10 YEARS AFTER THE IMPLEMENTATION OF DSHEA: THE STATUS OF DIETARY SUPPLEMENTS IN THE UNITED STATES

HEARING

BEFORE THE

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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10 YEARS AFTER THE IMPLEMENTATION OF DSHEA: THE STATUS OF DIETARY SUPPLEMENTS IN THE UNITED STATES

WEDNESDAY, MARCH 24, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

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

Present: Representatives Burton and Watson.

Also present: Representative Davis of California.

Staff present: Mark Walker, chief of staff; Mindi Walker and Brian Fauls, professional staff members; Nick Mutton, press secretary; Danielle Perraut, clerk; Sarah Despres, minority counsel; Richard Butcher, minority professional staff member; Earley Green, minority chief clerk; and Cecelia Morton, minority office manager.

Mr. BURTON. Good morning.

A quorum being present, the Subcommittee on Human Rights and Wellness will come to order. And I ask unanimous consent that all Members' and witness' written and opening statements be included in the record. And, without objection, so ordered.

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

Today, the subcommittee has the honor of being joined on the dais by my colleague Congresswoman Susan Davis from California along with my ranking member, Ms. Watson.

We have a guest who is very welcome, a former Member of the House, Senator Durbin. So, Senator Durbin, we will welcome you to the witness chair. And if you would give me just a second to make a statement here, we will get started.

The subcommittee is convening today to discuss the Federal Government's implementation and status of the Dietary Supplement Health and Education Act of 1994, commonly referred to as DSHEA. To aid us in this dialog, the subcommittee will be hearing from the U.S. Food and Drug Administration, dietary supplement industry leaders, medical professionals, and policy researchers regarding the impact of this law in the United States.

I, along with millions of Americans, firmly believe that dietary supplements have been shown through research and historical use to be of immeasurable benefit to human health.

That is why I proudly serve as co-chairman of the Complementary and Alternative Medicine Caucus in Congress, along with my colleague, Representative Dennis Kucinich, who everybody knows is running for President—of Ohio—and Senators Orrin Hatch of Utah and Tom Harkin of Iowa who have been true champions on the other side of the building.

Given this role as well as my duties as the chairman of the Subcommittee on Human Rights and Wellness, I am particularly concerned with the status and implementation of the Dietary Supplement Health Education Act of 1994. This legislation has provided the framework for how the Federal Government ensures the safety and efficacy of dietary supplements sold in the United States.

Prior to DSHEA, dietary supplements were treated and regulated as food products. Seeing a need for the Federal Government to address the American consumer's growing interest in dietary products and public safety, Congress overwhelmingly passed the DSHEA bill in 1994 to make sure that all dietary health products sold in the United States are held to the highest and safest quality standards.

This legislation ensures the safety of dietary supplements by requiring manufacturers to follow standards called "good manufacturing practices." Essentially, all ingredients in supplements sold in the United States must be previously approved by the FDA and listed on the bottle label, and distributors must follow strict guidelines on any claims that are made in regard to a particular product to provide consumers with the most accurate information on supplements.

Additionally, if at any time the FDA decides that a particular product or dietary ingredient is detrimental to human health, it reserves the right to have those items removed from the marketplace. And that has happened.

Now that we have reached the 10th anniversary of the enactment of this legislation, I found it necessary to conduct an oversight hearing to ensure that our Federal health agencies and the dietary supplement industry have maintained the integrity of this act so that Congress might consider ways in which the act could be improved and educate American consumers to the latest developments in dietary supplement policy and nutritional labeling practices.

To explain in greater detail the status of DSHEA's implementation on the Federal Government level, the subcommittee has the pleasure of hearing, in addition to Senator Durbin, from the Honorable Robert Brackett, M.D., and Director of the Center for Food Safety and Applied Nutrition, whom I met yesterday, with the U.S. Food and Drug Administration. As Director of CFSAN, Dr. Brackett is directly responsible for overseeing the day-to-day implementation of DSHEA in the United States.

And to provide insight into how DSHEA has affected the dietary supplement industry, the subcommittee will also be hearing from a good friend of mine, Mr. David Seckman, chairman and CEO of the National Natural Foods Association [NNFA], on these matters.

Founded in 1936, even before I was born, the NNFA is the Nation's oldest and largest trade association in the natural products industry, and they represent over 5,000 retailers, manufacturers, suppliers, and distributors of health-related products.

The subcommittee will also be hearing testimony on the impact of DSHEA from Ms. Annette Dickinson, president of the Council for Responsible Nutrition, which represents many suppliers, manufacturers, and marketers of dietary supplements in the United States.

In today's rapidly changing health care delivery system, many medical practitioners have combined traditional medical treatments with complementary and alternative medicine to create the discipline of "integrative medicine" in an effort to give more complete health care to their patients. And I go to one of those doctors.

Dr. Marc Micozzi, director of the Policy Institute for Integrative Medicine at Thomas Jefferson Hospital in Philadelphia, PA, will testify before this subcommittee on the current research of the PIIM and how DSHEA has played a successful role in the integrative care of many American patients.

The subcommittee will also hear from Alan Dumoff of the American Association for Health Freedom on these most important issues.

As I stated before, dietary supplements have been shown through credible scientific research to provide substantial health benefits for the users. Mr. Doug Rose, a good friend of mine from Indianapolis, the great State of Indiana, and a businessman from our State, is here to discuss his experiences about the potential health benefits of folic acid, and how this supplement may decrease the likelihood of birth defects in children, such as Spina Bifida.

From my own personal experience and observations over the last decades, the FDA's implementation and execution of DSHEA has generally provided the dietary supplement industry with the increased opportunity for competition, as well as easier access to safe health products for the millions of American consumers like me who use these products and supplements to maintain and improve their health.

While no government program is perfect, I would like to congratulate all the men and women of the U.S. Department of Health and Human Services for their hard work over the years to put into place and strengthen the principles originally outlined in DSHEA 10 years ago.

It is my sincere hope that this hearing will help point out the positive effects of the Dietary Supplement Health and Education Act, while at the same time providing suggestions from our witnesses that could further improve this program to better accommodate U.S. health policymakers and supplement consumers many more years to come.

And I look forward to hearing from all of our witnesses. And with that, Ms. Watson, do you have an opening statement?

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

Opening Statement
Chairman Dan Burton
Subcommittee on Human Rights & Wellness
Government Reform Committee
"10 Years After the Implementation of DSHEA:
The Status of Dietary Supplements in the United States"
March 24, 2004

The Subcommittee is convening today to discuss the Federal government's implementation and status of the Dietary Supplement Health Education Act of 1994, commonly referred to as DSHEA. To aid us in this dialogue, the Subcommittee will be hearing from the U.S. Food and Drug Administration, dietary supplement industry leaders, medical professionals, and policy researchers regarding the impact of this law in the United States.

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That is why I proudly serve as Co-Chairman of the Complementary and Alternative Medicine Caucus in Congress, along with my colleague Representative Dennis Kucinich of Ohio here in the House, and Senators Orrin Hatch of Utah and Tom Harkin of Iowa who have been true champions on these issues in the other body.

