

**DIETARY SUPPLEMENT HEALTH AND EDUCATION
ACT: IS THE FDA TRYING TO CHANGE THE
INTENT OF CONGRESS?**

HEARING

BEFORE THE

**COMMITTEE ON
GOVERNMENT REFORM
HOUSE OF REPRESENTATIVES**

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

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**DIETARY SUPPLEMENT HEALTH AND
EDUCATION ACT: IS THE FDA TRYING TO
CHANGE THE INTENT OF CONGRESS?**

THURSDAY, MARCH 25, 1999

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

The committee met, pursuant to notice, at 10:06 a.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Davis, Horn, Ros-Lehtinen, Morella, Gilman, Biggert, Terry, Hutchinson, Sanford, Souder, Chenoweth, Waxman, Norton, Kucinich, Tierney, and Schakowsky.

Staff present: Kevin Binger, staff director; Daniel R. Moll, deputy staff director; Barbara Comstock, chief counsel; David A. Kass, deputy counsel and parliamentarian; S. Elizabeth Clay, professional staff member; Mark Corallo, director of communications; John Williams, deputy communications director; Carla J. Martin, chief clerk; Lisa Smith-Arafune, deputy chief clerk; Maria Tamburri, staff assistant; Phil Schiliro, minority staff director; Phil Barnett, minority chief counsel; Kristin Amerling and Sarah Depres, minority counsels; and Jean Gosa and Earley Green, minority staff assistants.

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 opening statements be included in the record. And, without objection, so ordered.

Today we are here to talk about the implementation of the Dietary Supplement Health and Education Act [DSHEA], by the Food and Drug Administration. At our hearing in February, we heard from the delightful actress Jane Seymour about her use of complementary and alternative medicine, including herbal products and other dietary supplements to maintain good health for herself and her family.

At that hearing, we also heard from Dr. Brian Berman of the University of Maryland about the importance of research in dietary supplements, such as glucosamine, to help Americans with arthritis and ginkgo biloba in delaying the onset of Alzheimer's disease. The potential cost savings to the Federal Government in these two debilitating illnesses is enormous and certainly justifies more research funding.

In our March 10 hearings on chelation therapy, we learned from a panel of expert physicians that dietary supplements is used in conjunction with chelation therapy to improve circulation and cardiovascular health. In studying various alternative systems of healing, whether it's Ayurveda, Native American healing, or traditional Chinese medicine, two currents run through each of these systems: the importance of spirituality in healing and the important role of botanical products and nutrition in healing.

The Food and Drug Administration does a very good job of protecting the public. We are pleased that the new FDA Commissioner is joining us today to discuss the improvements she is making to assure that the FDA continues to protect the public and facilitate patients' access to clinical trials.

Congress passed the Dietary Supplement Health and Education Act in 1994. The American people demanded to be heard on this issue and Congress listened to them. More letters and faxes were received on this topic than any other single piece of legislation in U.S. history.

Over 50 percent of Americans use dietary supplements on a regular basis to improve their health. I personally began using supplements after a telephone conversation with Nobel Prize-winning scientist Linus Pauling, who told me that high doses of vitamin C would help prevent cancer and other diseases.

Every Member of Congress is pulled in many directions at once every day. We work long, exhausting hours under great deals of stress. I was delighted to learn in our February hearing from my colleague on the committee, Helen Chenoweth, that she has successfully used the dietary supplement zinc in the treatment of a rare disorder Meniere's disease. It has helped her stay healthy and prevent brain surgery. I think that the Office of Dietary Supplements and the Office of Rare Diseases at the National Institutes of Health need to work together to determine where dietary supplements can be helpful in the treatment of rare diseases and disorders and to make this information known to the public.

When Congress passed the Dietary Supplement Health and Education Act, it was made very clear that Americans would have access to these products and that information was a key factor. Quality, accurate, useful information on the labels, in the labeling, and in third-party literature is vital to Americans' needs to make informed, safe choices. This is the cornerstone of this first hearing on dietary supplements.

The committee has been in frequent contact with the FDA on a variety of concerns about proposed rulemaking, as well as the actions of the FDA on a variety of topics in this area. It is particularly timely that we begin this discussion now as there is a new Commissioner of Food and Drugs, Dr. Jane Henney, who will testify this morning. There are several issues of concern in this area.

We cannot address each of the topics regarding dietary supplements in depth today. However, they do warrant mentioning: nutritional labeling, good manufacturing practices, the Dietary Supplement Commission on labeling, the structure function statement and the redefinition of disease, the authoritative statement health

claims, *Pearson v. Shalala*, Pharmanex's Cholestin, adverse events reporting, ephedra, Stevia, and CODEX. And we have an attachment to the statement which I would like to enter into the record as well.

[The information referred to follows:]

Attachment A**Food and Drug Administration Topics of Concern on Dietary Supplements**

Nutritional labeling: On Tuesday, March 23, of this week, three final rules went into effect regarding labeling. Commissioner Henney will be explaining these rules. In essence, all supplements must bear nutrition information entitled "Supplement Facts" similar to nutrition content labeling for conventional foods.

Good Manufacturing Practices: Of any of the topics in supplement regulation, this should have been the top priority. The industry has urged the FDA to set a standard for Good Manufacturing Practices (GMPs) in order to assure consumer protection. As yet, the FDA has not done so.

Dietary Supplement Commission on Labels: This Commission created as a result of the legislation spent two years developing suggestions to the FDA. We have stated on the record that we felt the Commission did not fulfil the mandate outlined by Congress. We will hear from three members of this Commission today.

Structure/Function: In April 1998, the FDA published a proposed rule defining the types of statements that can be made concerning the effect of dietary supplements on the structure or function of the body. This is one of the cornerstones of the Dietary Supplement Health and Education Act which allows for statements on the benefits of dietary supplements on structure and function, but prohibits claims that supplements treat or prevent disease. The agency received over 100,000 comments regarding this issue which clearly indicates that the proposed regulation is fraught with problems. Of particular concern is that the FDA redefined the word "disease" in such a manner that it could include conditions such as aging, menopause, and pregnancy. This new definition so broadens the definition as to exclude any useful structure function statement. If this rule became final, it would be in direct contradiction to the Dietary Supplement Health and Education Act's intent of improving the amount of information available on labels and in labeling.

Authoritative Statement Health Claim: A proposed rule has been published regarding the use of health claims based on authoritative statements for dietary supplements under the notification procedures established in the Food and Drug Modernization Act. The Committee's concerns have included that FDA's nine interim final rules misinterpret Section 303 of the FADMA which were intended to serve as an alternative to health review under the Significant Scientific Agreement Standard. Congress intended that FDA authorize health claims if they were based on authoritative statements published by Federal health agencies. We are pleased to learn that a public meeting is planned for May to further discuss this topic.

Pearson Versus Shalala: A recent court case in the U.S. Court of Appeals for the DC Circuit addressed the health claims issues. In this case, it was found that the FDA violated the first amendment by refusing to use disclaimers and authorize health claims.

The FDA also violated the first amendment by prohibiting four specific health claims. Additionally, the Court ruled that the FDA violated the Administrative Procedure Act by refusing to define its health claims review standard for dietary supplements. I joined several of my colleagues in the Congress urging the FDA not to waste taxpayer dollars by dragging this case through a long appeals process. We have learned that the FDA has indeed appealed this case.

Pharmanex's Cholestin: We will hear today from one of the attorney's from the Cholestin case about how the FDA caused a long intense court battle over the introduction into the U.S. market of a dietary supplement containing red yeast powder, attempting to force it through the arduous drug clearance process. A Salt Lake City judge recently ruled that red yeast powder was a dietary supplement not a drug.

Adverse Events Reporting: We have been in communication with the FDA about our concerns that this system is so poorly constructed as to be a waste of taxpayer dollars. In our investigation, we have learned that this reporting system, while a vital link in the regulation of supplements, is not accurate and while the FDA recognizes that the system is problematic, has used information derived from this system in policy setting. We have learned from manufacturers that even when deaths are reported on this system, that the FDA does not communicate this back to the manufacturer and work with them to determine if the death report is accurate and if the dietary supplement proposes a risk to the public. This reporting system will be the subject of another hearing in the near future.

Ephedra: Also known as Mu Huang, a substance used safely for thousands of years, Ephedra has raised controversy. We have concerns that the decision making on this substance is not based on the science, but on faulty reporting and a long-standing bias in the agency against this product. I recently joined colleagues in the Congress to urge the Secretary of Health and Human Services and the Secretary of State to oppose a United Nations measure to make ephedra, ephedrine products Schedule IV products under the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. This would mean that a prescription by a DEA approved physician would have been required to purchase dietary supplements containing ephedra as well as over the counter products for asthma and hemorrhoid ointments. We are pleased that in the meetings earlier this month that indeed the measure was returned to the WHO for reconsideration. This will also be the topic of a future hearing in conjunction with the Adverse Events Registry.

Stevia: Stevia has been imported in the United States as a dietary supplement. Stevia is used in other countries as a natural sweetener. One store owner, Texas was selling books that discuss the use of Stevia in cooking. This product has not been cleared in the United States as a food additive. The FDA sent agents into company headquarters and demanded that the owner get rid of his Stevia cooks books. The FDA sent a letter stating that Federal agents would witness the destruction of the books. In this case, FDA overstepped its bounds and violated his first amendment rights.

CODEX: We have grave concerns that the United Nations is promulgating global harmonization regulations that would have an adverse effect on the availability of products, imposing upper limits and other restrictions on dietary supplements. We adamantly oppose this interference and will be calling a hearing this year to discuss the topic and its implications not only for the American consumer, but to the devastating effect on US manufacturers for the international market.

Attachment B**FDA has the power to:**

- Refer for criminal action any company that sells a dietary supplement that is toxic or unsanitary [Section 402(a)]
- Obtain an injunction against the sale of a dietary supplement that has false or unsubstantiated claims [Section 403(a),(r6)]
- Seize dietary supplements that pose an "unreasonable or significant risk of illness or injury" [Section 402(f)]
- Sue any company making a claim that a product cures or treats a disease [Section 201(g)]
- Stop a new dietary ingredient from being marketed if FDA does not receive enough safety data in advance [Section 413]
- Stop the sale of an entire class of dietary supplements if they pose an imminent public health hazard [Section 402(f)]
- Require dietary supplements to meet strict manufacturing requirements (Good Manufacturing Practices), including potency, cleanliness and stability [Section 402(g)]

Additionally, industry self-regulatory efforts supplement these governmental powers, as do Federal Trade Commission powers over advertising and state safety laws.

Mr. BURTON. We have heard interviews in the media from FDA officials that, since the passage of the Dietary Supplement Health and Education Act, FDA has no authority to regulate dietary supplements. This is not a factual statement. In fact, the FDA has several specific authorities that are listed on the poster and I think we have that poster someplace. Do you want to put that up there? Those who are interested can take a closer look at that. I'm sorry the print is a little bit small. Do we have a handout? Mr. Waxman's asked for one, so if we could get that, we would like to have it.

As for the safety of supplements, an interesting comparison was published last year; 106,000 people die a year from prescription drugs; 42,000 a year from automobile accidents. It is more likely that you will be struck by lightning and die in this country than it is that you will die from using a dietary supplement, with just 16 deaths reported from that last year. We wish to continue to work with the FDA to assure that these numbers do not increase. Research to learn more about drug interactions will help, as well as a better reporting system.

The primary focus of today's hearing with the FDA will be the proposed rule on structure function statements. The Dietary Supplement Health and Education Act was explicit in allowing for manufacturers to include information on labels regarding the benefits of a supplement on the structure or the function of the body, while specifically not allowing for disease claims to be made. The proposed rule does not comply with the legislation. Instead, this proposed rule would supersede legislation passed by the Congress and be in direct opposition to the will of Congress and the American people.

We are delighted today to hear from Miss Raquel Welch, who will be with us shortly. She is a lovely lady who has entertained us in her many movie and stage performances. And she will share with us how she uses dietary supplements to maintain good health. And I just found out a few minutes ago that she is one of your constituents, Mr. Waxman. It's kind of nice to know you have one of the most beautiful women in the world in your district, don't you think? [Laughter.]

We will also hear today from Scott Bass. I don't know how beautiful Scott is. Where are you Scott? [Laughter.]

He is an adjunct professor at Georgetown University and an attorney with the law firm of Sidley and Austin. Mr. Bass is a legal expert on dietary supplements and will outline for us the history of dietary supplement legislation and the effect of proposed structure function regulations.

We will also hear from Daniel Kracov of Patton Boggs, regarding one of the laws involved in the Cholestin case. I think that was just resolved recently. He will share with us information about Pharmanex's interactions with FDA and the legal case.

There is an increasing amount of research being published on the benefits of dietary supplements. A week does not go by that the press does not report on the benefits of some of these supplements. Dr. Edward Croom of the University of Mississippi will discuss the role and the level of research in botanicals, as well as outline the need for further research. Dr. Croom has been called an advisor to

many Federal agencies as well as international organizations such as the World Health Organization.

We will also be hearing from three members of the Dietary Supplement Commission on Labeling. Robert McCaleb, president of the Herb Research Foundation; Dr. Annette Dickinson, from the Council for Responsible Nutrition; and Margaret Gilhooley, of Seton Hall Law School.

We will also hear from Attorney James Turner, chairperson of Citizens for Health, a consumer advocate organization. In addition to dietary supplement issues, Mr. Turner worked with the FDA on reclassification of acupuncture needles.

I am pleased that my colleagues in the Senate, Senators Tom Harkin and Orrin Hatch, have been supportive of our efforts to resolve these issues. I think we have a couple of staff people from Senator Hatch's office with us today. Both Senator Harkin and Senator Hatch were instrumental in passing the Dietary Supplement Health and Education Act in 1994. Additionally, colleagues here in the House, Congressman Dennis Kucinich, who is on our committee, and Peter DeFazio have worked diligently to ensure that Americans have health freedom.

We have shown that good health is not a partisan issue. We have shown on this committee that there is interest in assuring that Americans have the right to make their own health care choices and have access to an integrated system of healing on both sides of the aisle. And, toward that end, we will hold the record open until April 8 to allow written submissions for the record from members of the committee.

I now recognize my colleague, Mr. Waxman, for his opening statement.

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

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OPENING STATEMENT
CHAIRMAN DAN BURTON
COMMITTEE ON GOVERNMENT REFORM

**“Dietary Supplement Health and Education Act: Is the
FDA Trying to Change the Intent of Congress?”**

Thursday, March 25, 1998

10:00 AM

Room 2154, Rayburn House Office Building

Washington, D.C.

Good morning. We are here today to talk about the implementation of the Dietary Supplement Health and Education Act (DSHEA) by the Food and Drug Administration (FDA). At our hearing in February we heard from the delightful Jane Seymour about her use of complementary and alternative medicine, including herbal products and other dietary supplements to maintain good health for herself and her family. At that hearing we also heard from Dr. Brian Berman of the University of Maryland about the importance of research to the use of dietary supplements such as Glucosamine to help Americans with arthritis and ginkgo biloba in delaying the onset of Alzheimer's disease. The potential cost savings to the Federal Government in these two debilitating illnesses is enormous, and certainly justifies more research funding. In our March 10 hearing on Chelation Therapy, we learned from a panel of expert physicians that dietary supplements can be used in conjunction with chelation therapy to improve circulation and cardiovascular health.

In studying various alternative systems of healing, whether it is Ayurveda, Native American healing, or Traditional Chinese Medicine, two currents run through each of these systems – the importance of spirituality in healing and the important role of botanical products and nutrition in healing.

The Food and Drug Administration does a very good job of protecting the public. We are pleased that the new FDA Commissioner is joining us today to discuss the improvements she is making to assure that the FDA continues to protect the public and facilitate patients access to clinical trials.

Congress passed the Dietary Supplement Health and Education Act in 1994. The American people demanded to be heard on this issue and Congress listened to them. More letters and faxes were received on this topic than any other single piece of legislation in history. Over 50 percent of the American people use dietary supplements on a regular basis to improve their health. I personally began using supplements after a telephone conversation with Nobel Prize winning scientist Linus Pauling, who told me that high doses of vitamin C would help prevent cancer. That conversation was so convincing, that I have continued to take vitamin C to this day.

Every member of Congress is pulled in many directions at once every day. We work long, exhausting hours under great deals of stress. I was delighted to learn in our February hearing from my colleague on the Committee, Helen Chenoweth, that she has successfully used the dietary supplement zinc in the treatment of a rare disorder, Meniere's disease. It has helped her stay healthy and prevent brain surgery. I think that the Office of Dietary Supplements and the Office of Rare Diseases at the National Institutes of Health need to work together to determine where dietary supplements can be helpful in the treatment of rare diseases and disorders and to make this information known to the public.

When Congress passed the Dietary Supplement Health and Education Act, it was made very clear that Americans would have access to these products, and that information was a key factor. Quality, accurate, useful information on the labels, in the labeling, and in third party literature, is vital to American's need to make informed, safe choices. This is the cornerstone of this first hearing on dietary supplements.

The Committee has been in frequent contact with FDA on a variety of concerns about proposed rule making as well as the actions of the FDA on a variety of topics in this area. It is particularly timely that we begin this discussion now as there is a new Commissioner of Food and Drugs, Dr. Jane Henney, who will testify this morning. There are several issues of concern in this area.

We cannot address each of the topics regarding dietary supplements in depth today; however, they do warrant mentioning.

- Nutritional labeling,
- Good Manufacturing Practices,
- Dietary Supplement Commission,
- Structure Function Statement and the Redefinition of Disease,
- Authoritative Statement Health Claims,
- Pearson Versus Shalala,
- Pharmanex's Cholestin,
- Adverse Events Reporting,
- Ephedra,
- Stevia, and
- CODEX.

(See Attached).

We have heard interviews in the media from FDA officials that since the passage of the Dietary Supplement Health and Education Act, FDA has no authority to regulate dietary supplements. This is not a factual statement. In fact, the FDA has several specific authorities (See Attached).

As for the safety of supplements, an interesting comparison is also attached. 106,000 people die a year from prescription drugs, 42,000 a year from automobile accidents. It is more likely that you will be struck by lightning and die in this country than it is that you will die from using a dietary supplement with just 16 deaths reported last year. We wish to continue to work with the FDA to assure that these numbers do not increase. Research to learn more about drug interactions will help as will a better reporting system.

The primary focus of today's hearing with the FDA will be the Proposed Rule on Structure/Function Statements. The Dietary Supplement Health and Education Act was explicit in allowing for manufacturers to include information on labels regarding the benefits of a supplement on the structure or function of the body, while specifically not allowing for disease claims to be made. The proposed rule does not comply with the legislation. Instead, this proposed rule would supercede legislation passed by Congress.

We are delighted to hear today from Ms. Raquel Welch. She has wooed us in her many movie and stage performances. She will share with us today how she uses dietary supplements to maintain good health.

We will also hear today from Scott Bass. He is an Adjunct Professor, Georgetown University, and an attorney with the law firm Sidney and Austin. He is a legal expert on dietary supplements, and he will outline for us the history of dietary supplement legislation and the effect of proposed structure/ function regulations.

We will also hear from Daniel Kracov of Patton Boggs, one of the lawyers involved in the Cholestin case. He will share with us information about Pharmanex's interactions with FDA and the legal case.

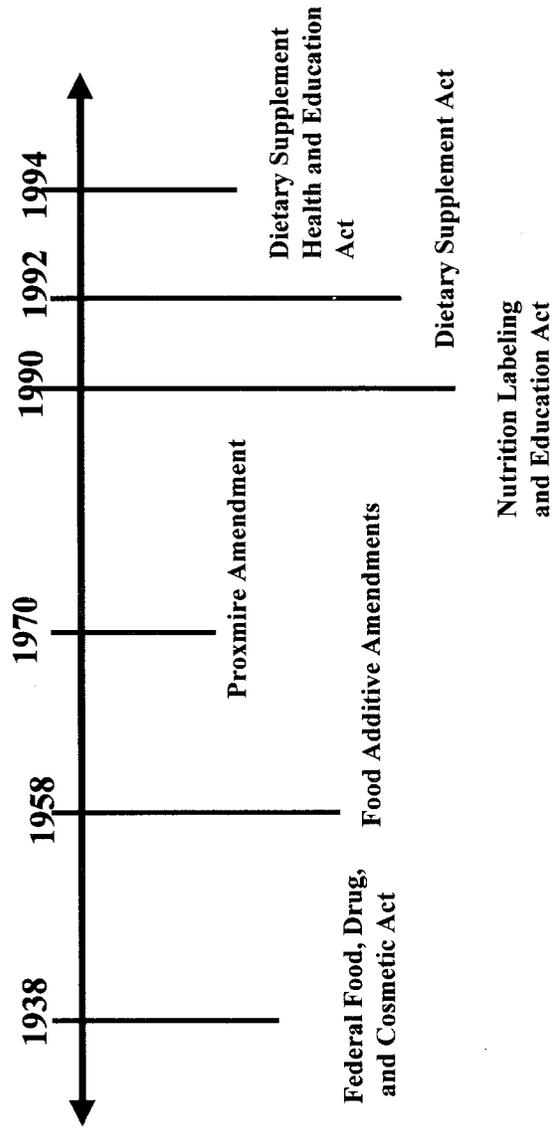
There is an increasing amount of research being published on the benefits of dietary supplements. A week does not go by that the press does not report on the benefits of supplements. Dr. Edward Croom of the University of Mississippi will discuss the role and level of research in botanicals as well as outline the need for further research. Dr. Croom has been called as an advisor to many Federal agencies as well as international organizations such as the World Health Organization.

We will also be hearing from three members of the Dietary Supplement Commission on Labeling. Robert McCaleb, President of the Herb Research Foundation, Dr. Annette Dickenson, from the Council for Responsible Nutrition and Margaret Gilhooley, of Seton Hall Law School. We will also hear testimony from attorney James Turner, Chairperson of Citizens for Health, a consumer advocate organization. In addition to dietary supplement issues, Mr. Turner worked with the FDA on the reclassification of acupuncture needles.

I am pleased that my colleagues in the Senate, Tom Harkin and Orrin Hatch have been supportive of our efforts to resolve these issues. They both were instrumental in passing the Dietary Supplement Health and Education Act in 1994. Additionally, colleagues here in the House, Congressmen Dennis Kucinich and Peter DeFazio have shown worked dilligently to insure that Americans have health freedom. We have shown that good health is not a partisan issue. We have shown on this Committee that there is interest to assure that Americans have the right to make their own health care choices and have access to an integrated system of healing on both sides of the isle.

We will hold the record open until April 8 to allow written submissions to the record.

Legislative History of Dietary Supplement Regulation



DIETARY SUPPLEMENTS HOW SAFE ARE THEY REALLY?

When compared to prescription drugs, very safe. In fact, according to statistics compiled by the National Nutritional Foods Association, Americans have a greater chance of being killed by lightning than dying from consuming supplements, as the chart below indicates.

ANNUAL DEATHS & THEIR CAUSES

Prescription Drugs

106,000

Motor Vehicle

42,000

Salmonella

9,000

Struck by Lightning

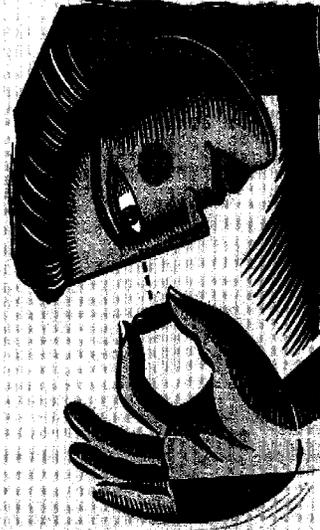
89

Skating

79

Dietary Supplements

16



Proposed New Definition of Disease

“Any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms (including laboratory or clinical measurements that are characteristic of a disease), or a state of health leading to such a deviation, impairment, or interruption; except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included within this definition.”

Mr. WAXMAN. Thank you very much, Mr. Chairman. I have a number of remarks I want to make about the topic of dietary supplements. But, before I do, I want to welcome FDA Commissioner Henney.

Commissioner Henney was sworn in only a few months ago and I understand this is the first time she has appeared before our committee. As her written testimony indicates, she has identified five priorities for FDA, including enhancing the agency's science base, protecting the Nation's food and blood supply, and reducing teen smoking. These are essential priorities for improving and protecting the health of the American people. It is crucial that we in Congress work with Commissioner Henney in achieving these priorities.

Today's hearing addresses an issue that I have been involved in for years, dietary supplements. Five years ago, I worked with Senator Hatch and my colleagues on the Commerce Committee in crafting the Dietary Supplement Health and Education Act of 1994. Since I was intimately involved in the negotiations that produced the legislation, I think I am in a good position to address the topic of this hearing, the "Dietary Supplement Health and Education Act: Is FDA trying to change the intent of Congress?"

It is clear to me that the FDA is doing a good job implementing a complex, challenging, and sometimes deliberately ambiguous law. The law we enacted in 1994 was a series of compromises. DSHEA allowed makers of supplements to market their products without having to demonstrate that they are safe or effective, but, at the time, it authorized FDA to remove products that are later proven to be dangerous from the market. It allowed manufacturers to claim that dietary supplements will benefit the structure or function of the body but, at the same time, it prohibited manufacturers from making unproven claims that supplements will cure diseases. Our hope was that the law would balance the goal of providing consumers with wide access to dietary supplements and the goal of protecting consumers from dangerous or ineffective products.

Today we will hear arguments that Congress did not intend for the FDA to have an active role in protecting the consumer from dangerous products being sold as dietary supplements. We will also hear that FDA's recent efforts to protect the consumer are inappropriate and heavy-handed intervention. This is simply erroneous. When we passed DSHEA, we knew that many dietary supplements, such as minerals and vitamins, can play an important role in promoting health. But we also knew that, without proper regulation, dietary supplements can sometimes be lethal.

We knew that L-tryptophan, a product that was marketed in the 1980's as a sleep aid, was linked to EMS, a painful, debilitating, and sometimes fatal disease. At least 1,500 people were struck with this disease and at least 38 people died from it before FDA issued regulations banning L-tryptophan.

Events since enactment of DSHEA have confirmed the need for an active FDA. Sometimes it seems that there is a new article about the dangers of dietary supplements every month. For example, in 1997, the Washington Post reported about the danger of Nature's Nutrition Formula One, which contained a dietary supplement called ephedra. Products like Nature's Nutrition Formula

One and other products containing ephedra like herbal ecstasy and herbal fen-phen are marketed for weight loss, energy boost, and natural high. But, in fact, according to the Washington Post, these products have been linked to at least 38 deaths. FDA also received hundreds of reports of other adverse events associated with products containing ephedra. These adverse events included increased blood pressure, chest pains, insomnia, heart attack, stroke, psychosis, and seizure.

More recently, in March 1998, FDA warned consumers against Sleeping Buddha, a product being marketed as a dietary supplement, but which actually contains a prescription-strength drug ingredient, Estazolam, which is known to have serious side effects, including potential damage to a fetus if consumed by a pregnant woman. Earlier this year, FDA issued a warning against dietary supplements containing GBL, a substance marketed as a performance enhancer. When GBL is taken orally, it is converted in the body to GHB, a potent and unapproved drug. GBL has been associated with at least 55 incidents of adverse health affects, including seizures, vomiting, comas, and death. Five of the reported victims were children under 18 years of age.

These are not the only products that have caused problems. For example, certain teas with plant-derived laxatives have been associated with the deaths of four young women. And, as Commissioner Henney states in her testimony, which we had an opportunity to read in advance, some dietary supplements containing the ingredient plantain were actually contaminated with digitalis, a powerful stimulant which can cause nausea, vomiting, dizziness, headache, confusion, low blood pressure, vision trouble, and abnormal heart rate and heart rhythm.

I don't recite these examples in order to alarm the public or criticize the dietary supplement industry. There are many important and effective dietary supplements on the market. But the purpose of DSHEA was to make these products available and to ease the fears that many people had that the products would be removed from the market or they would have to go to the doctor to get a prescription simply to get a vitamin. We made clear that we weren't going to permit that sort of practice. No one disputes the importance of products such as calcium in maintaining healthy bones or the link between folic acid and the prevention of certain birth defects. Consumers need to learn about these products.

My point is that we need an active and vigilant FDA to help us weed out the dangerous dietary supplements and identify the safe and effective ones. The answer isn't to attack FDA every time the agency takes even baby steps toward regulating dietary supplements. The answer isn't to criticize the agency for failing to adhere to the intent of Congress when, in fact, the agency is trying its best to implement a complex and ambiguous law. Instead, the answer is to establish a regulatory framework for dietary supplements at FDA that appropriately balances the interests of consumer access and public health. This position is supported by a variety of consumer groups, including the American Dietetic Association, which

represents nearly 70,000 food and nutrition professionals. And I would like, Mr. Chairman, to ask that the statement of the American Dietetic Association be entered into the record.

Mr. BURTON. Without objection.

[The prepared statement of the American Dietetic Association follows:]



THE AMERICAN DIETETIC ASSOCIATION

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**Statement of
The American Dietetic Association
House Government Reform Committee Hearing
Food and Drug Administration Regulations on Dietary Supplements
March 25, 1999**

The American Dietetic Association (ADA) represents nearly 70,000 food and nutrition professionals serving the public through the promotion of optimal nutritional health and well being. ADA endorses the need for consumers to have a choice regarding dietary supplements, as long as that choice is made in the context of accurately informed choice and appropriate public safety measures. To this end, ADA supports the need for stricter regulation and oversight of dietary supplements and the efforts of the Food and Drug Administration. The comments below reflect statements ADA has made publicly to FDA and the Commission on Dietary Supplement Labels on dietary supplement regulations.

Claims of Nutritional Support (Structure/Function Claims) and Health Claims

ADA believes that health claims and statements of nutritional support authorized for dietary supplements should be based on the totality of the publicly available scientific evidence, including results from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles.

ADA supports FDA's attempts to more clearly define structure/function claims and generally agrees with the agency's definition of disease. However, while ADA agrees that guidance on such label statements is needed, the proposed rule on structure/function claims (*Federal Register*, Vol. 63, No. 82, April 29, 1998) highlights the inadequacies of such claims and the potential for consumer confusion. No guidance to industry or attempt to define structure/function claims will solve what is generally viewed by the scientific community as one of the many challenges created by the Dietary Supplement Health and Education Act of 1994 (DSHEA). The Presidential Commission On Dietary Supplement Labels emphasized this challenge when it stated that "It can be difficult, however, to clearly distinguish an allowable structure/function statement of nutritional support from one that might be considered an unauthorized health or drug claim." (*Final Report of the Commission on Dietary Supplement Labels*, Nov. 1997, page 36)

Authoritative Statements

FDA's implementation of the Food and Drug Administration Modernization Act of 1997 (FDAMA) provisions regarding the use of authoritative statements as the basis for health claims is accurate and reflects both the intent of the law and the Congress.

As specifically stated in the House Report (*H.R. REP. NO. 105-306*) accompanying FDAMA, this legislation maintains the rigorous scientific standard health claims must meet under existing law. The House Report goes even further than the Nutrition Labeling and Education Act of 1990 and FDA's implementing regulations regarding health claims by stating that authoritative statements for health claims must be supported by "scientific consensus to the extent the Secretary considers appropriate to allow the claim." When passing FDAMA, Congress clearly and appropriately intended that health claims based on authoritative statements should be supported by significant scientific agreement (*S. REP. NO. 105-43*, page 49).

Mr. WAXMAN. I have learned one thing about dietary supplements over the years. It is that we also need to reduce the mistrust and polarization that has surrounded this issue for far too long. I don't think it is in the interests of those who support dietary supplements to have products on the market that harm people because then the public will be distrustful of all dietary supplements. I don't think it is helpful for the American people to allow products to be marketed with claims that are made for which there is no substantiation and no validity. This is going to lead to cynicism and distrust.

I believe that Commissioner Henney understands this and I look forward to hearing her ideas and those of the other witnesses about dietary supplements. I am pleased to welcome Raquel Welch, who is one of my constituents, and all the other witnesses that we have scheduled for today. This is an issue that engenders a lot of interest because there is nothing more important than trying to protect the health of the American people.

Mr. BURTON. I understand that Dr. Henney is under time constraints. If any Members would like to make a brief opening statement, we will allow it, but, otherwise, we will just have them submitted for the record. With that, Dr. Henney, would you like to come forward?

Mrs. Chenoweth, would you like to have your statement submitted for the record? Without objection, so ordered.

[The prepared statements of Hon. Helen Chenoweth, Hon. Benjamin A. Gilman, and Hon. Dennis J. Kucinich follow:]

Statement of Representative Helen Chenoweth
Committee on Government Reform
Regarding the FDA's Jurisdiction Over Dietary Supplements
March 25, 1999

Thank you, Mr. Chairman. It is a pleasure to be here today. As anyone who knows me well will tell you, I am a very big supporter of dietary supplements.

My own personal experiences with herbal treatments and with a daily vitamin regimen have taught me not only the importance of dietary supplements, but also of the great diversity of human physiology. Working with herbalists and specialists in the field I have created an overall plan for my own health that is tailored for me and fits my unique physiology and lifestyle.

It has become very clear to me that when it comes to health, one size does not fit all. Lifestyles vary, physiologies vary, mental and emotional needs vary. It is simply unreasonable to put arbitrary restrictions on health care options. Restrictions remove from individuals the right to decide for themselves what they need and what tradeoffs they are willing to make.

Dietary supplements are not drugs. Dietary supplements are not controlled substances. Dietary supplements are naturally occurring and rarely contain chemicals. The Dietary Supplement Health and Education Act of 1994 was right on in recognizing that dietary supplements are more closely related to food than to drugs.

And yet the FDA insists on trying to regulate dietary supplements as drugs. This lumbering bureaucracy is trying to determine how best to meet the individual health needs of over 250 million people. That's a pretty ambitious project. The FDA is consistently stretching the limits of the Dietary Supplement Health law in order to impose more restrictions on these excellent alternatives to drug therapy and sometimes to surgery.

For example, the FDA has ruled that it is *illegal* for companies who market psyllium to speak about the benefits of this nutrient. *Illegal to speak*. The FDA took it upon itself to alter this little bit of the Constitution without bothering to check with the rest of us on it. Interestingly, and I believe one of our witnesses here today, Susan Haeger, will have something to say about this -- that rule was tested by Durk Pearson and Sandy Shaw of Nevada. They sued the FDA for violation of the First Amendment, and won.

I hope that we are able to get some answers today about this case and about its impact on the health and well being of the American people. I appreciate very much the opportunity to pursue this, and I thank the Chairman for calling this hearing.

Rep. Benjamin Gilman
Statement for Govt Reform Hearing on Dietary Supplements
March 25, 1999

PASSAGE OF THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994 (**DSHEA**) HAS BROUGHT ABOUT A NUMBER OF IMPORTANT IMPROVEMENTS FOR THE MILLIONS OF AMERICANS WHO REGULARLY CONSUME DIETARY SUPPLEMENTS TO PROTECT AND IMPROVE THEIR HEALTH. **DSHEA** GUARANTEES THE RIGHT OF AMERICANS TO HAVE ACCESS TO THE TRADITIONAL SUPPLEMENTS THAT CONSUMERS HAVE USED FOR A NUMBER OF YEARS AND NEW PRODUCTS THAT ARE JUST BEGINNING TO HIT THE MARKET TODAY. **DSHEA** ENSURES THAT THESE NEW PRODUCTS ARE SAFE AND PROPERLY LABELED FOR SALE IN THIS COUNTRY.

STUDIES AND TESTIMONIAL STATEMENT FROM CONSUMERS HAVE SHOWN THAT SUPPLEMENTS CAN AND DO PROMOTE GOOD HEALTH. HOWEVER, THE **FDA'S** SLOW ACKNOWLEDGEMENT OF THE BENEFITS OF DIETARY SUPPLEMENTS HAS BROUGHT US HERE TODAY. WITHOUT **DSHEA**, THERE IS NO UNIFORM QUALITY OF PRODUCTS AND A LACK OF INFORMATION ABOUT THESE SUPPLEMENTS AVAILABLE TO THE PUBLIC. ONCE THE REGULATIONS ARE IN PLACE AND PRACTICED, CONSUMERS WILL BE CONFIDENT THAT THE SUPPLEMENTS ARE SAFE AND REGULATED. WE MUST MAKE SURE THAT THE **FDA** IMPLEMENTS **DSHEA** AS PRESCRIBED FOR IN THE ACT OF 1994.

I AM PLEASED THAT THE NEW **FDA** COMMISSIONER MS. JANE HENNEY HAS TESTIFIED HERE THIS MORNING THAT SHE IS DEDICATED TO HELP THE **FDA** FAIRLY INTERPRET,

IMPLEMENT AND ENFORCE THE PROVISIONS OF **DSHEA** AS THEY WERE INTENDED WHEN CONGRESS PASSED THE ACT. WHILE SOME HAVE ARGUED THAT **DSHEA** IS FULL OF COMPLEX QUESTIONS OF FACT, POLICY AND LAW, IT IS THE DUTY OF THE **FDA** AND ITS COMMISSIONER TO ENACT **DSHEA** AND PROVIDE THE AMERICAN CONSUMER WITH SAFE AND REGULATED DIETARY SUPPLEMENTS.

