-2}, the weight loss was greater with caffeine and ephedrine treatment. Blood pressure declined significantly in both groups (7.8/4.6 mm Hg in the dexfenfluramine group and 10.6/3.5 mm Hg in the caffeine and ephedrine group) but the differences were not significantly different from each other. Pulse rate declined 1.1–2.7 bpm and was not different between the groups. The subjects treated with dexfenfluramine had more gastrointestinal symptoms (diarrhea, dry mouth, and thirst) and the subjects treated with caffeine and ephedrine had more symptoms of central nervous system stimulation (tremor, insomnia, agitation). Symptoms in both groups declined by the end of the first month of the 15-week trial (82).

Although dexfenfluramine is no longer available due to cardiac valvular toxicity, caffeine and ephedrine are available without prescription. The cardiac valvular problems associated with fenfluramine and dexfenfluramine are felt to be related to serotonin and have not been associated with caffeine and ephedrine which have a noradrenergic mechanism of action. Fenfluramine with phentermine, fenfluramine with mazindol, caffeine with ephedrine and mazindol alone were compared in their ability to reduce weight, cardiovascular risk and low density lipoprotein (LDL) cholesterol. Caffeine with ephedrine was found to be the most cost-effective treatment (83).

Ephedrine (25 mg) and 200 mg of caffeine given three times a day for 10 d had no effect on resting cardiovascular function measured by thoracic bio-impedance, automatic sphygmomanometry or continuous electrocardiographic recording. During cycle ergometer exercise, there was a small increase in the cardiac ejection fraction. Based upon these results, the authors concluded that, in the doses studied, caffeine and ephedrine had no undesirable effects on cardiovascular function in the obese (84).

The efficacy of caffeine and ephedrine in the treatment of human obesity is summarized in Table 1. The safety of caffeine and ephedrine in human obesity studies are summarized in Table 2. Table 2 compiles the incidence of side-effects in the various trials of caffeine and ephedrine, expressing them as a percentage of the total number of subjects studied. Since one trial compared caffeine and ephedrine to diethylpropion and another to dexfenfluramine, some comparison to the safety of these compounds can also be made (see Table 2).

Another way to evaluate the safety of caffeine and ephedrine is to compare the dropouts in caffeine with ephedrine groups to placebo groups or to groups of compounds with which caffeine with ephedrine have been compared in obesity studies (see Table 3). The raw dropout rates, however, do not reflect the reasons for the dropouts.

Table 1 Efficacy of caffeine and ephedrine

Author	Start D/P	End D/P	Dose (E/C)	Length	Kg lost D/P	% wt. lost D/P	Comments
(3)	49/33	42/31	80/300 mg d^{-1}	12 wk	8.1/4.1	8.3/4.5	Diethylpropion & E/C gave equal wt. loss
(69)	16	16	22/130 mg d^{-1}	1 d	0	0	E/C normalized TEF of postobese to lean level
(70)	29	11/13	150/150 mg d^{-1}	8 wk	2.2/0.7	–	E/C with aspirin 330 mg d^{-1}
(71)	6	6	20/200 mg d^{-1}	1 d	0	0	E/C dose synergistic
(72)	45/45	35/35	60/600 mg d^{-1}	24 wk	16.6/13.2	17.5/13.6	E or C alone and placebo gave equal wt. loss. C/E maintained wt. loss for 24 wk on open label C/E
(77)	7/7	6/6	60/600 mg d^{-1}	8 wk	10.1/8.4	–	C/E gave more fat loss & less lean tissue loss than placebo
(78)	20/20	16/16	60/600 mg d^{-1}	8 wk	9.0/7.6	9.6/8.2	C/E gave no drop in HDL
(79)	8	8	75/880 mg d^{-1}	1 d	0	0	Ephedrine loses its effect without methylxanthine in adolescents
(82)	50/53	38/43	60/600 mg d^{-1}	15 wk	9.0/7.0	9.7/7.8	P = dexfenfluramine 30 mg d^{-1} in this study
(89)	20	20	75/600 mg d^{-1}	24 wk	–	8.6	C/E was most cost-effective obesity treatment in the trial
(84)	9/9	9/9	50/400 mg d^{-1}	10 d	0	0	C/E gave no cardiovascular toxicity at 10 d
(80)	16/16	16/13	30/300 & 60/600 mg d^{-1}	20 wk	7.9/0.5	14.4/2.2	C/E toxicity negligible and equal to placebo by 4 wk in adolescents
(86)	152/73	27/13	60/600	12 wk	−0.2/−1.5	− 0.3/−2.1	Abstinent smokers – C/E gave less weight gain