Given this role, as well as my duties here as the Chairman of the Subcommittee on Human Rights and Wellness, I am particularly concerned with the status and implementation of the Dietary Supplement Health Education Act of 1994. This legislation has provided the framework for how the Federal government ensures the safety and efficacy of dietary supplements sold in the United States.

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This legislation ensures the safety of dietary supplements by requiring manufacturers to follow standards called "Good Manufacturing Practices," or GMPs. Essentially, all ingredients in supplements sold in the United States must be previously approved by the FDA and listed on the bottle label, and distributors must follow strict guidelines on any claims that are made in regard to a particular product – to provide consumers with the most accurate information on supplements. Additionally, if at any time the FDA decides that a particular product or dietary ingredient is detrimental to human health, it reserves the right to have those items removed from the marketplace.

Now that we have reached the 10th Anniversary of the enactment of this legislation, I found it necessary to conduct an oversight hearing to ensure that our Federal

health agencies and the dietary supplement industry have maintained the integrity of this Act so that Congress might consider ways in which the Act could be improved, and educate American consumers to the latest developments in dietary supplement policy and nutritional labeling practices.

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Dr. Marc Micozzi (Mick-koh-zee), Director of the Policy Institute for Integrative Medicine (PIIM) at Thomas Jefferson Hospital in Philadelphia, Pennsylvania, will testify before the Subcommittee on the current research of the PIIM, and how DSHEA has played a successful role in the integrative care of many American patients. The Subcommittee will also hear from Mr. Alan Dumoff (Doom-off) of the American Association for Health Freedom on these most important issues.

As I stated before, dietary supplements have been shown through credible scientific research to provide substantial health benefits for their users. Mr. Doug Rose, a good friend and private businessman from my home State of Indiana, is here to discuss his experiences about the potential health benefits of folic acid, and how this supplement may decrease the likelihood of birth defects in children, such as Spina Bifida (Spine-uh, Bih-fid-uh).

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access to safe health products for the millions of American consumers like me who use these supplements to maintain and improve their health.

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It is my sincere hope that this hearing will help point out the positive effects of the Dietary Supplement Health and Education Act, while at the same time providing suggestions from our witnesses that could further improve this program to better accommodate U.S. health policy makers and supplement consumers many more years to come. Once again, I look forward to hearing from today's witnesses.

Ms. WATSON. Thank you so much, Mr. Chairman.

And I feel that natural foods and supplements are very important to a healthy population. Natural foods and supplements are the completion of what I call the "global circle." In the beginning of life we came from the Earth, and in death we return to the Earth. Natural foods and supplements come from the Earth and support the rhythm of nature. If one understands what should go into a body, then it is possible to live a healthier and more productive life. Breast milk nurtures an infant and promotes accelerated learning. Vitamins and minerals give cells and organs the proper building blocks for optimal performance. Herbs and trace elements have medicinal value and sickness-preventing properties.

I have long believed that we need to put a greater emphasis on our health care system into prevention, wellness, and self-care. The natural foods and supplement industry can help more and more Americans take charge of their own health. They can assist our constituents in adopting healthier lifestyles that include a good diet, exercise, supplementation, and becoming more educated about all of the above.

The Dietary Supplement Health and Education Act [DSHEA], is a very important piece of legislation. Prior to the enactment of DSHEA, the FDA regulated dietary supplements as food. Because manufacturers' claims are often promising and completely positive, Congress created guidelines to address supplement definitions, safety concerns, ingredient and nutrition labels, supplement claims, good manufacturing practices, and new dietary ingredients.

In addition, DSHEA created a Supplement Commission and an Office of Dietary Supplements at the National Institutes of Health.

In the oncoming educational process, our purpose today is to review its report card. Americans are very concerned about their health. Recent news about supplements containing ephedra and black cohosh have received national attention. Natural nutritions are nothing to be scared of, but they should be respected, treated with care, and used properly.

So, Mr. Chairman, thank you for your foresight, and as chair, and myself as ranking member, of an appropriately named subcommittee, Human Rights and Wellness, I look forward to working with you and to hearing our witnesses as we promote a healthier America. Thank you very much.

Mr. BURTON. Thank you, Ms. Watson. And I like your broach and earrings. Very pretty. That is not part of the program; I just thought somebody ought to tell her.

Ms. Davis.

Mrs. DAVIS OF CALIFORNIA. Thank you. Thank you, Chairman Burton and Ranking Member Watson, for convening this important hearing today. I am honored to be a part of it, and welcome the opportunity for some thoughtful dialog today.

Dietary supplements, as we know, are readily available and appeal to many consumers who are looking to improve their health. Some supplements have very important health benefits, and I believe we are going to be talking about some of those today. Folic acid, for example, can prevent certain birth defects, and calcium is important for healthy bones.

However, since the passage of the Dietary Supplement Health and Education Act [DSHEA], 10 years ago, the market has grown considerably and now includes supplements for which there is little evidence of either benefit or, perhaps more troublesome, of safety.

There are also potentially dangerous products out there right now. According to Bruce Silverglade from the Center for Science in the Public Interest, a respected consumer group, "The challenge for most consumers is to determine which supplements are beneficial and which are nothing more than 21st century snake oil, or even dangerous."

Since coming to Congress, I have sought to provide the FDA and American consumers with information about both the benefits and the risks associated with other dietary supplements on the market. With the support of my colleagues, Representatives Waxman and Dingell, we introduced the Dietary Supplement Access and Awareness Act this fall. Our bill, H.R. 3377, addresses the gaps created by DSHEA to greater information exchange and accountability. And I understand that there are some individuals here who would like to comment on that, and I appreciate that.

Some dietary supplements present a serious consumer protection and public health problem. The average citizen believes dietary supplements are safe because they are sold off the shelves of our convenience and grocery stores. However, potential consumers do not know about the burden of proof the FDA must meet before taking an unsafe product off of the market. As former FDA Director David Kessler wrote in the New England Journal of Medicine a couple years ago, "Congress has put the FDA in the position of being able to act only after the fact and after substantial harm has already occurred."

My own interest in dietary supplements goes back to my tenure in the California State Assembly when I was chair of the Committee on Consumer Production. Constituents using ephedra diet pills approached me to share their accounts of serious side effects. Just this past July, I heard heartbreaking testimony from the Beckler and Riggins families. Both families lost their sons as a result of taking ephedra pills. These families represent countless numbers of people who have already been adversely affected by dietary supplements. Every day, young men are drawn to the supplements in the hopes of enhancing their athletic ability, and our young women are seduced into believing they will lose weight by simply popping pills.

It is critical that we remember that the discussion regarding DSHEA does not begin and end with ephedra. We are looking for a long-term solution, not a Band-Aid approach. As Members of Congress, we can prevent a repeat of the ephedra tragedy where for 9 years thousands of adverse effects were amassed and FDA was unable to act.