**OPENING STATEMENT
CONGRESSMAN DENNIS D. KUCINICH
GOVERNMENT REFORM HEARING
MARCH 25, 1999**

Mr. Chairman, fellow Committee members, and members of the panel, thank you for providing us with this forum to discuss Dietary Supplements. Again the Committee is allowing us the chance to increase our acceptance of a relatively new entity in providing for a healthier population. I look forward to advancing our understanding of these issues and determining how we go about increasing the public's knowledge and access to beneficial products while at the same time providing them in a manner that is safe.

Through previous hearings held by this Committee we have learned that Complimentary and Alternative medicine is a growing specialty within modern medicine. We have also learned that gaining acceptance can be a somewhat difficult process and perhaps rightly so. I believe that anything that can benefit the health of the people around the world must be made available and shared. I also believe that it must be safe and proven with a tested scientific basis.

Understandably, dietary supplements are growing in popularity. Anything that offers individuals a choice or aid in providing for their own well being is needed. We must, however, determine where the line is drawn between food and drug. Because of so many rapid advances in our understanding of natural products and their use in modern medicine and nutrition, this is becoming an ever graying area. We must allow healthy products into the marketplace, but we also have a duty to

determine if their benefits outweigh their risks.

I sympathize with the fact that the FDA has an unenviable task in attempting to protect the American Consumer from harmful products while allowing wholesome and beneficial products onto the market. This is a tight rope for an agency to walk and if they were to err, I would prefer it to be on the side of safety. I look forward to hearing from Dr. Henney on how the FDA defines this gray area between food and drug and how they go about their task of regulating a dietary supplement. I also look forward to hearing about any advances the FDA may have made on this issue.

I am happy to see that we have another panel that has the courage to share their experiences with this Committee. I say courage because anything that is still new or under speculation always has a large amount of critics, and to stand up for something you believe in is courageous. Without the ability to bring positive experiences into the open we fail at the democratic process. I thank the panel for exercising their democratic right.

Mr. BURTON. We will do it for everyone, yes.

Dr. Henney, would you like to come forward? You can still stand. We normally swear in our witnesses.

[Witness sworn.]

Mr. BURTON. Welcome, Dr. Henney, and congratulations on your new appointment. We are anxious to hear what you have to say, so you are recognized to make an opening statement.

STATEMENTS OF JANE HENNEY, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY JOE LEVITT, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, AND MARGARET PORTER, CHIEF COUNSEL

Dr. HENNEY. Mr. Chairman and members of the committee, my name is Dr. Jane Henney. I am accompanied this morning by Dr. Joe Levitt, who is the Director of the FDA Center for Food Safety and Applied Nutrition, and Margaret Porter, our Chief Counsel. I am honored to address you, as the Commissioner of Food and Drugs, and pleased to be here today to discuss the implementation of the Dietary Supplement Health and Education Act of 1994.

Because this is my first appearance before this committee as Commissioner, I would like to take this opportunity to briefly share my priorities for the FDA. I hope that they will provide a context for our dialog today and in the future. My first priority is the full and effective implementation of the FDA Modernization Act. I intend to build on this collaborative, constructive model by working closely with the Congress, the regulated industry, patients, consumers, and health professionals.

My second priority is enhancing the agency's science base. To meet our statutory obligation to regulate cutting edge scientific discovery and development, we must have cutting edge expertise in our staff. We must also harness the scientific expertise of those outside the agency.

My remaining three priorities are also those of the administration, the safety of our food supply, the safety of our blood supply, and reducing tobacco use by young people.

Beyond these priorities, the agency must use its finite resources wisely. We must focus on those areas that maximize public health promotion and protection. And this is the perspective with which we approach implementation of the Dietary Supplements Act of 1994.

I know that this statute was passed with broad, bipartisan support. I know that you and others in Congress worked hard to develop an appropriate statutory scheme that would facilitate consumers' access to dietary supplements, as well as to provide FDA with the authority to remove products from the market if they present a significant or unreasonable risk of illness or injury. I know that many Americans place great faith in dietary supplements to maintain and improve their health. And I know that the scientific evidence documenting the benefits of a number of supplements is increasing.

With these facts in mind, I want to assure you that, as the new Commissioner of the Food and Drug Administration, I am focusing attention on dietary supplements. Last month, FDA's Center for Food Safety and Applied Nutrition published a 1999 program prior-

ities document. This document includes on its A list for completion an overall dietary supplements strategy by the end of the year. I am committed to developing a comprehensive strategy for effective regulation of dietary supplements. And in so doing, to reach out to those affected by our regulation and to listen receptively to their views.

I am equally committed to ensuring that FDA's implementation of the statute is true to congressional intent. Congress has given a challenge to the FDA under this statute to strike the right balance between preserving consumer access to potentially health-improving supplements, while assuring the safety and proper labeling of these products. I think it is clear that the agency still has a way to go both in developing a workable regulatory framework and in achieving full implementation of the Dietary Supplement Act of 1994.

I want to take this opportunity to acknowledge our progress, shortcomings, and remaining challenges. Let me first note that the dietary supplement marketplace has changed significantly since the passage of the act. The dietary supplement industry itself has grown exponentially. So have the number of Americans buying these products. Surveys show that more than half of the U.S. adult population now uses dietary supplements, spending upwards of \$12 billion per year on these products.

Access to dietary supplements also has changed. In the past, with the exception of vitamin and mineral products, dietary supplements were available primarily in health food stores. Dietary supplements were marketed principally to adults. Now a wide range of dietary supplements are available in supermarkets and via the Internet. This makes dietary supplements readily available to children and adolescents, as well as to adults.

Many of these changes would appear to be consistent with the intent of the Dietary Supplements Act of 1994. However, a rapidly expanding industry and a changing demographic mix of consumers eager to manage their own health care present significant regulatory challenges, many of which were not foreseen at the time the act was passed.

Let me turn to FDA's progress to date in implementing the Dietary Supplements Act of 1994. Initially, the agency concentrated on publishing the many regulations mandated by the statute. The agency also began a number of other regulatory actions to establish the framework for implementation of the new law.

Since the passage of the statute, FDA has published 25 Federal Register notices regarding dietary supplements. These notices, which are described in more detail in my written testimony, include a final rule requiring that all dietary supplement labels carry nutrition information in a box, entitled "supplement facts," which became effective just this week; an advance notice of proposed rule-making on good manufacturing practice that would assure purity and consistency for dietary supplements; and a proposed rule to permit health claims on dietary supplements, based on authoritative statements.

Notwithstanding these actions, I want to acknowledge that FDA has a long way to go to achieve full implementation of the Dietary Supplement Act of 1994. I mentioned earlier that the agency in-

tends, this year, to issue an overall strategy for regulation of dietary supplements. The strategy will address all of the elements of an effective dietary supplement program, including defining the boundaries between dietary supplements and conventional foods and between dietary supplements and drugs; claims made for dietary supplements; good manufacturing practice or GMP regulations; adverse event reporting, review, and followup; laboratory capabilities; research needs; enforcement; and, finally, resource needs.

I would like to note here that, while the agency may not have moved quickly on this in the past, we are committed to accelerating the development and implementation of GMP regulations. FDA also is committed to quickly addressing safety problems that arise with dietary supplements.

Several important regulatory challenges lie ahead for FDA in fully implementing the Dietary Supplement Act of 1994. We must delineate some difficult boundaries between dietary supplements and conventional foods; and between dietary supplements and drugs; and between dietary supplements and cosmetics. We must clarify what types of claims may be made for dietary supplements. And we must be sure we are able to use efficiently the tools Congress provided to us to protect consumers from unsafe products.

Mr. Chairman, we share the goal of making safe dietary supplement products available to consumers who want to make informed personal choices to improve their health. The Dietary Supplement Act of 1994 was enacted to ensure access to those products. I also believe the act provides FDA with the necessary legal authority to protect the public health. We will do our best to marshal the scientific information and expertise necessary to exercise that authority when the public health is threatened.

The dietary supplement industry sells products on which millions of Americans rely. I am aware that in the past, the relationship between FDA and some in the industry has been, at times, antagonistic and counterproductive. I am committed to developing a positive relationship with the industry so that we may, together, meet our shared goal of providing safe products to the American public. The statute is still in its early stages of implementation and I look forward to working with Congress and other interested parties to ensure that resource constraints or other issues do not impede FDA's ability to use this statutory authority most effectively. And I will be happy to respond to any questions the committee may have.

[The prepared statement of Dr. Henney follows:]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

STATEMENT

BY

JANE E. HENNEY, M.D.

COMMISSIONER

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

MARCH 25, 1999

FOR RELEASE UPON DELIVERY

I. Introduction

Mr. Chairman, and Members of the Committee, my name is Jane Henney. I am honored to address you as the Commissioner of Food and Drugs and pleased to be here today to discuss implementation of the Dietary Supplement Health and Education Act (DSHEA) of 1994.

Since this is my first appearance before this Committee as the Commissioner, I would like to take this opportunity to share with you my priorities for the Food and Drug Administration (FDA or the Agency). They will give you context for our dialogue on specific matters today and in the future. My priorities are:

- 1) Full and effective implementation of the FDA Modernization Act (FDAMA). I intend to build on this collaborative, constructive model by working closely with Congress, the regulated industry, patients, consumers, and health care professionals. This means not just implementing the letter of the law but the spirit of the law.

- 2) Enhancing the Agency's science base. It should be a concern to us all that, at the very time the public and private research enterprise in this country is flourishing, the FDA, an essential science-based regulatory Agency, may have difficulty recruiting and retaining strong scientists. If we are to meet our statutory obligations to regulate cutting-edge

scientific discovery and development, we must have comparable cutting-edge expertise in our staff.

The remaining three priorities are not only priorities of the Agency but of the Administration:

- 3) The safety of the Nation's food supply;
- 4) The safety of the Nation's blood supply; and,
- 5) Reducing young people's use of tobacco products.

These priorities are limited in number but encompass many activities. We need to allocate our finite resources wisely and when we undertake activities beyond these priorities we need to do so with deliberation and intention and in the areas of highest public health promotion and protection. This is the perspective from which we approach our implementation of DSHEA.

I understand that this statute was passed with bipartisan support and by the hard work of you and others in Congress in developing an appropriate regulatory scheme that would facilitate consumers' access to dietary supplements. It is important that the Agency's implementation of the statute be true to Congressional intent. As I stated during my confirmation process, I am aware that many Americans place great faith in dietary supplements to help them maintain and improve their health and that the scientific

evidence documenting the benefits of a number of supplements is increasing. The challenge to FDA is to strike the right balance between preserving consumers' access to both products and information and assuring the safety and proper labeling of all of these products. It is clear, with the benefit of hindsight, that we still have a way to go both in achieving full implementation of DSHEA and in developing a workable regulatory framework. I want to take the opportunity to acknowledge our progress, shortcomings, remaining challenges, and commitment to fully implement the statute.

II. Changes Since DSHEA

There have been many changes in the size and scope of the industry and the consumers using dietary supplements, since 1994. Let me briefly outline some of these changes. The dietary supplement industry has grown exponentially since the passage of DSHEA. Surveys show that more than half of the U.S. adult population uses dietary supplement products. Annually, consumers spend approximately \$12 billion on dietary supplements, according to Nutrition Business Journal in their 1998 Annual Industry Overview.

Just as the industry and consumption have grown, access also has changed. In the past, except for vitamin and mineral products,

dietary supplements, particularly botanical products were available mainly in health food stores. These products were marketed principally to adults. Now such products are available in supermarkets and other retail stores, and even via the Internet. This makes dietary supplements readily available to children and adolescents, as well as to adults. While many of these changes would appear to be consistent with the expectations and intent of DSHEA, they nevertheless present new regulatory challenges.

III. DSHEA

DSHEA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to define the term "dietary supplement" and establish a regulatory framework for dietary supplements. In doing so, Congress made 15 significant findings that emphasize the importance of diet and nutrition, including dietary supplement use, in promoting health and reducing the risk of disease. FDA acknowledges these findings. DSHEA provides for broad access to dietary supplements for consumers and also recognizes that there is a need for a rational regulatory framework that provides FDA authority to remove from the market products that pose a "significant or unreasonable" risk to consumers or that are otherwise adulterated and to require that labeling for dietary supplements be accurate.

Congress defined "dietary supplement" to mean products that are intended to supplement the diet that contain one or more of certain dietary ingredients, such as:

- a vitamin or a mineral,
- an herb or other botanical,
- an amino acid,
- a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or
- a concentrate, metabolite, constituent, extract, or
- combination of the preceding ingredients,

and, that meet other criteria specified in Section 201(ff)(2)-(3).

Since Congress considered dietary ingredients marketed prior to passage of DSHEA to be generally safe, dietary supplements containing these ingredients are permitted to be freely marketed, just like regular foods (e.g., fresh fruits and vegetables). If a supplement contains a new dietary ingredient that has not been in the food supply, however, Congress required the manufacturer to notify FDA at least 75 days before marketing, and to include in the notification the manufacturer's basis for its conclusion that a dietary supplement containing the ingredient will reasonably be expected to be safe. There is no requirement that the firm wait for a safety determination from FDA before marketing the product.

Should safety problems arise after marketing, DSHEA makes "adulterated" any dietary supplement that creates a "significant

or unreasonable" risk to consumers, thereby subjecting it to FDA enforcement action. Further, in particularly compelling cases, DSHEA allows the Secretary to ban a dietary supplement if she finds it to be an "imminent hazard."

Finally, as a preventive measure, DSHEA grants FDA explicit authority to establish good manufacturing practice (GMP) regulations for dietary supplements. Such regulations would be intended to establish a mechanism to help assure purity and consistency in dietary supplement products.

Regarding labeling, DSHEA seeks to provide consumers with information to help guide personal choice. This includes specially tailored requirements for ingredient labeling and nutrition labeling.

DSHEA also provides for use of claims to affect the structure or function of the body, claims of general well-being from consumption of a nutrient or dietary ingredient, and claims of benefits related to classical nutrient deficiency diseases. These claims require notification to FDA within 30 days after marketing, must be substantiated, and must be accompanied by the disclaimer: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."

Finally, DSHEA contains ground rules for publications used in connection with the sale of dietary supplements.

IV. FDA's Role in Implementation of DSHEA

In its initial efforts under DSHEA, the Agency concentrated on promulgating the many regulations mandated by DSHEA and began a number of other regulatory actions to establish the framework for implementation of the new statute. Since passage of DSHEA, FDA has published 25 Federal Register notices regarding dietary supplements (see Appendix). Let me briefly discuss a few specific DSHEA regulatory actions we have taken.

- Supplement Facts: On September 23, 1997, FDA published a final rule in the Federal Register implementing the nutrition labeling provisions of DSHEA. As of March 23, 1999, the effective date of the regulation, all dietary supplements must bear nutrition information entitled "Supplement Facts." This labeling is similar to nutrition content labeling for conventional foods but is tailored to the special characteristics of dietary supplements.
- Good Manufacturing Practice: On February 6, 1997, FDA published in the Federal Register an Advance Notice of Proposed Rulemaking requesting comment on whether FDA should

institute rulemaking to develop current GMP regulations for dietary supplements and dietary ingredients. In February 1998, we asked our Food Advisory Committee to establish a working group to assist us in defining GMP for dietary supplements. While we have not moved as rapidly on this rulemaking as we might have, the Agency is committed to accelerating the development and implementation of GMP regulations. I have made it one of my priorities. The general view we have received is that GMP regulations would be a useful tool for both the industry and the Agency. By including GMP regulations in the overall priority-setting strategy, we recognize the importance of such regulations as an effective mechanism for consumer protection. As noted earlier, such regulations would help assure the purity and consistency of dietary supplement products.

- Structure/Function: On April 29, 1998, FDA published in the Federal Register, and sought public comment on, a proposed rule defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. This action is intended to implement the provisions of DSHEA that permit structure/function claims but prohibit claims to treat or prevent disease. The comment period closed on September 28, 1998, and the Agency received over 100,000 comments, many of which addressed the proposed

definition of disease. The Agency currently is reviewing each of the comments, and we will re-evaluate each of the elements of the proposed rule in light of these comments.

- Authoritative Statement Health Claims: On January 21, 1999, FDA published a proposed rule in the Federal Register to permit the use of health claims based on authoritative statements for dietary supplements under the notification procedures established in FDAMA. This proposal tracks the language of Section 303 of FDAMA and would place dietary supplements on an equal footing with conventional foods with respect to health claims based on authoritative statements. On May 11, 1999, a public meeting is planned to gather stakeholder input on the proposal and other issues relating to the Agency's implementation of Sections 303 and 304 of FDAMA.

Many of the proposals referenced in the Appendix, or above, are open rulemakings that are still in progress.

Mr. Chairman, notwithstanding our actions to date, I want to acknowledge that FDA still has a long way to go to achieve full implementation of DSHEA. I assure you that as the new Commissioner of Food and Drugs, I am focusing attention on dietary supplements, an issue that is currently a priority for FDA's Center for Food Safety and Applied Nutrition (CFSAN).

Last month, CFSAN published a 1999 program priorities document which includes on its "A" list completion of an overall dietary supplement strategy by the end of the year. The Agency is committed to developing an overall strategy for achieving effective regulation of dietary supplements under DSHEA, and in doing so, to provide ample opportunity for stakeholder input. In developing its strategy for implementing DSHEA, the Agency will be guided not only by the basic tenets of DSHEA, but also by the priorities I articulated earlier that include commitment to the Agency's mission for promoting and protecting the public health and basing our regulatory decisions on sound science.

The dietary supplement strategy will address all elements of the dietary supplement program, including:

- definitional boundaries between dietary supplements and conventional foods, between dietary supplements and drugs, and between dietary supplements and cosmetics;
- claims;
- good manufacturing practice regulations;
- adverse event reporting, review, and follow-up;
- laboratory capability;
- research needs;

- enforcement; and
- resource needs.

CFSAN also is committed to enhancing outreach efforts to stakeholders to assure effective communication as we move forward with the development and implementation of this strategy.

Mr. Chairman, I think important progress has been made towards achieving the central objective of DSHEA: that of assuring consumer access to safe dietary supplements. At the same time, none of us could have foreseen the great increase in products claiming to be dietary supplements promoted on the Internet and elsewhere. A small but disturbing number of these products have a potential for harm or bear unsupported claims. In this context, a rapidly expanding industry and a changing demographic of consumers eager to manage their own health care needs provide a significant regulatory challenge.

Just as the Agency is committed to implementing DSHEA fully and ensuring consumers have access to dietary supplements, FDA also is committed to quickly removing unsafe products from the market or taking other timely actions to protect consumers. FDA has tools at its disposal to take enforcement actions against dietary supplements found to have safety, labeling, or other violations of the FD&C Act, as amended by DSHEA. The Agency has used a

variety of regulatory tools from enforcement actions to rulemaking, when it has found dietary supplements that cause safety concerns. A good example is digitalis-contaminated plantain.

After being notified of a young woman with life-threatening abnormal heart function who required hospitalization for six days, FDA conducted an investigation. The Agency detected the botanical Digitalis lanata in samples of raw material labeled "plantain" that was an ingredient in one of the dietary supplement products used by this young woman. Digitalis is a powerful heart stimulant whose effects may include nausea, vomiting, dizziness, headache, confusion, hypotension (low blood pressure), vision disturbances, and abnormal heart rate and rhythm.

FDA then traced all uses of the contaminated ingredient and asked manufacturers and retailers to recall these products from the market. FDA issued several press releases in May and June 1997 warning consumers not to purchase or ingest certain dietary supplement products labeled as containing plantain because these products might contain Digitalis lanata, a plant that can cause life-threatening heart reactions, including cardiac arrest, if ingested. In the press releases, FDA listed the names of distributors, manufacturers, and retailers, as well as the

products involved, and urged consumers to obtain updates from FDA's Consumer Hotline and FDA's "Foods" website. Fast and effective actions by FDA prevented serious adverse effects, which would likely have occurred if these contaminated products had remained in the marketplace.

IV. Challenges

A. Boundaries

Before Congress passed DSHEA, dietary supplements (including vitamins and minerals) were regulated either as foods or as drugs, depending on their intended use. If a product was used primarily for its taste, aroma, or nutritive value, it was regulated as a food. This meant that the ingredients used in such dietary supplements were subject to the food additive provisions of the FD&C Act, which require the safety of an ingredient to be demonstrated before it can be marketed. The supplement was subject to regulation as a drug if therapeutic claims were made, i.e., claims to treat or prevent disease; if claims were made to affect the structure or function of the body through a non-nutritive mechanism; or if there was other evidence that the intended use of the product was as a drug. The supplement, with such claims, would have to meet the rigorous drug safety and efficacy requirements of the FD&C Act, including, in the great majority of cases, premarket approval.

When Congress passed DSHEA, it created a regulatory framework for dietary supplements that previously did not exist. The purpose of creating this new framework was to strike the right balance between providing consumers access to both products and truthful information about the products while retaining authority for FDA to take action against products that present safety problems or are improperly labeled. We are now engaged in the difficult task of delineating boundaries between drugs, dietary supplements, and conventional foods. This is a task that requires great care if the Agency is to fulfill Congressional intent with regard to the availability of dietary supplements while preserving the established food additive and drug regulatory frameworks for products that fall outside the dietary supplement boundaries.

For example, Congress has permitted dietary supplements to be intended to affect the structure or function of the body, but it has not permitted dietary supplements to be intended to treat, prevent, mitigate, cure, or diagnose disease, except that dietary supplements may bear authorized health claims. DSHEA required FDA to draw a line between two types of intended use that the Agency never needed to distinguish previously. Congress also drew a line between conventional foods and dietary supplements by saying that a dietary supplement may not be represented for use as a conventional food. This boundary, too, raises many complex issues that the Agency is responsible for clarifying.

Aspects of DSHEA's dietary supplement definition that have proven especially problematic to implement are the statute's limitation of dietary supplements to products that are intended to supplement the diet and its inclusion of dietary substance[s] for use by man to supplement the diet as dietary ingredients that may be used in dietary supplements. It is clear that the dietary ingredients specifically listed in DSHEA (vitamins, minerals, herbs or other botanicals, and amino acids) were intended by Congress to be broadly available under DSHEA, and many of these have a long history of safe use. Products are now being positioned as dietary supplements, however, by purporting to fall within the "dietary substance" language. The terms "dietary substance" and "intended to supplement the diet" are broad, but they must not allow the inclusion of ingredients never intended to fit within the universe of dietary supplements. Now, products that contain substances similar to those found in prescription drugs are marketed for children as dietary supplements. Likewise, products with ingredients that simulate illicit street drugs are marketed as dietary supplements to adolescents via the Internet and shops specializing in drug paraphernalia. FDA is working toward a solution that will be consistent with the intent of DSHEA.

B. Claims

DSHEA also amended the FD&C Act to permit certain types of claims for dietary supplements that formerly would have made them drugs, including claims to affect the structure or function of the body through a non-nutritive mechanism. Congress recognized that if foods and dietary supplements were permitted to make disease treatment and prevention claims without premarket review, the burden would have been on consumers to evaluate the validity of a myriad of claims about products marketed for serious and life-threatening conditions. In addition, dietary supplements would be given an unfair advantage over prescription and over-the-counter drugs in the marketplace.

Thus, as I have noted above, the Agency issued a proposed rule intended to provide direction to the industry as to the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body and to clarify the line between disease and structure/function claims. This is important because disease claims for drugs as well as for conventional foods and dietary supplements continue to require pre-market authorization by FDA.

For foods, including dietary supplements, disease claims are "health claims." These claims describe the relationship between a food substance and a disease. The claim is usually in the

context of risk reduction of the disease. Any person or firm may petition FDA to authorize a health claim. FDA then reviews the scientific evidence for or against the claim. If the Agency finds that the claim is supported by significant scientific agreement among qualified experts, it will issue a regulation authorizing the claim. Recently, FDAMA authorized a second method for streamlined review of health claims. This involves the use of authoritative statements made by certain federal scientific bodies and the National Academy of Sciences in their publications. With this latter method, an interested party notifies FDA of its intent to make a health claim based on an authoritative statement and provides information as to the source of the statement.

C. Safety

With the passage of DSHEA, dietary supplements are deemed to be foods, except for purposes of the drug definition. In addition, Congress specifically excluded "dietary ingredients" in dietary supplements from the definition of "food additive." As a result, dietary ingredients used in dietary supplements no longer require premarket documentation of safety for submission to FDA unless they are new dietary ingredients subject to the notification requirement in Section 413(a)(2) of the FD&C Act. The notification requirement stipulates that the manufacturer or distributor of the dietary supplement submit to FDA information

which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe at least 75 days before marketing.

Because in most cases dietary supplement manufacturers are not required to provide safety information to FDA before marketing a product, FDA has the responsibility for gathering information before the Agency can take action to restrict the sale of a dietary supplement product for safety reasons. This means that the Agency must rely on adverse event reports, product sampling, information in the scientific literature, and other sources of evidence. The Agency's scientists have to determine whether a safety problem exists, and evidence adequate to support a regulatory action has to be gathered and assembled. As is the case whenever the Agency considers regulatory action against a product, it must take care to ensure that statutory requirements for an action against a dietary supplement are met. This process is often complex and warrants being thoughtful but timely.

VI. Conclusion

Mr. Chairman, I share the goal of making safe products available to consumers who want to make informed personal choices about using dietary supplements to improve their health. DSHEA was

enacted to ensure access to those products. I also believe DSHEA provides FDA with the necessary legal authority to protect the public health. We will do our best to marshal the scientific information and expertise necessary to exercise that authority when the public health is threatened.

The dietary supplement industry sells products on which millions of Americans rely. I am aware that in the past the relationship between FDA and some in the dietary supplement industry has been at times antagonistic and counterproductive. FDA is committed to developing a positive working relationship with the industry so we may together meet our goals of providing safe products to the American public.

The statute is still in the early stages of implementation, and I look forward to working with Congress and other interested parties to ensure that resource constraints or other issues do not impede FDA's ability to use this statutory authority most effectively.

I would be happy to respond to any questions the Committee may have.

Appendix

- October 6, 1994, Proposed Rule, "Iron-Containing Supplements and Drugs; Label Warning Statements and Unit-Dose Packaging Requirements" (59 FR 51030)

- December 6, 1994, Advance Notice of Proposed Rulemaking; Withdrawal, "Regulation of Dietary Supplements; Withdrawal of Advance Notice of Proposed Rulemaking" (59 FR 62551)

- February 9, 1995, Notice of Intent, "Food Labeling; General Requirements for Nutrition Labeling of Dietary Supplements; General Requirements for Nutrient Content Claims for Dietary Supplements" (60 FR 7711)

- April 19, 1995, Notice, "Dietary Supplements: Notice of Withdrawal of Regulatory Guidance" (60 FR 19597)

- December 28, 1995
 - Final Rule, "Food Labeling: Reference Daily Intakes" (60 FR 67164)

- Proposed Rule, "Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements" (60 FR 67176)
- Proposed Rule, "Nutrient Content Claims: Definition for High Potency Claim for Dietary Supplements and Definition of Antioxidant for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods" (60 FR 67184)
- Proposed Rule, "Food Labeling; Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements" (60 FR 67194)

- April 22, 1996, Notice, "Inapplicability of the Dietary Supplement Health and Education Act to Animal Products" (61 FR 17706)

- September 27, 1996
 - Proposed Rule, "Food Labeling; Dietary Supplement; Nutritional Support Statement; Notification Procedure" (61 FR 50771)
 - Proposed Rule, "Premarket Notification for New Dietary Ingredient" (61 FR 50774)

- January 15, 1997, Final Rule, "Iron-Containing Supplements and Drugs; Label Warning Statements and Unit-Dose Packaging Requirements" (62 FR 2218)

- February 6, 1997, Advance Notice of Proposed Rulemaking, "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements" (62 FR 24619)

- June 4, 1997, Proposed Rule, "Dietary Supplements Containing Ephedrine Alkaloids" (62 FR 30678)

- September 23, 1997
 - Final Rule, "Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation" (62 FR 49826)

 - Final Rule, "Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements" (62 FR 49859)

 - Final Rule, "Food Labeling; Nutrient Content Claims: Definition for 'High Potency' and Definition of

- 'antioxidant' for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods" (62 FR 49868)
- Final Rule, "Food Labeling; Notification Procedures for Statements on Dietary Supplements" (62 FR 49883)
 - Final Rule, "Premarket Notification for New Dietary Ingredient" (62 FR 49886)
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- April 29, 1998
 - Notice, "Comments on Report of the Commission on Dietary Supplement Labels" (63 FR 23633)
 - Proposed Rule, "Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body" (63 FR 23624)

 - June 5, 1998, Revised Final Rule, "Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation" for volume measure on liquid extracts (63 FR 30615)

 - June 11, 1998, "Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on Authoritative Statement of a Scientific Body" (pursuant to FDAMA)

- January 12, 1999, Proposed Rule, "Food Labeling: Nutrition Labeling of Dietary Supplements on a 'Per Day' Basis" (64 FR 1765)
- January 21, 1999, Proposed Rule, "Food Labeling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements" (pursuant to FDAMA) (64 FR 3250)

Mr. BURTON. Thank you very much, Dr. Henney. And I want to apologize for not recognizing Ms. Porter and Dr. Levitt when you first came up. So welcome to both of you, as well.

First of all, I would like to congratulate you on bringing to the consumer the supplements facts statement. I think you sent it to us a couple of days ago. This is a good move for the agency toward getting very accurate and good information to the public. I really appreciate that. Under your direction, the FDA seems to be doing a much better job with the problem products that we have had to deal with in the past. And I think that is a good signal to Members of Congress. So congratulations on a good start.

First of all, let me ask you about the proposed rule on the structure function statements. There is some question about what the FDA and what you are going to do with that. Could you comment?

Dr. HENNEY. Mr. Chairman, let me describe what the agency has done thus far. As you know, the agency did issue a proposed rule in that area. It is fair to say that this is a matter of great interest because we have received over 100,000 comments that have commented on many aspects of that proposed rule, all of which we are obligated to take into account before we move to final rule stage.

I would say that most of the concerns sort of center around the issue of the disease definition used by the agency that relied very heavily on reference books from medical dictionaries and the like. I think that we still have a ways to go in our evaluation of all comments on the particular definition that we have selected and whether it was too broad or not. So we will be working diligently on coming to closure on that rule before we would issue it in final.

Mr. BURTON. Well, there is some concern among some Members of Congress and many in the public sector, that the law, which was passed in 1994, 1995 would be circumvented by that regulation. And I presume that you are going to take a hard look at the compliance with the current statute.

Dr. HENNEY. I think, Mr. Chairman, it is fair to say that it is very important that we settle on this key issue of definition of disease because it is that definition that will also guide that critical issue of boundary for a dietary supplement and what happens in the drug arena. So we realize the interest and we will want to deal with this quite thoughtfully and deliberately.

Mr. BURTON. Do you think that the FDA has enough authority right now to deal with dietary supplements?

Dr. HENNEY. Mr. Chairman, I believe, as outlined in the act, appropriate authority is either given to the agency within the context of the Dietary Supplement Act or in the law that it is embodied in the basic FDA act as well. However, I would say that we are very early into the implementation of this new law. We believe that we have the appropriate authorities that we need. But please be assured that if we do not and find ourselves in a situation where we do not have adequate authority to protect the public health, we will bring it to your attention.

Mr. BURTON. How many courtesy letters has the FDA sent out on the structure function statement? And what percentage is that to the total number of statements that have been made?

Dr. HENNEY. Mr. Chairman, it is very good, as Commissioner, to have people who know more facts than I do after only 3 months.

Mr. BURTON. I couldn't agree with you more. You have got to have good help.

Dr. HENNEY. Good help is hard to find. But I am told that about 300.

Mr. BURTON. About 300. Excuse me, what were the total number of statements, do you know?

Dr. HENNEY. This is about 10 percent or about 3,000 statements.

Mr. BURTON. About 3,000. As a physician, can you really accept the definition of disease as the absence of a normal state?

Dr. HENNEY. Mr. Chairman, I am going to be compelled to look at this issue, both as a physician and Commissioner. I think that, as I indicated, the definition of disease that was drawn on in the proposed rule did come, in large part, from reference texts, so we are having to rely on a number of resources as look not only at what we did originally but at what others would like us to consider now. And I have not come to a conclusion in that matter yet.

Mr. BURTON. Do you think that the FDA should create a separate advisory committee for dietary supplements rather than have only a subcommittee to the Foods Advisory Committee?

Dr. HENNEY. Mr. Chairman, the matter of having an advisory committee in one specific area of regulation is certainly something that we could give consideration to. The Foods Advisory Committee itself was established during the time that I was at the agency before, when we felt that we needed more expertise and outside help from a variety of sources to help us with the whole area of food. I believe that, as we move forward into developing our framework, our regulatory framework for the dietary supplements area, we will likely be using a wide variety of means to garner information and expertise from individuals outside the agency. Whether that will call for the establishment of a permanent advisory committee, we have not made any decision in that regard.

I would cite one case in which we have done that in the past and it was, again, in an area that the agency was moving into, the over-the-counter products. And an advisory committee was established simply for that area as a drug might move from the prescription area to over-the-counter. So it is not without precedent that we might do something like that. But please be assured, whether or not we have a fixed and permanent advisory committee, both Mr. Levitt and I are very committed to seek the outside support, help, and expertise from many as we move forward.

Mr. BURTON. Thank you very much. I will probably have a couple more questions in the second round. Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman. Dr. Henney, this may not be a good example. This is maybe more of a food product. But I have a glass with some liquid in it. Let us say I wanted to bottle this and sell it and tell people that, if they drink this, it will cure cancer. Will FDA stop me?

Dr. HENNEY. Mr. Waxman, it would be a daunting challenge to stop you from anything. [Laughter.]

However, since you would be making—

Mr. WAXMAN. The chairman's had some success.

Dr. HENNEY. Since you would clearly be making a disease claim, which is prohibited, yes, we would stop you.

Mr. WAXMAN. If I sold this product and I didn't make a disease claim but I made a claim that this could really help improve your health, any problem with that?

Dr. HENNEY. We at the agency would likely have much less problem with that because drinking water is known to help improve an individual's health.

Mr. WAXMAN. When we drafted this legislation, there were some people who argued a manufacturer ought to be able to sell a product and make any claim that he wants to if he has some substantiation, but it doesn't have to be a great deal. And let the marketplace operate.

On the other hand, other people felt, well, that is just too wide open. And we made a distinction in the law between disease claims, claims that a product is intended to treat, prevent, mitigate, cure, or diagnose a disease. And we said those products are drugs and they ought to be reviewed by FDA to be sure they are safe and effective. But if it is a product that simply is intended to affect the structure or function of the body, we said that the manufacturer can make claims in that regard. Now they have to be accurate, but you wouldn't police the accuracy of those claims, as I understand it.

Dr. HENNEY. Mr. Waxman, to the latter point, I think that there is a provision that, on the label there would have to be a disclaimer in that regard. The statement must be truthful and not misleading, as well.

Mr. WAXMAN. Disclaimer, right. But the question that I wanted to ask you—I may be not fully correct in that saying that if there is something so outlandish, even though it wasn't a disease claim, you still may have peripheral authority. But, for all practical purposes, the intent of Congress was to allow some of these claims to be made. What would happen if you allowed something to be marketed with disease claims and what dangers are there associated with marketing a product that makes a disease claim, without having demonstrated scientific substantiation for such claims? A lot of people think that products ought to be out there. It will make it more available to people. Give them information that is valuable. Why wouldn't you think it would make sense to allow disease claims to be made?

Dr. HENNEY. Mr. Waxman, I think that there are at least two concerns in that regard. One is of concern to the consumer of having a claim, particularly in terms of the treatment of disease, that would be wrong or, at best, false and misleading and consumers acting on that information would clearly be misled. And so I think Congress struck a good balance in saying disease claims could not be made.

It also, I believe, is one of those areas where there is a definitional boundary in terms of making a drug claim, in terms of not infringing upon a drug industry's mode of working with the agency as well; where premarket approval clearly is rigorous, premarket approval clearly is required.

Mr. WAXMAN. Well, I think there is another reason also. If a manufacturer of a drug could just market it as a dietary supplement without having to go through all the research, he might start marketing a product and we wouldn't even fully know the impact

of that product because all the clinical tests might not be completed. They can go out and market it and make a profit and not even know whether there is going to be a full success or other problems associated with that.

The FDA has been criticized because the line between the structure function claim and a disease claim is not always clear, but I don't think that is your fault. The statute forces you to draw a distinction between the two types of claims when, in fact, there may be no clear distinction. What is your opinion on this? And could you also answer this question: about if the court decision on Cholestin is not overturned, what problems do you see with that decision in the context of our discussion?

Dr. HENNEY. Mr. Waxman, to the point of structure function, it is critical that we get this issue correct. The boundary for a dietary supplement and drug or dietary supplement and health claims or food claims is equally important. I think to the specific issue of Cholestin, the issue is not so much about the claim, but whether the product in question is really not the original food of red yeast rice but has been converted through a manufacturing process to the active ingredient of a drug.

Mr. WAXMAN. Well, if you have a product that then competes with a drug because it has the same active ingredient yet it doesn't go through the clinical tests and you don't know about the whole manufacturing process, is there a concern that you have about that?