The table lists the human caffeine (C) and ephedrine (E) studies by number in the reference list. The number of subjects that started and finished the studies in the drug (D) and placebo (P) groups are listed. The study length is given, and the weight lost in kilograms and/or percent initial body weight lost is also given. The comment section lists special aspects of the various studies. –, no data; HDL, high density lipoprotein cholesterol.

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Table 2 Adverse effects

Symptom	C & E	No.	Pl.	No.	DEP	No.	Dex.	No.
Agitation (jitteriness, anxiety)	3.9%	(15/388)	0%	(0/216)	8%	(4/50)	0%	(0/53)
Dizziness	16.7%	(65/388)	8.3%	(18/216)	0%	(0/50)	7.5%	(4/53)
Headache	1.0%	(4/388)	0%	(0/216)	0%	(0/50)	5.7%	(3/53)
Tremor	6.2%	(24/388)	2.8%	(6/216)	4%	(2/50)	0%	(0/53)
Depression (fatigue)	0.5%	(2/388)	0%	(0/216)	0%	(0/50)	5.7%	(3/53)
Insomnia	8.2%	(32/388)	4.2%	(9/216)	10%	(5/50)	1.9%	(1/53)
Postual hypotension	0.5%	(2/388)	0.5%	(1/216)	0%	(0/50)	0%	(0/53)
Nausea	16.5%	(64/388)	8.3%	(18/216)	0%	(0/50)	11.3%	(6/53)
Thirst	0.3%	(1/388)	0%	(0/216)	0%	(0/50)	9.4%	(5/53)
Paresthesias	0%	(0/388)	0%	(0/216)	0%	(0/50)	5.7%	(3/53)
Diarrhoea	0%	(0/388)	0%	(0/216)	0%	(0/50)	11.3%	(6/53)
Dysrhythmia	21.6%	(84/388)	6.5%	(14/216)	0%	(0/50)	1.9%	(1/53)
Constipation	1.2%	(3/256)	0.9%	(2/216)	2%	(1/50)	3.8%	(2/53)
Urinary problems	0.3%	(1/388)	0.5%	(1/216)	2%	(1/50)	0%	(0/53)
Dry mouth	1.0%	(4/388)	0%	(0/216)	0%	(0/50)	1.9%	(1/53)
Heart rate	0.5%	(2/388)	0%	(0/216)	0%	(0/50)	0%	(0/53)
BP elevated	0.3%	(1/388)	0.5%	(1/216)	0%	(0/50)	0%	(0/53)
Glucose	0%	(0/388)	0%	(0/216)	0%	(0/50)	0%	(0/53)
Sweating	19.1%	(74/388)	8.3%	(18/216)	0%	(0/50)	0%	(0/53)
Other	2.6%	(10/388)	4.2%	(9/216)	0%	(0/50)	0%	(0/53)

Adverse events reported in trials of caffeine and ephedrine are listed as a percent incidence with the number of subjects experiencing the symptoms and the total number of subjects in the trials in parentheses. One trial compared caffeine (C) and ephedrine (E) to Diethylpropion (DEP) 25 mg tid in 50 subjects and another trial compared caffeine and ephedrine to dexfenfluramine (Dex) 15 mg bid in 53 subjects. No., number, Pl, placebo.