We already know a dietary supplement called bitter orange is gaining in popularity. This is a substance derived from orange rinds. It is a stimulant sold in combination with other stimulants, and some experts fear that it could pose similar risks as ephedra. Ephedra should be viewed as the canary in the coal mine that it is. Without changes, we could see more and more potentially dangerous supplements follow in ephedra's wake. Current regulations

that cover dietary supplements are loose at best and completely ineffective at worst.

Mr. Chairman, I look forward to the hearing and from hearing from today's witnesses, and I really do appreciate the ability to sit in today. Thank you very much.

Mr. BURTON. Thank you, Ms. Davis.

We are very happy to have our former colleague, Senator Durbin, with us. He for some reason decided to go to the lower House, so we let him go. But he is back here today to testify, and we welcome you. And you are welcome to make a statement, Senator.

STATEMENT OF HON. RICHARD J. DURBIN, A U.S. SENATOR FROM THE STATE OF ILLINOIS

Senator DURBIN. Chairman Burton, Congresswomen Watson and Davis, thank you very much for allowing me to testify. The reason I feel so good today is that I returned to the House to witness your meteoric rise in leadership, Mr. Chairman. And, second, because I got up this morning and took my vitamin. In fact, I took a multivitamin and a couple other supplements, and I feel pretty good about it. And like a lot of Americans who do that, we think we are doing the right thing to stay healthy and to maintain our energy despite advancing years.

So I want to tell you that I don't come here with any prejudice against vitamins and minerals and those supplements which really do help people. And I think people should have the right to make a choice to go in and take those things which they think will be of value to their health. Of course, we like to believe someone will counsel them along the way, but, more importantly, we like to make sure that the products that they are taking are safe.

If you walk into a drugstore today and you pick up your prescription drug, you know that drug has gone through clinical tests to determine whether it is both safe and effective. If you take an over-the-counter drug, you will find in the monograph a similar test that has been given to the basic compounds that are included in over-the-counter drugs.

Such is not the case, though, when you walk into a natural food store or a dietary supplement store. The products that you are using there quite likely have never been tested. In fact, you are the person who is conducting the test. As a consumer, you are ingesting this compound, whatever it may be, in the hopes that it will help you. But there has never been a clinical trial or test to establish that fact. It is, in fact, the consumer who is playing the role of the rat in the laboratory, the guinea pig. And that, I think, is something that we should reflect on.

I would say that there are many who have questions about dietary supplements, legitimate questions. I want to salute Congressman Davis for her leadership on this. Before I held hearings in the Senate, she had introduced a bill with Congressman Waxman and others, and I know that it is an interest that is based on a real concern about ephedra.

At the time that we started holding hearings on ephedra, the following had occurred: Canada had banned the sale of products containing ephedra; the American Medical Association had warned those in America that ephedra could be a dangerous compound to

some individuals; we had prohibited the sale of ephedra—products containing ephedra on military bases across the United States and around the world because of adverse events involving soldiers. We had also seen major sporting associations such as the Olympic Committee and Major League Baseball and others that had banned or at least suggested that their players shouldn't use ephedra.

Despite all of that mounting evidence, we couldn't really say with any degree of certainty that the government in our country was going to step in and stop the sale of products containing ephedra, and that is why the hearings were held.

We need to make a couple critical changes in the DSHEA. We need to require premarket safety review of supplements containing stimulants like ephedra. And we need to require companies to report serious adverse event reports to the FDA.

I don't believe that every natural substance needs to be subject to premarket safety testing but, at the least, stimulants should be. When a supplement raises people's blood pressure, increases their metabolism, constricts their blood vessels, it is only prudent that we test the product before it is marketed. Supplement manufacturers who have come to see me say they test their products that they market. And maybe some do and I hope that they do. In my experience, many do not.

Last July I wrote seven companies that market ephedra-free products containing citrus aurantium, also known as bitter orange. This citrus aurantium contains the chemical synephrine, a substance very similar to ephedra, that stimulates the central nervous system and can cause hypertension, heart attacks, and strokes.

My interest was supported by a statement from FDA Commissioner Mark McClellan who said at the University of Mississippi last fall, "there are other supplements with chemically distinct and less-well-understood components that may have similar adverse pharmacologic effects to ephedra or pose health risks for other reasons. An example of these is bitter orange or citrus aurantium."

I by letter to these companies that sell dietary supplements containing bitter orange or citrus aurantium, asked them whether or not they had conducted any studies in-house or independently on the safety or efficacy of this supplement. I also asked for information on the number of employees dedicated to monitoring product safety. Only four companies of the seven responded. The letters were distressing.

Neil Reithinger of Baywood International, which sells numerous ephedra-free products, answered none of the questions posed either in whole or in part. Instead, he stated, "as with all of the company's dietary supplemental products, we believe that our ephedra-free products lawfully may be sold as currently formulated or promoted."

He is exactly right. Under DSHEA, he has no requirement to test citrus aurantium or any of the supplements that he is selling before he can lawfully sell them in the United States.

Now, Robert Occhifinto—and I hope I am not mispronouncing his name—the president of NVE Pharmaceuticals, is the marketer of something you might have seen on TV, Stacker 2, ephedra-free. He wrote to me and said, "In our experience, it is unusual for companies to conduct in-house testing for neutraceutical compounds."

On the subject of safety, Mr. Occhifinto cited a study that was conducted by a highly regarded pharmacologist, but the study didn't substantiate his assertions. He said the study showed that blood pressure and cardiac effects of citrus aurantium were found to be no different than water. "No different than water."

In fact, the study was not evaluating the safety of supplements containing citrus aurantium; it was examining whether orange juice—orange juice, a natural source of the active ingredient in citrus aurantium—is safe to use in drug metabolism studies.

So we went and contacted one of the pharmacologists who really conducted the study that Mr. Occhifinto used as the basis for justifying selling his product. This is what the pharmacologist responded, and I want to add this—all of these letters for the record so you can make them part of your testimony, this is from the pharmacologist, "I don't consider our study using Seville orange juice even remotely sufficient to assess the safety of synephrine-containing dietary supplements. If the industry is doing that, then in my opinion they are committing an egregious error."

I am going to give you the letters. I want you to take a look at them. I do believe, when we are talking about stimulants, credible testing needs to take place.

There is another change I would like to see in DSHEA, and that is making adverse event reporting mandatory so that serious adverse events become part of a public record. I am not talking about someone getting dizzy after taking a supplement. I am talking about death, incapacity, and hospitalization. It is absolutely necessary we know when a product is seriously harming people.

This morning's Washington Post, Mr. Chairman, talks about antidepressant drugs and whether or not Prozac and other drugs should be recommended. Well, there are some British studies and foreign studies that are leading this inquiry, but also adverse event reports that are coming in from drug companies that sell these prescription drugs containing antidepressants are starting to accumulate and raise questions.

In the dietary supplement industry, under DSHEA there is no requirement for this reporting. And let me tell you how this works. Metabolife is one of the giants in the supplement industry. In 1999, Metabolife told FDA, "Metabolife has never been made aware of any adverse health events by consumers of its products. Metabolife has never received a notice from a consumer that any serious adverse health event has occurred because of the ingestion of Metabolife 356." 1999, Metabolife to the FDA.