Dr. HENNEY. Then there is, essentially, no protection for those drug manufacturers who invest and go through all of the rigors of that clinical trial and meet the standard of new drug approval.

Mr. WAXMAN. And maybe they won't make that investment next time around.

Mr. BURTON. Mrs. Chenoweth.

Mrs. CHENOWETH. Thank you, Mr. Chairman. Commissioner, welcome. Is it the overall objective of the FDA to support access to dietary supplements or try to suppress out of concern for the purchaser?

Dr. HENNEY. Mrs. Chenoweth, I think that the agency is obligated to follow the law in this regard and the law very clearly was intended to provide access to dietary supplements while charging the agency and giving the agency appropriate authority that, if these products were unsafe or presented unreasonable health risks, the agency could take action. It also clearly wanted to provide access to a product that was appropriately and properly labeled.

Mrs. CHENOWETH. Wouldn't the FDA want the population to have access to information that will help them to make educated decisions about the products they use in terms of health claims as opposed to disease claims? I ask you this because there is evidence that the FDA is deliberately suppressing information which could help health consumers make an educated decision about products which could help them. The FDA limits what producers of health supplements may say about their products.

For example, psyllium is widely known to be helpful in lowering cholesterol which is a health claim which is a contributing factor to heart disease. They make the distinction there. Now this is a nutrient found in many commercial food products; Post and Kellogg

and the big companies use it on their products, like cereal and other whole grains. But the FDA has approved the health claim associating consumption of psyllium in food with reduced risk of heart disease. Producers will often print that information on the labels of their products so consumers can make an educated choice.

But that isn't true for psyllium sold off the shelf as a dietary supplement. In fact, if producers of psyllium as a dietary supplement wanted to educate consumers about the benefits of psyllium—that is the health decisions, the health choice—the FDA would prevent it. And this is precisely the issue at stake in the case that you just appealed to the Supreme Court involving Pearson and Shalala, the difference between a claim and a disease claim.

And then the second part of my question, of course, is why can Post and Kellogg's and the big companies get by with that, making those claims, those health claims, while the small individual nutrition stores may not?

Dr. HENNEY. Mrs. Chenoweth, let me respond to you in terms of the issue of health claims. You raise many specific items during the course of your question and I would like the opportunity to tease those apart and get back to you if I could, explicitly, for the record.

[The information referred to follows:]

FDA authorizes health claims for use in food labeling under provisions of the Nutrition Labeling and Education Act of 1990 and established requirements at 21 CFR 101.14. FDA has authorized use of a health claim for the relationship between soluble fiber from certain foods, including psyllium, and a reduced risk of coronary heart disease (21 CFR 101.81). Consequently, any food, including a dietary supplement that meets the eligibility criteria in FDA's regulations at 21 CFR 101.14 and 21 CFR 101.81 may bear that claim in its label or labeling. The Agency is aware that there are products marketed as dietary supplements that bear a claim about the relationship between psyllium and coronary heart disease.

Dr. HENNEY. I think to the matter of health claims, be they for a food or a drug, if they relate specifically to a disease, they go through a different kind of process or a preauthorization process than those that relate to the structure and function of the body, on dietary supplements. With respect to psyllium, FDA has approved a health claim for this and its relationship to coronary heart disease, but I will be more than glad to look into other applications we might have in hand with respect to that particular product and see if there is anything else, in-house, that has been requested of us.

Mrs. CHENOWETH. Thank you, Doctor. You know, I know that the Federal Government has not been entirely lax in trying to provide information to consumers about health products. For example, the Department of Health and Human Services in their Dietary Guidelines for Americans publication which provides information about the effect of the diet on health and disease. I am sure that you are familiar with this publication. So let us say that this publication includes a statement on the benefits of psyllium in fighting heart disease. And let us say I produced psyllium for sale over the counter as a supplement, but if I quote the Dietary Guidelines for Americans directly anywhere on the literature, prior to the change that I don't know specifically yet what the change is in labeling associated with marketing my product, the FDA can enjoin me and possibly file criminal charges.

I look here at the CDC's annual review of nutrition which claims that antioxidants, micronutrients appear to play many important roles in protecting the body against cancer. Now that is the CDC's own report. The USDA Human Nutrition Agriculture Research Service Quarterly Report, fourth quarter, 1996 states, "Antioxidants are thought to help prevent heart attack, stroke, and cancer." USDA and DHHS Dietary Guidelines for Americans states in their publication that the antioxidant nutrients found in plant foods are presently of great interest to scientists and the public because of their potentially beneficial role in reducing the risk of cancer.

So, while the agency is able to make disease claims, if the dietary supplement producers tried to make the same claims that the agency does, they would be having to face those consequences.

Dr. HENNEY. Mrs. Chenoweth, let me respond by saying that Congress did look at this area reasonably recently when they were considering the FDA Modernization Act. And I think that there is provision within the context of that act to try to clarify the issue of authoritative statement. And, at least as we have tried to track the legislative history of the portion of the FDA Modernization Act known as section 303 I think there was a statement that authoritative statements such as those you cite could be used by the agency if they represented deliberative reviews. And so we have tried to follow the intent and the letter with respect to that.

Sometimes when you go back to those documents or to those bodies to see whether the body itself believes that there has been a deliberative review for some of those statements or even to document as to whether those statements represented preliminary findings on their part, there is sometimes that information that becomes available. But I believe that, if these statements have come from such a body and do represent, in that body's view, a deliberative review process having taken place, that FDA can accept these types of statements. So there is that ability to do what you are talking about. But there is a process outlined that I believe that we have to follow.

Mr. BURTON. Thank you, Mrs. Chenoweth. Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. Dr. Henney, I am new at this job as well, but neither of us is really new to these kind of issues. I started becoming active in the community in the early 1970's on an effort to get expiration dates on food products. As a young housewife I felt that the more informed we were about the products we were buying, the better choices we would be able to make. And, of course, we have come a long way since then in terms of labeling on products so that we can look at those and decide what is best for us, what is safest for us.

And I think that most Americans make the assumption—it is not always valid—that somebody is protecting us, that the products that we buy, wouldn't be on the shelf if somebody weren't there to make sure that they are OK. And I think we try as best as we can to make sure that that assumption is based in fact. And I would hope that on this issue we do that as well.

I think a large component of what we need to do, in addition to setting rules and regulations, is getting this information out to the public on how to use it and how to make informed choices. What

kinds of programs are there at the FDA in terms of public health education programs so that we widely disseminate accurate information on how to use the 1994 law and what it really means?

Dr. HENNEY. Ms. Schakowsky, I very much appreciate somebody else being new to this as well, but I also appreciate your long-standing interest in this whole area of the informed consumer. I think with respect to the safety issue, I think consumers can continue to rely that, in terms of a premarketing review of safety, that clearly is done in the area of conventional foods, new foods, food additives that might come to the marketplace, and drugs.

With dietary supplements, I think, embodied in this act, was the presumption and knowledge that many of these products have been used for years and, therefore, there was not a need for preauthorization but an assumption of safety. And that is some of the concept, I think, that was embodied in this act, to have access to products that, by their history, had been established to be safe. But when that was not the case, the agency was given the authority to remove them from the market.

With respect to initiatives to make consumers more informed about the products that they are using, I think that a few years ago, under the NLEA, the Nutrition Labeling and Education Act, the agency's first step was to develop that new food label that we saw come onto the market in the last few years. And a few weeks ago, we announced that a similar, very clear label, a consistent label, a concise label would also be coming onto over-the-counter products. And just this week, we have finalized that issue with respect to supplements and the supplement label. And so on dietary supplements in the future, the elements that we will be seeing on all labels will easily identify for the consumer the type of supplement it is; per servings; the nutrients; other dietary ingredients that might be in the product; and, if it is a botanical, the plant or herb that the product comes from.

So I think that there will be a step up with these new labels in terms of the kind of information that a consumer can use.

Ms. SCHAKOWSKY. And when will consumers—when can they expect to see those new labels on the products?

Dr. HENNEY. The final rule was published on September 23, 1997, with an effective date of March 23, 1999, giving industry 18 months to comply. Products labeled prior to March 23 can continue to be sold until stocks are depleted. Some companies have already introduced products with the new labels.

Ms. SCHAKOWSKY. I do have one other question, Mr. Chairman. Can I go ahead? It is my understanding that the FDA issued interim rules prohibiting the use of nine different health claims on foods. We were talking about that. And that the petitioner for these claims, the manufacturers, had submitted statements describing those claims as authoritative and that there has been some criticism, including that of the chairman, that the FDA said that these statements were not, in fact, authoritative. And you were talking about going back to these scientific bodies that I guess were used as the basis of those claims.

And I would like to clarify what Representative Chenoweth was saying. On the one hand, internally, in their documents, they seem to be making those same claims. When you go back to them and

say are those authoritative claims? Can they be used by the manufacturers? Those same bodies are saying no. How do we reconcile that difference?

Dr. HENNEY. One of the key issues, and, again, it was in the legislative history of the FDA Modernization Act, was to describe what authoritative meant, in that authoritative meant, within the context of the legislative history, that the statement had come through a deliberative review. I am told that, as the agency and the Department face this issue, that Secretary Shalala asked for representatives of many of those bodies to come together to represent a liaison group from those organizations so that—

Ms. SCHAKOWSKY. But those organizations, just to clarify, are those like the CDC? Who are we talking about?

Dr. HENNEY. CDC, NIH, and National Academy of Sciences. To establish a channel of communication. One of the key issues of those discussions was to learn the context of the Dietary Supplement Act of 1994 as well as the context of the FDA Modernization Act in terms of deliberative review and to know what we would be asking if we queried does the statement represent that of your organization? Has it come through a deliberative review?

And the nine statements which you referred to, I believe, although I can't go through every one this morning, in large part, were sent back to those bodies when they sit as organizations and asked that question. And sometimes they said yes or no and there are some documents, and I believe Representative Chenoweth cited one, where the body doesn't sit but perhaps once every 5 years. And at the time they are making their statements, they may be preliminary, so we have no body to go back to, so we rely on the context of the statement within the document. And often a statement is made, an accompanying statement might say, but these results are preliminary. So we have to be guided by both the statement and its context.

Mr. BURTON. Thank you. Mr. Souder.

Mr. SOUDER. I would like to first yield to Mrs. Chenoweth.

Mrs. CHENOWETH. Thank you, Mr. Souder. I do want to clarify something, Doctor, that you just mentioned. The cites that I made were actually public cites; they were published. And so, therefore, they became part of the public domain. They were not internal documents. There were actual published with page numbers, volumes, everything. So I think that takes on an entirely different context, once it becomes part of the public domain, with regards to authoritative statements that can be closely held internally.

Mr. SOUDER. One of the difficulties you have at FDA is if you have products out there that are unsafe and then you are held accountable. But I was curious also about the liability that FDA might have if you list a company in this area as having killed someone when they may not have manufactured the product. And, also, if the report is incorrect, then what do you do to correct it in the cite? In other words, what is your liability if you have false information or information that would say that, in effect, a distributor was responsible when they didn't manufacture? Have you run into the liability question?

Dr. HENNEY. Mr. Souder, I would love to be in a position to answer your question, but I have a feeling that my Chief Counsel is in a better position to answer your question about the liability.

Ms. PORTER. Mr. Souder, if you are talking legal liability and you are referring to the agency's adverse event reporting system, I think under ordinary circumstances, the agency's good faith effort to receive and evaluate adverse events would be viewed as a discretionary act and, therefore, exempt from tort liability in the legal sense. If you are referring to the agency's efforts to do its best to assure within its authority and its resource constraints that the reports are correct, well then, of course, the agency would try to do that.

Mr. SOUDER. And if there was a false report, would you make an effort on your Internet site to correct that and is there not just a legal liability, but also an ethical liability if you have damaged a company?

Dr. HENNEY. Mr. Souder, when we are made aware that there is not even the extreme of false, but information that would appear to be not full or complete, when we are made aware of that, we do have an ability to at least footnote those reports in that way. We do not change in any way the original report that we would have received, but we would footnote it as having received information to the contrary. And that is how we would handle that.

Ms. PORTER. Mr. Souder, let me also add that the adverse events that are reported to the agency as a general matter are made available under the Freedom of Information Act. We try to keep confidential the names of the reporters and the names of the individual patients, but the rest of the report is, in fact, legally available. So I think that would be another reason why the agency wouldn't be held legally liable. But, as is indicated, within our constraints, we want to be sure consumers have accurate information.

Mr. SOUDER. Why, if a report is false or incorrect, wouldn't it be deleted? Why would it just be footnoted?

Ms. PORTER. I can't—I am sorry.

Mr. SOUDER. The response was that if the report was proven to be false or just incorrect or you got additional information, you would footnote it. Why wouldn't you delete the false information?

Ms. PORTER. It is part of the entire record. I think that would be the answer.

Mr. SOUDER. I have some concerns about that. I am not even familiar with the general issue, but there is, in corporate issues, I find that that is an uncomfortable answer.

In the research area of dietary supplements, in particular, complex herbal preparations, does the FDA have a specific team of experts who assist researchers in getting IND clearances? And how do dietary supplements differ from drugs in this area?

Dr. HENNEY. Mr. Souder, if you will permit me, I would like Mr. Levitt to respond to that question of expertise.

Mr. LEVITT. If I understand your question correctly, in terms of if a company wants to submit an IND investigation or a new drug application, then that would be done through the Center for Drug Evaluation and Research. And in that case, they have the divisions separated according to specialty, so it would depend upon the purpose that they would be trying to study.

Mr. SOUDER. So there are not or are there dramatic differences in dietary supplements from other sorts of drugs, whether they be prescription or over-the-counter? In other words, you are saying there are different divisions, but they are not necessarily treated differently? They just go to a different place?

Mr. LEVITT. I believe that all investigational new drug applications are handled together in one unit within the agency and that is the Center for Drug Evaluation and Research.

Mr. SOUDER. Thank you.

Dr. HENNEY. And, Mr. Souder, we may be trying to split this hair too finely. When you used the term investigational new drug, that definitely would put the herb into a drug category, like a natural product category of drug, and out of the dietary supplement area.

Mr. SOUDER. So you are saying it depends on the claim for the dietary supplement as to how you would assign it?

Dr. HENNEY. In part, yes.

Mr. SOUDER. Or would it take the claim for a dietary supplement or something you suspect that they may it?

Dr. HENNEY. If you had a natural product, an herb, a plant, let us take digitalis, and you were going to develop that for the treatment of arrhythmias for heart disease, and you wanted to market it as a drug, you would come in through our Center for Drugs for review. It would require clinical studies and it would require pre-market review for the safety and the efficacy of that drug that was derived from a plant or an herb. However, if it was an herb intended to supplement the diet in some way and met the criteria of the Dietary Supplement Act and was not being intended to treat a particular disease, you would come in through the dietary supplement area which lies over in the Center on Foods.

Mr. SOUDER. Thank you very much.

Mr. BURTON. Mr. Kucinich, what I would like to do is finish with Dr. Henney and her panel. We have two votes on the floor. And then, when we come back, we will take the next panel. So, Mr. Kucinich.

Mr. KUCINICH. I will yield to Mr. Waxman. I am fine. I will yield to Mr. Waxman.

Mr. WAXMAN. Well, I thank you for yielding. I appreciate it because I did want to get another question in and take advantage of the fact that you are here, Dr. Henney. On another subject, I understand an FDA advisory committee is meeting tomorrow to review the safety of Rezulin and I am concerned that no one, not the FDA, not Warner-Lambert, not the public knows the exact number of deaths and injuries associated with Rezulin. What we have are voluntary adverse event reports which we all recognize constitute only a fraction of actual deaths and adverse events. Right now Rezulin labeling calls on patients to be tested regularly to ensure their livers are functioning properly, but Warner-Lambert is doing nothing to confirm that patients are actually getting tested the way they should.

In your February 25 letter to me, you wrote that the FDA is conducting an observational epidemiological study on whether Rezulin patients were getting tested in 1998. But that is a look backward, not a way to guarantee compliance in the future. Is the agency considering requiring the company to determine, for certain, in the fu-

ture that patients are getting tested consistent with Rezulin's labeling?

Dr. HENNEY. Mr. Waxman, one of the reasons why we are holding the advisory committee tomorrow is to get advice from experts on exactly next steps that should be taken. I do have with me today Janet Woodcock who is the center director for drug evaluation and research. She might want to add additional information, but it is just in this context that we are holding the meeting with the advisory committee to give them an update on where we are with this product to see if any further monitoring, labeling, or action with respect to the drug is warranted at this point.

Mr. WAXMAN. Before she comments on that question, let me also ask you about the fact that on Monday the British FDA, the Medicines Control Agency, decided Rezulin was unsafe to be marketed in Britain. Has the FDA reviewed the facts and the medical basis for their decision? And is the FDA aware of all the same reported deaths and injuries that the British were aware of in making their decision to ban Rezulin?

Dr. HENNEY. I will have to ask Dr. Woodcock to respond to that.

Dr. WOODCOCK. Yes. To answer your second question first, we have been in close contact with the British authorities and their deliberations, so we are aware of that. As far as knowing the exact number of deaths from the use of any drug in the United States, that would require 100 percent registry of all patients taking the drug and that is an extraordinary step that FDA has taken only very rarely, such as with thalidomide. We do believe that we have fairly good information on new deaths that have occurred with this drug, for a variety of reasons. We will be discussing, as Dr. Henney said, any additional steps that should be taken and the results of the epidemiologic study on the monitoring.

Mr. WAXMAN. Coming back to the subject that is not unrelated, manufacturers are currently required to report adverse events when it is a drug. Do you believe that dietary supplement manufacturers should report adverse events and have you discussed what steps FDA has taken to try to enhance its adverse event reporting system?

Dr. HENNEY. Mr. Waxman, our adverse event reporting system is open to all products that FDA regulates. We do believe that there are enhancements to that system that certainly should occur. We currently have before the Appropriations Committee a request to increase the level of funding that we would have available so we can enhance that kind of injury reporting system so we could have a better handle on events, be they with the devices, drugs, or dietary supplements, in terms of actions that the agency might need to take.

Mr. WAXMAN. With a drug, I think there is a requirement to report adverse events. On dietary supplements, is there any kind of requirement or are you relying solely on—

Dr. HENNEY. Mr. Waxman, most of our reporting systems are voluntary. The required reporting system that I am aware of—within the agency there may be others—is with device manufacturers that must report to us. But in terms of individual physicians seeing events with their patients, we rely heavily on a voluntary reporting system in all of our products.

Mr. BURTON. Mr. Kucinich, did you have any questions you would like to ask? Well, do you want Dr. Henney and the panelists to wait? If you have any questions, we have a few minutes.

Mr. KUCINICH. Well, I am going to submit some questions in writing. OK?

Mr. BURTON. Would you be willing to respond to those questions in writing?

Dr. HENNEY. Oh, absolutely.

Mr. KUCINICH. Thank you.

Mr. BURTON. Well, I think we have concluded all of the questions for you. I want to thank you very much. It has been nice having you here today and we will look forward to working with you in the future.

Dr. HENNEY. All right. Thank you.

Mr. BURTON. Thank you very much, all of you. We stand in recess at the call of the Chair. We will be back in about 10 or 15 minutes. We have two votes on the floor.

[Recess.]

Mr. BURTON. If everybody could take their seats, we will be prepared to start with the next panel.

Ms. Welch, you are welcome to sit right there.

Ms. WELCH. OK. Thank you.

Mr. BURTON. First of all, on behalf of the Congress and the committee, we want to welcome you to the U.S. Congress. I think everybody has been an admirer of yours for years. We have watched you on screen and stage and we have really not only admired your beauty, but your acting skills as well. And we are very happy to have you here today to testify about nutrition and supplements. So if you are prepared for an opening statement, proceed.

Ms. WELCH. Yes, I am. Thank you very much.

Mr. GILMAN. Mr. Chairman, could I—

Mr. BURTON. Oh, excuse me. Pardon me. Mr. Ben Gilman, our chairman of the International Operations Committee had a brief statement he wanted to put in the record. So—

Mr. GILMAN. Thank you. We are conducting a hearing across the hall on Russian policy and I thank you for the opportunity. I regret I couldn't be here earlier. And I want to apologize to our witness. But I do want to put in an opening statement.

The passage of the Dietary Supplemental Health and Education Act of 1994 I think has brought about a number of important improvements for millions of Americans who regularly consume dietary supplements to protect and improve their health. DSHEA guarantees the right of Americans to have access to the traditional supplements that consumers have used for a number of years and new products that are just beginning to come into the market today and DSHEA ensures that these new products are safe and properly labeled for sale in our Nation.

Studies and testimonial statements from consumers have shown that supplements can and do improve good health. However, the FDA's slow acknowledgement of the benefits of dietary supplements has brought us here today and, without DSHEA, there is no uniform quality of products and the lack of information about these kind of supplements that are available to the public. So once the regulations will be in place and practice—and I am pleased that

the Commissioner Jane Henney has indicated that they are moving in that direction—once they are in place and practice, consumers can be confident that supplements will be safe and regulated.

We must make certain that the FDA implements DSHEA as prescribed for in the act of 1994. So I am pleased the new FDA Commissioner, Ms. Jane Henney, has testified here this morning that she will be dedicated to help FDA fairly interpret, implement, and enforce the provisions of this act as they were intended when Congress initially passed the act. And while some have argued that DSHEA is full of complex questions of fact, policy, and law, it is the duty of FDA and its Commissioner to enact this measure and provide the American consumers with safe and regulated dietary supplements.

And I want to commend our witness, Raquel Welch, for coming to us today to give us her thoughts with regard to these supplements. Thank you, Mr. Chairman.

Mr. BURTON. Well, before I yield to Ms. Welch, Mr. Waxman is your Congressman and he would like to say a word of welcome. And I don't blame him a bit.

Mr. WAXMAN. I want to tell you how pleased I am to be here to hear your testimony and to welcome you to our committee hearing. We came back from the vote anxious to hear your testimony and I am going to be able to hear it, but I was also able to hear Mr. Gilman's statement as well. Unfortunately, I want to apologize to you because I am not going to be able to join you and other Members for the lunch after your testimony because I have a previous engagement with Bishop Desmond Tutu from South Africa. But I want to welcome you here. I look forward to your testimony. I hope I will be able to stay to ask some questions, but I just appreciate your willingness to come here and tell us your views.

Ms. WELCH. Thank you.

Mr. BURTON. OK, Ms. Welch.

STATEMENT OF RAQUEL WELCH, ACTRESS

Ms. WELCH. Well, good morning, Chairman Burton, members of the committee, and a special greeting to my Congressman, Henry Waxman of California.

I am Raquel Welch and, before I begin, I would just like to say that I am not a paid spokesperson for the dietary supplement industry nor do I have any financial connections with it. I am here today because of a statement made by former Surgeon General C. Everett Koop, who is quoted as saying, "If you want to be successful in life, pursue good health."

I am a woman who has played many roles: an actress, a wife, a mother, and a person who made a decision some 25 years ago to take an active role in maintaining my health and well-being. It has been one of the most important roles of my life and, much like a demanding role in a film or a play, it requires preparation and study. On the screen and on stage, you prepare with a script. If you have chosen to make dietary supplements part of your life, as I have, you prepare by getting information.

The availability of truthful, balanced information on the dietary supplement labels is guaranteed now by the Dietary Supplement Health and Education Act. Congress unanimously voted in favor of

the consumer's right to know what dietary supplements are for and how they work. Most importantly, this information is mandated to be where customers can look first, on the label.

For the past 5 years, customers have had access to valuable information on how supplements affect the structure and function of the body. These congressionally mandated structure function statements now appear on dietary supplement labels, allowing customers like me to make informed choices. However, I have recently been informed by the National Nutritional Foods Association that the FDA has proposed rules which would severely curtail these structure function statements. And, therefore, restrict the information that Congress intended these statements to impart.

Mr. Chairman, as you well know and as I have learned, structure function statements must not say that a dietary supplement is intended to cure, treat, prevent, or diagnose any disease and a disclaimer to that effect must appear on the label in conjunction with any structure function statement. My understanding is that what the FDA proposes is to expand the definition of disease to the point that virtually all structural function statements would be discouraged or outlawed.

I know that there are instances where label statements have been made beyond the explicit limits stated in the Dietary Supplement Act. I believe that even the FDA records will show that these claims are found on only an infinitesimal number of products, approximately 1 percent. As a consumer, it seems to me that the FDA should use its enforcement powers to eliminate these questionable and unsubstantiated claims. That would be understandable and logical. However, instead, the agency is proposing virtual elimination of an entire category of consumer information with broad restrictions and confusing rules. I would say that is like killing a flea with a cannon.

Mr. Chairman, millions of consumers like me have and will benefit from learning more about these supplements from the structure function statements. What the FDA is proposing seems like a regulatory sleight-of-hand to stifle such statements. I implore you and the members of this committee to urge the FDA to withdraw its proposed rule. The language in the existing Dietary Supplement Act already gives sufficient direction and establishes explicit limitations on structure function statements. And it gives FDA the authority it needs to chase down delinquent companies and their products.

The FDA's proposal ignores congressional intent and flies in the face of the best interests of the 100 million Americans who, like me, take dietary supplements every day. We need and ask for your help if health-conscious citizens are to continue to be able to make informed health choices. It is, after all, part of the American way.

I have been taking supplements since 1 million years B.C.
[Laughter.]

So please support us. Thank you very much.

[The prepared statement of Ms. Welch follows:]

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Statement

on the

Regulation of Dietary Supplement Labels

by

Raquel Welch

before the

House Oversight Committee on Government Operations

Hon. Dan Burton, Chairman

March 25, 1999

GOOD MORNING, CHAIRMAN BURTON, AND MEMBERS OF THE COMMITTEE. AND A SPECIAL GREETING TO MY CONGRESSMAN, HENRY WAXMAN.

I AM RAQUEL WELCH. I AM NOT A PAID SPOKESPERSON THE DIETARY SUPPLEMENT INDUSTRY, NOR DO I HAVE ANY FINANCIAL CONNECTIONS WITH IT.

I AM HERE TODAY BECAUSE OF A STATEMENT MADE BY FORMER SURGEON GENERAL C. EVERETT KOOP, WHO IS QUOTED AS SAYING, "IF YOU WANT TO BE SUCCESSFUL IN LIFE, PURSUE GOOD HEALTH."

I AM A WOMAN WHO HAS PLAYED MANY ROLES, AN ACTRESS, A MOTHER, AND A PERSON WHO MADE A DECISION SOME 25 YEARS AGO TO TAKE AN ACTIVE ROLE IN MAINTAINING MY HEALTH AND WELL BEING.

IT HAS BEEN ONE OF THE MOST IMPORTANT ROLES OF MY LIFE. AND, MUCH LIKE A DEMANDING ROLE IN A FILM OR PLAY, IT REQUIRES PREPARATION AND STUDY. ON THE SCREEN AND STAGE, YOU PREPARE WITH THE SCRIPT. IF YOU'VE CHOSEN TO MAKE DIETARY SUPPLEMENTS PART OF YOUR LIFE, AS I HAVE, YOU PREPARE WITH INFORMATION.

THE AVAILABILITY OF TRUTHFUL, BALANCED INFORMATION ON DIETARY SUPPLEMENT LABELS IS GUARANTEED NOW BY THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT. CONGRESS UNANIMOUSLY VOTED IN FAVOR OF THE CONSUMER'S RIGHT TO KNOW WHAT DIETARY SUPPLEMENTS ARE FOR, AND HOW THEY WORK.

MOST IMPORTANTLY, THIS INFORMATION IS MANDATED TO BE WHERE CONSUMERS LOOK FIRST: ON THE LABEL.

FOR THE PAST FIVE YEARS, CONSUMERS HAVE HAD ACCESS TO INFORMATION ON HOW SUPPLEMENTS AFFECT THE STRUCTURE AND FUNCTION OF THE BODY. CONGRESSIONALLY-MANDATED "STRUCTURE/FUNCTION STATEMENTS" NOW APPEAR ON DIETARY SUPPLEMENT LABELS, ALLOWING CONSUMERS LIKE ME TO MAKE INFORMED CHOICES.

HOWEVER, I RECENTLY HAVE BEEN INFORMED BY THE NATIONAL NUTRITIONAL FOODS ASSOCIATION, THAT FDA PROPOSED RULES THAT WOULD SEVERELY CURTAIL THESE "STRUCTURE/FUNCTION STATEMENTS." AND, THEREFORE, RESTRICT THE INFORMATION CONGRESS INTENDED THESE STATEMENTS TO IMPART.

MR. CHAIRMAN, AS YOU WELL KNOW, AND AS I HAVE LEARNED, "STRUCTURE/FUNCTION STATEMENTS" MUST NOT SAY THAT A DIETARY SUPPLEMENT IS INTENDED TO CURE, TREAT, PREVENT OR DIAGNOSE ANY

DISEASE-AND A DISCLAIMER TO THAT EXACT EFFECT MUST APPEAR ON THE LABEL IN CONJUNCTION WITH ANY "STRUCTURE/FUNCTION STATEMENT."

MY UNDERSTANDING IS WHAT THE FDA PROPOSES IS TO EXPAND THE DEFINITION OF DISEASE TO THE POINT THAT VIRTUALLY ALL "STRUCTURE/FUNCTION STATEMENTS" WOULD BE DISCOURAGED OR OUTLAWED.

I KNOW THERE ARE INSTANCES WHERE LABEL STATEMENTS ARE BEYOND THE EXPLICIT LIMITS STATED IN THE DIETARY SUPPLEMENT ACT. BUT I BELIEVE THAT EVEN FDA RECORDS WILL SHOW THAT THESE CLAIMS ARE FOUND ON AN INFINITESIMAL NUMBER OF PRODUCTS, LESS THAN ONE PERCENT.

AS A CONSUMER, IT SEEMS TO ME THAT FDA SHOULD USE ITS ENFORCEMENT POWERS TO ELIMINATE THESE QUESTIONABLE AND UNSUBSTANTIATED DIETARY SUPPLEMENT CLAIMS. THAT WOULD BE UNDERSTANDABLE AND LOGICAL. HOWEVER, INSTEAD, THE AGENCY IS PROPOSING VIRTUAL ELIMINATION OF AN ENTIRE CATEGORY OF CONSUMER INFORMATION, WITH BROAD RESTRICTIONS AND CONFUSING RULES. I'D SAY THAT'S KILLING A FLEA WITH A CANNON.

MR. CHAIRMAN, MILLIONS OF CONSUMERS LIKE ME HAVE AND WILL BENEFIT FROM LEARNING MORE ABOUT THESE SUPPLEMENTS FROM THE "STRUCTURE/FUNCTION STATEMENTS." WHAT THE FDA IS PROPOSING SEEMS LIKE A REGULATORY SLEIGHT-OF- HAND TO STIFLE SUCH STATEMENTS.

I IMPLORER YOU AND THE MEMBERS OF THIS COMMITTEE TO URGE THE FDA TO WITHDRAW ITS PROPOSED RULE. THE LANGUAGE IN THE EXISTING DIETARY SUPPLEMENT ACT ALREADY GIVES SUFFICIENT DIRECTION AND ESTABLISHES EXPLICIT LIMITATIONS ON "STRUCTURE/FUNCTION STATEMENTS." AND IT GIVES FDA THE AUTHORITY IT NEEDS TO CHASE DOWN DELINQUENT COMPANIES AND THEIR PRODUCTS.

THE FDA'S PROPOSAL IGNORES CONGRESSIONAL INTENT AND FLIES IN THE FACE OF THE BEST INTEREST OF THE 100 MILLION AMERICANS WHO TAKE DIETARY SUPPLEMENTS EVERY DAY. WE NEED AND ASK FOR YOUR HELP IF HEALTH CONSCIOUS PEOPLE LIKE ME ARE TO CONTINUE TO BE ABLE TO MAKE INFORMED HEALTH CHOICES. IT IS, AFTER ALL, PART OF THE AMERICAN WAY.

PLEASE SUPPORT US. THANK YOU.

Mr. BURTON. Well, I saw "1 Million B.C.," and those supplements really work, I have got to tell you. [Laughter.]

First of all, let me thank you for coming today. You represent, as you said, a lot of Americans who take supplements, among which I am one. And how do you decide, as an individual, what supplements you should take?

Ms. WELCH. Well, I think I am a pretty average Joe in regard to that. I hear that something is effective and then I try to get the information about it. Sometimes you can work through a distributor who you can get in touch with personally and they can explain everything to you and ask all kinds of questions. But most times, I have to go in to a health shop, a health place, where they have all these supplements, and read the labels and decide for myself what I think is the best thing to do. But I want to just say, briefly, although you didn't ask me, that this is always in conjunction with regular medical check-ups.

Mr. BURTON. Sure.

Ms. WELCH. And, you know, under a doctor's care and everything. But I rely heavily on the labels and on the individual distributor who can tell me a lot about these things.

Mr. BURTON. You don't have to answer this question, but what kind of supplements do you take?

Ms. WELCH. Too many to mention. I just take supplements every day and I take a wide variety of multivitamins and I also take other things that I guess could be classified as women's supplements like calcium and those kinds of things. And I also take blue-green algae supplements.

Mr. BURTON. What kind of an impact do you think these supplements have had on your life?

Ms. WELCH. Well, I have found, very specifically, that when I have tried certain supplements, that they have helped my energy level, which I need when I am on Broadway. For instance, the last time I found something new in the way of a supplement was when I was in rehearsal for Victor/Victoria and I found my energy level, you know, sort of dropping lower and lower and I was eating all the right foods. I don't smoke and drink. And, as everyone knows, I am pretty much of a health creature and fairly disciplined.

But I found myself slumping and actually my brother said to me that he knew of a distributor that handled blue-green algae products and that they were very effective in boosting up energy in a very natural way, no caffeine or anything that revs you up, you know, and makes you speed away. So I started taking them and they were very effective and I have been taking them still.

Mr. BURTON. Well, I just have one last question and I think you may have answered it in your opening statement. You do believe the information that you are getting on these supplements that you buy in the health food store is adequate and well-enough labeled?

Ms. WELCH. I believe they are. I would like more information, but as, according to what, you know, the rules and the laws are now, I think to have less would be a very bad thing.

Mr. BURTON. We had the Commissioner in just before you testified and I believe they are going to try to expand the information on the labels and in the products so that consumers will even have more information.

Ms. WELCH. I think that would be very helpful. And when I was growing up as a young girl, there was nothing like a health food store or a health store which you could go in and get vitamins and supplements. That was just not in the mix at all. And as I have come along now, this is very much an everyday thing and everybody I know takes supplements of one kind or another. It is interesting to note that the next generation or certainly the generation that is, you know, out there now, you know, is conversant with this kind of thing and they usually hear on the grapevine that something is working well and they go in to find out for themselves.

It would be better if we had more specific information, I think, and more of it. Of course there are books and you can get whole books on herbal supplements and vitamins and what they do. Because I think most people now have an attitude about preventative medicine trying to go to the doctor on a regular basis, but for treatment only as a last resort if you can't cure your malady by something that can help your immune system or to keep you stronger and more energetic on a regular basis so you are not going into the doctor with all kinds of small fry stuff that really does affect the quality of your health on an everyday basis.

Mr. BURTON. Very good. Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman. Thank you very much for your testimony. You are sure right about the idea that it is only recently we have been learning so much about the impact of diet and how beneficial some of these vitamins and supplements can be. But to me the most shocking thing was that, for so many years, doctors didn't even take classes in nutrition in medical school. So we need to educate everybody about the value of nutrition in our diet, whether it is from food products themselves or from supplements that would make up for the lack of some of the essential nutrients that we need.

Ms. WELCH. I think that the stress in modern-day life makes us not absorb some of the nutrients from our food and that is why. And I think that the new woman—if I can call her that—of this last 100 years has been expanding her horizons so much that her energy is often taxed. I think men too, in modern society, have this problem so they try to shore up their resources as best they can in a natural way.

In defense of current physicians, I would just say that, I guess going to medical school is a pretty barrage of so much information that is about really serious illnesses, that it takes a great deal of time and effort to absorb that and, therefore, it is difficult, you know, because it isn't in our culture, common knowledge. I would think that probably the next generation of physicians will know more about this kind of thing.

Mr. WAXMAN. Well, I certainly hope so and I think the medical schools are trying to adapt and recognize the fact that it would certainly be beneficial for our society if we could prevent some of these diseases and not just deal with them after they occur. In getting the information, we all want accurate information. We want to know which products will be helpful and which ones will not. And I think that sometimes I get concerned when someone who stands to make a lot of money wants to tell me how their product is so good for me and I want to know that somebody is sort of watching

to be sure that, when they make those claims, there is some validity. Don't you feel that way too?

Ms. WELCH. I do feel that way. And I am certainly a supporter of the FDA and everything that it represents and all that it does. However, I do believe that, when we are talking about herbs and some of these supplements, we are talking about things that haven't just arrived yesterday. Only, perhaps, in this culture, but in other cultures throughout the world, they have been used for literally hundreds and thousands of years. So there is a kind of a knowledge, if you will, that is among kind of a—I want to say the word traditional—but historical knowledge of these herbs and other supplements and vitamins that is known to people and it isn't—I don't think—I don't think it is even advertised any near as strongly or with as much as the exploitation value as most of our other food products are on the market, television and magazines, today.