Table 3 Subjects withdrawn from the caffeine and ephedrine trials

Author	C & E	Placebo	DEP	Dexfen
(3)	0	4	4	–
(72)	10	10	–	–
(77)	1	1	–	–
(78)	4	4	–	–
(82)	10	–	–	7
(80)	0	3	–	–
(86)	15	7	–	–
–	11.3% (44/388)	10.6% (23/216)	8% (4/50)	13.2% (7/53)

All subjects that withdrew from the studies of caffeine (C) and ephedrine (E) are listed. Each study is identified by reference list number. The bottom row on the table expresses the dropout incidence in percent followed by the number of subjects who dropped and the total number of subjects in the trials. There was one trial in which caffeine and ephedrine were compared with 50 subjects on Diethylpropion (DEP) 25 mg tid and one trial in which caffeine and ephedrine were compared with 53 subjects on dexfenfluramine (Dexfen) 15 mg.

Table 4 Adverse events responsible for withdrawal listed for subjects participating in caffeine and ephedrine trials

Adverse event	C & E	Placebo	Dexfen
HTN	1	2	0
Dysrhythmia	2	0	0
Agitation	1	0	0
Vomiting	2	0	0
Insomnia	3	0	0
Headache	0	0	1
Diarrhea	0	0	1
Totals	3.3% (8/241)	1.6% (2/127)	3.8% (2/53)

This table lists the reasons given for study withdrawal in subjects dropping for adverse events during the caffeine (C) and ephedrine (E) trials. The bottom row lists the incidence of dropouts for adverse events described in the trials followed by the number withdrawing and the number in the trials. Dexfen, dexfenfluramine.

Safety can also be evaluated by comparing the dropouts for adverse events in the caffeine with ephedrine groups to the dropouts for adverse event in the placebo groups or other compounds with which caffeine with ephedrine have been compared (see Table 4).

Caffeine and ephedrine are unique in that the side-effects return to placebo levels by 8 weeks and remain at placebo levels at least to 24 weeks despite subjects remaining on the compounds (72) (Fig. 1). Therefore, the incidence of adverse events may over-estimate their true clinical significance in obesity studies, since obesity is a chronic disease and one for which chronic treatment is appropriate.

Catechins in green tea are synergistic with caffeine in stimulating thermogenesis in man. No adverse effects were detectable, even with acute dosing of caffeine with catechins in a study performed in a metabolic chamber (85).

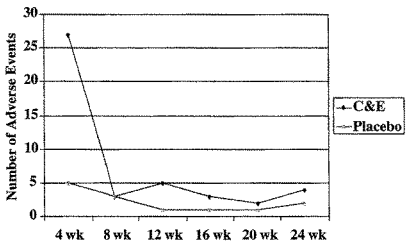

Figure 1 Incidence of adverse events with caffeine and ephedrine compared with placebo at monthly intervals during a 6-month trial (68). The incidence of adverse events (dizziness, tremor, headache, depressed mood, anxiety, euphoria, insomnia, postural hypotension, palpitation and tachycardia) were mild, transient and reached the placebo level at 8 weeks where they remained for the rest of the trial.

Additional literature

Caffeine (200 mg) and 20 mg of ephedrine tid have been tested for the prevention of weight gain after smoking cessation. Two thirds of 225 subjects were randomized to receive caffeine and ephedrine for 12 weeks and the rest were randomized to placebo. All subjects were off medication by week 39, and at 1-year weight loss and the percent not smoking were similar in both groups. At 12 weeks, however, weight gain was less in the caffeine and ephedrine group (86).

Concerns have been raised regarding the safety of caffeine and ephedrine use in subjects with controlled hypertension. One hundred and thirty-six overweight normotensive or drug-controlled hypertensive subjects were randomized to five groups. After 6-weeks of treatment systolic blood pressure was reduced 5.5 mmHg more in controlled hypertensive subjects treated with 200 mg of caffeine and 20 mg of ephedrine three times a day than placebo in subjects treated with medication other than β-blockers. The antihypertensive effect of β-blocker medication was not reduced by caffeine and ephedrine. Normotensive patients treated with caffeine and ephedrine had a 4.4/3.9 mmHg greater drop in blood pressure than those treated with placebo. The mean loss of weight of 4 kg was significant for all groups (87).