Then the Justice Department start investigating, and then class-action lawsuits were filed. And you know what they found? Metabolife has received 16,500 adverse event reports, including 2,000 significant cardiac, neurological, and psychiatric reports. Metabolife has misled the FDA. Metabolife refused to acknowledge the obvious. People were taking their product containing ephedra and having serious adverse health events.

Now, under the law, there is no requirement that Metabolife or any other supplement company even reports when people are dying from their product.

Now, another company, Rexall Sundown, marketed an ephedra product called Metabolite, discovered through a court case that

they had significant numbers of adverse event reports that they never turned over to the public. When we were made aware of that, we contacted the company and asked them for these reports. And they said, "well, you are talking about the old Rexall Sundown."

You know what they had done? They had used the old trick to shield themselves from liability: They dissolved their own company that sold this product and started a new one with the same name. They took all the assets to the new company, hoping to leave all their liability for the adverse health consequences from selling these ephedra products behind them. The lawyer in the case filed a motion to have the reports released, but the motion was denied.

Now, if companies aren't sharing information with the FDA that can help protect consumers, we have to make this system mandatory and give the FDA the authority to demand adverse event reports.

Congresswoman Davis mentioned the name Sean Riggins. Sean Riggins was a 16-year-old boy who lived just a few miles from my home in Springfield, IL. He was a football player. And he went to—in the hopes of having a better football game, went to a local gas station convenience store, and he bought one of these ephedra products, took a couple of the pills; legally purchased it, no questions asked, washed it down with Mountain Dew, and died of a heart attack the next day. Now, that really brought it home to me. Here was a young boy who went in and innocently bought a product that he thought would help him.

If you go to a high school or junior high in Indiana or Illinois, or in any State for that matter, ask them how many have heard of these products that we are talking about. They are going to tell you, a lot of these kids are aware that they are out there.

Mr. Chairman, I believe that vitamins and minerals and dietary supplements can be very good for all of us. But we have an obligation to the consumers across America to make certain that we don't sell them something that is dangerous. As Congressman Greenwood has said over and over, you can sell snake oil in America; that is up to you, and consumer beware. But we don't allow you to sell snake venom. And that, unfortunately, is the case with some of these products.

It is going to take some political will and courage for us to move forward on this. I hope that we can begin it in the House, perhaps in the Senate as well. Keep DSHEA in place, but make the modifications that will protect consumers across America. Thank you Mr. Chairman.

Mr. BURTON. Thank you, Senator Durbin. We really appreciate your testimony.

[The prepared statement of Hon. Orrin G. Hatch follows:]

Senator Orrin G. Hatch
Written Testimony for the United States House of Representatives
Subcommittee on Human Rights and Wellness
Committee on Government Reform
March 24, 2004

"10 Years after the Implementation of DSHEA:
The Status of Dietary Supplements in the United States"

I appreciate the opportunity to offer testimony concerning a topic very near and dear to my heart: the regulation of dietary supplements since the enactment of The Dietary Supplement Health and Education Act of 1994 (DSHEA). Unfortunately, I cannot be with you today as recent surgery has necessitated an abbreviated work schedule. Please know that DSHEA is a law that is very important to me, and there is very little that would keep me away from your excellent proceedings today!

I am pleased to discuss DSHEA, a bill that Senator Harkin and I authored with now-Governor of New Mexico Bill Richardson. I want to thank you, Chairman Burton, for your leadership in this area and for holding this hearing. DSHEA is a strong law that has all the provisions necessary to protect the interests of consumers when properly implemented. But as with any law, it has to be implemented for it to work.

The Dietary Supplement Health and Education Act of 1994 was a triumph of Congressional responsiveness to American consumer needs. It allows the more than 150 million Americans who regularly use dietary supplements to have access to these products in order to achieve health benefits. DSHEA enables Americans to buy relatively inexpensive dietary supplements of vitamins and minerals, which may achieve a wide array of health improvements. Its passage followed decades of Food and Drug Administration antipathy toward dietary supplement products beginning in the Kefauver years. This animosity and the lack of a clear regulatory structure for supplements were clearly demonstrated prior to passage of DSHEA. That is why two-thirds of the Senate and a majority of this House cosponsored the bill. And that is why the bill passed without one dissenting vote in either house.

The basic structure of DSHEA allows all products marketed as dietary supplements at the time the bill was enacted to continue to be marketed as dietary supplements, unless they are unsafe or otherwise violate prohibitions in the Federal Food, Drug and Cosmetic Act with respect to labeling, purity, etc. This is the so-called "grandfather" provision. In addition, for new dietary ingredients, those not marketed in the United States before the law was enacted, manufacturers must provide evidence of safety to the FDA 75 days in advance of marketing. Again, new dietary ingredients must also comply with the FFDCA requirements for safety, purity and labeling.

Another cause of concern is that the agency had not taken action against any product based on safety concerns until its actions with ephedra, as I will discuss below. And, it had not invoked the "grandfather" clause once since 1994 until the recent action on androstenedione.

I also am concerned that the appropriate federal agencies use the powers granted to them in DSHEA to protect the American public from misleading information in advertising regarding dietary supplements. Earlier this month, I co-authored a letter with Senator Harkin to the FDA and FTC to urge prompt action to address an advertisement that appeared to violate the claims provisions of DSHEA. In particular, we noted that an ad in the March 12th *Washington Post* for a product known as "ArthroZyme" appeared to violate provisions of DSHEA, by making unapproved drug claims regarding the product's efficacy for treating arthritis. We asked the FTC and FDA to use the consumer protections in DSHEA in reviewing the content of this ad and taking appropriate enforcement actions, and to keep us informed of their results.

While FDA was slow to use the regulatory authority of DSHEA after it was first enacted in the mid '90s, I am pleased that under the current agency leadership, we have been able to work together effectively to allow Americans access to safe dietary supplements while protecting them from risks.

As I mentioned, we have seen two examples recently of use of this authority.
The FDA used DSHEA in December 2003 when it announced its intent to ban the widely used weight-loss product ephedra. It followed this announcement in February 2004 with a final regulation banning the product as presenting an "unreasonable risk of illness or injury". This represented the first time the FDA had defined this important legal standard.

I am no apologist for ephedra. I recognize that literally hundreds of millions of servings have been consumed annually, most free from concern. But, the reports of adverse events -- however small by comparison -- are extremely troubling. Over the years, many on both sides urged me to take action on ephedra, both to ensure its continued marketing and to ban it. To each, I responded that the law must be enforced and that FDA, an agency of science, must make a determination about the product's safety and appropriate "dosage," if there is one. Congress is ill-equipped to make such decisions. Politics is often not the best protector of public health.

There is no question that the FDA's early tries to regulate ephedra were fraught with process concerns. The General Accounting Office has amply documented this, much of the work being conducted under your direction, Chairman Burton. There also is no question that it took the agency too long to get it done. I have to credit HHS Secretary Thompson and Commissioner Mark McClellan for having the guts and the fortitude to see this through to completion.