Mr. WAXMAN. Well, there is a lot more advertising, a lot more on television and newspapers and magazines for one product or another.

Ms. WELCH. Yes, it is an important thing to look out for. I personally don't think that we are to that level yet in this particular dietary supplement area where we are being delinquent in our claims. But that is just my opinion as a consumer.

Mr. WAXMAN. Yes, but when we passed the bill, though, some Members advocated that we allow people to say that their product would cure diseases without going through any FDA review or test.

Ms. WELCH. Well, that would be wrong.

Mr. WAXMAN. And I thought so too. So you don't want to let them say a product cures diseases, yet the structure function claims can get very close to saying a product cures a disease. So it is a hard line to draw. What we want the FDA to do is to draw that line in a way that will get the information that the public needs to know without having people deceived with claims that aren't accurate, that can't be checked out, and over which FDA would no—

Ms. WELCH. So I take you are in favor of this particular FDA regulation.

Mr. WAXMAN. The regulations? I haven't looked at them. I haven't looked at them specifically. I was in favor of the structure function claims and I want structure function claims to be permitted, but I don't want disease claims to go under the guise of a structure function claim. You wouldn't, would you?

Ms. WELCH. No, I wouldn't. But I don't know that they are claims as much as they are information. I mean, people have to know what they are taking it for.

Mr. WAXMAN. Well, information from somebody who is trying to sell you a product.

Ms. WELCH. Well, that is the American way, isn't that right? [Laughter.]

Mr. WAXMAN. Because I always get a little suspicious—I didn't hear what you said.

Ms. WELCH. I said that is the American way. We are all selling something.

Mr. WAXMAN. Well, I suppose that is true, but then a lot of times the consumers are deceived as a result of it so we want to make sure that—

Ms. WELCH. That is true, but I do think—

Mr. WAXMAN. When it comes to your health, people get very anxious about it. We do live in a time when there is a lot of anxiety, but we want people to have access to products that are going to be helpful, not harmful.

Ms. WELCH. I absolutely agree, but I think that the statutes, as they stand now, are sufficient guidelines to have protection for the public.

Mr. WAXMAN. The statute has to be implemented.

Ms. WELCH. Yes.

Mr. WAXMAN. So they have to decide what the statute is so they have to adopt regulations.

Ms. WELCH. The regulations, yes.

Mr. WAXMAN. So you would prefer they draft the regulations differently than what they have proposed and FDA is now considering all of the comments they have received and we will see what they come up with. But thank you very much.

Ms. WELCH. Thank you.

Mr. BURTON. Mrs. Chenoweth.

Mrs. CHENOWETH. Thank you, Mr. Chairman. Ms. Welch, I am just thrilled that you are here and the evidence is in the package, I guess. I would have to say you do handle such a tremendous schedule and, obviously, your personage speak volumes for our concerns. Thank you very much for taking the time out of your busy schedule to be here.

Ms. WELCH. Thank you. Thank you.

Mrs. CHENOWETH. You know, I guess I have the feeling, like most Americans, that I really want to take my own health concerns into my hands as much as possible and stay healthy, stay energetic, ahead of the power curve of getting sick and then having to seek medical help. And I kind of want to use an analogy, based on what Mr. Waxman said. Every morning, I juice up my own carrots and celery and apple and parsley. And that is an energy drink and very good for me. It is full of vitamin A and other vitamins. But I wouldn't want the Federal Government, because I drink this juice that is also sold in health food stores, because I know it gives me energy, to tell me whether or not I can go to the grocery store, who is probably making a small profit on those carrots that I am buying, and, you know, because of that, I still want to be free to be able to make my own juices or take my own supplements and take care of my own body, ahead of the power curve.

Ms. WELCH. Of course. Of course. We all need information about that. That is the thing. Especially the new generation who will be starting out. Let us say that there is some young woman or young man that is—and this is, of course, totally in agreement with what you are saying—and is going to come along and say, you know, I want to be healthy. I want to make the best of my life. I have this ambition and I know I am going to need optimum health and energy, like Koop said, you know, to make my way in life. So, you know, I have been told that if I take some vitamin C, I am not going to get, you know, sick as fast or if I feel the cold coming on. These kind of things will be passed along and they will go in and they will read a label. Now if the label doesn't say anything, they are going to be deterred from even trying because they don't—they

really literally—don't have any information. I think that we have to have on the labels things that help people understand.

It is up to them whether they take the vitamin C and say, forget about it, you know. This doesn't do a thing for me. You know, it is not like we are forcing people into this, to say, oh, you must do it. I mean, a lot of things that some people take don't work at all for me and I wouldn't do it, I wouldn't have them, I wouldn't buy them. Or I returned them after having bought them and thought, you know, this isn't for me at all.

Mrs. CHENOWETH. Thank you.

Ms. WELCH. Sorry to interrupt you, but I thought we were talking about the same thing.

Mr. BURTON. Thank you, Mrs. Chenoweth. Mrs. Morella.

Mrs. MORELLA. It is a great honor. Thank you very much for being here. I reiterate what the committee feels about your personal experience really enhancing the implementation of the Dietary Supplement Health and Education Act that this Congress passed. You know, I do look at labels of some of the supplements when I go to a health food store and I am always curious about what they will do and what they will not do. Do we, as consumers, have an obligation to do studying or other reading to help us in the decisionmaking? I always wonder, how much am I supposed to know when I look at these items in the health food store?

Ms. WELCH. How much? I don't know, you know. I am not, you know, an expert on this, I just can speak from my own personal experience. I think, short of making claims to cure and do something special for you, they just need to say, first of all, what they contain and what they do. And then I think you have to be deductive yourself and make your decision. And, like so many things in this world, it does come from trial and error. I think we are trying to save consumers from spending money unnecessarily or giving them hopes that are not going to be—

Mrs. MORELLA. We have to be careful of that caveat emptor, you know, let the buyer beware.

Ms. WELCH. Yes, exactly.

Mrs. MORELLA. And, yet, we have an obligation—I guess that is the balance I am trying to resolve—we have an obligation to also look at what we know about certain products before we automatically believe what we would like to have them be able to do.

Ms. WELCH. Well, I would agree if this was a drug we were talking about. What I am basically saying is that I think that there exists already all the provisions to protect the consumer. I think to go beyond that is going over the line. It is a fine line, but I think it is going over the line and could possibly inhibit the taking of these things to people who do take them now and the people who will not have access to them in the near future.

I mean, because it takes a tremendous amount of time to go through and test, so to speak, everything when some of these things have literally been around as if they had never been seen before. But since most of them have been around for, you know, the beginning of civilization, practically. You know, it seems to me, as I said, killing a flea with a cannon. I know that there is an obligation, but it is almost like saying, well, what will carrots do for you? Shall we ban carrots; they are not right for you. I mean, herbs have

been around for so long. I mean, you either don't want carrots or you do want carrots, you know.

Mrs. MORELLA. I love to believe what I see. And what I see and I read I am never sure. I mean, like I grew up with the idea that you take your carrots for your vision and fish was for the brain and, you know, some of those concepts. And, yet, I think there is a certain amount of self-education that is important.

Ms. WELCH. It is. You are right.

Mrs. MORELLA. You heard our new FDA Director this morning talk about her recommendations for the implementation?

Ms. WELCH. I am sorry.

Mrs. MORELLA. Did you hear the new Director?

Ms. WELCH. No, I am sorry I did not hear it. Her recommendations for—

Mrs. MORELLA. How she was going to implement this act. Did you?

Ms. WELCH. No, I am sorry. I did not hear that. I was not aware that she was making a statement.

Mrs. MORELLA. It will be very interesting to, for us, it would be our obligation, to see how she follows through on that. But I think, Mr. Chairman, the fact that you have this hearing makes us all very much aware and I think it helps the FDA, to know how Congress feels and how the citizenry feel. And your being here as a role model. We thank you very much.

Ms. WELCH. Thank you.

Mrs. MORELLA. Thank you, Mr. Chairman.

Mr. BURTON. Mrs. Biggert, do you have any comments or questions?

Mrs. BIGGERT. Thank you, Mr. Chairman. Ms. Welch, when you are talking about the diet supplements, are you talking about something that might have been—you said this goes back for like centuries, something like things that have been used by like Native Americans or—

Ms. WELCH. They could be, but they could be—

Mrs. BIGGERT. Like teas or like roots. Is this part of the dietary supplement or—

Ms. WELCH. I don't—yes, it would be part of dietary supplements. There are a lot of teas that are very useful, I think, for various functions, you know. The thing is that, you know, they are not going to—one particular product, whatever it may be, that is not a drug, is not going to work the same on each person. You know, camomile tea is supposed to calm you down and relax you. You can take it before sleep. I am sure this helps many, many people. It has never helped me. But it is not a bad tea. I am perfectly happy to have my camomile tea from time to time because of the taste.

Mrs. BIGGERT. It is like some people with caffeine. They can't drink it at night.

Ms. WELCH. Caffeine is very difficult for me. That is one of the reasons why—I mean, caffeine really causes, in my body, a very decided reaction that is negative. And I can get terrible migraine headaches from it and really, you know, throw my whole nervous system off which affects other parts of my body. It is not a nice thing. So I try to avoid that. So I am looking for other ways that

I can naturally, you know, shore up my energy without speeding around like a Looney Tunes. I don't like that kind of a thing at all.

Mrs. BIGGERT. What you are saying as far as finding the right diet, the right nutrition, is really the responsibility of each of us to find out what works.

Ms. WELCH. Yes. I think so. As in everything in life, I think that one of the beliefs I have is that each one of us really does have to find in everything in life what works for them. There are all these things available. I think that to try to take on the responsibility for what the individual person has to find for themselves is too much to ask of anybody, even the government.

Mrs. BIGGERT. I think that we probably do that. Like with pregnancy, years ago everybody took all the vitamins, took everything. And then there was this big thing about not using anything that might be harmful.

Ms. WELCH. I am sure that is true. And, yet, I am sure that pregnant mothers today would probably take a lot more vitamins or would want to. I haven't been pregnant in many years, so I can't tell you what they do now. [Laughter.]

Mrs. BIGGERT. No, I haven't either, fortunately. But thank you very much for coming. I appreciate it.

Mr. BURTON. Thank you, Ms. Welch. We are expecting Mr. Kucinich. I think he wants to ask just a few questions before we release you from the table. But I want to assure you that we will be watching and working with the Food and Drug Administration, as well as the people in the industry, to make sure that the structure function rule doesn't change the intent of the DSHEA law. It is extremely important, I think, that the will of the people expressed through the legislation passed by the Congress be followed by every bureaucracy in our government. And if we find a bureaucracy that tries to supersede existing law that has been passed by the Congress with a regulation, then I think that we need to hold them and call them to account. And we will certainly do that.

Ms. WELCH. Thank you.

Mr. BURTON. I will yield to Ms. Norton. Do you have any questions?

Ms. NORTON. Thank you, Mr. Chairman. As a result of hearing Ms. Welch's testimony, I must say that she has inspired some questions in me. The first is, Ms. Welch, have you ever heard of the placebo effect?

Ms. WELCH. Yes, I have. Isn't that where somebody takes a substance which is being tested and it really doesn't have anything in it, and then, because of psychological reasons, it seems to work or not work?

Ms. NORTON. Yes. It is, you know, when we take something, we want it to work and we are all human. That is why we require controlled studies for medicines, because it would be very dangerous to rely on the placebo effect and so, as a matter of the scientific method, it is understood worldwide. We normally do not rely on anecdotal evidence for the reason that, interestingly, you say, for the reason that something may work on me and not work on you. Camomile tea doesn't make everyone sleepy; it makes some people sleepy. Well, at some point, the world wants to know whether or

not it makes most people sleepy or only some people sleepy some of the time.

The only thing that disturbs me about your testimony is this notion that, despite all that the scientific method has established for hundreds of years, you seem to believe that, for something as precious as your body, how you receive it should be the answer, even if that may be, in fact, the placebo effect and you may be spending your good money on a placebo.

Ms. WELCH. No, I don't happen to believe that is true. I know what you are getting at, but I don't know how any study could help every person know how it is going to work on them. That is impossible. And—

Ms. NORTON. And no study purports to do that.

Ms. WELCH. And I don't think it is possible.

Ms. NORTON. The studies do purport to tell us whether, in the main, the claim to effect is valid or not. And I was interested, as you said, people do deserve as much information as possible. Isn't that the kind of information you would want people to have? In the main, recognizing that there are always some people who die of aspirin, even though most of us get our headaches cured by it, in the main, I would want to know that a very tiny percent die of aspirin. But I would also want to know whether or not aspirin cures headaches.

In the same way, and I speak as somebody who, in fact, takes all kinds of these things, so judges for herself, like you, but the more I know whether or not somebody who I trust, some scientific expert says it works, the more confident I am that I am taking what is right for me. And from what I hear you want it. I think you would feel better if you knew—

Ms. WELCH. No, I don't think so.

Ms. NORTON [continuing]. That somebody you trusted, in fact, said that this substance should work this way, as opposed to word of mouth telling you that it works this way.

Ms. WELCH. Well, I can only say that about 10 million Americans feel adequately informed at this point to take these supplements regularly and I happen to be one of them. I respect your disagreement with me.

Ms. NORTON. I would think that for somebody like you and me who have taken but relying on what is on the label, that what we would want the FDA to do is not fail to tell us what works and what doesn't work as a scientific matter. What I think we should be pressing the FDA to do is to find some way to test these substances faster so that we have information to rely on. We ought to be pressing the scientific agency to do its job, rather than saying, step back; we don't need you. Let us simply rely on what is in our head, which may be a placebo.

Ms. WELCH. I am not saying that. I am saying rely on what is existing right now in the FDA in the rules that are existing now. Instead of what I understand to be the idea is to take the definition of disease and expand it to such a degree that, for instance, pregnancy, menopause, things that like that are what I consider normal, would not be considered normal. And you are expanding the definition of the word disease to such a degree that pretty soon you can't say anything. I have heard you use the word claim many

times. I didn't use the word claim in my statement and I don't believe that the rules that are in place now, the laws that are in place now talk about any claim. In fact, I think it precludes making any claim. So I think we are talking about something that really is not—I am not talking about today. I am not talking about making a claim.

Ms. NORTON. The law doesn't exist, as a practical matter, until regulations are issued determining the law.

Ms. WELCH. Yes, I know. These technicalities, you will have to forgive me, I am not accustomed to them.

Ms. NORTON. Just let me say that I join you in your confidence in many of these substances and I think the only thing we can say about the 10 million people who take them is that the more information they have, the more confidence they will have in what they are taking. Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Ms. Norton. I am not sure Mr. Kucinich is going to make it. Let me just end up by saying that I share your concerns. I share your desire for adequate information about supplements and I share your concern that we not allow bureaucracies to supersede the rulemaking authority of the Congress of the United States when it passes a law. That law to which you referred in your testimony, the DSHEA law, was passed overwhelmingly by both the House and the Senate. And for any agency to try to impose a regulation that supersedes the intent of the law is just wrong. And this committee, which oversees the entire Federal Government and every agency of the Federal Government, will exercise its authority to make sure that the regulatory agencies adhere to the law. Now we will try to work with them to make sure that the consumer is protected, as you have stated in your statement. But we are going to make sure that the law is followed. And, toward that end, I want to thank you very, very much for being here.

Ms. WELCH. Thank you. My pleasure.

Mr. BURTON. Your celebrity not only adds a great deal to our hearing, but it adds a great deal to the American public's awareness of how important this issue is. And I am sure people across the country who may be watching this on television are going to appreciate you taking the time out of your busy schedule to come here and testify.

And, with that, let me just say that we are going to recess. And those who will be panelists this afternoon, along with Ms. Welch, if you would like to join us in the back for a brief respite where we can have a bite to eat, and maybe talk with her just a moment, I would really appreciate that. And, once again, thank you very, very much for being here, Ms. Welch.

Ms. WELCH. Thank you.

Mr. BURTON. We stand in recess until the fall of gavel, around 1 p.m.

[Whereupon, at 12:32 p.m., the committee recessed, to reconvene at 1:05 p.m., the same day.]

Mr. BURTON [presiding]. We will reconvene the hearing, and I would like to ask Mr. Bass, Mr. Kracov, Dr. Croom, Mr. McCaleb, Mr. Turner, Dr. Dickinson, and Ms. Gilhooley to please approach the table.

And, although we don't have the vast majority of media here to hear your testimony, I want you to know that it is very important for the record and it will help us make the proper case to other Members of Congress about the importance of dietary supplements. So I want you to know I really appreciate your patience and your being here to testify. And, with that, let me start. I will just start down at the left end by that sexy Mr. Bass—[laughter]—who we talked to and kidded with a little bit earlier. Didn't we, Mr. Bass? Would you like to start and make your opening remarks?

STATEMENTS OF I. SCOTT BASS, J.D., ADJUNCT PROFESSOR, GEORGETOWN UNIVERSITY; DANIEL A. KRACOV, J.D., ATTORNEY, PATTON BOGGS, LLP; EDWARD M. CROOM, JR., Ph.D., PHYTOMEDICAL PROJECT, NATIONAL CENTER FOR THE DEVELOPMENT OF NATURAL PRODUCTS RESEARCH, INSTITUTE OF PHARMACEUTICAL SCIENCES AT THE SCHOOL OF PHARMACY, UNIVERSITY OF MISSISSIPPI; ROBERT S. MCCAULEY, PRESIDENT, HERB RESEARCH FOUNDATION, BOULDER, CO; JAMES S. TURNER, CITIZENS FOR HEALTH; ANNETTE DICKINSON, VICE PRESIDENT, SCIENTIFIC AND REGULATORY AFFAIRS, COUNCIL FOR RESPONSIBLE NUTRITION; AND PROFESSOR MARGARET GILHOOLEY, SETON HALL UNIVERSITY SCHOOL OF LAW

Mr. BASS. Chairman Burton, thank you very much for the opportunity to testify today with respect to the Dietary Supplement Health and Education and, particularly, with respect to the FDA proposed structure function regulations. The committee has suggested that I speak from an academic legal perspective and I appreciate that.

I am an adjunct professor at the Georgetown University Graduate School of Public Policy and I head the Food and Drug Law practice at Sidley and Austin in Washington, DC. I am a graduate of the University of Michigan Law School, I have coauthored the principal book on the Food and Drug's Dietary Supplement Health and Education Act and was heavily in the drafting of that act in the 3 years proceeding the October 1994 enactment. Our clients include both pharmaceutical companies and dietary supplement companies, functional food companies as well as the National Nutritional Foods Association. Hopefully, then, I can bring a balanced perspective to the issues before this committee.

The first thing I would like to discuss is, very briefly, how dietary supplements were regulated before DSHEA, in order to set the framework for how dietary supplements are being treated under these structure function regulations. The main law that applies to dietary supplements is the 1938 Federal Food, Drug, and Cosmetic Act. Now, back then, it was quite easy to determine the line between the function of drugs and the function of foods. Essentially, any product that was intended to treat, mitigate, or cure disease was a drug and anything that was supposed to affect structure or function, except for conventional foods, was also a drug.

By the 1960's, the dietary patterns of Americans began to change and the demands for information about health changed. However, FDA continued, until DSHEA, to regulate health-related information under the 1938 act and those precepts that we discussed ear-

lier. It was huge public opposition in the 1970's to FDA's attempt to limit the potencies of vitamins and minerals that would be available to consumers that led to the enactment of what is popularly called the Proxmire amendments to section 411 of the act.

By the 1980's, people began to demand more and more ability to take control of their own health. Kellogg's came out with a campaign that fiber might lead to the prevention of certain types of cancers. FDA opposed this and, after many years of regulatory contention, Congress passed the Nutrition Labeling and Education Act that carved out an exception to this 1938 food/drug distinction. They said that companies that sell foods can make health claims.

Now that term "health claims" is not clearly understood in some quarters so I am going to spend just a second explaining that. A health claim is essentially a claim that you will reduce the risk of a long-term disease. A drug claim is a "treatment, cure, prevention" of a disease. Health claims are sort of a cut-out or carve-out from drug claims.

After FDA had essentially told the industry in its proposed NLEA regulations that they were not going to recognize any claims for herbs at all because they weren't nutritional products, that they weren't going to recognize structure function claims for dietary supplements, the type we have today, Congress passed DSHEA and, in so passing, created a brand-new definitional category for dietary supplements that wasn't present in the 1938 law. This brought much more information to consumers, but it also brought a host of interpretational concerns.

The one thing, Mr. Chairman, that you mentioned earlier today, which I think is probably the most important for the public, is the conception that people have read that DSHEA took the safety powers away from FDA. And I won't dwell on that because I think you very articulately set that straight. But let me say that that derives from an old theory FDA used to use when they said, "you can't sue a supplement because of claims, because it doesn't have any claims," but—using ginseng as an example—you have a ginseng capsule, they argued: because you add ginseng to the ginseng capsule, the ginseng is a food additive. Now one would say, who cares? Well, the answer was if FDA called it a food additive, they could never lose a case because they didn't have to prove it unsafe. All they had to do was submit an affidavit of one FDA scientist saying that, in my opinion, experts do not agree this is generally recognized as safe among experts in the field and that was the end of the case. There was no defense. As you will hear in a minute, that is very relevant to today's proposal on structure function claims.

We turn to claims in general, then. One of the most important parts of the Dietary Supplement Health and Education Act was section 6 that is before your committee today, structure function claims. Those claims essentially allow a company to tell how a substance beneficially affects the way in which the body functions, how you maintain or support your immune system or the mechanism by how that dietary ingredient operates in your body. They can also talk about general well-being claims.

Again, just to draw the record, a drug claim would talk about, for example, "fiber extract cures colon cancer." The health claim would be "eating fiber with exercise and a good diet might reduce

the incidence of certain types of cancers.” Whereas a structure function claim would be “a fiber supplement can help to maintain normal and healthy digestive systems and the functioning of your colon.” That distinction is very important today.

So I turn, then, to the last portion of my remarks, to the proposals that Congress is looking at today. That is the April 28, 1998 structure function proposed regulation. I have four points I would like to make today about that proposed regulation. The first is that, in my opinion, it must be withdrawn. I believe that that regulation undercuts the purpose that Congress had in enacting section 6 of DSHEA. I believe that FDA attempted in good faith to try to draw a line, but that that good faith attempt went awry and went into much too much detail and much too broad a scope to eliminate honest, good information to consumers. If we look at the preamble to DSHEA, the important preamble to DSHEA, where Congress said we want healthful diets to mitigate the need for expensive medical procedures, then look at this regulation, they contradict each other.

Now there are some people who would say that any structure function claim is an implied disease claim, that maintaining a good circulatory system is really a “wink” way of saying you’re going to prevent a heart attack. We do not believe that Congress should permit this government to make that claim illegal because somebody thinks that it might be an implied drug claim. Now there are many valid objections that have been filed in the 100,000 comments that Dr. Henney referred to. And I do want to say at this point that we are very encouraged that Dr. Henney has said that she believes that FDA has sufficient safety powers under DSHEA, a stance that contradicts her predecessors. And we think there are people at FDA now who exhibit the same attitude and we are hopeful that this process can go forward in a very positive way.

But let me just bring up four basic points about the structure function claim regs. First and foremost, FDA has put the word “normal” back into section 6 by redefining disease. They say a disease would have to be interpreted as any interruption or impairment of normal structure or function. We fought hard about that word, Mr. Chairman, during the drafting of DSHEA and there were those who tried to put the word normal into that law and Congress very definitively kept it out. Putting the word normal in takes a broad-based health message to the consumer and cuts it down to a narrow area that won’t allow this industry to function properly. For that reason alone, we believe this proposed regulation is not proper.

Second, the way that “disease claim” is defined can make almost any claim illegal. All the FDA has to do is get the affidavit of one health expert who says that in the opinion of the health expert community or the health community, this claim implies a disease. To use an example before, maintaining good circulatory system, it is really for people with heart attacks; that implies a disease; this is an illegal structure function claim. It is much too broad a definition. We don’t think that the government should live with that definition.

Third, Congress said, we don’t want consumers to be fooled. We believe consumers have brains. If you put this disclaimer on that says this is not intended to treat, mitigate, or cure a disease and

FDA hasn't evaluated it, those words have meanings. It is right there on the label. What this proposal does is take away from consumers the right to make that judgment. It makes that disclaimer meaningless. It says, essentially, to consumers: I don't care what you say on the label, what you read, if you have intelligence, we think if we have a health expert who might imply a disease claim from this, you can't get that information. We believe that is wrong as well.

Finally, this claim, this proposed reg, contradicts in its breadth some of the recent first amendment decisions from the D.C. Circuit, including the Washington Legal Foundation of *Pearson v. Shalala*. And, for that reason as well, for first amendment reasons, we believe there are serious issues with this regulation.

We have two proposals to make today, as a solution. The first is—and I have lived with this issue now for 7 years. I am aware of the complexities and I don't treat this as a simplistic issue—but I think that the only solution to this issue is a simple solution. I believe that FDA should be entitled to repropose the regulation, but it should just draw a very simple line to begin with until Congress and FDA have more experience. And that is, if you mention disease, it is a drug. If you don't mention disease, it is presumably a structure function claim. Let enforcement and an advisory body take it up after there.

The main message that we have is that you have to retain a line. Pharmaceutical companies must be given the opportunity to have protection for huge, hundreds of millions of dollars in investments, for important drugs that save lives and cure disease. That is a very important policy of Congress. On the other hand, Congress spoke in DSHEA that the people who want to maintain their health, prevent disease, and stay out of the hospital, they also need information and they are not going to get that information if this proposed reg is enacted.

We believe, therefore, that not only should FDA draw a simple line, but that the Congress should consider additional funds for FDA to enforce against the outliers, the people on the Internet you see who are committing fraud, who don't help the good people in this industry. The mainstream of this industry is bringing important information to consumers. They should be allowed to continue to do that.

And, finally, Mr. Chairman, I propose that an advisory group, modeled perhaps on the American Association of Feed Control Officials or International Milk Shippers, groups that contain government officials, academia, State officials, as well as academics and lawyers and provide nonbinding guidelines to FDA in the grey area, so that we don't have to sit here in oversight hearings for the next 10 years worrying about whether regulation overreaches. Thank you, Mr. Chairman.

[The prepared statement of Mr. Bass follows:]

TESTIMONY OF I. SCOTT BASS
BEFORE
THE COMMITTEE ON GOVERNMENT REFORM
HOUSE OF REPRESENTATIVES
MARCH 25, 1999

HEARING ON FDA'S REGULATORY PROPOSALS UNDER THE DIETARY
SUPPLEMENT HEALTH AND EDUCATION ACT

Mr. Chairman Burton and Honorable Members of the Committee on Government Reform, I thank you for the invitation to address the Committee with respect to the Dietary Supplement Health and Education Act ["DSHEA"], and, in particular, FDA's proposed regulations relating to "structure/function" claims.

Background

The Committee has suggested that I speak from an "academic legal perspective" about these issues. I serve as an Adjunct Professor at the Georgetown University Graduate School of Public Policy, teaching Food Regulatory Policy at the Center for Food and Nutrition Policy, and am a partner in the Washington, DC office of Sidley & Austin, where I head the Food and Drug Law Practice. I co-authored the Food and Drug Law Institute book on DSHEA, was heavily involved in the drafting of that law and have lectured extensively before a number of organizations on the implications of DSHEA. As our clients include prescription drug manufacturers, the National Nutritional Foods Association, dietary supplement manufacturers and companies involved in the marketing of functional foods, I hope to bring a balanced perspective to the issues before this Committee.

The Regulation of Dietary Supplements Before DSHEA

The principal statute regulating dietary supplements is the Federal Food Drug and Cosmetic Act ["FFDCA"], which was passed by Congress in 1938. In those days,

it was much simpler to draw a line between the functions of foods and drugs. Essentially, under the 1938 law, any product that claimed to prevent, treat or mitigate a disease -- or to affect the structure or any function of the body -- was regulated as a drug by FDA, requiring pre-market approval and a substantial research investment.

While the role of dietary supplements in the U.S. diet started to change in the 1960's, FDA continued to adhere to the regulatory precepts of the 1938 statute. In the early 1970's, FDA attempts to limit the potencies of vitamin and minerals met with huge popular opposition, leading to the enactment of Section 411 of the FFDC, known as the "Proxmire Amendments." While potency issues were ultimately put on the back burner, most health-related claims for dietary supplements continued to be treated as illegal drug claims by FDA. When Kellogg tried to get cancer prevention claims on its cereal boxes in the early 1980's, the dietary supplement industry soon followed suit. FDA resisted both efforts until Congress passed the Nutritional Labeling and Education Act of 1990 ["NLEA"]. That Act carved out health claims -- essentially, claims that eating certain foods will reduce the risk of onset of chronic diseases -- as an exception to the "drug" definition.

At the same time, in Section 403(r)(5) of NLEA, Congress gave FDA the opportunity to permit more information about advances in science to be communicated to consumers by adopting a different health claims evaluation process for supplements. FDA declined that opportunity. The net result was that since the rapidly-evolving science for dietary supplements had not yet reached the same point as the scientific research for fiber or calcium, there were no realistic health-related claims available for dietary supplements.

In addition, FDA essentially wrote off the possibility that an herb could bear any type of health claim because herbs were not "nutritional" in the sense that they did not have a Recommended Daily Allowance or Daily Reference Value. These FDA pronouncements spawned a second consumer effort, this time to pass the Dietary Supplement Health and Education Act. With its passage in October, 1994, DSHEA produced a new definitional category, brought more information for consumers and introduced a host of interpretational concerns.

DSHEA and Safety

You may have read or heard that DSHEA took away FDA's power to remove unsafe supplements from the market. FDA officials made that statement in the years immediately following the passage of DSHEA, and the press has continued to echo that refrain. It is not accurate.

DSHEA added new safety powers for FDA. Those safety powers are outlined in the chart for the Committee. New dietary ingredients cannot go on the market without prior notification to FDA with accompanying scientific support for their safety. If an ingredient poses an "imminent hazard to public health or safety," the HHS Secretary may declare the product adulterated immediately; and if the product presents a significant or unreasonable risk of illness or injury under its suggested dosage, FDA can pursue the product in court.

The theme that FDA lost its safety powers emanates from an FDA enforcement theory utilized until DSHEA was passed. FDA claimed that dietary supplements were "food additives," like chemicals added to foods for processing. For example, the Agency argued that ginseng capsules are foods; that ginseng is added to a ginseng capsule; and that ginseng is therefore a "food additive." The reason FDA pursued this theory was that it could not lose such a case. If FDA called ginseng a food, FDA had to prove it was unsafe. If FDA said it was a food additive, all that FDA had to prove was that a scientific expert (usually from FDA) thought that the ingredient was not "Generally Recognized as Safe" among experts in the field. Then the *manufacturer* had to try to disprove a negative: no amount of evidence by the manufacturer could overcome the FDA expert's conclusory statement.

In 1993, two Courts of Appeals invalidated FDA's food additive theory, and Congress confirmed in DSHEA that dietary supplements were not food additives. DSHEA thus did not change FDA's burden to prove its adulteration cases — that burden already existed. While DSHEA gives FDA additional safety powers, it does force FDA to prove its case in court.

It was very encouraging to hear the new FDA Commissioner, Dr. Henney, testify that she felt that FDA now *does* have sufficient safety authority under DSHEA to pursue unsafe dietary supplements. This is a promising change in position. A number of new people in relevant positions of authority at FDA appear to share this view.

Dietary Supplement Claims

One of the most important sections of DSHEA, Section 6, permits what are now called structure/function claims. A structure/function claim is essentially a claim that a substance beneficially affects the way in which the human body functions. A structure/function claim can be framed in terms of "maintaining or supporting" circulation in the body, good memory or the immune system, or it can describe the mechanism by which the substance performs that role. A structure/function claim can also legally promote a feeling of "well-being." Before DSHEA, FDA often considered

these claims to be "illegal drug" claims -- *i.e.*, claims for the "prevention, treatment or mitigation" of a disease.

It is important to note that a structure/function claim is not a health claim. A health claim talks about the long-term reduction of the risk of acquiring a disease. Structure/function claims do not explicitly talk about disease, but rather just about body structure or systems. A brief example illustrates the differences among these claims:

Drug claim: A new fiber extract cures colon cancer.

Health claim: Eating fiber, along with exercise and a good diet, may reduce the risk of developing certain types of intestinal cancers.

Structure/function claim: A fiber supplement can help to maintain a normal and healthy digestive system and functioning of the colon.

The April 28, 1998 Structure/Function Proposed Rule

For the reasons that I will articulate in greater depth in a moment, my view of the structure/function proposal is as follows:

1. The proposed rule should be withdrawn because it undercuts the purpose of Section 6 and contradicts the clear intent of Congress in DSHEA to provide more health-related information to consumers. While the proposal emanated from a good faith attempt by FDA to preserve the interests of both consumers and the pharmaceutical industry in retaining a strong drug research and delivery system, the proposal went awry.
2. FDA should propose a new, simpler regulation drawing a bright line distinction between drugs and dietary supplements. The regulation should not try to cover every conceivable claim. Given the indications of a recent change in FDA's approach to DSHEA issues, this process remains a worthwhile one.
3. Congress should consider additional funds for FDA enforcement against obviously fraudulent and/or unsafe dietary supplement products, exhorting FDA to tread more lightly on borderline claims for safe products.
4. Congress should consider establishing an advisory group modeled on the AAFCO handbook (American Association of Feed Control Officials) or the

Pasteurized Milk Ordinance (Interstate Milk Shippers), comprised of FDA, FTC, industry, legal and scientific representatives, to present non-binding guidelines for when supplement claims become drug claims.

* * * * *

Structure/function claims are about keeping people healthy. Congress spoke eloquently and quite definitively in the Preamble to DSHEA, finding that "healthful diets may mitigate the need for expensive medical procedures ...," "preventive health measures, including ... appropriate use of safe nutritional supplements would limit the incidents of chronic diseases, and reduce long-term health care expenditures" and that "there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health."

Section 6 of DSHEA was drafted to address these Congressional findings. The challenge in interpreting that section is recognizing that while some people might infer a disease-related claim from certain product labels, it is critical to permit helpful structure/function claims made in good faith. If some people think that "maintaining a good circulatory system" is an implied heart attack-prevention claim, that should not in itself make a structure/function claim illegal.

At the same time it is important to retain the line between drug and dietary supplement claims. Consumers are entitled to know when they are receiving medicine that treats, prevents or mitigate diseases — the clinical testing required for FDA approval of a drug provides an assurance to consumers. Similarly, in order to deliver important cures, pharmaceutical companies need to know that there is a reason to spend hundreds of millions of dollars to obtain that FDA approval without the concern that an unproven dietary supplement will be permitted to make the same treatment claims.

While the bright line between those interests can be drawn, it was not drawn properly in the proposed FDA regulation. There are many valid objections that have been raised in comments submitted to FDA in response to the proposal; I address today a few of these more salient issues:

- A. FDA tried to put the word "normal" back into Section 6 after Congress kept it out.

FDA proposes to redefine the word "disease" so that a "disease" would be defined as any interruption or impairment of "normal structure or function." I am not sure what "normal" means, but few people I know over the age of 40 would fit that description. During the negotiations leading to the passage of DSHEA, there were some efforts to insert the word "normal" in the structure/function section. Those efforts were met with strong resistance and Congress chose to leave it out. For this reason alone, the proposed regulation significantly undercuts the benefit of Section 6.

- B. The new "disease claim" definition can make almost any claim illegal.

It is viable to say that structure/function claims should not explicitly mention disease. However, some people will infer disease from any structure/function claim. FDA's redefinition of "disease claims" renders a dietary supplement illegal if the product claims an effect on "one or more signs or symptoms constituting an abnormality of the body." It is not difficult to imagine that some symptoms might be "recognizable to health care professionals" as referring to normal or *abnormal* people -- e.g, a pregnant woman, a woman enduring menopause, an aging individual or a person with allergies.

- C. The "disease claim" definition renders all dietary supplement manufacturers defenseless.

In much the same way as the old FDA "food additive" theory made it impossible to defend any case successfully, so too does this proposal. All that FDA has to prove is that a health care professional "recognizes" that a dietary supplement claim "implicitly ... has an effect on a consequence of a natural state" that the health care professional thinks is an implicit reference to an abnormality. Even assuming that one can figure out what that means, in practical terms it means the defendant loses. If FDA obtains the affidavit of one health care professional, the Agency would carry the day, even if thousands of consumer affidavits said that they did not recognize this as referring to as an abnormality.

- D. Congress required a structure/function disclaimer to inform consumers that the product had not been approved by FDA and was not intended to treat or cure disease. The proposal renders that disclaimer useless.

Congress' purpose in requiring that disclaimer was to trust consumers to read the label and to understand precisely that no drug claim was being made. The proposed regulation ignores the disclaimer language.

E. The proposal treads dangerously upon First Amendment ground.

Recent Court of Appeals decisions have struck down FDA efforts to regulate free speech by pharmaceutical companies in promoting prescription drug products and by dietary supplement manufacturers in making health claims. [Washington Legal Foundation and Pearson v. Shalala.] The net effect of these proposed regulations would be to stifle precisely the kind of information that Congress said that it wanted the public to receive. If enforced, these regulations would go far beyond the minimum necessary regulation of protected speech.