Caffeine was combined with phenylpropanolamine in the past to treat obesity (88). Since caffeine is not synergistic or even additive to phenylpropanolamine in stimulating weight loss, and can give central nervous system stimulation, it was removed from phenylpropanolamine products sold for weight loss (89). This is in contradistinction to caffeine and ephedrine that do give more weight loss when combined than either compound induces alone. The addition of caffeine to ephedrine in a 6-month trial blocked the rise in pulse rate seen with ephedrine alone (72). Energy expenditure with mention of caffeine has been reviewed (90), and nonprescription appetite suppressants including caffeine have also been reviewed (91).

Ephedrine has been proposed as an adjunct to cognitive restructuring (92). Ephedrine has been considered in reviews relative to nonprescription weight loss supplements (93), obesity management (94), energy balance (95) and obesity treatment (96).

Caffeine and ephedrine have been included in recent reviews of obesity medication (97–102). Thermogenic approaches to treat obesity have been reviewed (103). More specifically, caffeine and ephedrine relative to obesity treatment have also been reviewed (104–107). In a letter to the editor of the journal in which the clinical trial was published, the authors reported that ephedrine alone, on reanalysis, actually gave more weight loss than placebo, but less than ephedrine and caffeine, in the 24-week trial of caffeine, ephedrine, caffeine with ephedrine and placebo (108). Caffeine and ephedrine have also been used to induce weight loss prior to comparing different weight maintenance diets (109).

Discussion

Caffeine is a component of foods. Ephedrine has been used in oriental medicine for centuries. Ephedrine combined with methylxanthines including caffeine was a standard treatment for asthma in the 1960s and 1970s, and was sold for many years without prescription. In fact, it was the serendipitous finding of involuntary weight loss by a general practitioner in Denmark treating his patients with asthma using a caffeine and ephedrine product that initiated the use of this combination for the treatment of obesity.

Ephedrine products are sold without a prescription for the treatment of asthma and have a recommended dosage of up to 150 mg per day. Caffeine sold without a prescription has a recommended dose of up to 1600 mg per day. The popular herbal products containing caffeine and ephedrine and taken for weight loss have dosage recommendations up to 100 mg of ephedrine equivalent per day as ephedrine. The caffeine content of these herbal products containing caffeine and ephedrine varies, but is less than 600 mg a day. The most popular and widely sold herbal product containing caffeine and ephedrine has only 240 mg of caffeine per day, less than 3 cups of coffee. Pharmaceutical grade products have greater potency than the herbal products containing caffeine and ephedrine in equivalent doses because the herbal products contain some of the less active isomers of ephedrine.

The peer-reviewed literature documents central nervous system stimulation, an increase in pulse rate, an increase in blood pressure and an increase in glucose when caffeine

and ephedrine are given acutely either separately or together. These side-effects disappear with chronic treatment, and are no longer present after 4–12 weeks, depending on the trial. A 24-week trial of caffeine and ephedrine found a decrease in pulse rate and blood pressure. The pulse rate in that trial was no different than placebo in the caffeine and ephedrine group, but was significantly higher than placebo in the ephedrine group. There were no differences between the caffeine with ephedrine group and the placebo group relative to serum glucose, serum cholesterol or symptoms of stimulation.

Ephedrine and caffeine have each been sold for years without a prescription for the treatment of asthma and to combat drowsiness, respectively. Toxicity has not been a concern, even with recommended doses higher than that used in herbal products containing caffeine and ephedrine for weight loss. Overweight and obesity are common problems affecting more than half of the population, yet obesity is stigmatized by society. Therefore, it is not surprising that an effective weight loss product containing compounds with a long history of safe non-prescription use would be embraced enthusiastically by the public. When large numbers of the public are using any product, adverse events will inevitably occur, but the cause and effect relationship of these adverse events to the product use are usually unclear.

Obesity is a disease that predisposes to diabetes, hypertension and cardiovascular disease. These increased risks are reversed with weight loss. Although there may be small risks to the use of caffeine and ephedrine as a treatment for obesity, based upon the literature and the Danish experience, the risks appear to be outweighed by the potential benefits of weight loss.