Another example where FDA has been slow to act is the steroid precursor androstenedione. It has been almost three years since Senator Harkin and I first sounded the alarm bells at FDA on "andro". FDA has now verified what my Iowa colleague and I suspected: andro is neither a grandfathered dietary supplement nor a product for which a new dietary ingredient petition was submitted. In short, it is not legally marketed, it has not been legally marketed, and young athletes should not have been able to buy it.

NVE Pharmaceuticals

15 Whitehall Road
Andover, New Jersey 07861

Tel: 973-786-7862
Fax: 973-786-7860

VIA HAND DELIVERY

September 9, 2003

Honorable Richard J. Durbin
332 Dirksen Senate Office Bldg.
Washington, DC 20510-1304

Re: Stacker 2 ® Ephedra Free

Dear Senator Durbin:

This letter is in response to your letter of July 23, 2003, requesting information relative to the above referenced NVE Pharmaceuticals' dietary supplement.

Before addressing our ephedra-free product, I must respectfully disagree with the assumption made in the first paragraph of your letter that ephedra is dangerous and has been linked to some 120 deaths. As a matter of fact, the overwhelming objective scientific evidence is that when used as directed, ephedra is safe. In the recent government-sponsored study by the highly-respected Rand Corporation, the researchers concluded that there was insufficient evidence to conclude that ephedra caused *any* deaths.[1] Rand concluded that there was no evidence that ephedra is unsafe when used as directed for weight loss. Researchers noted that approximately three billion servings of ephedra containing products are used by 12 to 17 million Americans every year.[2] NVE retained the Weinberg Group, a respected scientific consulting firm, to review scientific data on ephedra for us. We enclose their report for your information. The Weinberg Group concludes that the current state of knowledge regarding the safety of ephedra-containing products *does not* warrant their removal from the marketplace.

With respect to Stacker 2 Ephedra Free, NVE began to manufacture this product in September 2001 to expand it's market by offering consumers an alternative to ephedra-containing products. Stacker 2 Ephedra Free contains citrus aurantium (synephrine) and caffeine, nutraceutical components that include substances (called sympathomimetic amines) that are similar to ephedra. The scientific literature contains ample information regarding the efficacy of citrus aurantium with respect to its effects on obesity and weight loss.[3] In addition, there is at least one

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[1] Shekelle P, Morton, S., Maglione M, et al. Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects. Evidence Report/Technology Assessment No. 76 (Prepared by Southern California Evidence-based Practice Center, RAND, under Contract No 290-97-0001, Task Order No. 9). AHRQ Publication No. 03-E022. Rockville, MD: Agency for Healthcare Research and Quality. February 2003.
[2] McGuffin, M. Statement before the Department of Health and Human Services Office of Public Health & Sciences; public meeting on safety of dietary supplements containing ephedrine alkaloids. August 8, 2000.
[3] Moro CO, Basile G. Obesity and medicinal plants. Fitoterapia. 2000 Aug; 71 Suppl 1:S73-82. Review.

clinical study where the blood pressure and cardiac effects of citrus aurantium extract (the substitute for ephedra in Stacker 2 Ephedra Free), were found to be no different than water.[4] Other studies have shown citrus aurantium to have the effect of lowering the blood pressure in animals.[5] These study results support our conclusion that Stacker 2 Ephedra Free (which contains citrus aurantium) possesses no untoward effects and may have the additional benefit of lowering the heart rate and blood pressure.

The science is considered sufficient enough for our company to forego in house testing as it would be redundant. In our experience, it is unusual for companies to conduct in-house testing for nutraceutical compounds. Indeed, the vast majority of pharmaceutical products commonly used in American medicine lack specific in house testing for the considerable amount of off-label use experienced today. Existing standards of care and science in the international scientific disciplines of plant pharmacology and herbal medicine – which we rely on – exceed the standards applied in the off-label prescription of pharmaceuticals.

All of our employees involved in our manufacturing operations are, to varying degrees through training and our good manufacturing practices, responsible for ensuring the safety and efficacy of our products. NVE has a five person Quality Assurance/Quality Control team that is comprised of the following:

- A Supervisor who has a B.S. degree in Biology from West Virginia Wesleyan College, 1971; and 30 years experience as a Quality Assurance Professional.
- A Quality Control Inspector who has a B.S. degree in Mechanical Engineering from the Technical University, Odessa, Ukraine, 1992; and whose prior training includes ISO 9000 and Six Sigma Quality techniques.
- A Quality Control Inspector, who has a B.S. degree in Engineering from the University of Del Quindio Colombia, 1996; and whose training includes programs on GMP/Quality.
- A Quality Assurance Specialist with prior experience in document control and quality, and who received in-house training on GMP/Quality Assurance provided by an outside consultant who was formerly an FDA Consumer Safety Officer/Investigator/Specialist.
- A Quality Assurance Specialist with prior experience in customer service, who attended in-house training on GMP/Quality Assurance provided by an outside consultant who was formerly an FDA Consumer Safety Officer/Investigator/Specialist.

The job descriptions of the Quality Control/Quality Assurance personnel are attached hereto as exhibits.

Respectfully submitted,

Robert Occhifinto
President, NVE Pharmaceuticals

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[4] Penzak SR, Jann MW, Cold JA, Hon YY, Desai HD, Gurley BJ. Seville (sour) orange juice: synephrine content and cardiovascular effects in normotensive adults. J Clin Pharmacol. 2001 Oct; 41(10):1059-63.
[5] Huang YT, Lin HC, Chang YY, Yang YY, Lee SD, Hong CY. Hemodynamic effects of synephrine treatment in portal hypertensive rats. Jpn J Pharmacol. 2001 Feb; 85(2):183-8.

August 31, 2003

Senator Richard J. Durbin
United States Senate
332 Dirksen Senate Office Building
Washington, D.C. 20510-1304

Dear Senator Durbin:

On behalf of Baywood International, Inc., I am responding to your letter of July 23, 2003, and to your press release of the same date, concerning the Company's sale of dietary supplements containing bitter orange (*Citrus aurantium*). At the outset, let me clear up some apparent confusion.

In your press release, you indicate that Baywood International is one of the eight largest dietary supplement makers in the United States. While the Company aspires to attain this status, to date Baywood International remains a relatively small company. Indeed, for the past 12 months, our total sales in the U.S. have been approximately $1.6 million. Of this total, the Company's sales of "Metabolic Burn Tropin-EF™," "Meta-Tropin-EF™," and "Thermogenic Burn Tropin™," combined, have been approximately $50,000.

Despite the Company's relatively modest sales, we are committed to ensuring full compliance with all of the laws and regulations enforced by the Food and Drug Administration ("FDA") and the Federal Trade Commission ("FTC"). As with all of the Company's dietary supplement products, we believe that the three products above lawfully may be sold as currently formulated and promoted.

Thank you for your inquiry.

Sincerely,

Neil Reithinger
President & C.E.O.