* * * *

Proposed Solution

This area is sufficiently complex as to require a simpler solution. The bright line I discussed earlier can be drawn and used as a basic enforcement guide. If utilized in a good faith manner, there will not be a need for the torturous interpretations that the current proposal forces upon the Agency.

To provide further shadings, Congress might consider the formation of an advisory group which could provide non-binding interpretations of claims that cross the line. There are groups that play an important role in providing informal industry guidance. One such group, the American Association of Feed Control Officials, combines industry, FDA and state officials in determining applicable testing guidelines and appropriate claims for ingredients placed in pet food. Another group, the Interstate Milk Shippers, works with industry, state, FDA and other government officials in developing standards for milk products. A similar association of dietary supplement officials could be comprised of FDA, FTC, state and local officials, along with legal, scientific and industry representatives.

With the foregoing in mind, it would also be helpful to ensure that FDA is given sufficient support to enforce against the fraudulent claims being made by some dietary supplement concerns. One need only scan the Internet to see that consumers are being subjected to patently false or exaggerated claims from many products, some of which are unsafe. Were Congress to increase FDA's enforcement budget for these

activities, it could also direct FDA not to use those funds to pursue "borderline" structure/function claim disputes.

* * * *

I wish to thank Mr. Burton and the other members of the Committee for the opportunity to present these views.

Mr. BURTON. Thank you, Mr. Bass.

Mr. Kracov.

Mr. KRACOV. Thank you, Mr. Chairman. On behalf of my client, Pharmanex, Inc., I want to thank you for the opportunity to provide testimony today regarding our experience in the Cholestin matter. Our hope is that participating in this hearing will play a constructive role in your oversight activities and in FDA's evaluation of its policies with respect to dietary supplement products.

Pharmanex, Inc., now a subsidiary of Nu Skin Enterprises of Provo Utah is a science-based company providing standardized dietary supplement products bearing substantiated claims. In addition to assembling a first-class scientific team that includes experts in medicine, nutrition, and natural product chemistry, Pharmanex invested enormous sums in research and development and put in place manufacturing facilities that employ sophisticated quality control and quality assurance methods. Pharmanex, in essence, represents precisely what the Dietary Supplement Health and Education Act was intended to promote: a responsible company providing quality products that benefit the health and well-being of consumers.

Cholestin, one of Pharmanex's products, is a natural dietary supplement that is composed solely of milled red yeast rice. Red yeast rice, which is a solid fermentation of yeast on rice, has a documented history of use as both a food and health product going back almost a millennium. The species of yeast in Cholestin was originally identified scientifically in 1895 and it has a long history of use in the manufacture of red yeast rice, red sake, and other food products that have long been available in the United States. Indeed, the earliest reported attempt to manufacture red yeast rice in the United States—in 1920—was undertaken by Margaret Church, an employee of the Bureau of Chemistry, U.S. Department of Agriculture, the direct predecessor to the Food and Drug Administration. That effort used the very same yeast strain employed by Pharmanex in making Cholestin.

Some traditional red yeast rice products naturally contain a range of substances known as HMG-CoA reductase inhibitors. These include, but are not limited to, lovastatin, as well as other natural compounds that promote and maintain healthy cholesterol levels. In developing Cholestin as a dietary supplement product, Pharmanex sought to employ modern quality control methods in the ancient recipe for red yeast rice in order to ensure that all of the beneficial constituents are consistently present. In addition, Pharmanex spent millions on clinical research to ensure the product is safe and beneficial.

In spite of this, however, FDA took the position, both in an administrative proceeding and, subsequently, in the *Pharmanex v. Shalala* litigation, that Pharmanex's Cholestin red yeast rice is a drug rather than a dietary supplement. According to the agency, Pharmanex, "manipulated," the production process to ensure lovastatin content and, "touted," the presence of lovastatin in the product. FDA did not challenge the safety of Cholestin.

FDA's legal case was built upon construing a phrase in section 201(ff)(3)(B) of the Federal Food, Drug, and Cosmetic Act as amended by DSHEA. This provision states that, "an article that is

approved as a new drug under section 505,” of the Federal Food, Drug, and Cosmetic Act cannot be sold as a dietary supplement unless marketed prior to that approval as a dietary supplement or as a food. The agency’s view was that Cholestin red yeast rice, a dietary supplement form of a traditional food, could not be marketed because a synthesized drug product, Mevacor, contains the active ingredient lovastatin. Notably, the agency’s construction of this statutory provision was completely at odds with its historical interpretation of the term “new drug approved under section 505” including an administrative decision issued in another matter as recently as December 1998.

The agency’s theory was also at odds with the facts regarding Cholestin. Lovastatin is 1 of 10 HMG-CoA reductase inhibitors in Cholestin, and the company does not control or even test for its level. Lovastatin varies from 20 to 60 percent of the total HMG-CoA reductase inhibitors in the product, which is actually composed mostly of rice. Pharmanex does not add or enhance any single constituent. Rather, Pharmanex has employed quality control measures common to the food industry to standardize the overall level of beneficial constituents. Such standardization is precisely what Congress sought to encourage in DSHEA. Indeed, it is worthwhile noting that, although Cholestin is simply ground red yeast rice, DSHEA specifically authorizes the use of metabolites, extracts, and concentrates as dietary supplements.

Moreover, rather than touting the lovastatin content of the product, the company has marketed the product as a natural dietary supplement: a food. Indeed, a Federal judge in a trademark case specifically found that Cholestin was not marketed as a drug and did not compete with drug products. The agency’s case was built entirely upon a few Pharmanex references to lovastatin in the context of overviews of clinical research, and a tiny warning formerly found on the back label of the product.

As to the historical marketing of red yeast rice containing lovastatin, even FDA’s own testing found that some other traditional red yeast rice foods on market contained lovastatin, including one with a lovastatin level equal to 39 percent of that found in Cholestin. Phamanex’s own comprehensive testing here and in China found traditional red yeast rice foods with more lovastatin than in Cholestin. The presence of lovastatin, a food product like red yeast rice, is not that surprising. The ability to produce HMG-CoA reductase inhibitors has been found to be widespread among fungi originating from different taxonomic groups and habitats. For example, lovastatin is found at high levels in a species of mushroom widely consumed in the United States.

Fortunately, on February 16, 1999, the U.S. District Court for the District of Utah found for Pharmanex in the *Pharmanex v. Shalala* litigation, holding that Cholestin is, in fact, a dietary supplement. Nevertheless, FDA’s position with respect to Cholestin placed an enormous burden on the company, resulting in millions of dollars in lost equity value and marketing investments, as well as significant litigation costs. Indeed, but for the district court’s earlier grant to Pharmanex of a preliminary injunction preventing FDA from initiating further detentions of Pharmanex’s red yeast

rice imports, it is quite possible that the company would have gone out of business entirely.

For Pharmanex, the FDA's position in the case has always been puzzling in that the company thought that it was a model for what FDA would like in a dietary supplement company: strict quality controls, extensive efforts to understand the nature and safety of its products, and substantial investments in clinical studies. The company always wondered why the matter was treated as an enforcement case with an approach of "detain imports and ask questions later." Over the many months of back and forth with the agency, Pharmanex repeatedly suggested ways that the matter could be resolved, but FDA seemed determined to stick to its initial legal theory, rather than find a way to maintain consumer access to what we believe is an important product.

In the aftermath of this decision, we hope FDA will reexamine its policies in light of the intent of Congress in enacting DSHEA. That intent was quite clear: FDA should do everything possible to ensure the availability of safe dietary supplement products. Regulation of these products should not be governed by a blind presumption that pharmaceuticals should be protected at all cost. Simply put, FDA needs to take dietary supplements seriously from a public health promotion standpoint, and should foster companies like Pharmanex that are willing to put funds into serious quality controls and research.

I know that my client continues to be willing to put this litigation behind them to work closely with the agency to foster the growth of a research-based dietary supplement industry. Such cooperation would be a significant step toward promoting the public health, as Congress intended in DSHEA. Once again, on behalf of Pharmanex, Inc., thank you for this opportunity.

[The prepared statement of Mr. Kracov follows.]

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**Testimony of Daniel A. Kracov
On Behalf of Pharmanex, Inc.**

**Committee on Government Reform
U.S. House of Representatives
March 25, 1999**

On behalf of my client, Pharmanex, Inc., thank you for the opportunity to provide testimony today regarding our experience in the Cholestin® matter. Our hope is that participation in this hearing will play a constructive role in your oversight activities, and in the Food and Drug Administration's evaluation of its policies with respect to dietary supplement products.

Pharmanex, Inc., now a subsidiary of Nu Skin Enterprises, Inc. of Provo, Utah, is a science-based company providing standardized dietary supplement products bearing substantiated claims. In addition to assembling a first class scientific team that includes experts in medicine, nutrition and natural product chemistry, Pharmanex has invested enormous sums in research and development, and has put in place manufacturing facilities that employ sophisticated quality control and quality assurance methods. Pharmanex represents precisely what the Dietary Supplement Health and Education Act was intended to promote -- a responsible company producing quality products that benefit the health and well-being of consumers.

Cholestin, manufactured and marketed by Pharmanex, is a natural dietary supplement composed solely of milled red yeast rice. Red yeast rice, which is a solid fermentation of yeast on rice, has a documented history of use as both a food and health product going back almost a millennium. The species of yeast in Cholestin was originally identified in 1895, and has a long history of use in the manufacture of red yeast rice, red sake, and other food products long available in the United States. Indeed, the earliest reported attempt to manufacture red yeast rice in the United States -- in 1920 -- was undertaken by Margaret B. Church, an employee of the Bureau of Chemistry, U.S. Department of Agriculture -- the direct predecessor to the Food and Drug Administration. That effort used the same yeast strain used by Pharmanex.

Some traditional red yeast rice products naturally contain a range of substances known as HMG-CoA reductase inhibitors -- including, but not limited to, lovastatin -- as well as other natural compounds that promote and maintain healthy cholesterol levels. In developing Cholestin as a dietary supplement product, Pharmanex sought to apply

modern quality control methods to the ancient recipe for red yeast rice in order to ensure that all of the beneficial constituents are consistently present. In addition, Pharmanex spent millions on clinical research to ensure the product is safe and beneficial.

In spite of this, however, FDA took the position both in an administrative proceeding and subsequently in the *Pharmanex v. Shalala* litigation that Pharmanex's Cholestin red yeast rice is a drug rather than a dietary supplement. According to the agency, Pharmanex "manipulated" the production process to ensure lovastatin content and "touted" the presence of lovastatin in the product. FDA did not challenge the safety of the product.

FDA's legal case was built upon construing the phrase in Section 201(ff)(3)(B) of the Federal Food, Drug, and Cosmetic Act, as amended by DSHEA. This provision states that "an article that is approved as a new drug under section 505" of the Act cannot be sold as a dietary supplement unless marketed prior to that approval as a dietary supplement or as a food. The agency's view was that Cholestin red yeast rice – a dietary supplement form of a traditional food – could not be marketed because a synthesized drug product, Mevacor®, contains the active ingredient lovastatin. Notably, the agency's construction of this statutory provision was completely at odds with its historical interpretation of the term "new drug approved under section 505" including an administrative decision issued in another matter as recently as December, 1998.

FDA's theory was also at odds with the facts regarding Cholestin:

- Lovastatin is one of ten HMG-CoA reductase inhibitors in Cholestin, and the company does not control or even test for its level – lovastatin varies from 20-60 percent of the total HMG-CoA reductase inhibitors in the product, which is actually composed mostly of rice. Pharmanex does not add or enhance any single constituent. Rather, Pharmanex has employed quality control measures common to the food industry to standardize the *overall* level of beneficial constituents. Such standardization is precisely what Congress sought to encourage in DSHEA. Indeed, it is worthwhile noting that, although Cholestin is simply ground red yeast rice, DSHEA specifically authorizes the use of metabolites, extracts and concentrates as dietary supplements.
- Rather than "touting" the lovastatin content of the product, the company has marketed the product as a natural dietary supplement – a food. Indeed, a Federal judge in a trademark case specifically found that Cholestin was not marketed as a drug and did not compete with drug products. The agency's case was built entirely

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- As to the historical marketing of red yeast rice containing lovastatin, even FDA's random testing found that some other traditional red yeast rice foods on the market contain lovastatin, including one sample with a lovastatin level equal to 39 percent that found in Cholestin. Pharmanex's own comprehensive testing here and in China found traditional red yeast rice foods with more lovastatin than in Cholestin. However, the presence of lovastatin in a food product like red yeast rice is not that surprising. The ability to produce HMG-CoA reductase inhibitors has been found to be widespread among fungi originating from different taxonomic groups and habitats. For example, lovastatin is found at high levels in a species of mushroom widely consumed in the United States.

Fortunately, on February 16, 1999, the U.S. District Court for the District of Utah found for Pharmanex in the *Pharmanex v. Shalala* litigation, holding that Cholestin is in fact a dietary supplement. Nevertheless, FDA's position with respect to Cholestin placed an enormous burden on the company, resulting in millions of dollars in lost equity value and marketing investments, as well as significant litigation costs. Indeed, but for the District Court's earlier grant to Pharmanex of a preliminary injunction preventing FDA from initiating further detentions of Pharmanex's red yeast rice imports, it is possible that the company would have gone out of business entirely.

For Pharmanex, the FDA's position in the Cholestin case has always been puzzling in that the company thought that it was a model for what FDA would like in a dietary supplement company – strict quality controls, extensive efforts to understand the nature and safety of its products, and substantial investments in clinical studies to support labeling and advertising claims. The company always wondered why the matter was treated as an enforcement case with an approach of "detain imports and ask questions later." Over the many months of back and forth with the agency, Pharmanex repeatedly suggested ways the matter could be resolved, but FDA seemed determined to stick to its initial legal theory rather than find a way to maintain consumer access to Cholestin.

In the aftermath of the decision in *Pharmanex v. Shalala*, we hope FDA will reexamine its policies in light of the intent of Congress in enacting DSHEA. That intent was quite clear – FDA should do everything possible to ensure the availability of safe dietary supplement products. Regulation of these products should not be governed by a blind presumption that pharmaceuticals should be protected at all cost. Simply put, FDA needs to take dietary supplements seriously from a public health promotion standpoint,

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and should foster companies – like Pharmanex – that are willing to put funds into serious quality controls and research.

I know that my client continues to be willing to put the *Pharmanex v. Shalala* litigation behind them to work closely with the agency to foster the growth of a research-based dietary supplement industry. Such cooperation would be a significant step toward promoting the public health as Congress intended in DSHEA.

Once again, on behalf of Pharmanex, Inc., thank you for this opportunity to provide our views.

Mr. BURTON. Thank you, Mr. Kracov. Dr. Croom.

Mr. CROOM. Thank you, Mr. Chairman and members of this committee. I am extremely honored to be given the opportunity to provide testimony to the Committee on Government Reform.

I think, as a way to simplify this, let me say that botanicals is what I am going to focus on, not all the things delineated in DSHEA, because I don't know all the other things. That is not my specialty. But let me say that my original motivation over 20 years ago was to say what could be a safe and effective and affordable and available part of primary health care throughout the world. And there is only one answer and that is botanical medicines, only one answer.

Today the other critical issue is—why my prepared testimony discusses so much science—is that, in my experience, for many years, that I could see traditional healers using very safe and effective therapies, however, they can never be translated into a broader cultural context without the scientific validation of those. Without that scientific validation—I will speak to a couple of issues that I heard raised today—we don't know what is reproducible and how much should you take, once we are beyond a mild tea. And some things are physiologically potent; most, however, are not. As a matter of fact, our biggest challenge is to say how can we have gentle therapies when science, like much else in the world, rewards quick, immediate, dramatic answers, not, I would say, wisdom and compassion and gentleness that we all say we are about as some of us approach middle-age crisis, but that is our real challenge.

And our challenge that why I believe in science is to make a reproducible product so I can believe I get consistency or what I, too, would buy in the marketplace to treat myself, is it can all be answered without conflict and without war if we start having this idea that there really is some value here. And let us study it and let us build up the foundation of not only our health care.

But, I am being very honest, that has not been part of this debate. The debate has always been, in recent times, the question of regulation and of marketing and of corporate interest. Let us broaden this whole discussion. Where is our health, our children's health, and the world's health? With that dedication, we can make changes. And that will come, working together in a cooperative way.

I, too, must comment. I was glad to hear more sense of cooperation. Because let me also say that over 20 years ago, my major professor said there would never be another new drug, even plant, derived, when I started graduate school. And, within 2 years, I was fortunate enough to direct the production of a Chinese traditional medicine anti-malarial drug for clinical trials by World Health.

He, too, had the same debate I heard today. Was it the warm water in the tea? Was it placebo? I had one advantage over my major professor. It was from being a Southerner, which we always study our ancestors. And I grew up with the knowledge that my great-grandfather was a founding member of the North Carolina Pharmaceutical Association and a physician. He used herbal medicine in his constant practice. I did not believe it was all safe and effective. I do not still believe that. But some of it was and it got dismissed by the quickness of time we went for very what I would

call dramatic chemistry and dramatic physiological results is what happened historically in this century.

So I guess if I have a message to you, it is, yes, garlic and ginseng and saw palmetto and St. John's wort, many people have tried these. And many people have benefited. But, really, we have just begun. We are like children who have just begun. So let us not ask for final answers today of where is all the science? Let us take this challenge to say, what can we do?

And I will respond to Raquel Welch's comment. You know science and worrying about placebos, we sometimes forget the individual. And we all know whether it is something we eat. I will be honest. I will leave it out so I won't have a trade association after me. But there are some foods I can't eat that I feel horrible after eating them and other people don't. I don't sleep well. I don't have the same energy level. Now we have to approach things scientifically that way to say both you as an individual and as a group what happens.

And I will speak to that same experience with over 6 years I worked on producing Taxol from renewable yew needles. I have never testified before Congress, but I heard one before. Because I started working to say how could we save the old-growth forest and help women's lives, which is where this issue started. And, therefore, what I found that was, after being official, let us face it, no matter all the clinical, some individuals that are friends of mine who have had Taxol have been greatly helped and some have not. So let us not be naive about our own individual health.

And my message, you can see today—which I appreciate the faith in your staff and my colleagues here, because I can see I didn't stick at all to my prepared testimony. But I understand you get to say both—is that we can do this and that it is really just a beginning. There is science—and there does need to be more science—but science should always be in service to our health and not seen as some kind of bar for us having good health. Thank you.

[The prepared statement of Mr. Croom follows:]

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Testimony

of

**Edward M. Croom, Jr., Ph.D.
Research Associate Professor
National Center for the Development of Natural Products
University of Mississippi School of Pharmacy**

**to the
Committee on Government Reform
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, D.C.**

March 25, 1999

**Dietary Supplement Health and Education Act: Is the FDA Trying
To Change the Intent of Congress?**

Botanical Products: Where is the Health?

Mr. Chairman and members of the Committee, I am extremely honored to be given the opportunity to provide testimony to the Committee on Government Reform.

My name is Ed Croom. I received a Ph.D. in Botany from North Carolina State University and have been a professor specializing in Ethnobotany and Pharmacognosy for the past 16 years. I have served on the World Health Organization's Scientific Working Group on the Chemotherapy of Malaria and Traditional Medicines, FDA's Special Working Group on Good Manufacturing Practices for Dietary Supplements, FDA's Special Working Group on Foods Containing Ephedrine Alkaloids, the United States Pharmacopeia Committee of Revision and Natural Products Subcommittee, and on the Strategic Planning Committee for the Office of Dietary Supplements at NIH.

I am currently on the faculty at the University of Mississippi where I am a Research Associate Professor at the National Center for the Development of Natural Products and an Associate Professor of Pharmacognosy. A portion of my salary is paid with funds provided to the Center by the US Department of Agriculture. I am not receiving any specific Federal research funding at the present time.

My main message to the Committee is that botanical products can be used to improve the health of Americans. I base this statement on my experience of working and living with traditional healers, producing the Traditional Chinese plant derived antimalarial drug artemisinin for pre-clinical and clinical trials by the World Health Organization, developing sustainable Taxol[®] supplies from yew needles, serving as an advisor to the FDA, and as a member of the U. S. Pharmacopeia in establishing standards of identity, purity, and strength for botanicals sold as OTC drugs and dietary supplements. In order to best use botanicals to improve the health of our citizens, we must make a strong commitment to establishing what are safe, effective, reproducible, high quality products that are also affordable and available.

Based on both their long- term use and strong citizen interest in using botanicals, we must rededicate ourselves to serving the public interest by enhancing the health benefits of botanical products. We must ask what is the health outcome of our public policies and scientific studies on enhancing reproducible, high quality, safe, effective, affordable products that are available to our citizens. Overall, the best way to ensure that we have safe and effective botanical products is to combine the knowledge gained by their traditional use with modern scientific studies. If we look at the large diversity of commercial botanical products, some have been subject to little scientific study and some are totally science driven but the majority of our most popular botanicals have a balance of past or traditional use and science.

When science is properly used to enhance the reproducible safety and efficacy of botanicals, we can obtain Garlic, Ginseng, Saw Palmetto, and St. John's Wort products with reproducible physiological effects with each dose or serving of the product. Although Garlic, Ginseng, Saw Palmetto, and St. John's Wort products have been used for many years, we could not know how to be sure that they would have reproducible physiological effects without scientific studies and we would have no possibility of understanding their full potential health benefits. We need public policies in the United States to encourage the further development of the scientific basis of botanical products including product standards to assure ourselves that the current popularity

of botanicals will not just be a fad but that we will receive a real and lasting health benefit. Additional research is the only guarantee that this will happen. Based on my personal experience, I believe that we have not even begun to reap the true potential benefits that the world's botanicals can offer us for maintaining and improving our health.

Herbal medicines can be separated into categories of mild, moderate, and strong physiological activity. For plants with a long and extensive history of human use most do not contain significant amounts of acutely toxic compounds and do not exhibit strong physiological activity so that the short term use of most botanicals cause few if any acute side effects. Although, we do not know the drug interactions of most of these botanical medicines, and this needs to be better understood, the same low level of knowledge is available for most potential food-drug interactions. The major concern with most of these mild remedies is how to evaluate the beneficial health effects of such gentle therapies that may not have a measurable physiological effect for weeks or even months.

Highly concentrated or pharmacologically potent botanicals can have significant adverse effects and cause drug interactions. For plants that exhibit strong physiological effects, we must have very detailed usage and product specification guidelines for their safe use. For botanicals that have the potential for serious side effects or serious drug interactions, we must make a special effort to protect consumers by having sufficient research to protect them from harm as our primary goal. For botanical products, more is not necessarily better but the question for each botanical is how much and for how long should an individual take the product to receive a benefit. To do no harm, we should only use botanical products that have been used by people for a significant time and extent, are consumed in the proper amount and for the correct duration, are correctly identified and processed to maintain their beneficial properties, do not contain significant levels of toxic compounds, are low in heavy metals, are free of toxic microbes, have little or no pesticides, and have minimal or no potentially toxic solvent residues. As the list of potential toxicity's shows most of the safety issues can be prevented by the selection of plants with extensive human use over a long time, are moderate in their physiological activity, and adhere to rigorous good manufacturing practices for identity, purity and strength or quality. What is less well understood by professionals and consumers today is that reproducible botanical products require systematic protocols for the plant material, the manufacturing process, formulation, and storage conditions.

To determine if a specific herbal product can be a safe, effective, and reproducible product, we must conduct a thorough evaluation of the traditional, commercial and scientific literature on the plant including botanical, agronomic, chemical, pharmacological, safety, and clinical information. Many of the factors that influence the quality of plant derived products are the same whether they are processed foods, spices, beverages, traditional plant medicines, or plant derived single chemical entities (such as Taxol® from Yew *Taxus* needles). I have attached in Table 1, a checklist on how to insure that botanicals are safe, effective and reproducible for their desired properties. The range and depth of technical knowledge and expertise necessary for the large scale manufacture of a safe, effective, and reproducible botanical product from batch to batch varies from the very simple (such as insuring that the mucilaginous inner bark of Slippery Elm *Ulmus rubra* is from the correct plant species and has less than 5% of the outer bark for OTC

lozenges) to the highly complex (such as Ginkgo *Ginkgo biloba* extracts that are standardized for 24% flavone glycosides and 6% terpene lactones).

The National Center for the Development of Natural Products has an active research program on Botanical Dietary Supplements. The goal of the program is to enable the safe, effective, and proper use of high quality botanical products by informed professionals and consumers. The research and educational objectives include:

1. Understanding what health care professionals and consumers know and don't know and how they are currently using traditional remedies and commercial botanicals.
2. Educating professionals and consumers regarding the proper use of botanical products for health and well-being.
3. Enhancing botanical product safety and efficacy.
4. Contributing to public policy development.

The botanical research program at the Center has included studies of the ethnobotany in the Southeast rural populations, a survey of Mississippi households and a national survey of pharmacist's perceptions. Educational activities have included a symposium entitled "Botanical Dietary Supplements: How Can Consumers Make Informed Decisions" and numerous continuing education programs for professionals. Scientific activities have included the identification and authentication of botanicals, the characterization of botanicals, chemically, botanically and pharmacologically, as well as studying the agronomics and cultivation of high quality medicinal plants.

Again let me emphasize that most of America's leading botanical products including Garlic, Ginkgo, Ginseng, St. John's Wort, Kava, and Saw Palmetto owe their reproducible properties to the scientific research that was used to substantiate the health benefits of these products. Globally and domestically, we have many botanicals that have a long history of human use, including botanicals used by American pharmacists and physicians during the first half of this century, that with the assistance of modern scientific studies can offer innovative and unique products to maintain our health and delay the onset of some of our most serious health conditions.

The demand of the American public for herbal products drives the need for good science and information in order for consumers to make good decisions. To realize the optimum benefits of these products we must work to increase knowledge and cooperation between business, government and consumers to enhance our individual and public health. This will require the commitment and senior leadership of government to insure that safe, effective, and affordable botanical products are available to consumers. As scientists, our commitment must be to conduct the most relevant scientific studies to enhance the quality, safety, and efficacy of botanical products.

I would be happy to answer questions from the Committee.

Thank you.

Table 1. Making Safe, Effective, Reproducible Botanical Products¹

DOCUMENTATION	Evaluation the traditional, commercial and scientific (botanical, agronomic, chemical, pharmacological, toxicological clinical) literature on the plant
HUMAN USE	Over-all evaluation of the accuracy and completeness of human usage data including: <ul style="list-style-type: none"> • the time and extent of general and specific uses • traditional and commercial collection • processing protocol • final product form • route of administration (internal, oral infusion or decoction; external, poultice)
GOOD PLANT PRACTICES	Insure the following steps are taken: <ol style="list-style-type: none"> 1. Use the correct plant species <ul style="list-style-type: none"> • correct scientific name(Latin binomial) • verified by a plant taxonomist with expertise in the local flora or plant group • the suppliers know how to distinguish the correct species of plant from closely related species and other plants that are known adulterants • only the desired plant parts 2. When possible, understand the influence of the following on the desired plant: <ul style="list-style-type: none"> • collection location, • climatic factors (light, temperature, water), • soil quality (nutrients density, fertility) • Biotic influences (animal, microbial, plant-plant interactions) • collection at optimal age, or stage of development, and drying temperature • collection at optimal time of day 3. Have established protocols for maintaining the quality of the plant material
GOOD MANUFACTURING PRACTICES	Correct plant Specifications for grinding and blending Type of heat Equipment Type of solvents <ul style="list-style-type: none"> • The amount of solvent, • Ratio of herb to solvent • Length of processing Written protocols for QA/QC: <ul style="list-style-type: none"> • In-process controls • Chemical or biological profiles for batch to batch consistency • % actives if standardized • Microbiology • Heavy Metals • Solvent residues • Pesticide residues
FORMULATION AND STORAGE	<ol style="list-style-type: none"> 1. Establish final product formulation protocols for each formulations (e.g. Powder in capsule, dry extract in tablet, plant tincture, tea bag) 2. Guidelines for storage and shipping that will result in a stable product with reasonable shelf life

¹ E. M. Croom, Jr., Ph. D., NCDNP, School of Pharmacy, University of Mississippi

Mr. BURTON. Thank you. Thank you, Dr. Croom.

Mr. McCaleb.

Mr. MCCALED. Thank you, Mr. Chairman, members of the committee. I would like to thank you for the opportunity to address you today on the FDA's handling of dietary supplement labeling issues.

The Herb Research Foundation is a 15-year-old scientific organization, nonprofit, tax-exempt organization, that compiles research on botanicals and gives information for the education of the public, the media, scientists, health professionals, pharmacists, and so on. We have perhaps the best library of scientific journal article collection in the country on the subject of herbal medicine and herbs used as dietary supplements. We have over 200,000 scientific articles in our files and provided a lot of those articles to Members of Congress during the debate over DSHEA. We have also provided a lot of the substantiation information for companies who want to make scientifically substantiated structure function claims.

I was also a member of the Commission on Dietary Supplement Labels, as you know, and, as part of that and through my 25-year career in herbal products, I have studied and understood the regulation of dietary supplements and the debates over them for years. I followed a lot of the things that Scott Bass was talking about a moment ago.

The FDA's proposed rules under discussion today do appear to me to be an attempt to sort of turn back the clock to circumvent the will of Congress and of the people and to prevent the very types of claims that DSHEA was written to allow. I believe DSHEA has produced very impressive public health benefits already. HRF is very aware of the increasing volume and quality of scientific research because we track it daily. We receive stacks of articles every week on the latest research on botanicals used in health care.

We have also witnessed a new public awareness in health and nutrition. Nobody wants to be a minimum-daily adult. People are not looking for just the disease preventive effects of taking vitamin C to prevent scurvy. In fact, I would venture to guess that nobody takes vitamin C to prevent scurvy any more. Rather, our concept of nutrition and health now has expanded to the point that we understand that certain types of foods and supplements can help maintain and promote and increase our health and, some people would say, prevent disease. And I understand that there is sometimes a fine line between those types of claims.

In addition, the passage of DSHEA has increased the sophistication in supplement formulation and created, I think, dramatic incentives for research. We have not seen this level of research in this country for many years on botanical products. In addition, technologically advanced companies created by the newly allowable supplement claims are raising standards of quality in the industry and bringing much-needed research funding to academic institutions for high-quality American supplement research.

DSHEA is producing just exactly the kinds of changes that we envisioned in supplement research, development, and use of dietary supplements. A better-informed public is using the best-researched supplement ingredients to produce real gains in public health. It is time for the FDA to abandon its continuing battle against dietary

supplements and against the right of the public to access truthful information about the known effects of supplements.

I am disturbed by the repeated misrepresentations made by the FDA alleging that supplements are unregulated, a word that has appeared in nearly every magazine and newspaper story since the passage of DSHEA on supplements. The FDA persists in alleging that Congress jeopardized public health to appease the so-called multibillion-dollar supplement industry and that DSHEA exempts supplements from government oversight. As we have heard today, none of these things is true.

My specific objections to the proposed rules: the redefinition of disease. The FDA's proposed definition would allow any deviation from a state of normal health to be considered disease. Armed with that ability to broadly redefine disease, FDA could consider any product which helps or which claims to help maintain normal health, a drug claim. Any deviation from perfect health could be called a disease, even if that deviation is a normal part of aging.

The Commission on Dietary Supplement Labels spent 2 years in careful consideration and often debate on regulation of supplement labeling. Throughout this process, we assumed that the definition of disease, drug, supplement, and food were not subject to change except by Congress. Indeed, the FDA testified before us that they were unable to change or interpret these definitions without an act of Congress. Now it seems the agency believes it has the power to radically alter the definition of disease and grant itself the power to define anything as a drug. By the FDA definition, thirst is a disease and drinking water a drug.

Implied claims. The FDA has always wanted the authority to decide what is implied in claims. The Commission recognized the difficulty of determining what is implied to a consumer by a particular statement. Regulation must be based on what is stated on a label, not what a consumer reads into it. The FDA endorsed in its proposal this claim, "Helps maintain cardiovascular function and a healthy circulatory system." One consumer reading that statement may conclude this helps keep my heart healthy, while another might think this can help me prevent heart disease. The manufacturer cannot be held responsible for a statement being interpreted as a wellness claim by one and disease-prevention claim by another.

The important point is that the public has a desire and a right to know about substances that can protect their health. Although heart disease can only be diagnosed by a doctor, every American wants to maintain a healthy heart.

Citation of publications. The FDA proposes the citation of a title of a publication or other reference could cause a supplement to be regulated as a drug if the publication or article named a disease. This would restrict the ability of supplement producers to inform the public of even the best quality of research, citing even the works of the National Cancer Institute and other health agencies, respected journals, and other high-quality sources of consumer education.

I think the FDA's proposed rules should be withdrawn and re-drafted with the serious intent to carry out the will of Congress and of the public. The current proposal appears to be a stubborn attempt to reverse the major provisions of DSHEA and prevent most statements of nutritional support. Thank you.

[The prepared statement of Mr. McCaleb follows:]

HERB RESEARCH FOUNDATION

1007 Pearl St. Suite 200
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US House of Representatives Committee on Government Reform
“DSHEA: Is the FDA Trying to Change the Intent of Congress?”
March 25, 1999

Testimony of
Robert S. McCaleb, President, Herb Research Foundation

Personal Introduction

My name is Robert McCaleb, President and founder of the Herb Research Foundation of Boulder, Colorado. Our organization provided hundreds of pages of scientific literature to legislators during the consideration of DSHEA and I served on the Commission on Dietary Supplement Labels. I have been asked to testify on the benefits of herbal remedies in health care. I was educated in Cellular Biology and Botany at the University of Texas and University of Colorado, and have studied beverage, aromatic and medicinal herbs since 1972. I am a PhD. candidate in Ethnobotany at Union Institute. From 1976-1989, I was Director of Research at Celestial Seasonings, and during some of that time headed the Research Committee of the American Herbal Products Association (and the Herb Trade Association) and served on their Board of Directors. In 1983, I founded the Herb Research Foundation, an internationally recognized research and educational resource nonprofit organization which is dedicated to providing facts on production, quality assurance and health benefits of herbs. I have been HRF's president since then, and have published hundreds of articles on herbs, and have been an invited presenter at many botanical symposia around the world, including medical education courses at Harvard and Columbia Universities.

The Herb Research Foundation provides information on the safety and efficacy of herbs for health to the public, the media, the natural products and pharmaceutical industries, the medical profession, and regulators and legislative bodies both here in the US and abroad. We have over 200,000 scientific papers on file for over 1,500 herbs, including ethnobotany and traditional herb information. We are currently writing *The Encyclopedia of Popular Herbs*, to be published later this year, which will provide documentation on the use of 40 popular herbs. HRF also provides herb information through the Natural Healthcare Hotline, whose information specialists use a proprietary database of over 200 herbs developed by HRF, with information on use, effect, dosage, toxicity and safety of these herbs. Some of the latest research information on herbs can be found on our website at www.herbs.org.

Work with governmental agencies

I was an appointed member of the Presidential Commission on Dietary Supplements, and an advisor on herbal topics to several government agencies, including OTA, NIH, OAM, ODS, FDA, and FTC. Most recently, HRF has consulted with the Office of Dietary Supplements on

their Strategic Plan and the new botanical and dietary supplement online database. We have also consulted with the National Institutes of Health on various topics, and the Office of Alternative Medicine in the early development of the botanical database. I have provided testimony and documentation regarding the safety and efficacy of herbs to the Congress during the development of both the NLEA and DSHEA. Last Fall, I was invited to participate in an FDA Consumer Research Working Group to determine what level of information consumers have regarding dietary supplements, and what types of information do consumers need regarding the appropriate use of supplements. To my knowledge, this group has not yet met.

HRF has worked with USAID since 1992 on botanical projects, and currently, we have a multi-year contract with USDA/USAID Africa Bureau providing expertise to African countries interested in developing botanical agribusiness. The projects involve herb market research, crop and product development, training of growers to produce higher quality crops for American and European herbal products, and linking growers with buyers in the United States. Full descriptions of my work with governmental agencies both in the US and abroad are listed in my *curriculum vitae*, attached.

The Role of Herbs in Health Care

Plants have always been and continue to be our most important sources of new foods, medicines and health supplements. Their earliest medicinal use predates written history, and they were virtually our only medicines for over ten thousand years. Only in 20th Century Western medicine did synthetic chemicals arise as major medicinal agents. Even in the modern pharmacy in the United States today, over 25% of medicines are extracted from higher plants, or are synthetic copies or derivatives of plant chemicals.¹ Throughout the rest of the world, herb use far surpasses synthetics. According to the World Health Organization, over 80% of the world's population still relies on "traditional medicines" including herbal medicine, for primary health care.² (Traditional medicine, as a term in international use, refers to systems of medicine in place since ancient times, and does not refer to "conventional" or "orthodox" medicine as practiced in the US today.) In the US, whole plants and their extracts have almost vanished from the pharmacy as approved drugs, but are sold as dietary supplements. This is largely the result of the high cost of drug research and of gaining regulatory approval, combined with the lack of patent protection for natural products. Simply put, in the United States, natural medicines are not economically viable candidates for drug research and development. A company which spends the required \$50-500 million to gain new drug approval for a plant would not have the exclusive right to sell it.³

In the absence of a realistic avenue for the approval of complex natural products as drugs, these products, many of which are approved as medicines in Europe and Asia, are thriving here as dietary supplements. Herbal products are becoming ever more popular in the United States, with annual growth rates in natural food stores as high as 60-80% for herbs in bulk, capsules, extracts, tinctures, tablets and teas used for health purposes.⁴ Botanicals have migrated from the pharmacy of the early 20th Century, to the health food store and now back to the pharmacy, grocery and discount stores, which are the bastions of mass-market sales. Botanical sales in the mass market have increased 300% since 1992.⁵ In 1995, Americans spent \$2.5 billion for herbal products, with multi-level market sales accounting for \$960 million of that total.⁶ The US market

in botanicals is approaching US \$4 billion in retail sales, and has grown at an annual rate of up to 100%.⁷ Top selling herbs include aloe, echinacea, garlic, ginkgo, ginseng, grape seed, kava, milk thistle, saw palmetto, St. John's wort, cranberry and valerian.