The most objective method of assessing risks and benefits is by evaluating the randomized double blind, placebo-controlled trials in the peer-reviewed literature. Studies of caffeine with ephedrine suggest that the risks (elevation of blood pressure, elevation of pulse rate, agitation, dizziness, headache, tremor, fatigue, insomnia, nausea, thirst, dysrhythmia and dry mouth) are usually mild and transient, existing primarily during the first few days to weeks of treatment. The cardiovascular, stimulatory and other potential adverse effects of caffeine and ephedrine are at placebo levels in a few weeks while the benefits of weight loss persist for at least a year. Since asthma is usually an acute intermittent disease, those who take ephedrine and methylxanthines to treat asthma are disproportionately exposed to its risks relative to those taking caffeine and ephedrine on a more chronic basis for weight loss.

There have been a relatively small number of serious adverse events reported to a surveillance system in response to government requests to do so, compared with the widespread use of herbal products containing caffeine and ephedrine. These reports are not an objective method upon which to restrict the use of these herbal products containing caffeine and ephedrine. This statement is based upon several observations. First is the safety and efficacy of caffeine with ephedrine documented in the scientific literature for the treatment of obesity. Second is the history of safety using higher doses of caffeine and ephedrine as non-prescription medications for other uses. Thirdly, the side-effects seen with the acute use of caffeine and ephedrine reach placebo levels in a few weeks of continued treatment. This suggests that the safety of caffeine and ephedrine used chronically for weight loss is at least as great, if not greater, than the safety of ephedrine and methylxanthines in the acute treatment of asthma. Lastly, the levels of caffeine and ephedrine contained in herbal products for weight loss are less than the amounts of caffeine and ephedrine recommended for sale without a prescription for other purposes.

There remains a caveat to these conclusions. Most of the herbal products containing caffeine and ephedrine also contain many other compounds such as minerals and herbs that might alter or interact with caffeine or ephedrine. Therefore, these herbal products containing caffeine and ephedrine should be tested in controlled clinical trials to confirm their presumed safety and efficacy which cannot truly be extrapolated from the peer-reviewed scientific literature using pharmaceutical grade caffeine and ephedrine in isolation.

Obesity is epidemic, and the incidence is increasing in all segments of the population. Being overweight or obese are health risks that have few effective treatments. Herbal products containing caffeine and ephedrine should remain an option for weight loss and to reduce the associated health risks of being overweight and obese while controlled clinical trials of these products are simultaneously encouraged. Voluntary case reports having no denominator with which to calculate incidence and no control group with which to compare – they do not represent persuasive arguments to restrict the use of herbal products containing caffeine and ephedrine (1). The peer-reviewed scientific literature suggests that the risks of caffeine and ephedrine are outweighed by the benefits of achieving and maintaining a healthy weight. Confirmation of that conclusion for herbal products containing caffeine and ephedrine awaits controlled clinical trials.

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METABOLIFE 356® IS SOLD FOR ADULT USE ONLY

- Metabolife 356® labels contain an explicit warning that the product is "not for use by or sale to persons under age 18."

- Metabolife supports a ban on the sale of ephedra-based supplements to minors.

Established Safety and Efficacy

SCIENTIFIC RESEARCH DEMONSTRATES THAT EPHEDRA-BASED SUPPLEMENTS ARE A SAFE AND EFFECTIVE MEANS OF WEIGHT CONTROL

Clinical, scientific studies have repeatedly found that responsibly produced and marketed ephedra-based supplements (with or without caffeine) are safe and effective when taken as directed by individuals that do not have the preexisting health conditions described on the Metabolife 356® warning label, such as thyroid disease and diabetes. These studies include:

- A prospective, six-month, randomized, double-blind, placebo-controlled, clinical safety and efficacy trial conducted by researchers from Harvard and Columbia Universities and published in the May 2002 issue of the *International Journal of Obesity* in which the combination of ephedra and caffeine was found to produce no adverse events and only mild side effects, when compared to placebo. Funded by grants from the National Institutes of Health and Science Toxicology and Technology Consulting, this study of 167 mildly to severely overweight subjects was conducted over a six month period, making it the only long-term clinical trial of an ephedra-caffeine combination to date. The treated group showed significantly greater reductions in body weight, body fat, and waist and hip circumference than the placebo group. The treated group's greater weight loss was accompanied by improved cholesterol and blood glucose levels. Notably, compared to placebo, the tested product produced no adverse events, serious or otherwise, and minimal side effects;

- Controlled, 3-month clinical studies, partially funded by the supplement industry and reported at the October, 2001 annual meeting of the North American Association for the Study of Obesity, both reaffirming that supplements containing a combination of ephedrine alkaloids and caffeine are a safe and effective means of weight control;

- A study of the Food and Drug Administration's adverse event reports, completed in 2000 by Dr. Stephen Kimmel, an Assistant Professor of Medicine in the Cardiovascular Division at the University of Pennsylvania School of Medicine and a member of the Ephedra Education Council Expert Panel, estimating that the percentage of people experiencing serious health events among consumers of ephedra-based supplements is little different than the percentage of people experiencing such events in the general population;

- A comprehensive risk analysis, completed in 2000 by Cantox Health Sciences International, an independent scientific consulting firm, and funded by the Council for Responsible Nutrition, an association representing 105 companies in the dietary supplement industry, demonstrating ephedra-based supplements (with or without caffeine) to be safe when taken as directed; and

- A recent 8-week clinical study, conducted by Columbia University researchers funded by Metabolife, demonstrating that patients taking Metabolife 356® lost an average of 8.7 pounds, compared to the placebo group, which lost an average of 1.8 pounds.

THE MARKETPLACE PROVIDES ADDITIONAL EVIDENCE OF SAFETY

- Broad public acceptance of ephedra-based supplements backs up the scientific research. Over three billion servings are consumed per year.

- Common sense tells us that the millions of Americans who use these products would simply discontinue buying them if they experienced adverse reactions or believed the products are ineffective.

EPHEDRA-BASED SUPPLEMENTS ARE NOT FOR EVERYONE

- Some people with pre-existing health conditions should not use these products or should consult health care professionals before using them. These health conditions are described on each Metabolife 356® label. They include such conditions as diabetes, thyroid disease, and high blood pressure.

- Additionally, Metabolife 356® labels include the following statements and Metabolife urges FDA to mandate their inclusion on the labels of all food and dietary supplements that contain ephedrine alkaloids:

    - A warning against sale to or use by minors;

    - A warning against use by those with enumerated health conditions;

- Specification of maximum single serving size and daily serving size limits, accompanied by a warning that those exceeding these limits may experience side effects, some of which may be serious; and

- Posting of a toll-free number for consumer inquiries.

Anecdotal Reports of Adverse Health Events Do Not Demonstrate that Ephedra-Based Supplements Cause Health Problems

Many news reports have stated that ephedra has been "*implicated in*," "*linked to*," or "*associated with*" up to 81 deaths and over 1000 adverse health conditions, implying that such events were caused by ephedra-based products. This is not the case.

FDA's AERs Provide No Evidence that Ephedra-Based Supplements Have *Caused* Any Adverse Health Problems

- Adverse event reports ("AERs") are anecdotal communications concerning people claiming (1) to have used a supplement, over-the-counter drug, or food additive and (2) to have experienced some health problem.

- FDA, the U.S. General Accounting Office ("GAO"), and critics of ephedra-based supplement have all affirmed that AERs provide no scientific evidence that these supplements caused the reported adverse health events.

    - The Director of FDA's Office of Nutritional Products, Labeling, and Dietary Supplements has stated, "AERs do not offer proof that any supplement caused the death or injury listed, only that the person ingested the supplement before his death or injury."

    - Drs. Haller and Benowitz, authors of an oft-cited *New England Journal of Medicine* article critical of ephedra-based supplements, acknowledged in an April 2001 edition that the AERs they reviewed - do not "prove causation, nor . . . provide quantitative information with regard to risk."