SOLUTIONS®
PURECHOICE®
La Femme® Complete
EVOLUTION™

Earle D. Bellamy II
General Counsel
Phone: 303-384-0080 ex 4380
Fax: 303-271-0916

August 28, 2003

The Honorable Richard J. Durbin
United States Senate
332 Dirksen Senate Office Building
Washington, DC 20510-1304

Dear Senator Durbin:

On behalf of Experimental and Applied Sciences, Inc. ("EAS) I am responding to your letter dated July 29, 2003, and your specific inquiries about BetaLean HP Ephedra Free and the ingredient citrus aurantium.

1. Has your company marketed the product referenced above as an alternative to products containing ephedra, either formally, by implication, or in discussions with distributors, customers, or potential customers?

BetaLean HP Ephedra Free evolved as a second generation ephedra-free product following the introduction in 1998 of EAS' original ephedra-free weight management product, Phen Free. Since 1998 EAS has marketed an ephedra-free thermogenic product for consumers who wish to supplement their exercise and nutrition program with a weight management product. From September 2000 to January 2003, EAS marketed BetaLean HP in both an ephedra-free and an ephedra version. EAS is currently marketing BetaLean HP Ephedra Free as we develop our next generation of ephedra-free products.

2. Did your company conduct any in-house testing of this product for safety before marketing? Did your company conduct any in-house testing for efficacy?

EAS typically conducts a thorough review of the available science of each component ingredient prior to formulating and marketing a product. EAS also relies on the prior safety determinations (including GRAS status) of the US Food and Drug Administration (FDA) for component ingredients and food additives. EAS reviewed the available scientific literature concerning the safety and efficacy of citrus aurantium, and by implication synephrine, as well as the GRAS determination for citrus aurantium as a food additive. Since the efficacy of the component ingredients was well established and/or the claims made for the product were appropriately qualified in proportion to the available science, EAS did not conduct efficacy testing on the finished product.

3. Has your company conducted any in-house testing of this product for safety after the product has been marketed? Has testing been conducted for efficacy?

EAS
555 Corporate Circle
Golden, CO 80401
Ph 303 384 0080

Please see response to number 2 above. EAS typically does not engage in post-market safety or efficacy testing of a product absent reasonable cause to do so. Safety and efficacy determinations are made in advance of introducing a product to market. These determinations are integral to the product development process, and for establishing label contents for component ingredients. EAS does, however, routinely conduct post-market testing of finished products to ensure that the component dietary ingredients are present in the amounts claimed on the label and that microbial counts are within acceptable limits.

4. Have any independent studies been conducted regarding the safety of your product? Have studies been conducted for efficacy?

Please see response to numbers 2 and 3 above.

5. Please provide me with any and all studies, either conducted in-house or by outside researchers, upon which your company bases claims of safety and/or efficacy of your product.

Please find copies of the following studies and encyclopedic entries enclosed with this response:

Fleming T, editor. 2000. PDR For Herbal Medicine. 2nd ed. Montvale, NJ: Medical Economics Co. p 86-87.

Blumenthal M, editor. 1998. The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines. Austin, TX: American Botanical Council, p 89-90, 313-314, 500

Schulz V, Hänsel R, Tyler VE. 1998. Rational Phytotherapy: A Physicians' Guide to Herbal Medicine. 4th ed. New York: Springer. p 208.

Leung AY, Foster S 1996. Encyclopedia of Common Natural Ingredients. 2nd ed. New York: Wiley. p 82-84, 286-287, 395-397, 489-492.

Penzk SR, Jann MW, Gold JA, Yi Y, Desai HD, Gurley BJ. 2001. Seville (sour) Orange Juice: Synephrine Content and Cardiovascular Effects in Normotensive Adults. J Clin Pharmcol 41:1059-5063.

Pellati F, Benvenuti S, Melegari M, Firenzuoli F. 2002. Determination of adrenergic agonists from extracts and herbal products of *Citrus aurantium* L. var *amara* by LC. J Pharmaceutical and Biomedical Analysis. 29:1113-1119.

Moro CO, Basile G. 2000. Obesity and medicinal plants. Fitoterapia. 71:73-82.

Additionally, please find the following sections of the Code of Federal Regulations reflecting the GRAS status of the following component ingredients:

21 CFR 146.146 Frozen Concentrated Orange Juice (permitting *Citrus aurantium* in frozen concentrated orange juice)

21 CFR 182.20 Essential oils, oleoresins, and natural extractives (reflecting GRAS status of Citrus peels; Orange, bitter, peel; and, Tea).

21 CFR 582.5191 Calcium carbonate.

6. How many employees work on ensuring your product is safe and effective? Please provide me with the job descriptions of the employees who have such jobs, as well as their qualifications for the jobs.

EAS employs a number of people in a variety of positions in an effort to ensure the quality, safety and efficacy of its products. The number of employees with significant job responsibility related to quality, safety and efficacy is approximately fifteen. The qualifications and training for each position vary, but include doctoral, masters and bachelors degrees in a variety of disciplines including human nutrition and food science, as well as specialized quality training. Because of EAS' relatively small size in terms of total employees we do not maintain formal job descriptions. However, the titles of these individuals are as follows:

Vice President, Science
Vice President, Research and Development
Manager, Quality Assurance
Assistant Manager, Quality (2)
QC Inspector (2)
Administrative/Records Assistant
Director, Research and Development
Senior Product Manager
Product Manager (3)
Assistant Product Manager
Product Development Technologist

EAS also maintains a Science Advisory Board (SAB) that is comprised of the Vice President of Science and twelve outside experts. Eleven of the thirteen members hold a Ph. D. in a related discipline, three have earned their M.D., and one member is a Registered Dietician.

If I can be of further assistance please do not hesitate to contact me.

Sincerely,

Earle D. Bellamy II
General Counsel

LWM/lr

Enclosures

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*PRACTICE WITHIN THE DISTRICT OF COLUMBIA IS LIMITED TO MATTERS AND PROCEEDINGS BEFORE FEDERAL COURTS AND AGENCIES

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January 8, 2004

BY HAND DELIVERY

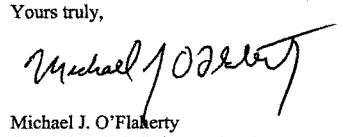
Attn: Christa Donahue
The Honorable Richard Durbin
332 Dirksen Senate Office Building
Washington, D.C. 20510

Re: Response to Sen. Durbin's July 23, 2003 Letter Request

Dear Ms. Donahue:

Pursuant to your request, enclosed please find a copy of the November 14, 2003 response previously sent to Senator Durbin.

Yours truly,



Michael J. O'Flaherty
Counsel to Twin Laboratories, Inc.

MJO:jdm
Enclosure

November 14, 2003

VIA FEDERAL EXPRESS

Senator Richard J. Durbin
United States Senate
332 Dirksen Senate Office Bldg.
Washington, DC 20510

Dear Senator Durbin:

Twinlab Corporation hereby provides its response to your letter request, dated July 23, 2003 ("the Request"), regarding certain products marketed by Twinlab and containing Citrus aurantium extract.

Preliminary Statement

Twinlab Corporation provides this response (the "Response") on a voluntarily basis, reserving its right to protect commercially sensitive and proprietary information. As an initial matter, your letter is directed to "Twinlab, Inc." There is both a publicly-traded holding company, named Twinlab Corporation, and a wholly-owned operating company, named Twin Laboratories Inc. This response is submitted on behalf of both entities, which will hereinafter be referred to collectively as "Twinlab."