Disease Prevention / Health Maintenance With Herbs

Prevention and self-care are the keys to lowering health care costs while improving our health. The former Director of the US Office of Alternative Medicine of the National Institutes of Health, Joseph Jacobs, M.D. described the American medical system as "a sick care system, not a health care system." The system is mostly devoid of the concepts of wellness and preventive medicine, and even the term "preventive medicine" is usually used to describe early disease detection.⁸ Preventive medicines, especially for self-care, are almost completely absent from our pharmaceutical system. In over 60 years of regulation by the US Food and Drug Administration (FDA), not a single over-the-counter (OTC) medication was approved for internal use for the prevention of any major disease. Ironically, aspirin was approved not long ago for stroke prevention, although it is among the most toxic blood thinners available. Prior to this, the only FDA-approved OTC preventive medicines were fluoride toothpaste, sunscreens, motion sickness pills, and recently, indigestion-preventives (which were formerly Rx ulcer drugs).

Meanwhile, herbal research continues to document the potential utility of natural health-promoting substances (which could be thought of as preventive medicines), including those with antioxidant, anticarcinogenic, cardioprotective and other health-protective properties. These, appropriately used, could help to reduce the risk of serious disease and dramatically lower health care costs. European and Japanese consumers have access to dozens of government-approved natural remedies which have disease preventive effects. Herbal dietary supplement products can help maintain healthy function of the heart, liver, eyes, prostate gland, memory and cognitive function, and many other aspects of health.

In the few years since the passage of DSHEA, interest in botanicals has grown from small, localized natural foods store customers to national consumption through the mass-market channels. Major drug pharmaceutical companies in the US are entering the herbal marketplace; colleges and universities are offering more courses in complimentary medicine, including botanicals as health care practitioners and pharmacists are demanding more education in this area. Besides national media attention (such as the cover story in *Time* magazine, November 1998), herbs have received in-depth attention in medical journals such as *The Journal of the American Medical Association* and its nine affiliated *Archives* journals, and in *The New England Journal of Medicine*.

Perspective on the FDA's Proposed Rules

The future of dietary supplement regulation in the US is uncertain, because of the FDA's proposed rules for implementation of DSHEA. These appear to be an attempt to circumvent the language of DSHEA by preventing the very type of claims which DSHEA was designed to allow. The FDA rules (Docket #98N-0044) suggest sweeping changes to the regulation of supplements, including a proposed redefinition of the term "disease." By changing the definition of disease, the FDA in effect changes what type of supplement label statements can be made about a health condition. For example, under the proposed FDA new definition, any deviation from the normal function of any combination of parts, organs and systems of the body would be classified as "disease," even if that deviation is universal, such as menstruation or menopause in women. By this proposed new definition, any dietary supplement with virtually any effect on the body could be classified as a drug. This runs counter to the letter, spirit and intent of the Dietary Supplement Health and Education Act of 1994.

Implied claims

On page 23625 the proposal states:

FDA agrees with the Commission that
an acceptable structure/function claim
must not imply prevention or treatment
of disease.

The Commission recognized the difficulty of determining what is "implied" to a consumer by a particular statement. The difference between a drug claim, a health claim and an acceptable statement of nutritional support is often a matter of semantics. If a substance has cardioprotective properties, for example, it could be labeled as a drug ("helps prevent heart disease"), a health claim ("may help reduce the risk of heart disease"), or as a statement of nutritional support ("helps maintain cardiovascular function and a healthy circulatory system"). One consumer reading the latter statement may conclude, "this can help prevent heart disease" while another might think "this will help keep my heart healthy." The manufacturer cannot be held responsible for a statement being interpreted as a "wellness" claim by one and a "disease prevention" claim by another.

The only valid criterion for determining the legality of a claim is a strict semantic reading of the claim. It must be a truthful statement and not misleading, which does not overtly claim prevention, treatment or mitigation of a disease. It is not a viable option to second-guess consumer perception of a claim nor to expect consistent public agreement on concepts of health and disease.

The FDA's position on this issue is internally inconsistent. The proposal states that elevated cholesterol fraction is a measurement characteristic of a disease, hence a claim to prevent such elevation would presumably be considered a drug claim. However, the agency presents the statement "helps maintain cardiovascular function and a healthy circulatory system" as an

acceptable statement of nutritional support. Consumers could interpret both claims either in terms of wellness or disease prevention. We believe that both claims, if supported by evidence, are truthful statements describing the effect of the supplement on the structure or function of the body. This was one specific intent of DSHEA, to allow product labeling to inform the public about the effects of a supplement on the structure or function of the body.

Congressional intent in this regard is clear in the Findings (DSHEA § 2, 21 U.S.C. § 321 note):

- (8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;
- (13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers.

New definition of disease

The FDA's proposed redefinition of disease is in clear conflict with the letter and spirit of DSHEA. DSHEA was passed within the context of the existing definition of disease (101.14(a)(6)), and specifically exempts dietary supplement statements of nutritional support from regulation as drug claims. Obviously, changing the definition of disease dramatically affects the types of claims which could be considered drug claims by the agency. This appears to be the intent of the proposed new definition. The proposed new definition is extremely and unacceptably broad:

"any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms (including laboratory or clinical measurements that are characteristic of a disease), or a state of health leading to such deviation, impairment, or interruption; except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included within this definition."

This definition would literally allow any deviation from "perfect health" (the normal function of any combination of parts, organs and systems) to be classified as a disease, even if that deviation is a normal part of aging. By the new definition any dietary supplement which has virtually *any* effect on the body could be classified as a drug. This redefinition of disease is not necessary, not consistent with Congressional intent and in our opinion, illegal. In all the deliberations and

discussions of the CDSL, we worked under the assumption that the existing definition of disease (101.14(a)(6)) was to be used in the application of DSHEA regulations.

DSHEA was passed unanimously by Congress and allows supplements to carry statements designed to inform the public of the effects of supplements in helping to maintain general health and well-being. The FDA proposed definition of disease basically asserts that *any* deviation from this state of "normal" health is disease, so any product which claims to help maintain this state of normal health is actually a claim to prevent disease. This appears to be a direct attempt to prevent the very claims which Congress and the public specifically intended to allow.

Criteria for Identifying Disease Claims

The FDA concept of what constitutes disease is counter to medical and scientific thought, to its own current disease definition, and to Congressional intent as articulated in DSHEA. For example, the agency suggests that "decreases the effects of alcohol intoxication" is a disease claim. Alcohol intoxication is a self-induced drug effect, not a disease.

Also in this section, the agency clarifies its meaning in its proposed definition through examples of statements that it considers disease claims because they relate to a measurable physiological parameter that can characterize a disease. The FDA attacks in this section, one of the key points in DSHEA. If a supplement has a measurable effect on the structure or function of the body, the label should be able to disclose this, so long as the claim is not a disease claim. The statement "lowers cholesterol" is *not* a disease claim. Though pathologically high blood cholesterol is a disease, a substance may be used to lower cholesterol levels that would not be considered high enough to warrant prescription medication. Further, some supplement ingredients have been shown to prevent a transient post-prandial (after eating) rise in cholesterol. This increase is a normal effect of the consumption of a high fat meal. Even a person with normal fasting cholesterol levels may *choose* to take with a high fat meal, a supplement that would limit or eliminate this post-prandial spike in blood cholesterol. Consequently, the truthful disclosure that a supplement lowers blood cholesterol levels, if supported by evidence, is a classic example of a forthright, truthful and not misleading statement describing the effect of a supplement on the function of the body. It is a prime example of a statement of nutritional support, which should be allowed. Similarly, if a supplement does in fact "improve urine flow in men over 50 years old," the label should be allowed to disclose this. Decreasing urine flow rate in mature men is a condition that affects most men, just as menopause affects mature women. Additionally, many botanicals are used in the same way as nutrients to maintain healthy body function. For example, people use extracts of bilberry and marigolds to maintain healthy eye function and vision in the same way they use Vitamin A. Maintaining healthy bodily functions into our later years is a goal of all Americans, and the Congress served us all well by passing DSHEA to allow truthful label statements to help the public make informed choices about products used in self care.

The FDA's attempt to prevent claims relating to natural states such as aging, pregnancy or menstruation also run counter to the letter and spirit of the law. For example, the characterization of premenstrual syndrome as an "abnormality of the body" is not medically valid. It is a common reaction of the body to hormonal changes caused by the menstrual cycle.

Citation of publications

The FDA proposes that citation of a title of a publication or other reference could cause a supplement to be regulated as a drug if the publication or article named a disease. This appears to be another attempt to restrict the ability of supplement producers to inform the public of even the best quality research. This FDA policy would create a disincentive to sponsor supplement research, and could prevent companies from citing the works of the National Cancer Institute and many other health agencies, respected journals and other high quality sources of consumer education.

Summary

The FDA proposed rules should be withdrawn and redrafted with a serious intent to carry out the will of Congress and the public. The current proposal appears to be a stubborn attempt to reverse the major provisions of DSHEA and prevent most statements of nutritional support. Dietary supplement legislation in the United States is designed to provide the public with access to scientific information about the uses of botanicals and other natural products without requiring an unachievable standard of evidence. The research and regulatory costs to achieve approval of new drugs are too high for non-patentable products. The passage of DSHEA has encouraged increasing sophistication in supplement formulation and created dramatic incentives for research. Technologically advanced companies and products are at the forefront of increased supplement sales. The competition among companies created by the newly allowable supplement claims is raising standards in the industry and bringing much-needed funding to academic institutions for high quality American research. DSHEA is producing just exactly the kinds of changes in supplement research, development and use which were envisioned in its passage. A better-informed public is using the best-researched supplement ingredients to produce real gains in public health. It is time for the FDA to abandon its continuing battle against dietary supplements, and against the right of the public to access truthful information about the known effects of supplements. FDA's proposed rules are a step in the wrong direction.

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 - ⁴ *Natural Foods Merchandiser* market reports for 1991, 1992, 1993 and 1994, New Hope Communications, Boulder Colorado.
 - ⁵ Brevoort, P. (1994) The economics of botanicals: the US Experience. Presentation at the NIH/OAM Conference on Botanicals: A Role in US Health Care?, Washington DC, December 16.

⁶ *Nutrition Business Journal*. October 1996.

⁷ Brevoort, Peggy. 1998. "The Booming US Botanical Market: A New Overview." *HerbalGram*. 44. p. 33-48

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Mr. BURTON. Thank you, Mr. McCaleb.

Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman. My name is James Turner and I am the chairman of the board of Citizens for Health. Citizens for Health generated about 1 million letters to Congress to support DSHEA. It has also been involved as one of the plaintiffs in the Pearson case, which was recently decided by the court here in the District against the FDA. Also, last September, it generated not 100, but over 175,000 letters to the FDA complaining about the structure function regulation that was put forward by the FDA.

Our concern about the structure function claim was underlined by the Commissioner's statements this morning. Just as she was slightly off on the 100,000 versus 175,000 names, she was slightly off on what the situation is with regard to the proposed regulation. She said that the FDA wanted to look at a bunch of medical books to find out what the definition of disease was so that they could then decide how properly to regulate the disease aspects of the law.

What she did not say is that FDA has in place a definition of disease by regulation which was in place at the time that DSHEA was passed and it is quite different than the one that they are currently proposing. That regulation says that disease is some damage to a bodily organ, heart, structure, or system which impairs its function, such as cardiovascular disease. The argument that Citizens for Health has made is that that definition should not be changed. Changing that definition completely essentially repeals the structure function aspects of DSHEA. It eliminates the ability to make the kinds of claims that the law was designed to pass.

We are prepared at Citizens for Health. We have already mounted a campaign of 175,000 letters. That is how many they have counted. They are still counting. We are prepared to go to court and argue that the intent of Congress, when the bill was passed, was to recognize by law the definition that FDA had in place at that time, that, as a matter of law, the definition that existed at that time was the definition that Congress put into the act.

We have one minor recommendation to Congress in the future. When taking an action of the kind that they did in DSHEA, probably the exact language of such definitions should be written into the legislation. I have been working on food and drug law since 1968. I was involved in the passage of the Proxmire Act, NLEA, and DSHEA. Every time Congress has moved forward to make more information available to the public about dietary supplements, the FDA has moved backward and tried to undo that action by their regulatory efforts. The FDA, for some reason, seems to be institutionally incapable of having an open mind about the interests of the public about the consumer having information about how to make their own health decisions.

In pursuing this desire—wherever the desire comes from—to keep rolling back these acts of Congress, it also—I don't want to say misleads—but it certainly leads Congress off in ancillary directions. This discussion, for example, this morning about looking in medical books for the definition of disease is completely off-point about the issue. As I have said, the issue is that a definition exists. Congress passed a law fully cognizant of that definition existing.

And now the FDA wants to change that definition. They have provided absolutely zero information as to why that definition should be changed. Incidentally, they have also provided no legal basis upon which they could change that definition.

They have undertaken the same kinds of activities in several other areas which are in our written testimony, which we submit for the record, and, hopefully, it will be published in the final document of the hearing today. Thank you very much.

[The prepared statement of Mr. Turner follows:]

Testimony of James S. Turner, Esq.
Chairman of the Board, *Citizens For Health*
"DSHEA: Is the FDA Trying to Change the Intent of Congress?"
Committee on Government Reform
March 25, 1999

I would like to thank Chairman Burton for the opportunity to speak at this hearing on behalf of consumers of natural health products. *Citizens For Health*, as the consumer voice of the natural products community, has a special perspective to bring to this issue and a strong interest in seeing that FDA supports the Congressional intent of DSHEA.

Citizens For Health is the only national organization representing consumers on issues of choice, information and access to natural health products and therapies. Through our nationwide network of community-based chapters, we marshaled more than one-million consumer signatures and conducted a three year campaign for passage of DSHEA. Our collaborative campaign with the organic foods community to "Keep 'Organic' Organic" resulted in over 300,000 letters to USDA protesting their efforts to change the meaning of organic. And most recently, *Citizens* organized the "Write to Know" Campaign generating over 175,000 comments opposing FDA's proposal to change the definition of disease and restrict information available to consumers on product labels.

Despite such tremendous public outcry, FDA has been unwilling to address the concerns of consumers for the hard-won rights established by DSHEA. *Citizens* requested a meeting with then-Acting Commissioner Friedman after the September 28, 1998 close of the comment period on the proposed labeling regulations to address our concerns. We renewed our meeting request again in November to Commissioner Henney following her confirmation by the Senate. After repeated efforts, we were told in late February 1999 that we should instead meet with the Director of CIFSAN. The continued reluctance of Commissioner Henney to schedule a meeting with us is disturbing in light of the tens of thousands of consumers who voiced their concern that FDA's proposed regulations would undermine DSHEA.

Consumers spent \$12.4 billion on supplements in 1998 compared with \$3.2 billion in 1997 and the numbers continue to grow. According to *N/sight, Winter 1998-99*, a publication by The Hartman Group, the natural products and service industry has grown 20 times faster than the overall economy. Sixty percent of Americans currently use a multi-vitamin and the numbers promise to grow due to "fundamental shifts in the American culture made by widespread interest in 'wellness'" (*N/sight, Winter 1998-99*). These are informed consumers looking to improve their overall health, with the highest supplement usage by the over 50 generation closely followed by the 30-50 age group, according to The Hartman Group.

While supplements have become a solid part of our mainstream culture, there is still room to improve consumer education. People want to know which are the best products to buy and how to evaluate their choices in an expanding dietary supplement market.

With interest in dietary supplements crossing age, racial, economic, and educational divisions, consumers are clamoring for more opportunities to educate themselves about the health benefits of supplements. One of the principle purposes of DSHEA was to expand access to information about dietary supplements so that consumers could make their own "informed and appropriate health care choices for themselves and their families" (Sec. 12(c)). This is the area where FDA has spectacularly failed to live up to the Congressional intent of DSHEA.

In advocating passage of the bill, Senator Orrin Hatch (R-UT) cited examples of "how the FDA has tried to protect the public against unsafe products for which there is no evidence that the product is unsafe" and that "FDA has also acted to restrict the information that the public may receive about dietary supplements." Five years later, after successful passage of DSHEA, FDA's approach to dietary supplement regulation has not changed much.

FDA appears unfazed by DSHEA and has hindered rather than helped consumer education. FDA's proposed regulations for structure/function labeling claims, proposed restrictive ephedra regulations, and lack of published good manufacturing practices (GMPs) -- despite specific direction in the law -- are examples of FDA's resistance to implementing DSHEA.

FDA's Proposed Structure/Function Regulations

FDA's effort to use regulations to expand the agency's authority over dietary supplements by redefining disease (21 CFR Part 101/#98N-0044) undermines DSHEA and is a source of outrage to supplement consumers.

Section 6 of DSHEA allowed the use of structure/function claims on dietary supplement labels as one of the primary ways to get information to consumers about how supplements affect health. A structure/function claim is defined as a statement that "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or that "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function."

If FDA's proposed regulations were to be finalized consumers would lose valuable information about vitamins, minerals and herbs:

- By redefining "disease" in such a broad manner, the proposed regulations would severely limit allowable structure/function claims that could be made on dietary supplement labels. Any deviation from the body's "natural" state would

be considered a disease, leaving the door open for FDA to classify such states as pregnancy, aging and menopause as diseases. (21 CFR 101.93 (II)(B))

- Additionally, the proposed regulations specifically prohibit manufacturers and retailers from citing or referring to in their labeling or extended labeling (ads, brochures, package inserts, etc.) the title of a publication if the title refers to or includes the name of a disease. This would eliminate the use of many scientifically valid articles in publication like *JAMA*, *NEJM*, *The Lancet*, etc. (21 CFR 101.93 (g)(2)(iv)(C))

- FDA establishes a "consumer intent of use" basis for reclassifying a dietary supplement as a drug based on how a consumer intends to use a product—even if it is properly labeled with an allowable structure/function statement.

--"FDA also notes that a dietary supplement for which only structure/function claims are made in the label or labeling in accord with section 403(r) of the act may nevertheless be subject to regulation as a drug if the agency has other evidence (see 21 CFR 201.128) that the intended use of the product is for the diagnosis, cure, mitigation, treatment, or prevention of disease."

(21 CFR 101.93 (I) Introduction)

These proposed regulations would effectively curtail consumers from receiving labeling information about how dietary supplements can be used to maintain health. Producers of dietary supplements would not be able to tell consumers how new scientific research has been linked to supplements that address "natural" states--or how their products can be used to address them.

Citizens ran the "Write to Know" Campaign to organize consumer and industry response to FDA's proposed regulations on structure/function claims. The public comment period ended on September 28, 1998, but FDA has not yet completed counting the number of comments the agency received. So far, FDA publicly acknowledges receiving over 175,000 comments. The agency has issued no official reaction to the overwhelming number of comments or how they intend to proceed. As I mentioned earlier, *Citizens* is working to schedule a meeting with Commissioner Henney about this and other important DSHEA-related issues.

FDA's Proposed Ephedra Regulations

In June 1997, FDA published proposed regulations, "Dietary Supplements Containing Ephedrine Alkaloids" (62 Fed Reg 30678, Docket No. 95N-0304) based on questionable scientific data and would severely limit consumers' access to ephedra products. The proposed regulations:

- would limit potency to less than 8 mg of ephedrine alkaloids per serving with daily intake limited to less than 24 mg
- would require the following label statement: "Do not use this product for more than 7 days."

- would not allow the combination of ma huang with other stimulants, like caffeine
- would not allow label claims encouraging long-term use -- i.e. for weight loss or body building
- would require that label claims associated with short-term effects, like energy boosting, must warn: "Taking more than the recommended serving may result in heart attack, stroke, seizure or death."

However, FDA's concerns about the safety of herbal ephedra-containing dietary supplements is premised on faulty data and has no scientific basis. FDA used incidents from its Adverse Events Monitoring System in an attempt to link negative events with the use of herbal ephedra products. But toxicological experts, industry, and other federal agencies have disputed FDA's assertions and the validity of linking these adverse events with the use of herbal ephedra supplements.

The Small Business Administration (SBA) in its comments on FDA's proposed ephedra regulations said that: "FDA's data do not demonstrate the need for the regulation" and that "there is no research or data to support any of the proposed restrictions." Additionally, SBA commented on FDA's reliance on these adverse reports: "... industry experts who carefully reviewed each AER (adverse event report) in the docket discovered some astonishingly peculiar and irrelevant information. The experts found cases where adverse events occurred absent the use of an ephedra product, cases where no adverse effect was listed, events medically unrelated to ephedrine ingestion, and other bizarre reports ... These reports have no rational relationship to the safety or efficacy of ephedrine alkaloid products."

Herbal ephedra is a common ingredient in dietary supplements used in weight loss programs and energy products. Herbal ephedra has been used safely in Chinese medicine for 5,000 years in the treatment of asthma and bronchial conditions. Clinical trials examining the use of herbal ephedra in weight loss and energy products are currently in process. Conservative estimates are that over one million servings of supplements containing herbal ephedra are consumed daily in the United States -- and over five million people consume these products each year.

FDA has not finalized its proposed ephedra regulations in the face of the high level of controversy generated by the proposal. The limitations placed on consumers by these proposed regulations would be severe and have questionable scientific justification. Several states, including Ohio and Texas, have worked with the dietary supplement industry and consumer groups to address safety concerns about ephedra products within reasonable and scientifically justified parameters. FDA, however, has been resistant to following the lead set by these cooperative efforts.

FDA's Failure to Implement GMPs

FDA's failure to propose or implement good manufacturing practices (GMPs) violates Section 9 of DSHEA which mandated the agency to propose GMPs for dietary supplement products. Congress intended GMPs as a consumer protection mechanism to ensure access to quality products. Five years after passage of DSHEA, FDA has yet to propose or implement GMPs. Senators Harkin and Hatch in their comments to FDA on the proposed structure/function regulations expressed concern at FDA's reticence in this area, stating: "There is no good reason for this delay."

Additionally, due to FDA's lack of action in this area, industry developed its own GMPs and presented them to FDA for approval. FDA would not sign off on industry's efforts but has still taken no action of its own -- another issue *Citizens* is trying to address with Commissioner Henney.

Critics contend that DSHEA removed FDA's authority to regulate dietary supplements, that no checks and balances exist for the industry, and no protections exist for consumers. Admittedly, while many responsible manufacturers already use tough quality-control standards, industry as a whole needs to create more self-regulatory measures, like GMPs, for manufacturers and products so that only top-quality products make it to retailers' shelves. *Citizens*, working on behalf of its consumer members, will continue to make sure industry follows up on these efforts.

In truth, however, FDA can remove supplements from the market when products pose a safety hazard, just as the agency does with contaminated food, biologicals, or pharmaceuticals. And FDA can exercise its ability to test dietary supplement products for dose, safety, and efficacy to hold dietary supplement manufacturers responsible for the quality of their products.

Often critics fail to distinguish between dietary supplements which are foods and pharmaceutical products which are drugs. The reason that dietary supplements are sometimes classified as a drug is that any food or beverage -- including water -- can be classified as a drug if the substance carries a claim to prevent, mitigate, treat or cure a disease. When supplements attempt to make such a claim they should be more stringently reviewed by FDA.

FDA approval and regulation alone is not a panacea for safety concerns. Serious problems exist in the prescription drug area that are driving more and more consumers to consider dietary supplements. One of the major reasons for the increasing popularity of alternative medicine is the use of natural therapies, as opposed to drug-based treatments, according to a survey by The Hartman Group. It is little wonder that the public is looking for alternatives when:

- In 1996 alone, over 108,000 Americans died in hospitals from adverse reactions to FDA-approved drugs properly administered by licensed medical

professionals, as reported in the *Journal of the American Medical Association* (JAMA, Apr. 15, 1998, "Incidence of Adverse Drug Reactions in Hospitalized Patients").

- In the same year, JAMA reports 2.2 million Americans had adverse reactions to FDA-approved drugs.
- A USA Today editorial (Sept. 17, 1998, "Antibiotic overkill boosts risks"), reports that "each year, patients fill about 150 million antibiotic prescriptions, with a third wrongly prescribed."
- The same USA Today editorial also asserts that, "At one seminar, 80% of doctors admitted to having written antibiotic prescriptions against their better judgment."
- Additionally, 40% of all antibiotics are used to promote growth in animals, undermining the ability of humans to effectively use these drugs -- an issue FDA has apparently been unable to address.

There is a major debate underway in this country as to the safety and efficacy of the use of pharmaceutical products. Dietary supplements are not pharmaceutical products. They are now, and have been regulated since 1938, as foods for special dietary uses. It is unsound law, bad policy, and against the consumer interest for FDA to attempt to regulate dietary supplements, which are special dietary foods, as if they were drugs. Dietary supplements can help consumers to avoid the unnecessary use of pharmaceuticals through healthy lifestyle choices.

Consumers want the chance to take control of their own health. Passage of DSHEA was an important and essential step in assuring dietary supplement consumers broad access to supplement information and products. FDA's resistance to implementing DSHEA as Congress' intended is an ongoing threat to the rights established by the Act. Consumers have shown time again with their dollars and their voices that they want to use dietary supplements and they are willing to fight for the right to make informed health choices.

Mr. BURTON. Thank you, Mr. Turner.
Dr. Dickinson.

Ms. DICKINSON. Thank you and we do appreciate the opportunity to be here to comment on FDA's implementation of DSHEA.

The Council for Responsible Nutrition is a trade association representing the dietary supplement industry. Our hundred manufacturing companies are responsible for producing most of the dietary supplements that are currently available to you in health food stores, supermarkets, drug stores, by direct sales, and by mail order. We were intimately involved in the bipartisan effort to pass DSHEA by 1994 and have been monitoring every step of FDA and congressional implementation of that law.

We believe that DSHEA strikes exactly the balance that Mr. Burton and Mr. Waxman spoke of this morning, that is the balance between protecting consumer access to products that they want to improve their health and also allowing FDA ample authority to enforce the requirement that the products be safe and that the products be appropriately labeled and that any statements on the label be substantiated. We believe DSHEA quite intentionally allows that balance to be struck.

We think the most damaging thing that is happening today that could endanger DSHEA and endanger the industry is the widespread perception that is being spread by the media and, sometimes, supported by some individuals even within the regulatory agencies that these products are unregulated. It would be bad for industry, it would be bad for consumers if, indeed, these products were unregulated. But they are not. FDA has authority over the safety of these products and DSHEA specifically spells out procedures to be followed before a new ingredient can be introduced in a dietary supplement. It also gives FDA ample authority to withdraw or seize products that are found to be unsafe and CRN supports these procedures.

We think the only thing that could be done that would be better in terms of making DSHEA better would be for FDA to step up to the plate to its duties in the way of enforcement. We think that companies who are trying to do the right thing are not well-served by an agency that does not enforce the requirement that statements on the label be truthful, not misleading, and substantiated. Nor are they supported, nor are they helped by an agency that doesn't take swift action when there are issues of safety to be addressed.

Recently FDA seems to be moving in the direction of being somewhat more active in these areas. For example, they have been reviewing the 75-day notices for new ingredients that are required under DSHEA and, just this year, they moved against a product called GBL, which they had already determined to be unsafe, but was being marketed anyway. CRN supported that action and we would continue to support FDA actions in the interest of assuring the safety of products that are available to consumers.

Our written testimony addresses other areas where CRN and other members of the industry have supported FDA action, which unfortunately has been slower in coming than it should be, for example, in the area of finalizing good manufacturing practices, which DSHEA recognized are essential to assure the quality of

products available to consumers. Also, there needs to be extensive improvements in FDA's current handling of adverse event reporting for nutritional supplement products. There needs to be a dietary supplement advisory committee established for FDA. FDA currently relies on its Food Advisory Committee, which, unfortunately, does not have the kinds of individuals, the kind of expertise, represented on it that it needs in order to address dietary supplement issues.

On the issue of the current proposal of FDA on statements of nutritional support, CRN has submitted extensive comments to FDA criticizing virtually every element of that proposal. FDA recognizes in its preamble that there is very little difference between promoting health and preventing disease and that almost any disease claim can be stated as a statement supporting structure or function of the body. We think that this very recognition by FDA underlines what is wrong with the current structure function proposal.

Congress drew the only bright line that can be drawn between permissible statements of nutritional support and disease claims when Congress said in DSHEA that a statement of nutritional support may not mention a disease or related condition nor may it use the kinds of terms that are embodied in the drug definition, such as prevent, treat, cure, mitigate. Beyond that, the act clearly anticipates that any statement that, on its face, is a statement about affecting structure and function should be permitted under DSHEA. Once FDA leaves that solid ground and launches off into trying to draw another line between statements of nutritional support that may be implied disease claims and statements that may not, we believe they enter an area where there really is no logical line that can be drawn.

For example, in the proposal, FDA says that it is quite OK if you say, as a statement of nutritional support, that a product maintains a healthy cholesterol level or that it maintains a healthy heart. We would agree with that statement. However they also say that it would not be an acceptable claim if you say a product lowers cholesterol. What do you think people believe maintaining a healthy cholesterol means? They obviously think it means having a lower cholesterol. So FDA is trying in this case to draw an indefensible line between what they would consider to be an implied statement and a disease claim. We believe that all of these statements should rightly be permitted as statements of nutritional support regarding effect on the structure and function of the body.

The FDA proposal would even prevent the provision of adequate information to consumers regarding the research basis for some of these statements. As Robert McCaleb mentioned, the proposal would prevent manufacturers, in labeling—and remember that the rule applies to labeling as well as to labels, so informational brochures that are prepared by the company and distributed with the product would have to comply with this rule—it forbids the citation of articles that contain the mention of a disease.

CRN published a statement on benefits of nutritional supplements early last year citing almost 200 references. And we went back and checked how many of those have the name of a disease in the title of the article and it is more than 50 percent. One could not do a competent review of the science on any subject related to

health without mentioning such articles. So we are very concerned about that aspect.

CRN believes that FDA would do well to follow the USDA model in this case. When USDA published an organic rule that was hugely opposed by consumers and on which they also got more than 200,000 letters, the Secretary stood up to the bar and said, OK, we got it wrong. We are going to withdraw this regulation. We are going to go back to the drawing board and reconsider what is needed. We think that should be FDA's response also in this case.

In general, our philosophy in dealing with FDA is to try to cooperate for the betterment of FDA and the industry and we are glad to hear Dr. Henney say that, under FDAMA with its instruction to FDA to deal more directly with its stakeholders, that they are going to work with us more closely. We look forward to working both with you and with FDA to resolve these issues.

[The prepared statement of Ms. Dickinson follows:]



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**STATEMENT OF
ANNETTE DICKINSON, Ph.D.
VICE PRESIDENT, SCIENTIFIC AND REGULATORY AFFAIRS
COUNCIL FOR RESPONSIBLE NUTRITION
ON FDA IMPLEMENTATION OF DSHEA**

**SUBMITTED TO
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES**

MARCH 25, 1999

Mr. Chairman, the Council for Responsible Nutrition (CRN) appreciates the opportunity to testify as this Committee reviews how the industry and the Food and Drug Administration (FDA) have implemented the Dietary Supplement Health and Education Act of 1994, which is now in its fifth year of operation. CRN represents 100 companies that manufacture dietary supplements, including vitamins, minerals, herbs, and botanical products. These products account for a large share of the \$15 billion in sales anticipated for this industry in 1999 – products which are used by more than half of our nation's population.

CRN and its members were actively involved in building the bipartisan support that permitted the passage of DSHEA in 1994, and we have been actively involved in working with FDA and with Congress to assure that DSHEA is fully and appropriately implemented.

BEFORE AND AFTER DSHEA

There is widespread misunderstanding of DSHEA in the media, among health professionals, and even within regulatory agencies themselves. To more fully explain the provisions of DSHEA, and to describe the regulatory situation that existed before DSHEA as well as after passage of the legislation, CRN has just released a comprehensive report called *Before and After DSHEA*. There is also a short companion document called *Be Smart About DSHEA*, which describes the provisions of the law in a brief, easy-to-read format. These publications have been sent to all members of Congress, to industry members, and to hundreds of media representatives and health professionals. We are hopeful that these documents will help correct some of the misinformation that one frequently hears, charging that dietary supplements are "unregulated."

IMPLEMENTATION OF DSHEA

Many of the provisions of DSHEA were self-implementing. For example, manufacturers moved quickly to take advantage of Statements of Nutritional Support, notifying FDA as required by DSHEA and making use of the prescribed disclaimer. Likewise, manufacturers who have introduced new dietary ingredients have filed notifications with FDA, informing the agency of their basis for concluding that the ingredients are reasonably expected to be safe.

Other provisions of DSHEA required action on the part of government agencies, and CRN has been working to assure that any actions taken were appropriate. For example:

- DSHEA mandated the establishment of a Commission on Dietary Supplement Labels, to be appointed by the President. I was pleased to be appointed as a member of the Commission, which submitted its final report in November 1997. In addition, CRN monitored and commented on the draft report, testified at Commission hearings, and held workshops to permit member companies an opportunity to express their views.

- DSHEA affirmed the requirement for dietary supplements to meet quality standards and authorized FDA to establish Good Manufacturing Practices (GMPs) for dietary supplements, modeled after food GMP regulations. CRN took the lead immediately following DSHEA in drafting appropriate GMPs for dietary supplements, based on CRN's already-existing GMPs. CRN invited other associations to join in this effort, and several industry groups jointly submitted a GMP draft to FDA in November 1995. This was published by FDA as an Advance Notice of Proposed Rulemaking in February 1997, and a large number of companies and associations submitted comments. In February 1998, FDA asked its Food Advisory Committee for recommendations regarding certain provisions of the GMPs, including appropriate tests for product identity. CRN was present at that meeting and urged FDA to form a working group including industry members with expertise in GMPs, to work on that issue. This was done, and the working group has recently submitted its report. Now is the time for FDA to move forward with next steps, by proposing a formal rule, receiving additional comments, and then moving to a final rule.

Mr. Chairman, it is evident to CRN that DSHEA is working. It could work even better if FDA had sufficient resources to complete some of its remaining obligations under DSHEA. CRN has submitted testimony supporting increased FDA appropriations to permit the agency to complete efforts such as finalizing GMPs and to allow FDA to improve some of its procedures relating to dietary supplements. Perhaps the most critical activity which urgently needs improvement is the adverse event reporting system for dietary supplements.

ADVERSE EVENT REPORTING

The Office of Special Nutritionals at FDA established an Adverse Event Reporting System (AERS) five years ago to compile adverse event reports related to medical foods, infant formula, and dietary supplements. At this time, there are 2621 adverse reports in the system. Many are minor complaints, but some are serious, and there are some reported deaths.

During 1998, the reports were put on the FDA website. Unfortunately, a company can find itself in the position of having its company name and brand associated with a serious adverse event posted on the Web without having any prior warning that such an event has occurred. Further, the background information on the case is unlikely to be available under FOIA, because FDA does not have adequate staff to purge personal case information not releasable under FOIA. In addition, FDA does not have adequate staff or other resources to properly evaluate the adverse event reports, and the reports are released with no comment regarding the likelihood of any actual causal relationship between the product named and the event which occurred. This puts every company at risk of being held "guilty until proven innocent," without investigation. The industry is at risk of being charged with causing a large number of adverse events, many of which may be minor complaints and many of which may not, in fact, be due to dietary supplement use.

It is essential that some scientific evaluation be applied to the adverse event reports dealing with dietary supplements, in order to identify those areas where a genuine safety issue exists, so that FDA and industry can take appropriate action. Criteria have already been established for determining the likelihood of a causal relationship between a product and an adverse event, and FDA applies such evaluations in some other product areas.

For example, FDA received about 3000 adverse event reports in 1997 regarding veterinary drugs. Scientific evaluation revealed that only 1% of the veterinary adverse events were definitely associated with product use; 31% were probably associated, 45% were possibly associated, and 12% were definitely not related to the product. In 11% of the cases, there was inadequate information to evaluate likely causality. A similar analysis of the adverse event reports on special nutritionals would be valuable in better understanding the likelihood of a causal relationship between the dietary supplements used and the adverse events reported. Criteria used in evaluating likely causality include whether the effects are consistent with the known pharmacology of the product, whether there are other explanations for the event, whether the timing of the event suggests a relationship to use of the product, and whether the effects went away when use of the product was stopped or reappeared if the product was given again.