    - In its 1999 report, "Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids," GAO found AERs to be inherently unreliable, noting that the majority of those that purportedly involved ephedrine-containing products lacked sufficient information "important in determining potential underlying conditions that might have caused the adverse event."

- Reports of adverse health events are quite common for many products. For example, in 2000 alone, the American Association of Poison Control Centers received nearly 17,000 reports in response to exposure or potential exposure to aspirin and approximately

57,000 reports relating to acetaminophen (*i.e.*, Tylenol®), compared with less than 1,400 adverse event reports for all ephedrine-containing products during the entire eight-year period for which FDA has collected such records.

MANY OF FDA'S AERS WERE ACTUALLY TOTALLY UNRELATED TO THE USE OF EPHEDRA-BASED SUPPLEMENTS, EVEN THOUGH MOST PRESS REPORTS CONTINUE TO USE THE AGGREGATE TOTALS

Among the AERs purportedly demonstrating a "link" between ephedrine containing products and adverse events were such totally unrelated incidents as:

- Report of person who shot and killed a store clerk;
- Reports of two deaths due to automobile accidents;
- Report of a suicide due to a gunshot wound;
- Report of a death due to smoke inhalation;
- Report of a death due to environmental hypothermia;
- Report of hirsutism (hairiness);
- Report of heartburn three days after discontinuing use of an ephedra-based supplement, in a patient who had gastric reflux;
- Report of "cardiac arrest," with accompanying E.R. records showing that no cardiac arrest had occurred and that the patient's heart was completely normal;
- Report of a 75 year old woman who began menstruating;
- Report of facial/ankle swelling, although her doctor's records show no mention of swelling or edema; and
- Report of an attempted suicide.

The Use of Ephedra-Based Supplements for Athletic Enhancement

Metabolife 356® is neither sold nor marketed for athletic performance, and Metabolife has never conducted product-specific research on this topic. Nonetheless, the following points are worth noting:

- According to a recent report issued by the National Collegiate Athletic Association, the use of ephedra-based supplements by college athletes appears to be minimal. The NCAA reports that only 3.9% of college athletes are using ephedra-based supplements.

- No scientific studies have assessed the impact of ephedra-based supplements on young athletes or other minors to our knowledge. Nonetheless, Metabolife 356® contains a warning against use by minors.

The Desire for Strong Regulation

METABOLIFE SUPPORTS STRONG, SCIENTIFICALLY-BASED REGULATION

Metabolife, and the responsible members of the dietary supplement industry, are strongly urging FDA to enact a balanced, science-based regulation, such as those adopted by Nebraska and Ohio, to protect public health and to ensure that the millions of Americans who consume ephedra-based supplements responsibly and without incident can continue to do so. Such regulatory reform should include the following elements.

Consumption Limits

Adoption of a consumption limit for ephedrine alkaloids in dietary supplements of 25 mg/serving and 100 mg/day, commensurate with regulatory requirements in Hawaii, Michigan, Nebraska, Ohio, and Washington. This limit is more stringent than the long-term use limit of 25 mg/serving, 150 mg/day that FDA has already established with respect to ephedrine's use in over-the-counter drug products.

Responsible Marketing/Sales

Unfortunately, there are some unscrupulous companies in the industry that engage in shady business practices, such as promoting their products as thinly veiled street drug alternatives and by marketing to minors. These companies are giving the rest of the industry a bad name and are either confusing or scaring consumers. Adoption of the following rules will put a stop to these irresponsible practices:

- Prohibition of marketing or sales of ephedrine alkaloid dietary supplements to minors.