We specifically request that your office treat as confidential the internal product specification and testing procedure information documents we provide in response to Request Nos. 2 and 3. To prepare this response within the timeframe specified in the Request, we were unable to individually mark each document containing confidential and proprietary business information. Therefore, we respectfully request that the Committee consult with Twinlab prior to release of product specification and testing information documents provided in response to Request Nos. 2 and 3.

Twinlab thinks it is important that there be no misunderstanding concerning the context of its reponse to your letter. The first and second paragraph of your letter include several statements with which Twin respectfully disagrees. For example, your letter characterizes synephrine as a "very close chemical cousin of ephedra." While there are structural similarities between ephedrine and synephrine, Twinlab does not agree that the characterization in the letter is scientifically correct. Twinlab also disagrees with your attribution of "problems" to use of ephedra. In short, Twinlab's response to your letter should not be interpreted as an express or implied agreement with the statements in the first or second paragraphs of your letter.

Twin Laboratories Inc., 150 Motor Parkway, Hauppauge, N.Y. 11788 • 631/467-3140 • Fax 631/630-3484

The responses are numbered below to correspond to each category of the Request. Twinlab believes this Response, and the records contained herewith, are substantially complete, with two exceptions. As indicated in e-mail exchanged with your staff, Twinlab filed a voluntary petition for relief under Chapter 11 of the U.S. Bankruptcy Code in the U.S. Bankruptcy Court for the Southern District of New York on September 4, 2003. This filing was made in conjunction with the entry by Twinlab into an asset purchase agreement, executed the same day, to sell substantially all of the assets of the company pursuant to section 363 of the Bankruptcy Code, which requires that an asset purchase agreement be subject to an open bidding/auction procedure supervised by the Court to determine if a higher bid for the assets is available. Due to the financial situation of Twinlab, the section 363 bidding/auction process and other portions of the bankruptcy process necessary to close on the proposed transaction had to be done on a very fast track. I am the sole attorney in the in-house legal department of Twinlab. Without getting into the details of the bankruptcy, I have been overwhelmed with work since your Request was received; first to prepare Twinlab for its bankruptcy filing and to take the company through a pre-petition sale process to reach the asset purchase agreement entered on the day of the bankruptcy filing, and then to take the company through the bankruptcy process. The matters have not only required my full attention but also the full focus of the entire company. In that light, the two exceptions referenced above relate to declarations regarding efficacy made by individuals who have used the Twinlab products at issue in the Request (as referenced below in Response to Request No. 3), and the list of employees sought in Request No. 6. Twinlab will forward information to your office to complete it Response in this regard next week.

Responses

Request No. 1:

Has your company marketed the products referenced above [i.e., "Metabolife® New and Improved Ma-Huang Free Thermogenic Diet Formula" and "Ripped Fuel® Ephedra Free" dietary supplements] as alternatives to products containing ephedra, either formally, by implication, or in discussions with distributors, customers, or potential customers?

Response to Request No. 1:

Twinlab does not manufacture any ephedra-free "alternatives" to its ephedra products. Twinlab does, however, manufacture over 1,200 products that do not contain ephedra. The Company also sells (or has sold) certain products that are marketed for similar purposes as its ephedra-containing products under the same brand names as certain of its ephedra-containing products, including certain products that contain the words "ephedra free" on the label. These products were introduced as "line-extensions," not "alternatives" and their first dates of availability (including modified formulations) are set forth on Exhibit 1 hereto.

Request No. 2:

Did your company conduct any in-house testing of these products for safety before marketing? Did your company conduct any in-house testing for efficacy?

Response to Request No. 2:

Understanding that "testing" is a term that has broad and varied definitions, prior to its marketing of ephedra-free products containing Citrus aurantium, Twinlab relied on independent studies, included in response to Request No. 5 herein, that establish the safety and efficacy of Citrus aurantium as used in Twinlab's products. Twinlab did not otherwise conduct any controlled in-house testing or studies of the safety or efficacy of its ephedra-free products containing Citrus aurantium prior to marketing those products. However, before marketing ephedra-free products containing Citrus aurantium, Twinlab implemented and followed a Standard Test Procedure to ensure that the Citrus aurantium extract content of such products met designated specifications for safety and efficacy. A copy of the Twinlab Raw Material Specification for Citrus aurantium extract is attached hereto as Exhibit 2, and a copy of a Twinlab Standard Test Procedure, effective July 24, 1997, for raw materials and finished product containing Citrus aurantium, immature bitter orange or zhishin ("Method Syn 1.0") is attached hereto as Exhibit 3.

Request No. 3:

Has your company conducted any in-house testing of these products for safety after the product has been marketed? Has testing been conducted for efficacy?

Response to Request No. 3:

Understanding that "testing" is a term that has broad and varied definitions, since it began marketing ephedra-free products containing Citrus aurantium, Twinlab has not conducted any controlled in-house testing or studies of the safety or efficacy of such products. Since it began marketing these products, Twinlab has continued to follow a Standard Test Procedure to ensure that the Citrus aurantium extract content of its ephedra-free products containing Citrus aurantium meet designated specifications for safety and efficacy. Method Syn 1.0, attached hereto as Exhibit 3, was superceded by Method Syn 1.1, which is attached hereto as Exhibit 4, effective December 14, 2000. Twinlab also has followed comprehensive Standard Operating Procedures covering all aspects of its manufacturing, quality control and quality assurance operations which help ensure the safety and efficacy of its products including products containing Citrus aurantium. In addition, at various times since it began marketing ephedra-free products containing Citrus aurantium, Twinlab has received declarations regarding the efficacy of the products from individuals that have used the same in accordance with the directions for use provided by Twinlab. Twinlab will forward to your office next week a copy of such declarations as well as advertisements based on the same.

Request No. 4:

Have any independent studies been conducted regarding the safety of your products? Have studies been conducted for efficacy?

Response to Request No. 4:

To Twinlab's knowledge, and apart from the declarations referenced in Response to Request No. 3, no independent studies have been conducted specifically regarding the safety or efficacy of Twinlab ephedra-free products containing Citrus aurantium. However, numerous independent studies have been conducted, as set forth in part in Response to Request No. 5, regarding the safety and efficacy of Citrus aurantium.

Request No. 5:

Please provide me with any and all studies, either conducted in-house or by outside researchers, upon which your company bases claims of safety and/or efficacy of your products.

Response to Request No. 5:

The following studies/information are provided to you in response to Request No. 5, and are attached as Exhibit hereto as set forth below.