It is essential for FDA to update the special nutritionals adverse event reporting system on a regular basis, and to be able to screen and release background information on the case reports before they are made publicly available. Finally, FDA must have the capacity to evaluate the likely association between the events that occurred and the products that were used.

NEW DIETARY INGREDIENTS

DSHEA places a great deal of responsibility on the industry and on FDA to assure that only safe ingredients are marketed in dietary supplements. Ingredients that were marketed in dietary supplements before October 15, 1994, are "grandfathered" and may continue to be marketed. However, even grandfathered ingredients may be considered adulterated if they are injurious to health or if they are not reasonably expected to be safe under the intended conditions of use.

DSHEA requires any marketer of a new dietary ingredient (one first marketed on or after October 15, 1994) to submit a notification to FDA at least 75 days prior to marketing. The notification is to include a statement of the manufacturer's basis for concluding that the ingredient is reasonably expected to be safe. FDA reviews the notifications, and the file is placed on public display approximately 90 days following its receipt.

For example, a new dietary ingredient notification was recently filed for gamma butyrolactone (GBL), a precursor to gamma hydroxybutyrate (GHB), a substance with activity similar to the so-called "date rape" drug. Based on the information submitted and based on other information available in the scientific literature, CRN believes FDA was right to object to the marketing of GBL, and CRN supported the agency's recent action in requesting a recall. The companies contacted by FDA have apparently complied with the request for a recall, but we note that there are still numerous Internet sites promoting and selling both GBL and GHB.

Further actions need to be taken against such marketing. It is essential that the industry rigorously observe the notification requirement for new dietary ingredients, that FDA promptly review new ingredient notifications, and that the agency take effective enforcement action when necessary to prevent the marketing of adulterated (unsafe) dietary supplement ingredients.

DIETARY SUPPLEMENT ADVISORY COMMITTEE

FDA must deal with a wide variety of critical issues affecting dietary supplements. In the past several years, three out of six meetings of the existing Food Advisory Committee have been devoted to consideration of dietary supplement issues. Unfortunately, the Food Advisory Committee does not have the appropriate expertise to deal with dietary supplements, and FDA has found it necessary to convene other experts to participate in evaluating dietary supplement issues, including the safety of ephedra, necessary provisions of Good Manufacturing Practices, improving postmarket surveillance, and evaluating consumer understanding of dietary supplement labels.

CRN believes FDA urgently needs a Dietary Supplement Advisory Committee, comprised of individuals representing a wide range of background, but also with expertise with dietary supplement products and knowledgeable about the scientific evidence relating to a dietary supplement ingredients. Funding to establish, staff, and support this critical advisory committee is essential, and should be included in the FY2000 appropriations for FDA.

PROPOSAL ON STATEMENTS OF NUTRITIONAL SUPPORT

In addition to taking effective action when needed, FDA needs to recognize when intervention is not needed. Since the passage of DSHEA, FDA has received over 3000 notifications regarding statements of nutritional support. The vast majority of these have apparently been deemed to be appropriate, indicating that the industry and the agency generally share a common view of the permissible scope of these statements. FDA has responded to about 7% of the notifications with an objection (in the form of a "courtesy letter"). This does not suggest a need for regulatory clarification of the criteria for statements of nutritional support. Yet in April 1998, FDA issued an extensive proposed rule. The proposal includes an overly broad definition of "disease" which encompasses many structure/function effects.

The proposed structure/function rule has drawn a large number of comments, including almost 200,000 consumer letters. The overwhelming majority of the comments are critical of the proposal. We believe that the U.S. Department of Agriculture's response to public comment on the misguided "organic" proposal would serve as a good model for FDA on this issue. As USDA did with the "organic" proposal, FDA should simply withdraw the structure/function proposal. Instead of creating a new regulation, FDA should rely on the language of DSHEA, which clearly states that statements of nutritional support cannot mention a disease. Beyond that, all statements that are literally about affecting the structure or function of the body should be permitted.

RESPONSIBLE DIETARY SUPPLEMENTS FOR THE FUTURE

The dietary supplement industry is made up of hundreds of companies, including many of the large pharmaceutical manufacturers as well as numerous smaller players. Many dietary supplement companies are publicly held and thus accountable not only to their customers but to their stockholders – not only to the FDA and the Federal Trade Commission but to the Securities and Exchange Commission.

This is the dietary supplement industry that CRN knows and represents, and the industry that over a hundred million American consumers rely upon. The core of the industry is responsible and provides consumers with safe and beneficial products. We recognize that sometimes enforcement is needed to prevent irresponsible or fringe players from wrongfully marketing unsafe products as dietary supplements or illegally making unsubstantiated claims. We are committed to working with the Congress and with FDA to resolve any problems that may arise, in order to assure that the dietary supplements available to consumers are safe, beneficial, and made to high quality standards.

Mr. BURTON. Thank you, Dr. Dickinson.

Ms. Gilhooley.

Ms. GILHOOLEY. I am Margaret Gilhooley. I am a professor at Seton Hall Law School and was a member of the Commission on Dietary Supplement Labels. I appreciate the opportunity to testify on DSHEA and whether FDA is carrying out its intent.

I will first address the criteria to identify disease claims. DSHEA permits dietary supplements to make structure and function claims, but not disease claims. Under FDA's proposed rules, disease claims include references to specific diseases, but not more general references to body systems or functions. Thus, FDA tentatively regards as appropriate a claim that a supplement helps maintain cardiovascular function, inhibits platelet aggregation, and helps maintain a healthy cholesterol level.

I believe FDA's criteria are too narrow. General references to bodily functions can still imply usefulness to prevent disease conditions and especially so when the claim refers to bodily organs and functions that normally receive medical attention. The Commission members disagreed about appropriate claims for supplements and some of us found troubling and problematic claims mentioning organs such as the heart or systems such as the circulatory system associated with major clinical conditions.

In my view, a claim to maintain normal cardiovascular function implies a need to use the product to prevent an abnormality, an abnormality which would be a disease. Moreover, when a claim relates to a matter beyond the ability of the consumer to assess from their own experience, the potential to mislead increases. Thus, I think the FDA proposal needs to be revised.

The FDA proposal also recognizes as an appropriate structure and function statement a claim that a product improves absent-mindedness. In my view, this claim should not be viewed as an appropriate claim for a dietary ingredient. There are no foods that affect absent-mindedness and this claim is not for the role of a dietary ingredient or a dietary supplement in any meaningful sense. That claim should not be permissible for the same reason that a claim of a dietary supplement to be an oral contraceptive would not be permissible. The claim is simply not one for the affects of a dietary ingredient.

With respect to health claims, the Commission found that the standard of significant scientific agreement is appropriate and serves the public interest and that the process for approval of health claims should be same for dietary supplements and conventional foods. While FDA has adopted this approach, the recent decision by the D.C. Circuit of Appeal in *Pearson v. Shalala* has found constitutional and legal difficulties with FDA's actions. Under the decision, the FDA regulations are unconstitutional in failing to allow supplements to make a health claim, even when there is no significant scientific agreement to support the claim, so long as the supplement bears a disclaimer about the inconclusiveness or other limits of the supporting evidence and the lack of FDA approval.

I will not comment about the constitutional law aspects of the decision, but will point out the important decision FDA will have to make on remand in determining what constitutes an adequate disclaimer to inform consumers with respect to particular health

claims. In my view, in addition to the other disclaimers, consideration needs to be given to stating on the label that there is no significant scientific agreement to support the claim. The difficulties of using disclaimers to inform consumers is also illustrated by the National Cancer Institute's study of the affects of the antioxidant supplement beta carotene. The Institute's investigators found in two studies that the supplements were clearly not effective to prevent cancer or heart disease and may even be harmful.

Disclaimers may simply not be adequate to convey this information on the label. Moreover, even under the court's decision, preclusion of a claim, rather than a disclaimer, may be appropriate when the weight of the evidence shows the claim to be ineffective.

With respect to safety substantiation, consumers use dietary supplements because they assume the supplements are safe, as safe as foods. The supplements are not, however, subject to the requirements for general recognition or FDA approval that provides assurance of the safety of other ingredients. FDA bears the burden of proof to show that the product poses a significant risk. And the Commission report also indicates the difficulties and resource burdens involved in meeting that standard. In my view, supplement manufacturers should have a legally enforceable affirmative obligation to do the testing needed to establish that supplements are safe. I think that responsible manufacturers will do that and it is really only the irresponsible manufacturers who will evade that obligation and may bring discredit to the dietary supplement industry.

If a manufacturer does not do safety testing, the manufacturer should put a warning on the label that the safety of the supplement has not been substantiated. I recommended in the Commission report that FDA require this warning to prevent deception, but FDA has not acted on that measure.

Finally, there is debate about whether FDA is carrying out the intent of DSHEA. But the underlying reason why it is hard to resolve that issue is because DSHEA is an enigma. The provisions are ambiguous and can be interpreted in various ways. Thus, while I believe FDA can and should do more to guard against inappropriate claims, I recognize that not all will agree that FDA has that authority under DSHEA. And if FDA does not have this authority, in my view, Congress should revisit DSHEA and provide clear criteria to limit inappropriate claims and give FDA stronger authority to assure the safety supplements. Thank you for the opportunity to testify.

[The prepared statement of Ms. Gilhooley follows:]

TESTIMONY OF PROF. MARGARET GILHOOLEY OF SETON HALL LAW SCHOOL
HEARING OF THE HOUSE COMMITTEE ON GOVERNMENT REFORM
ON DIETARY SUPPLEMENTS, MARCH 25, 1999

I am Margaret Gilhooley. I teach at Seton Hall Law School and was a member of the Commission on Dietary Supplement Labels. I appreciate the opportunity to testify on DSHEA and whether FDA is carrying out its intent.

1. Criteria to Identify Disease Claims. DSHEA permits dietary supplements to make structure and function claims but not disease claims. Under FDA's proposed rules (63 Fed. Reg. 23624), disease claims include references to specific diseases, but not more general references to body systems or functions. Thus, FDA tentatively regards as appropriate a claim that a supplement "helps maintain cardiovascular function," "inhibits platelet aggregation," and "helps maintain a healthy cholesterol level."

I believe FDA's criteria are too narrow. General references to bodily functions can still imply usefulness to prevent disease

conditions, and especially so when the claims refer to bodily organs and functions that normally receive medical attention. The Commission members disagreed about appropriate claims for supplements, and some of us found "troubling" and "problematic" claims:

"ostensibly relating to 'normal bodily functions' that actually imply the need to remedy an underlying abnormal or unhealthy state and statements mentioning organs (e.g. heart, liver, and prostate) or systems (e.g. circulatory) associated with major clinical conditions. P. 36-37 (emphasis added).

In my view, a claim to "maintain normal" cardiovascular function (or similar claims) implies a need to use the product to prevent an abnormality, an abnormality which would be a disease. Moreover, when a claim relates to a matter beyond the ability of the consumer to assess from their own experience, the potential to be misled increases.

I think the FDA proposal needs to be revised to restrict supplement claims that relate to the maintenance of bodily conditions and functions closely associated with the occurrence of disease and beyond the ability of the consumer to evaluate.

2. Need to Identify an Understandable "Dietary" Relationship.
The FDA proposal recognizes as an appropriate "structure and

function" statement for a dietary supplement a claim that the product "improves absentmindedness." In my view this claim should not be viewed as an appropriate claim for a "dietary" ingredient, There are no foods that affect absentmindedness, and this claim is not one for the role of a dietary ingredient or a dietary supplement in any meaningful sense. That claim should not be permissible for the same reason that a claim on a dietary supplement to be an "oral contraceptive" would not be permissible-- the claim is simply not one for the effects of a "dietary" ingredient.

The FDA rule should preclude structure and function claims for supplements unless the claim had an understandable "dietary" relationship. Products can be sold simply as dietary supplements, but when they go beyond that to make a structure and function claim, the statement should relate to the role of the dietary ingredient in the diet in achieving effects like those associated with the effects of foods. An appropriate dietary claim would be that the supplement is a substitute source for effects like those produced by foods in the diet. For example, a supplement might claim that it provides energy, has a wake-up effect like coffee or a calming effect like tea.

3. Health Claims and Dietary Supplements. The Commission recommended that the process for approval of health claims should

be the same for dietary supplements and conventional foods, and supported "the concept of fairness" under which the requirements for health claims are the same for foods and for dietary supplements. P. 34-35. While FDA had already adopted this approach, a recent decision by the D.C. Circuit Court of Appeals has found constitutional and legal difficulties with FDA's actions. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

Under the court decision, the FDA regulations are unconstitutional in failing to allow supplements to make a health claim even when there is no significant scientific agreement to support the claim, so long as the supplement bears a disclaimer about the inconclusiveness or other limits of the supporting evidence, and the lack of FDA approval. I will not comment upon the constitutional law aspects of the decision, but will point out the important decision FDA will have to make on remand in determining what constitutes an adequate disclaimer to adequately inform consumers with respect to particular claims. In my view, in addition to the other disclaimers, consideration needs to be given to stating on the label that there is "no significant scientific agreement" to support the claim. The level of scientific agreement that supports a claim is important to scientists in evaluating a claim, and should be disclosed in order to adequately inform consumers.

The difficulties of using disclaimers to inform consumers is illustrated by the National Cancer Institute's decision to end a study of the effects of beta carotene supplements. The study was ended early when investigators concluded not only that the supplements were not helpful but also that there was "a hint of possible harm" in increasing a cancer risk. See "Studies Find Beta Carotene, Used by Millions, Doesn't Forestall Cancer or Heart Disease," New York Times, p. A 16, Jan. 16, 1996. Disclaimers may simply not be adequate to convey the information.

The Court of Appeals was also concerned that FDA provide a better articulation of the meaning of "significant scientific agreement." The Commission report has a discussion that may be of some assistance. The report pointed out ways that the FDA process can be improved, including by holding scientific conferences and workshops. P. 34-35. The report also notes that there is scientific literature concerning the ways of evaluating a body of scientific evidence that involves uncertainties and matters of judgment. P.31.

The Commission also recognized the difficulty in doing research to support health claims, because of the chronic nature of the conditions, and the inappropriateness of direct experimentation for many claims. See p. 31. These factors make the evaluation of the claims more difficult and also make the existence of

significant scientific agreement important in determining whether there is sufficient support.

The Court of Appeals found inadequate FDA's explanations for why the agency found particular claims lacking in scientific support. The decision highlights the importance of FDA making a careful examination of the evidence for each claim, and providing a full and well-documented explanation if the agency finds the support inadequate.

4. Safety Substantiation. Consumers use dietary supplements because they assume the supplements are safe--as safe as foods. The supplements are not, however, subject to the requirements for general recognition or FDA approval that provides assurance of the safety of other food ingredients. FDA bears the burden of proof to show that a product poses a significant risk. The Commission report indicates the difficulties and resource burdens involved in meeting this standard. P. 22.

Supplement manufacturers should have a legally-enforceable affirmative obligation to do the testing needed to establish that supplements are safe. If they do not do safety testing, the manufacturer should put a warning on the label that the safety of the supplement has not been substantiated. Such a measure would not involve pre-market approval by FDA. I recommended in the Commission report that FDA require this warning to prevent

deception, but FDA has not acted on this measure.

5. *Pharmanex v. Shalala*. I understand that the Committee is also interested in views on the District Court decision in *Pharmanex v. Shalala*, 1999 U.S. Dist. Lexis 1659 (D. Utah 1999). DSHEA excludes from the definition of dietary supplements "an article that is approved as a new drug" unless FDA, by rule, provides otherwise. The court found that this exclusion applied only to finished drug products, and not to a supplement that contains the active ingredient of an approved new drug. The decision emphasizes the textual language, and prior cases, and views Congress' purpose as leaving the existing law in place with respect to the basis for determining drug intent.

The length and detail of the definitional exclusion suggests Congress' purpose may have been broader. A commentary on DSHEA indicates that the exclusion covers "ingredients" and that Congress had a wider purpose to protect research investment, and to guard against the marketing of supplements containing botanical ingredients such as those in *Taxol*:

"Under this provision, ingredients first marketed as new drugs would not be dietary supplement ingredients....The purpose behind the provision was to protect bona fide new drug ingredients as well as research investment into natural ingredients for use in new drugs. [Footnote] At

the time of negotiations leading to the enactment, another concern was that abortifacient ingredients and anti-neoplastic agents derived from botanicals, such as taxophen, might be marketed as dietary supplements." See Bass & Young, DSHEA:A Legislative History and Analysis 36 (1996).

The provision for FDA regulatory review and approval of the marketing of these supplements provides a forum to consider the labeling of the product and all the factors that can be considered in determining a manufacturer's intent. Congress may have believed this additional review was needed in the unusual case in which a supplement has the same active ingredient found in a marketed new drug sold by prescription.

The impact of the Supreme Court cases cited by the District Court was to expand FDA's ability to regulate products as drugs, and the impact of the Pharmanex decision is to narrow FDA's authority to regulate a supplement as a drug. This difference in impact may need further consideration in determining Congress' intent.

6. Determining DSHEA's intent. Finally, there is debate about whether FDA is carrying out the intent of DSHEA. But the underlying reason why it is hard to resolve that issue is because DSHEA is an enigma. The provisions are ambiguous, and can be

interpreted various ways. Thus, while I believe FDA can, and should, do more to guard against inappropriate claims, and to ensure that manufacturers substantiate safety, I recognize that not all will agree that FDA has that authority under DSHEA. If FDA does not have this authority, in my view, Congress should revisit DSHEA and provide clear criteria to limit inappropriate claims and give FDA stronger authority to ensure the safety of supplements.

I ask that a full copy of my testimony be included in the record of the hearing. I would be glad to answer questions or to provide further information.

Thank you.

Mr. BURTON. Thank you, Ms. Gilhooley. I have a number of comments and questions. I think, Mr. Bass, you suggested that there ought to be an advisory panel on this whole issue to at least work with the head of the FDA. And, toward that end, we will contact the new Commissioner and suggest that we think that might be a good idea. It is not binding, but it would help, maybe, illuminate some of the issues and problems so that they could be solved without regulations being proposed before all sides have been heard. So we will suggest that and we will contact her by mail and in person about that.

Mr. Kracov, regarding Cholestin, you made some inferences—I am not sure I read you correctly—but you were talking about lovastatin and I think—was it Merck that produces lovastatin?

Mr. KRACOV. That is correct.

Mr. BURTON. Yes. Do you believe or did I read in your remarks that possibly some of the pharmaceutical companies may be involved in trying to stop some of these supplements that may take away some of their business?

Mr. KRACOV. I agree and disagree in that at least one pharmaceutical company was interested in stopping our particular product. But, in general, one of the ironies of the Cholestin case is that FDA was supposedly protecting incentives to develop pharmaceutical products, but neither the pharmaceuticals industry association or any other pharmaceutical company commented in the docket against Pharmanex. And, indeed, the only other pharmaceutical company that commented actually supported our position on cholesterol claims for the product.

Mr. BURTON. Do any of you believe that the pharmaceutical industry has, behind the scenes, tried to influence people at the FDA or any government agency regarding the stopping of certain supplements from being marketed? Do you have any idea?

Mr. TURNER. That is a very tough question to answer because the evidence is not right there in the record. But I have been involved with the herbal sweetener Stevia for a number of years and we know that FDA has restricted its access into the United States. We know that there has been industry complaints from other industries about it. We don't know really who they are. And we know that it competes directly with Nutrasweet. There is a buzz around that there is some role that Nutrasweet plays in helping the FDA not allow this sweetener to be widely distributed. Now the way it works, once DSHEA was passed, the products could continue to be sold, it could be sold, but it just can't be labeled as a sweetener.

Mr. BURTON. Do any of you have knowledge or information that people who work at the FDA, Health and Human Services, the National Cancer Institute, or National Institutes of Health, have been influenced by pharmaceutical companies in their decision or the decisionmaking process over there at any of those institutions?

Mr. KRACOV. I can comment that in the Pharmanex administrative proceeding, there was extensive involvement by one pharmaceutical company in particular and there was significant—

Mr. BURTON. What was that company?

Mr. KRACOV. It was the maker of Mevacor, Merck.

Mr. BURTON. Merck.

Mr. KRACOV. And the information provided to the docket was obviously, heavily weighted or attempted to weight the case against Pharmanex. Fortunately, we were able to rebut that and go to court and win. I think that is unusual. I think, actually, if you look at the products that are on the table here, many of those dietary supplement products are made by pharmaceutical companies.

Mr. BURTON. Oh, yes.

Mr. KRACOV. And I think a lot of those companies are actually seeing the promise of the Dietary Supplement Health and Education Act and are taking advantage of it.

Mr. BURTON. Well, you know, I know that is the case because it is a burgeoning industry. And people are more concerned about their health and, as a result, I think a lot of the pharmaceutical companies are seeing additional marketing that they can do, additional products that they can market and make money. Which is fine.

The line of questioning I am taking right now is, I don't believe that any industry, even though they have a lot of money at risk because of scientific research into certain products, should try to influence government agencies for their benefit while, at the same time, it is to the detriment of another industry and, ultimately, maybe, to the American people. And that is why I asked that question.

I understand—and I think Mr. Bass mentioned this in his comments—pharmaceutical companies invest millions, billions of dollars, in research and we want to make sure that they don't go out of business because they spend a lot of money on research and then they can't recoup that by selling their product, you know, through having control of that product for a long period of time. But, at the same time, if somebody comes up with a less expensive approach to, curing a form of cancer, I think it is unseemly for the pharmaceutical industry to come in and say, hey, we want to stop that and try to use our influence with a governmental agency to do so. And that is why I ask that question.

And if any of you have any indication that some person at any of these agencies are ever being unduly influenced or influenced at all by somebody in one of these industries or one of these companies, I wish you would bring it to my attention because I would certainly like to pursue that. OK?

I think, Dr. Croom, you talked about placebos and one of the concerns that I have had, we have had a number of people testify before our committee who have had Hodgkin's disease or had children who were terminally ill with lymphoma or some other disease and there have been alternative therapies that have been proposed by certain doctors in other parts of the country. And I believe it was Health and Human Services that have said that, you know, these aren't proven therapies as far as they are concerned. And, as a result, they told these doctors, if they used their procedures on the individuals who testified before our committee, that they could lose their license to practice medicine.

And the ultimate result was that these people had no hope. They had been adjudged terminally ill and the parents of the boy that was in question and another fellow who had Hodgkin's disease, they were told, in essence, go home and die. They didn't say it just

that callously, but they said, go home and die. And that the possibility that these alternative therapies used by other doctors had not yet been proven to the satisfaction of these government agencies meant that the people couldn't go down there and pursue that therapy.

I also was concerned because we had people who wanted to have therapies and they were told that there was trials being undertaken and that they had to either take a placebo or take a product under question. And they really were terminally ill and they didn't want to take the placebo, they wanted to try the therapy that they thought would save their life.

So I would like you to comment on that real briefly, if you would.

Mr. CROOM. I would be glad to. I have faced those same questions, obviously, from family and friends. I am really hoping we are on a new beginning. And I am going to say it is—I had a sentence written I guess I didn't read—and I say we must ask what is the health outcome of our public policies and scientific studies on the enhancement—and I would take it to just what you asked. Not just botanicals.

In other words, if I say to you, I haven't studied it, but I am not going to give you money to study it. And, believe me, I have had people at a number of alternative cancer therapies who have asked me, over the last year, to help them design the clinical trials because they involved botanical products. Quite honestly, at this point, there has not been sufficient funding—and I am talking about—my job is not to do the clinical trial, my job is to say what is that optimum product you are using? What is the purity and identity and standard? We haven't backed up and asked that question and funded that research yet.

Because, again, of course, I want to be the same way. I have friends who have gone to Switzerland for therapy from Oxford, MS. I have friends who have gone to Mexico. And people come to me and I have to say, you know, you have just pointed out a problem. Of course, I would rather have faith that something is happening to me. It is a well-known case that if I tell you you are going to die, you are more likely to die if people tell you that every day. And that is an absolute—I am sorry—transgression of medical ethics to tell you that. To say that is unproven, I think, is not.

In all honesty, there are so many things like this that touch all our lives, that I am saying to you that, and I agree. And, believe me, 16 years ago, when I became a professor and was doing botanical medicines, I started doing the anti-malarial and then the drug ones because no one would fund our research and business was giving us incentive.

But you can tell me, Chairman Burton, if you would approach it differently, but I don't have that same honest answer. I want to know that a person is competent and compassionate about the therapy that I can trust the results they tell me, to say who would this help and who it would not help and know that answer. Because, right now, I don't think, in many cases, we know. And I think in other cases—and I will respond to some of the things—we have asked certain high standards to just tell you you are unproven and you are foolish to do it. And you will never even know if it helped you, you know, even if you did it.

I think that is just arrogance. And that is my plea, is to say let us have some humility and get the knowledge base. I hope that is responsive to your question.

Mr. BURTON. Well, I guess to a degree it is. I will yield to my colleague in just a moment. But we have had some severe cancer problems in my family in the last year. My mother and father both died of cancer within a month of one another. My wife had breast cancer 5 years ago and she was given about a 50 percent chance to survive 5 years. You know, they always use these statistics. And we were putting her into a special cancer program that I read about where they stimulate your immune system. It was in Highland Park, IL. I had read about it in Life magazine, I believe.

They were going to close that down after I brought it to the attention of the FDA, because I thought it should be expanded because they were only working on about 72 women. And it really bothered me a great deal because these women were calling me, because of my position in the Congress, in the middle of the night, crying saying, you know, this is our only hope.

And then these people that have testified before our committee over the last year, who had terminal illness had been adjudged terminal. And some of them had had miraculous results by going to a physician who was practicing and offering alternative therapies. And, yet, those physicians were threatened with the loss of their licenses, as were the physicians up in Highland Park where they were going to close the program down, because they said that either they hadn't had all the paperwork done or it hadn't been proven to the satisfaction of the governing agencies.

And so I guess my concern is, if a person whose life is in jeopardy, if their life has been threatened, if they have been adjudged to be terminal or they have a 50-50 chance to live over a certain period of time, shouldn't they have the opportunity to try anything that they really want to to save their lives? And should government agencies preclude that possibility by saying if a doctor who has an alternative therapy that they believe works or has worked on some patients and hasn't been proven to the satisfaction of the government agencies, should the government be able to stop that person from trying that therapy? And that is, I think, something that all Americans would really be concerned about if it was their life.

And I will tell you—I don't want to make a big long speech out of this—but we had the former head of HHS, who was a friend of mine, I served with him in the Indiana General Assembly, he was speaker of the house there, that was Dr. Boehm. Dr. Boehm is a very fine man and a great physician. We had alternative therapies and procedures we talked about in the Indiana General Assembly when I was in the legislature there. And he, supporting the AMA's position and other's positions, was dead set against those alternatives. I understand that. We had hundreds of cancer patients who wanted to try these alternative therapies back in those days. His wife ultimately became terminally ill with cancer and it is my understanding that he tried some of the alternative therapies that had not been proven but had been turned down and looked upon with disdain by these agencies, the same as what we were talking about.

The point I am trying to make is, when it is your life, when it is your loved one's life, when it is someone else's life in your family that is at stake, you want to do everything you can to save them. And for a government agency to be so callous as to say, hey, that hasn't been proven, you are terminally ill or judged terminally ill, should that agency be able to say, if a doctor tries to provide this alternative therapy, we are going to take away his license, thus closing the door to that person's only alternative to live? I personally don't think they should.

Mr. CROOM. And, because I actually live with people who are doing this, I am trying to give you a fair answer instead of maybe quite as direct of what I hear you saying, but let me put it this way. Again the parallel is alternative therapy. Once I am at a regular hospital, do you realize how much you have put me in the fringe and I am seen as not a legitimate physician or scientist, once you call me that? And that is why I am calling to remove all the emotional issues and get down to the health issues, is to say, of course, I have had friends who I won't describe the therapies I have seen official medicine to do them for their cancers, that were horrendous.

Mr. BURTON. Sure.

Mr. CROOM. That were absolutely horrendous. And, yet, the same highest level institutions, if we go and ask this very question you are—and I am saying the way that will turn that around is to say, then, let us say to our most prestigious places, we want you to evaluate this and then you remove all the conflict. You remove all the conflict.

But my point to you is, like anything that I have found, including in science, you need to have someone that is unbiased and an expert, but also is enough of—I would still say—a person who would be very careful and fair in the results. It does not come in a priori, either way. So you can question that. Because I have those same experiences and I guess that is what I am pleading with you. Look, I have been asked by the Canadian Government to evaluate ESSIAC, for example, type therapies or Hocksy remedies in Mexico.

And I am being honest with you, I left it in the background because I figure most people don't worry the details like I do. I am the opposite of the don't worry, make money. I worry, don't make money. And so, there are a huge amount of things to actually do it right is why I left it in the checklist in the last of my testimony. And, believe me, my personal experience is with things like cancer. That is how thorough I want to be.

I will give you a simple answer. We could say there is this Chinese medicinal plant that cured malaria. Isn't that enough? And we have given it to some people and they made a tea and it cured their malaria. Well, I am going to tell you, that is what the army thought. And, instead, I went and collected all kinds of plant lines, got material from where it was originally used in China. It was only that plant material, only that genetic line. The stuff here on the Potomac was worthless. You could have taken the tea all day long and you would have still died, then, from malaria.

So my point is the same with your cancer and our other serious things. I have family members that have had Alzheimer's or Parkinson's, all this. There is another way. We keep debating this. But

let me also say, I want to see Congress encourage how can we have—there are actually botanicals that should go IND NDA routes. Nothing has come out the other end of that door. So, again, my criteria is safe, effective, affordable, and available. And if you never make it available to me, then, just like yours, I have created an undoable situation. Because I believe we have things that will help on not only cancer, but neuroprotection and other serious diseases. And some of those, let me say, need to be under a direct physician's care.

So I hope I am understanding your mission and I appreciate the opportunity. That is why I am going to leave you with that. You have many opportunities. It is a great—I would just have to say blessing—to see what you are having this committee do.

Mr. BURTON. Mr. Horn.

Mr. HORN. Thank you very much, Mr. Chairman. I commend you for holding this series of hearings on alternative medicines and alternative therapies and other aspects of our health care in the Nation. Let me start with you if I might, Dr. Croom. I am curious if you could put together a research focus, what supplements would you feel deserve that attention at this point, that are, perhaps, in common use and what hasn't been done in terms of examining them along the lines you are talking about?

Mr. CROOM. I may later give you a handout I just did at Harvard that will be there for continuing medical education, I guess. I would say—

Mr. HORN. Well, we can put that in the record, if you would like. Without objection, Mr. Chairman.

Mr. CROOM. OK. We could do that. Miss Clay has that.

[The information referred to follows:]

**Major Herbal Medicines:
What We Know and Need to Know
for Their Scientific Validation**

Edward M. Croom, Jr., Ph. D.
School of Pharmacy, University of Mississippi

Echinacea	<i>Echinacea angustifolia</i> , <i>E. pallida</i> , <i>E. purpurea</i>
Main uses	Colds and Flu
Quality	The different species, plant parts, and dosage forms each have different characteristics for quality. For fresh root or liquid preparations, Echinacea has a 'bite' or tingling sensation that is believed a good marker of quality.
Chemical standards	<i>E. purpurea</i> expressed juice is not well characterized chemically; <i>E. angustifolia</i> and <i>E. pallida</i> have echinacoside as a major component in the roots; <i>E. purpurea</i> roots have cichoric acid as a main component and no echinacoside. Both <i>E. angustifolia</i> and <i>E. purpurea</i> have been report to have alkylamides present.
Dosages	Expressed juice: 6-9 ml; Capsules: up to nine 300-400 mg capsules a day. Tinctures: 60 drops, 3X day, or follow manufacturer's directions.
Cautions	Allergic potential for those allergic to ragweed and other members of the daisy family. Germany cautions against use by those with immune disorders including HIV, multiple sclerosis, and tuberculosis.
Overall +/-	Although popular; and with extensive chemical and pharmacological studies, as well as a number of clinical studies, the lack of definitive markers of quality impedes our ability to evaluate the actual utility of many Echinacea products. Without rigorous collection guidelines, wild harvested Echinacea is subject to adulteration with <i>Parthenium</i> and other species of Echinacea. Although a variety of species, plant parts and dosage forms, including a 1:5 50% ethanol tincture of <i>E. purpurea</i> root, have been used and shown positive results in clinical trials, the most extensively studied form of Echinacea is the expressed fresh juice of <i>E. purpurea</i> flowering tops. Echinacea should be further studied for both reproducible product production standards and in more clinical trials to determine Echinacea's true benefits in treating the common cold.

Garlic	<i>Allium sativum</i> L.
Main uses	Cardiovascular Health
Quality	As a supplement, almost all clinical trials have been on enteric coated, dried product in an effort to preserve the allicin yield
Chemical standards	Alliin content with allicin yield of 0.6%
Dosage	600-900 mg of extract equal to 1,800-2,700 mg raw garlic
Cautions	Rare cases of allergic reaction, garlic odor, potential interaction or additive effects with agents that affect clotting or bleeding time.
Overall +/-	Although, the effect of garlic supplements is modest on blood lipids, the overall epidemiological data and physiological activity of fresh and carefully dried garlic suggests that it is a rational supplement for maintaining cardiovascular health. Future clinical studies are needed to determine the overall, long term health benefits of garlic supplementation.

Ginkgo	<i>Ginkgo biloba</i>
Main uses	Cerebrovascular and peripheral circulatory disorders including dementia, intermittent claudication, and impotence.
Quality	The only rational products are those based on highly concentrated and chemically standardized products. The traditional preparations have little similarity to the standardized commercial products for any utility to be assumed for the above uses.
Chemical standards	50:1 concentrated extracts standardized for 22-27% flavone glycosides and 5-7% terpene lactones (approx. 3% ginkgolides A, B, & C; 3% bilobalide), and low content of ginkgolic acid.
Dosage	120-240 mg of standardized extract per day
Cautions	Although uncommon, hypersensitivity to Ginkgo preparations, GI upset, headaches, and allergic skin reactions are noted by German health authorities. It has been suggested in a few case reports that Ginkgo could contribute to serious bleeding disorders.
Overall +/-	Most clinical and pharmacological studies have been done on the above well defined 24:6 extracts. The use of powdered leaves or simple extracts had rarely been used in traditional medicine and have little evidence of activity from scientific studies, so currently only the highest quality and clinically supported products should be used. Both cerebral and peripheral circulatory improvement may take 4-6 weeks before any benefit to the patient can be properly determined. The potential of ginkgo to increase micro-circulation, act as a potent antioxidant that reaches the brain, and act as a PAF inhibitor for inflammatory conditions including asthma should justify additional clinical studies to more completely evaluate effectiveness beyond moderate improvement of mental function in Alzheimer's patients.

Ginseng, Asian	<i>Panax ginseng</i>
Main uses	Endurance, tonic for fatigue
Quality	Extracts and powders should contain a minimum of 2-3% ginsenosides
Chemical standards	Ginsenosides
Dosage	Daily 0.5-2 g of root or equivalent preparations, extracts may be 200-600 mg per day
Cautions	At recommended doses few side effects occur. Those with high blood pressure should exercise caution in using large amounts of ginseng.
Overall +/-	Long and extensive human use, pharmacological studies, and a limited number clinical trials support the use of ginseng as a gentle tonic for enhanced mental function and physical activity. Larger clinical trials including those with people over fifty years old and that could distinguish the benefits for women and men separately would be useful.

Goldenseal	<i>Hydrastis canadensis</i>
Main uses	Anti-microbial, inflamed mucous membranes
Quality	Pure Goldenseal root & rhizome
Chemical standards	Hydrastine & berberine
Dosage	Typical dose is up to six 500-600 mg capsules or 20-25 drops of 1:5 (70% alcohol) tincture
Cautions	No recent toxicity reports but the physiological effects are unstudied regarding past concerns including skin ulceration and large doses causing uterine contractions, GI disturbances, hypertension, and seizures. At typical doses any side effects should be limited to possible disruption of the normal intestinal flora.
Overall +/-	Most uses of Goldenseal preparations are based on direct contact with infections and inflammation since protoberberine alkaloids are not well absorbed. Common uses have included the treatment of diarrhea and to increase mucus viscosity in later stages of upper respiratory infections. The popular commercial use of Goldenseal alone, or in combination with Echinacea, for the initial stage of upper respiratory infections is controversial with traditional herbalists. The plant does not mask urine drug tests for drugs of abuse. Goldenseal's high level of berberine type alkaloids lend sufficient pre-clinical evidence to suggest that Goldenseal and other berberine rich plants should be evaluated in clinical trials for the treatment of upper respiratory and gastrointestinal infections.

Hawthorn	<i>Crataegus</i> spp
Main uses	Mild coronary insufficiency (functional stage II of NY Heart Assoc.)
Quality	Leaf with flower extracts defined by procyanidin or flavonoid content
Chemical standards	Extract daily dose should contain 30-170 mg of procyanidins or 4-20 mg of flavonoids
Dosage	160-900 mg of aqueous alcohol extract for a minimum of 6 weeks
Cautions	Because of the seriousness of heart disease, should be used only after adequate medical diagnosis and under professional supervision. No side effects are known.
Overall +/-	Of 14 clinical studies, the best clinical efficacy has been shown at 600-900 mg/day for stage II patients that have increased tolerance to exercise in comparison to placebo; in one clinical trial Hawthorn was equal to the ACE inhibitor, captopril. Due to lack of side effects and enhanced exercise tolerance in those with some loss of cardiac function, hawthorn is worthy of further clinical study for enhanced heart function in those with mild coronary insufficiency.