- Prohibition of labeling claims and promotions that suggest that a food or dietary supplement containing ephedrine alkaloids is an alternative to an illicit drug, or that it may help the user to achieve an altered state of consciousness, euphoria, or ecstasy. Such a ban would apply to product claims such as the following:

    - "For maximum effect alcoholic beverages may enhance the euphoric sensations." (Herbal Ecstasy)

    - "It is definitely one of the strongest party means of the moment." (Yellow Jacket 3 Caps)

Product Labeling Standards

Adoption of a reasonable warning label standard is needed to ensure that ephedrine-containing dietary supplements are used only by appropriate individuals. Metabolife supports adoption of labeling requirements that would include the following warnings:

- The product is not for use by anyone under the age of 18.
- Pregnant or nursing women should not use the product.
- Individuals with heart disease, thyroid disease, diabetes, high blood pressure, depression, or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, as well as those using a monoamine oxidase inhibitor (MAOI), or any other dietary supplement, prescription drug, or over-the-counter drug containing ephedrine, pseudoephedrine, or phenylpropanolamine (ingredients found in certain allergy, asthma, cough/cold, and weight control products) should consult a health care professional before using the product.
- Use should be discontinued and a health care professional should be contacted immediately if the individual experiences rapid heart beat, dizziness, severe headache, shortness of breath, or other similar symptoms.

Metabolife additionally urges FDA to require the labels on food and dietary supplements containing ephedrine alkaloids to disclose the following:

- The amount of ephedrine alkaloids in each serving (and the amount of product that constitutes a serving);
- That taking more of the product than recommended (or taking it at greater frequencies) may increase the risk of adverse experiences; and
- That the maximum recommended daily serving of ephedrine alkaloids is 100 mg.

Metabolife further urges FDA to require labels on food and dietary supplements containing ephedrine alkaloids to facilitate consumer inquiries by listing a toll-free number that is maintained by either the manufacturer, distributor, retailer, or third-party.

Manufacturing Standards

- Prohibition on the use of synthetic ephedrine alkaloids in dietary supplements, in keeping with the most stringent state regulatory requirements.
- Adoption by FDA of "good manufacturing practices" to help ensure product quality and consistency. These standards should include:
    - Batch testing;

- Product expiration dates;
- Distribution tracking procedures; and
- Retention of samples from each batch for a minimum of one year following the product expiration date.

CONTINUED FDA DELAY IS UNACCEPTABLE

FDA's Failure to Issue a Timely, Science-Based Regulation

Although it has been more than eight years since FDA began to collect AERs purportedly relating to ephedrine alkaloid dietary supplements and first issued its public warning of potential safety issues associated with such products, the agency has yet to issue a regulation.

- In 1997, after four years of compiling its AERs, FDA issued a proposal to regulate ephedra-based dietary supplements.
- In 1999, GAO issued a report highly critical of FDA's proposed rule. Among the inadequacies GAO highlighted were:
    - FDA's proposed restrictions lacked a scientific basis,
    - FDA relied upon incomplete AER data;
    - FDA based its conclusions of causality and risk on AER data which, as GAO noted and FDA has acknowledged, are inherently unreliable for such purposes; and
    - FDA provided over-inflated estimates of the prospective benefits of its proposed rule.
- In 2000, FDA withdrew major portions of its proposed rule in response to GAO's critical report.
- FDA has yet to issue a final rule.
- In 2001, FDA announced that it considers the issuance of a new ephedrine regulation to be a diminished priority, demoting the issue from its "A-List" of items – those given top priority – to its "B-List" of items – those to be completed "when Agency resources allow."

FDA Inaction on Recommended Reforms of its Adverse Event Reporting System

- In April 2001, the Inspector General of the Department of Health and Human Services published an evaluation of FDA's AER system. The report documented serious problems with the system and recommended specific remedies.

- FDA has yet to implement the recommended reforms.

FDA's Needless Delays Have a Profound Negative Impact on Consumers and the Dietary Supplement Industry

FDA's delay in issuing a reasonable, science-based regulation has negatively impacted consumers and the dietary supplement industry in a number of ways. These include the following:

- FDA's failure to establish appropriate industry standards has permitted a few unscrupulous companies to tarnish the entire industry.

- FDA's failure to reform its AER system and its reliance upon discredited analytic methodologies, propagate unsubstantiated, negative media attention. This, in turn, has generated additional problems, such as:

    - Confusion and fear among consumers, and,

    - Decreased use of these products by consumers who would benefit from them.

Metabolife would be pleased to provide additional information regarding this issue.