Kava	<i>Piper methysticum</i> G. Forster
Main uses	Anxiety, insomnia, stress, smooth muscle relaxant
Quality	Standardized root/rhizome extracts of kavapyrones
Chemical standards	Kavapyrones (kavalactones)
Dosage	Average dose of extracts is 60-120 mg of kavapyrones
Cautions	May effect judgement and motor reflexes so that driving and operating dangerous machinery should be avoided. May potentiate the effects of substances acting on the CNS such as alcohol, barbiturates and psychopharmacological agents. Long term use of high doses leads to lethargy and kava dermatosis with yellow skin, which with stoppage of use will resolve. Large overdoses can lead to total loss of motility.
Overall +/-	Standardized extracts are very effective but should not be consumed in doses larger than 210 mg of kavapyrones per day for extended periods of time, unless under medical supervision.

St. John's Wort	<i>Hypericum perforatum</i> L.
Main uses	Mild/moderate depression, Seasonal Affective Disorder, anxiety
Quality	Dried flowering tops with little stem. Ethanolic extracts and dried methanol extracts are the most proven formulations
Chemical standards	hypericin, pseudohypericin, and/or hyperforin
Dosage	Generally 300-900 mg per day of standardized extract
Cautions	Potential drug interactions with SSRI's, MAO inhibitors, and other anti-depressants; potential photosensitivity; unknown effects for pregnant and lactating women.
Overall +/-	Extensive traditional use, chemistry, pharmacology, and clinical trials all show St. John's Wort to be a safe and effective medicine. To date, all potential adverse effects and drug interactions have proven to be extremely rare or undocumented. Benefits should be apparent within a maximum of 4-6 weeks with a good quality product. Initial dosage in depressed patients should be 900 mg of extract, while 300-600 mg is probably sufficient for maintenance and milder cases. Larger NIH sponsored trials are being conducted to better understand St. John's Wort.

Saw Palmetto	<i>Serenoa repens</i>
Main uses	Enlarged Prostate, Benign Prostatic Hyperplasia, stages I & II
Quality	Ethanollic and liquid CO ₂ extracts of the berries
Chemical standards	Standardized extracts of the fruits with 85-95% lipids (mainly fatty acids) and sterols
Dosage	320 mg of lipophilic extract per day
Cautions	Rare gastric upset
Overall +/-	Standardized extracts in clinical trials for up to three years have shown significant reduction in symptoms of BPH stages I & II including nocturia, residual urine volume, and urine flow. Some clinical trials have shown less significant side effects for Saw Palmetto than common prescription drugs for BPH. While using Saw Palmetto to relieve the symptoms of an enlarged prostate, consumers and patients should not neglect to have their physician regularly check their prostate status including PSA or other tests for prostate cancer since Saw Palmetto has no effect on prostate cancer.

Slippery Elm	<i>Ulmus rubra (U. fulva)</i>
Main uses	Demulcent lozenge for sore throats
Quality	98% inner bark (for USP), high content of mucilage cells
Chemical standards	USP TLC typical chromatogram (USP23:supp. 3, p.2923)
Dosage	lozenges for sore throat, as needed; tea is ½ tsp. in one cup of hot water, 2-3 times a day
Cautions	None
Overall +/-	Slippery Elm inner bark contains large amounts of mucilage that soothes irritated mucous membranes. Although, mainly used for sore throats today, the tea has been a popular herbal for stomach ulcers, colitis, and as a mild soothing laxative. Since the inner bark swells in water like Psyllium husks, this very mild laxative effect is probably true. In the past, it was popular for many uses and believed to be a nutritious food for infants and adults during convalescence. More chemical, pharmacological and clinical studies should yield new rational uses for this very safe, soothing, and probably nutritious plant.

Mr. CROOM. Specifically, let me understand your question. I must say that I refrained from this because I was getting concerned that everybody would just want to pick my brain to say that now if I have an enlarged prostate, is there anything to supplement, pumpkin seed or what? But I will say, yes.

Mr. HORN. Well, I mean, you have come into contact with a lot of people. They have a lot of suggestions. They feel some of it has done well by them. And, in terms of the research approach, which areas that seem to have a high demand and use by people, is there a way you can develop a protocol that research could be done and to see if it really is, is it chance? Is it just psychology or what?

Mr. CROOM. I think you will see there are a number of the products I think we already know. For example, like saw palmetto and St. John's wort, that have enough evidence that I would say that a number of people are going to benefit, OK, from it. And, certainly, whether you are taking it to just have a mood elevator or for mild depression, you are going to feel better. A lot of people have a safer therapy with that.

If you are asking how we would do a research prioritization, actually, some of mine that I have commented on is not just selected products. I will be glad to get that back to you. I would love to.

[The information referred to follows:]

Botanical Research Priorities for Enhancing Human Health

Edward M. Croom, Jr.

The botanical research priorities that I would recommend are that Congress must significantly increase the NIH Funding focused on botanical products for the National Center for Complementary and Alternative Medicine, the Office of Dietary Supplements as well as other NIH centers. In addition, other government agencies involved with botanical products, including the Food and Drug Administration, the Department of Agriculture, the Environmental Protection Agency, and the Federal Trade Commission, need increased funding to properly develop research programs and regulatory policies that are based on a scientific foundation. Currently, NIH funding on botanicals has included clinical trials of a few botanical products. These clinical trials must be expanded to include more of the well researched botanicals and also must begin to fund a larger diversity of small, preliminary trials of botanicals that have not been clinically evaluated.

A major challenge is that we must have better botanical ingredient standards to ensure that the clinical studies are conducted on well characterized, reproducible products. A well characterized, reproducible product is essential so that the clinical studies will be relevant to the actual products used by consumers. Although DSHEA created the Office Of Dietary Supplements, the current funding is totally inadequate to evaluate the health impact on a group of products that fifty percent of Americans consume. I believe that increasing the funding of the NIH Office of Dietary Supplements to a minimum of \$10 million dollars a year is necessary so that investigator initiated research proposals (RO1's), targeted specific research topics (RFA's), and multiple Botanical Research Centers of Excellence including the following with specific objectives are funded:

- 1) Botanical Risk Assessment Centers – Risk Assessments should include pesticide residues, solvent residues, microbial contamination, and heavy metals to ensure the public health.
- 2) Botanical Ingredient Standards Center -- Botanical identity guidelines and standards from the stage of the collection of the plant through the manufacturing process of the final dosage form to ensure product integrity.
- 3) Botanical New Crop Centers -- Cultivation Requirements and Improved Botanical Cultivar Development to enhance the sustainable supplies of high quality products.
- 4) Botanical Product Centers – The focus is on multidisciplinary research to enhance the overall evaluation and development of high quality, safe, effective botanical products. These centers can work independently or with government agencies or industry to provide a range of scientific studies to enhance the safety, efficacy or reproducible properties of botanical products.

The major goal of these research recommendations is to further developing the science base of botanical to ensure their health benefits to our citizens.

Mr. CROOM. Part of my focus is to say things just as have been addressed here. I have been on the FDA working group on GMPs. We need to increase our knowledge of product definition and get that over with. What are we buying? What makes good quality and consistency products? That is the first step, I think. I think there are a number of significant things that, again, I would say that if we broadened it to where it was not thought of as alternative and I am going to be involved in a NIH conference on liver diseases, for example. It is starting to progress.

If you as Congressmen just say to NIH, these are serious and you help us get these answers, they are the experts that know what are the best liver diseases or worst for retrieval kidney. If those guys ask us that, then I say we take it one at a time, like these come and say what are our best shots, what do we develop? I think that is the most rational approach, instead of giving you a total checklist. Is that all right?

Mr. HORN. Well, it is a start. I wonder if any other members of the panel will answer that question? Mr. McCaleb.

Mr. MCCALEB. Mr. Chairman, if I could comment on that subject, I think a rational strategy for deciding what to study first is to take those things where we have the greatest chance of success in research, those studies that—those botanicals that have been well-studied in European studies, but in which American physicians are saying we need to replicate those in American studies. I am pleased to see the NIH is doing this with respect to St. John's wort. I think we will probably find that is effective. A few more of those to confirm that the results of European research are valid and maybe we can start following the European lead in looking at the best researched of the European phytomedicines and researching those in I would say a priority order according to what will have the greatest public health impact.

I appreciate your mentioning the immune stimulation approach to treating cancer. And, for so many years, medical science has been locked into a pattern of testing anti substances. That is, we had antibiotics. We have antivirals. We have antitumor agents and so on. Immune stimulants or substances that work with our bodies to help our own immune systems work more effectively against disease and that is a part of a wellness approach that I think is going to yield very great public benefits for us.

Mr. TURNER. I think there is an additional point that should be made and that is that, in addition to the scientific strategy, there should be a legal policy strategy that goes along with it, specifically in areas where there is not a safety question. The period of time that it takes us to gather the information about a new substance should be a time in which consumers can have access to that substance while the decision is being made. And there are many situations in which we are held back because the FDA and other regulators take the position that, until we know and can prove that a substance is, "effective," then we should not allow consumers to have access to it.

I believe that this is a misreading of the efficacy amendments to the law. When they were made in 1962, it said that there should be substantial evidence to support efficacy. Substantial evidence traditionally means more than a scintilla, but less than a prepon-

derance of evidence. What the law was designed to do was to oppose fakery or quackery and make claim for something for which there was no evidence, for which there was not a scintilla. The public policy change that would address the point that you were making is to allow people to have access to situations that are supported by emerging science that is more than a scintilla, that is some evidence, but not necessarily enough to establish efficacy.

My belief is that if we could establish that kind of an approach, we would create a framework for providing social support behind the kind of science that our two scientists here have been describing.

Mr. HORN. Anybody else on the panel want to comment on that question? Ms. Gilhooley.

Ms. GILHOOLEY. To the extent that this relates to products that would be sold as drugs with the AIDS crisis FDA has changed its policy and Congress has enacted a program for fast-track approval of drugs that deal with life-threatening and serious conditions. But the manufacturer still has to be in the process of doing adequate, well-controlled studies and complete them afterwards.

Mr. HORN. I think a lot of people have felt that if you are terminally ill, what is wrong with trying it. And the people of California showed by a majority vote that if you are terminally ill, you have pain, in the case of many cancer victims, that you should be allowed to use marijuana. That is a very rational decision for people.

Ms. GILHOOLEY. I had a comment on the question before about people who are terminally ill who want to use products and maybe alternatives out of the hope that it will help them. And maybe there really isn't any scientific evidence for it. That came up with laetrile. It is a long-time issue. It is a very compelling dilemma. But there is also a concern not to have people spend all their last money and be taken in by people.

I teach a food and drug course and one of the students in my class who is a doctor gave me a copy of New Jersey's provision on laetrile, which is a provision to allow doctors to administer laetrile, as long as there is a limit on their making more money out of it and charging more than they would for their regular payments. And I could supply that to the committee, if you would like.

[The information referred to follows:]

practice medicine and surgery in another state provided the practitioner does not open an office or place for the practice of his profession in this State.

(b) A licensed physician may prescribe, administer or dispense amygdalin (laetrile) to such physician's patient, consistent with the following standards and providing that the patient has signed the "written information request . . . for medical treatment" as set forth herein:

1. Generally:
 - i. As an adjunct to recognized, customary, or accepted modes of therapy; or
 - ii. Utilized exclusively in the treatment of any malignancy, disease, illness or physical condition; and
 - iii. If and when the physician has received a confirmed diagnosis of said malignancy, disease, illness or physical condition;
2. In the course of medically justifiable dietary supplement therapy;
3. As a prophylactic medication.

(c) The informed request for prescription of laetrile for medical treatment must utilize the wording appearing on a form which is available on request from the Board.

1. The form shall be prepared in quadruplicate and distributed as follows:
 - i. Original copy to State Department of Health;
 - ii. Copy to be retained by the physician;
 - iii. Copy to patient or person who signed form for the patient;
 - iv. Copy to pharmacist.
2. When amygdalin-(laetrile) is utilized in the treatment of a malignancy, the diagnosis of malignancy shall be documented by a positive tissue diagnosis rendered by a qualified pathologist which shall include the size, location and type of malignancy. In the absence of tissue for diagnosis, the treating physician shall be required to obtain consultative and/or professional reports to support a positive diagnosis of a malignancy.
3. The alternative medically recognized and accepted form of therapy offered by a physician shall be thoroughly discussed with the patient and documented in writing.

(d) Complete and accurate records shall be maintained and made available to include:

1. Copy of signed informed request.
2. History of previous therapy to be included where indicated.
 - i. Surgery;
 - ii. Radiation;

13:35-6.8 Prescribing, administering or dispensing amygdalin (laetrile)

(a) The prescription or administration of amygdalin (laetrile) is a medical procedure which may only be performed by a physician licensed to practice medicine and surgery in the State of New Jersey, or a physician duly licensed to

- iii. Chemotherapy.
3. Complete record of dates of office visits, examination and evaluation of patient with detailed progress notes.
- i. Complications and/or untoward reactions from amygdalin (laetrile) shall be reported immediately to the State Department of Health.
- ii. Fee for service: The patient record shall include fee charged per visit which fee shall not be greater than the physician's usual and customary fee for an office visit. When fee includes administering or dispensing amygdalin (laetrile), the charge is to be itemized and recorded. When a physician administers or dispenses amygdalin (laetrile), the fee to the patient shall not exceed the cost to the physician of such substance and shall be so itemized in the charge or billing.

- iii. Copies of all laboratory and follow-up examinations; and
 - iv. Periodical clinical measurements of tumor activity.
4. Date or procurement of amygdalin (laetrile), quantity, cost, name and address of manufacturer and supplier, batch number and expiration date when administered or dispensed by a physician.
 5. Records are to be readily available without prior notice for inspection by the appropriate official agency, including, but not limited to the New Jersey Board of Medical Examiners and the New Jersey State Department of Health.
 6. Copies of records shall be forwarded to State Department of Health at quarterly intervals.

(e) Solicitation is prohibited. Such prohibited activity shall include, but is not limited to, the dissemination of information concerning amygdalin (laetrile) which may be found by the Board of Medical Examiners as:

1. False, fraudulent, deceptive, misleading or flamboyant;
2. Using testimonials;
3. Guaranteeing that satisfaction or cure will result from the use of amygdalin (laetrile);
4. Making claims of professional superiority;
5. Stating fees for professional services which are false, deceptive and/or misleading.

(f) A licensed physician may, in the regular course of medical practice and pursuant to a justifiable medical basis, prescribe, administer, or dispense amygdalin (laetrile) in accordance with the Act concerning Laetrile (Chapter 318, P.L. 1977) and these rules and regulations.

As amended, R.1984 d.67, effective March 19, 1984.
See: 15 N.J.R. 2029(b), 16 N.J.R. 552(a).
Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Deleted reference to specific statute.

Mr. HORN. I enjoyed reading your testimony. I have got to ask you a personal question. I knew a Gilhooley in a previous incarnation and are you any relation to the great Gilhooley who was Assistant Secretary of Labor under President Eisenhower? He was also a lawyer.

Ms. GILHOOLEY. I believe he might be a distant cousin. I think all of the Gilhooley's come from Leitrim way back in Ireland. We are all cousins.

Mr. HORN. And they all became lawyers, right? [Laughter.]

Well, I come from the Malones and the McCaffreys and the McSherries and they all have lawyers as the second cousins after the first cousins make it. So I just wondered. He was a very able public servant. Thank you very much. We appreciate all your testimony.

Mr. BURTON. Thank you, Mr. Horn, for that view into your ancestry. I really appreciate that. [Laughter.]

A lot of lawyers?

Mr. HORN. That is right. I am not one of them.

Mr. BURTON. Well, how did you become a university president?

Mr. HORN. Well, I am not one of them and my son, who everybody expected to go to law school says, dad, if I go, I want to just be a prosecutor. [Laughter.]

Mr. BURTON. OK. Well, let me just end it by saying to all of you I really appreciate your testimony today. I think it has been a real service for the country and people are watching across the country. And, hopefully, it will give us some guidance in Congress on how to deal with these problems. And it will also help us in our work with the Food and Drug Administration and other health agencies in this country. And I hope you will all stay in touch with me, even those who disagree with me. I would really like to have as much input as possible so that we can make sure that this committee, which has oversight responsibilities over a lot of these areas, does its job well.

Thank you very much. This committee stands adjourned.

[Whereupon, at 2:28 p.m., the committee was adjourned.]

[Additional information submitted for the hearing record follows:]



March 25, 1999

Representative Dan Burton, Chairman
Committee on Government Reform and Oversight
U.S. House of Representatives
2137 Rayburn House Office Building
Washington, DC 20515-6143

Dear Representative Burton,

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to submit a written statement for the record regarding the Food and Drug Administration's (FDA) implementation of the Dietary Supplement Health and Education Act of 1994 (DSHEA). CSPI is a non-profit consumer organization supported by more than 1,000,000 members, that has worked since 1971 to improve national health policies.

Recent scientific developments have shown that dietary supplements can play an important role in maintaining good health and can sometimes provide a valuable adjunct to conventional medical treatment. As Americans increasingly use supplements to promote their health, it is all the more important that Congress ensure that such products are safe and that label claims are truthful and non-misleading.

Unfortunately, DSHEA has made it difficult to achieve those objectives. In enacting this law, Congress changed the prevailing approach to product safety under the Federal Food Drug and Cosmetic Act. The manufacturers of food additives, drugs and medical devices must prove that their products are safe before they can be sold. Under DSHEA, dietary supplements are presumed safe until FDA can prove that they may pose a significant or unreasonable risk. While assigning the FDA this new enforcement burden, Congress failed to provide the agency with any additional resources. Thus, as a practical matter, the FDA has not been able to effectively utilize its authority to remove dangerous products from the marketplace and instead has been forced to rely on inadequate remedies such as issuing public warnings and requesting voluntary recalls.

The wisdom of this approach must be seriously questioned. Since DSHEA became law, the FDA has had to issue numerous consumer alerts, industry alerts, public warnings, and requests for voluntary recalls about supplement ingredients that pose health threats. Such ingredients include:

- Chaparral - liver disease, possibly irreversible
- Comfrey - obstruction of blood flow to liver, possibly leading to death
- Dieter's teas- nausea, diarrhea, vomiting, stomach cramps, chronic constipation, fainting, possibly death

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Executive Director: Michael F. Jacobson, Ph.D.

- Ephedra - high blood pressure, irregular heartbeat, nerve damage, injury, insomnia, tremors, headaches, seizures, heart attack, stroke and death
- Germander- liver disease, possibly leading to death
- Lobelia - breathing problems, rapid heartbeat, low blood pressure, coma and death
- Magnolia-Stephania preparation - kidney disease, possibly leading to permanent kidney failure
- Willow bark- Reye syndrome, allergic reaction
- Wormwood- neurological symptoms, characterized by numbness of legs and arms, delirium, and paralysis.
- Germanium - kidney damage, possibly death
- Herbal "Fen-Phen" - high blood pressure, heart rate irregularities, insomnia, nervousness, tremors, headaches, seizures, heart attacks, stroke and death.

Yet, because of the enforcement burdens imposed by DSHEA, and the lack of resources provided by Congress, the FDA is forced to "regulate by news release," warning the public of the dangers of particular dietary supplements but not actually removing them from the marketplace.

In addition, DSHEA permits supplement producers to make claims regarding their products' health benefits without first demonstrating that such products are truly effective. This is particularly disturbing considering that the presumed benefits of supplements are often based on anecdotal evidence, folklore, or studies that were not conducted in accordance with modern scientific techniques.

Congress should begin addressing these problems by mandating a research program, paid for by the industry and overseen by the Department of Health and Human Services, that would systematically review the safety and efficacy of dietary supplement ingredients. Vitamin and minerals known to be Generally Recognized as Safe (GRAS), and whose role in maintaining health is not the subject of controversy within the scientific community, could be exempted from such review.

In developing such a program, Congress could look to other statutory programs it has created whereby members of an industry jointly contribute to study the health effects of their industry's products. For example, under EPA's pesticide reregistration program, pesticide manufacturers pay fees, based on market share, that fund the agency's review of pesticides. Under Congressionally enacted "checkoff programs," administered by the U.S. Department of Agriculture, cattle ranchers, hog farmers, egg and dairy producers pay into funds that conduct research on beef, pork, egg and dairy consumption.

None of those programs has operated perfectly. The EPA's pesticide reregistration program has moved at a glacial pace. The USDA "checkoff programs" devote some resources to questionable research activities. Nevertheless, we urge Congress to examine those programs, identify the best elements in them, and craft a new program that requires the supplement industry to sponsor reviews of existing research and, if necessary, conduct additional research to

demonstrate the safety and efficacy of supplement ingredients.

Dietary-supplement consumers deserve no less. As Americans come to depend on supplements to address serious health concerns, it is all the more important that government ensure that products are safe and that claims on labels are backed by solid scientific evidence.

We wish to thank the Committee for the opportunity to submit this statement.

Sincerely,

A handwritten signature in cursive script, appearing to read "Bruce Silverglade".

Bruce Silverglade
Director of Legal Affairs



*Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Formerly Nonprescription Drug Manufacturers Association

Statement of the Consumer Healthcare Products Association

Submitted by R. William Soller, Ph.D.

Senior Vice President and
Director of Science & Technology
Consumer Healthcare Products Association
1150 Connecticut Ave. NW
Washington, DC 20036

**Committee on Government Reform
Congress of the United States
House of Representatives**

Hearing:

**Dietary Supplement Health and Education Act: Is FDA Trying to
Change the Intent of Congress?**

Thursday, March 25, 1999
2154 Rayburn Office Building
Washington, D.C.

Mr. Chairman and members of the Committee. Thank you very much for the opportunity to provide this statement to the Committee on Government Reform. My name is William Soller, Ph.D. I am Senior Vice President and Director of Science & Technology of the Consumer Healthcare Products Association, or CHPA.

CHPA, formerly known as the Nonprescription Drug Manufacturers Association (NDMA), is the 118-year-old trade organization representing dietary supplements and nonprescription medicines. Our members market both national and store brands of all of the major OTC drug active ingredients and vitamin, mineral and herbal ingredients. Over

the years, CHPA has been very active on a wide range of self-care issues relating to health promotion and disease treatment, including many comments to the Food and Drug Administration (FDA) on a variety of dietary supplement ingredient and labeling issues.

The American consumer would benefit by Congress ensuring that three approaches are undertaken to maximize the future public health benefits of dietary supplements:

- First, the House Committee on Government Reform should encourage the Food and Drug Administration (FDA) to develop a regulatory strategy consistent with the intent of DSHEA. For example, FDA's recent proposal on structure/function claims went well beyond what was intended by DSHEA. CHPA is optimistic that with Jane E. Henney, M.D., on board as FDA's new Commissioner and Joseph A. Levitt in place as director of the Center for Food Safety and Applied Nutrition (CFSAN), a public dialogue can be engaged to ensure that DSHEA is appropriately implemented. FDA should be given the time necessary to develop and refine this activity, which is described as a 1999 Program Priority of the CFSAN.
- Second, Congress should make certain that adequate funding is available to the National Center for Complementary and Alternative Medicine for applied research, training and dissemination of information on dietary supplements. Although substantial information supports the health-related benefits of dietary supplements, there is real potential to further define the health/disease relationships of dietary supplements through sound research from the National Institutes for Health.
- Third, the government should not be expected to be the principal source for research funding on dietary supplements. Market-based incentives should be offered to encourage those in private industry to conduct their own clinical research studies. However, in developing these incentives, the government

should not lose sight of the rights of companies to continue to make truthful and not misleading claims to consumers on currently-marketed dietary supplements.

CHPA strongly encourages Congress to consider this three-pronged approach as it reexamines FDA implementation of DSHEA. If adhered to, American consumers will benefit greatly.

I. The Need for FDA to Implement DSHEA as the Law Was Intended by Congress

The Dietary Supplement and Health Education Act of 1994 (DSHEA) represents a singular milestone in public health, by empowering consumers to make informed choices about dietary supplements for health promotion and health maintenance. CHPA fully supports this significant initiative by Congress and opposes unreasonable regulatory barriers that undermine the Congress' intent for this category of consumer self-care products.

For example, FDA issued a proposed rule on structure/function claims on April 29, 1998. This proposal went well beyond what was intended by DSHEA, particularly as it relates to the proposed new definition of disease and the proposed amplification of so-called "clarifying criteria" as to what constitutes a drug claim vs. a dietary supplement claim. FDA's proposal would, for example, make "normal aging" a disease-type claim, one that could not be addressed in a health promotion claim for a dietary supplement.¹

Furthermore, FDA's proposed rule suggested regulatory criteria to draw the line between health promotion and disease prevention, which in their practical application are

¹ Aging is an example that demonstrates just how inappropriately far-reaching FDA's proposed definition is. FDA states in the preamble to the proposed rule (i.e., "certain natural states, such as . . . aging . . . are themselves not 'diseases' . . . 63 Fed. Reg. 23627, 1998). However, "aging well" would constitute a disease state under FDA's proposed definition in 21 CFR §101.93(g)(1). That is to say, someone who exhibits structural and/or functional attributes such that she is "younger than her years" -- perhaps due to ingestion of dietary supplements -- would be defined as having a disease under FDA's proposed definition. Her youthful features would be characteristic of a "deviation" from the norm -- i.e., "aging well."

at best confusing and at the worst potentially misleading.² As a result of unusual intricacy of the link between “disease prevention/treatment” and “health promotion/maintenance to prevent disease”, it would be virtually impossible to create meaningful structure/function claims that do not *imply* disease prevention. We have suggested an approach that would cut through these ambiguities and allow a consistent implementation of DSHEA by FDA. In the absence of CHPA’s proposed amendments, however, the dietary supplement companies represented by CHPA do not support FDA’s proposed rule.

Another example of FDA’s overreach in this area relates to its recent proposal on health claims based on statements from authoritative bodies identified by Congress (e.g., National Institutes of Health, Institute of Medicine, Centers for Disease Control). We oppose FDA’s proposal to insert itself as the mediator as to whether a supportive “health claim” statement developed by an authoritative body, such as NIH, is valid. FDA should only define the approval standard for health claims on dietary supplements or foods for those claims which are specifically submitted to FDA for approval. FDA should not define the standard that would be used by other authoritative bodies to define statements/policies supporting health claims for dietary supplements or foods. Indeed, FDA’s own wording for proposed §101.90(a) specifies that the claims under consideration in the proposed rule are those that are “not authorized by the Food and Drug Administration.”

Though CHPA supports the principle that FDA should undertake enforcement action against dietary supplements that make unsubstantiated claims or unapproved drug claims, there appears to be a need to ensure that the congressional intent embodied in DSHEA is accurately and reasonably reflected in any regulations that might be developed by FDA. Happily, there also appears to be an opportunity today for FDA to reassess its

² FDA’s examples of “lowers cholesterol” versus “helps maintain a healthy cholesterol level” highlights the ambiguities inherent in FDA’s proposed construct of disease claims under proposed criteria #2 and #3. What is a healthy cholesterol level, but a lower cholesterol level? The FDA-defined disease-related endpoint is a lowering of, presumably, a higher cholesterol level; the health-related endpoint is maintenance of a “healthy” cholesterol level -- which itself is a “lower” cholesterol level generally recognized as the goal of disease prevention.

position. A new Commissioner, Dr. Jane Henney, has just recently taken the reins of the agency, and the director of the Center for Food Safety and Applied Nutrition, Mr. Joe Levitt, has been in his position a relatively short period of time, working principally on the important national program, the President's Food Safety Initiative. With this recent turn-over in key policy level personnel at the agency, CHPA believes that FDA should be given the opportunity to define a workable strategy, consistent with the intent of Congress under DSHEA. Interest in this matter, if expressed directly by Congress, would have a salutary effect in ensuring that CFSAN will define by the end of this year such a workable strategy for dietary supplements claims.

II. Adequate Funding of Research on Dietary Supplements

CHPA strongly supports efforts to further enhance the scientific basis for nutritional enhancement of health promotion and disease prevention and treatment. Today, we have a good understanding of the significant health-related benefits of dietary supplements, from Antioxidants, through Ginseng, to Zinc. But, this is not to say that even more cannot be discovered. There is real potential to further define the health/disease relationships of dietary supplements and foods through sound research.

Therefore, CHPA supports the basic mission of the National Center for Complementary and Alternative Medicine (NCCAM) to conduct and support basic and applied research, training and the dissemination of information on complementary and alternative medicine to practitioners and the public. CHPA also supports Congress' significant increase in NCCAM's current budget, from \$20 million in 1998 to \$50 million in FY1999. The success of the NCCAM research program should be encouraged by Congress.

However, the government should not be expected to be the principal source of financial support for research on dietary supplements. Currently, there is no provision in DSHEA that establishes research incentives though, of course, companies must have evidence supporting their claims, which may come from government- or industry-sponsored research on dietary supplements. Market-based incentives should be

developed to encourage private industry to undertake clinical and other research on dietary supplements. Importantly, whatever system of market-based incentives that might be developed must not interfere with the rights of companies to make truthful and not misleading claims to American consumers on currently-marketed dietary supplements.

III. Conclusion

In conclusion, CHPA supports a new effort by FDA under the new Commissioner to implement DSHEA in the manner intended by Congress; full funding of NCCAM, and the development of a broad-based dialogue on market-based incentives for research on dietary supplements.

Thank you very much for the opportunity to submit this statement. The continued interest and support for reasonable government approaches to dietary supplement that your Committee shows will ensure that the increasingly important role that dietary supplements are playing in promoting and maintaining good health of Americans will be realized.

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KayJay Organization

March 20, 1999

Beth Clay, Professional Staff Member,
Government Reform Committee,
U. S. House of Representatives,
2157 Rayburn House Office Building
Washington, DC 20515

Dear Sir,

RE: TESTIMONY ON (DSHEA) ACT OF 1994

We are an organization set up in Nigeria for the sole purpose of manufacturing and marketing of a herbal preparation known as **JUBI FORMULA**. We commenced operation early in 1997 and have since then been marketing this product predominantly in the Nigerian market. We are making some incursion into the American and European market through the internet. We have thousands of customers who have been patronizing us and many of them apply the preparation for the treatment of Anemia in:

- Sickle-Cell Anemia
- Breast Cancer
- Leukemia
- Multiple Myeloma
- Aplastic Anemia
- HIV/AIDS

BACKGROUND

Jubi Formula was discovered about 25 years ago and has since then be used in our Alternative medical practice in Nigeria. We have used this preparation to provide relief to several thousands of patients mostly with serious ailments. The success we have achieved in the alternative practice encouraged us to proceed to confirm the efficacy of the preparation in scientific laboratories. This process commenced about 2 years ago when we first carried out clinical trials in a Medical Center for patients with chronic and moderate anemia. The results showed that all the patients have their hematocrit restored within a period of 7 days therapy. We then proceeded to commission a full-scale laboratory studies at the Lagos University Teaching Hospital. At the end of the exercise we came to the following conclusions:

- Jubi Formula restores hematocrit faster than blood transfusion and any other orthodox therapy in current use. It therefore solves the problem of Anemia and therefore helps in the management of blood-related diseases such as Cancer, Breast-Cancer, Sickle-Cell Anemia, Aplastic Anemia and HIV/AIDS.
- It normalizes the Leukocytosis in bacteria and viral infections and therefore boosts the immune system of the body to enable it combat many serious diseases.
- The results obtained by the use of Jubi Formula has been consistent and can be replicated under almost all conditions.

Jubi For the Healing of the Nations

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- we are not in a position to ascertain how exactly Jubi Formula works to restore harmony to the body and therefore ensure that the body 's mechanism is enabled to defend itself against diseases. Jubi Formula, without doubt contains a biological factor not yet identified, which restores harmony in human biological system.
- Jubi Formula holds a very noteworthy prospect of helping in solving the problems associated with terminal illnesses such as Cancer and HIV/AIDS.

We have developed Jubi Formula into capsules which we are currently marketing in Nigeria and some other parts of the world.

Jubi Formula was introduced into the market about a year ago and we have recorded the successful treatment of more than 1000 sickle-cell patients in Nigeria. It is noteworthy that none of the patients has experienced any crisis after commencing the treatment. No blood transfusion has been given to any of the patients as well. We have got a record of the patients including those of some sickle-cell associations who obtain this preparation from us at a subsidized price.

A noteworthy case of Jubi administration in the USA was summarized by our medical consultant as follows:

An American, whose wife is an associate professor in the department of occupational therapy, Boston University, Massachusetts, USA.

He had Acute Myeloid Leukemia, refractory type M-O.

He received three courses of chemotherapy between October and January 1996 -1997. Two weeks after the last chemotherapy, his leukemia relapsed.

He subsequently underwent a bone marrow transplant, but the leukemia relapsed later. He went for another protocol in which he received lymphocyte infusion (helper - T cells) followed by three weeks of interleukin 2 injections. In spite of all these, his blasts continued to increase and the hematocrit kept going down. He was transfused with two pints of whole blood every other day. He also received multiple platelet transfusions. His case was dismissed by his doctors at Dana Farber Cancer Center (one of the best two cancer centers in the world) as irredeemable. He was given two days to live after discharge from hospital.

His wife, Elsie, placed an order for Jubi capsules through the internet. Though the patient is now deceased, his condition while on this therapy could best be summarized in the spouse's own words "The Jubi Formula definitely stabilized his hematocrit (i.e. no longer required blood transfusion) for as long as he took it and it may have prolonged his life a few weeks. Having been able to keep him alive for a month after they thought he was going to die was worth it.

We are attaching the e-mail correspondences that were recorded during the period of this experiment. The file is Elsie Vergara Summary.

PROJECT DIRECTORS:

Chief A. K. Awoyemi

He is the chairman of the project and he is the inventor of Jubi Formula. He retired from the University of Ibadan Teaching Hospital in 1973 as a Senior Laboratory Technician. He has been practising Alternative Medicine in his private clinic for more than 30 years.

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Mr. M. O. Okubena.

He is a Chartered Accountant and a professional Management Consultant. He retired as an executive director from the firm of Peat, Marwick, Mitchell & Co. (Nigeria) in 1983 and became the Managing Director of Bena Farms Ltd., a Poultry business. He is a co-inventor of Jubi Formula and has spent the last five years directing the research work, clinical trials and market development for Jubi Formula. He is the chief executive for the project.

Mr. Abimbola Okubena.

He is a Chemical Engineer by profession having qualified from Obafemi Awolowo University, Ile-Ife about 9 years ago. He is a director of the project and has been fully involved in the development work in the last five years. He is specifically taking charge of international marketing for Jubi Formula.

Dr. Charles C. Obinwanor

He is a Medical Doctor, having qualified from University of Ibadan about 13 years ago. He is the medical director for Golden Heart Medical Centre, Ojota in Lagos State of Nigeria. He is the medical consultant to the project and has been directing the clinical trials for Jubi Formula in the last three years.

The Research Team

The research team is headed by Dr. Mrs. C. I. Okochi of the department of BioChemistry of the University of Lagos. Other members of the research team are Professor (Mrs.) Igwilo of the Pharmacology department and Dr. (Mrs.) Kemi Odukoya (the acting head of the department of Pharmacognosy).

INTERACTION WITH FEDERAL AGENCIES

We are not based in the USA and therefore we could not have interaction with the Federal agencies including the FDA. The regulating authority for drugs and food in Nigeria is NAFDAC (National Agency for Food and Drug Administration and Control). They are not empowered to regulate herbal preparations but they encourage manufacturers to submit their products for listing. We are in the process of complying with this in due course.

OUR GOALS

We want the whole world to benefit from this discovery that we have made. We intend to market Jubi Formula in the United States in due course and would comply with all the laws as stipulated by the FDA concerning herbal preparations. In addition to this, we would be too pleased to co-operate with the relevant bodies to carry out confirmatory clinical trials for Jubi Formula anywhere in the United States. We would make available sufficient samples of Jubi Formula capsules for this exercise. We propose that this trial should cover a very broad area including the following:

- Anemia of different etiology
- Cancer including Breast-Cancer, Leukemia, Multiple Myeloma
- Sickle-Cell Anemia
- Hypertension
- Diabetes
- HIV/AIDS.

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We attach to this submission, a copy of the Laboratory Studies carried out at Lagos University Teaching Hospital and the Case Reports compiled at Golden Heart Medical Centre in Lagos. These could provide a basis for any confirmatory studies that may be required in the USA. The file's name is: Laboratory Studies. The relevant graphs and charts are also attached with the file name: Graphs & Charts3. The attachment - Laboratory Studies is recorded with MSWord and the Graphs & Charts3 is Excel formatted.

We promise to co-operate with you to enable us develop this idea of Jubi Formula which we believe would assist in improving health world-wide.

We have published our work on Jubi on the internet and our website is at <http://www.jubi-formula.com>

We look forward to hearing from you in due course.

Yours faithfully,
FOR: KAYJAY ORGANIZATIONS

M. O. Okubena.