- Exhibit 5: 21 C.F.R. 182.20 – finding Citrus aurantium L. to be generally recognized as safe ("GRAS").
- Ehxibit 6: Carlon M. Colker, et al., *Effects of Citrus aurantium Extract, Caffeine, and St. John's Wort on Body Fat Loss, Lipid Levels, and Mood States in Overweight Healthy Adults*, Current Therapeutic Research, Vol. 60, No. 3 (March 1999). Note: This study was supported by a grant from Twin Laboratories, Inc.
- Exhibit 7: Scott R. Penzak, et al., *Seville (sour) Orange Juice: Synephrine Content and Cardiovascular Effects in Normotensive Adults*, J. Clin. Pharmacol, (41) 1059-63 (2001).
- Exhibit 8: PDR for Herbal Medicines at 86-87.
- Exhibit 9: The Complete German Commission E Monographs, Therapeutic Guide to Herbal Medicines (1990) at 89-90, 313-314.
- Exhibit 10: *Study on the Effectiveness of Ultra Slim Down® for the Reduction of Body Weight*, Dr. Penny Kendal-Reed, ND (2000).

Request No. 6: How many employees work on ensuring your products are safe and/or effective? Please provide me with the job descriptions of the employees who have such jobs, as well as their qualifications for the jobs.

Response to Request No. 6:

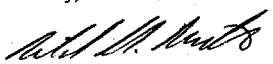
While Twinlab believes that all of its employees work to ensure the safety and efficacy of its products, there are employees specifically charged with oversight of those issues.. As

referenced in the preliminary statement above, we are still in the process of collecting information responsive to Request No. 6, and we will forward the same to your office next week.

Conclusion

The above information, and the Exhibits enclosed herewith, are respectfully submitted to you on behalf of Twinlab. As set forth above, additional responsive information will be forwarded to your office next week. Should you have any additional request for information, Twinlab reiterates its commitment to provide a prompt reply and appropriate supporting documentation.

Sincerely,



Richard H. Neuwirth
Acting General Counsel

March 24, 2004

The Honorable Richard Durbin
United States Senate
332 Dirksen Senate Office Building
Washington, DC 20510-0001
Fax: (202) 228-0400

Dear Senator Durbin:

Please vote in favor of the national asbestos trust fund that would be created by S.1125, the Fairness in Asbestos Injury Resolution Act of 2003.

A national trust fund is a vast improvement over the current situation, which is unfair to both the real asbestos victims and to the many employees of the companies who have been harmed by abuses of the current system.

Everyone agrees that the process for handling asbestos lawsuits is broken and needs to be fixed. I hope that I can count on you to support the compromise that will be voted on by the Senate in the coming weeks.

Thank you very much.

Sincerely,

Mary A Martin
1024 Lakeshore Blvd
Evanston, IL 60202

American Medical Association
Physicians dedicated to the health of America

February 17, 2004

The Honorable Richard J. Durbin
United States Senate
332 Dirksen Senate Office Building
Washington, DC 20510-1304

Dear Senator Durbin:

On behalf of the American Medical Association (AMA), I am writing to thank you for introducing S. 722, the "Dietary Supplement Safety Act of 2003." The physician members of the AMA are very concerned about the quality, safety, and efficacy of dietary supplement products, especially herbal (botanical) products and supplements containing anabolic steroid-like ingredients and their precursors, i.e., substances that have the potential to be converted into testosterone or other anabolic steroids. Because of the dangers of these products and their increasing use, the AMA supports a ban on all dietary supplements containing ephedra and restrictions on anabolic steroids and dietary supplements with anabolic steroid-like ingredients.

Moreover, the AMA believes that the Dietary Supplement Health and Education Act of 1994 (DSHEA) fails to provide for adequate regulatory oversight by the U.S. Food and Drug Administration (FDA) of dietary supplements, and we support legislation such as S. 722 that would amend DSHEA so that dietary supplements are regulated the same way as are prescription and over-the-counter drugs. Among the provisions of your bill that are especially important are the mandatory adverse event reporting requirements and the post-market surveillance requirements. In addition, imposing the burden of proof about the safety of dietary supplement products on the product manufacturer rather than the FDA, as is the case under current law, is especially critical.

We believe your bill is an important step forward in correcting many of the deficiencies in DSHEA and are pleased to support your bill. Thank you again for your efforts to protect the nation's consumers from the dangers of dietary supplement products.

Sincerely,

Michael D. Maves, MD, MBA

USA TODAY January 5, 2003

Law lets risky stimulants take ephedra's place

As the federal government inches toward an overdue ban on the deadly diet supplement ephedra, supplement makers and consumers are rushing to risky substitutes.

And the government can't stop them.

On Dec. 27, the Food and Drug Administration (FDA) said it soon will issue a ban on ephedra to take effect 60 days later. The action comes nearly a decade — and 155 deaths — after medical experts began noticing a surge in troubling reports about the amphetamine-like stimulant, which was being peddled to athletes and dieters.

Yet the ban fails to correct a regulatory system that assumes dietary supplements are safe until proved harmful. That standard is more lenient than those for prescription and over-the-counter drugs, which must be shown to be safe before they can be sold.

In ephedra's case, the system led to untold numbers of heart attacks and strokes as well as deaths, among them Baltimore Orioles pitcher Steve Bechler last year.

But ephedra is just the most notorious of the unproven supplements readily available in stores, online and by mail. Now that ephedra is being banned, marketers are pushing "ephedra-free" stimulants based on herbs such as bitter orange, green tea, grape-seed extract and guarana. Industry officials say that in anticipation of a ban, consumers already have been shifting to substitutes.

Their search for safety may be illusory. Consider bitter orange. Research at the University of Arkansas suggests it reacts with many prescription drugs to undermine their effectiveness. Other studies have shown that bitter orange raises blood pressure in animals, suggesting it could carry some of the same risks as ephedra for humans.

Even less is known about the potential effects of most other ephedra substitutes.

The FDA publishes a list of commonly available supplements that are known to have caused nausea, vomiting, liver and kidney disease, high and low blood pressure, paralysis and death. Still, little reliable scientific research on these substances exists, and the industry's clout in Congress has blocked the FDA from banning a substance unless the agency is prepared to prove in court that it poses "an unreasonable health risk."

Even with ephedra's tragic record, the government didn't test that hurdle until now. Thousands of reports of illness and death linked to ephedra prompted the FDA to commission outside studies that it believes provide the evidence needed to withstand a legal challenge from the industry.

Other supplements associated with health risks are still getting a free pass. The FDA doesn't even have the authority to require their manufacturers to turn over any reports they receive about consumers who are harmed by the products.

While Health and Human Services Secretary Tommy Thompson wants Congress to require that manufacturers report customers' adverse reactions, he has not made passage of such legislation a priority.

The industry says the current law and self-regulation are adequate. Yet, it has fought efforts to improve safety. When the FDA tried to tighten supplement regulation in 1994, the industry persuaded Congress to strip the agency of the little authority it had.

Ephedra is finally on its way out. But until the industry and its allies in Congress make consumer protection a higher priority, too many other potentially dangerous supplements remain on store shelves.

The Washington Post

Friday, January 2, 2004; Page A20

What Took So Long?

"THE TIME TO STOP taking this product is now," Health and Human Services Secretary Tommy G. Thompson said this week in announcing that the government would ban the sale of ephedra, the herbal weight-loss supplement. Actually, the time was years ago. The dangers of this amphetamine-like stimulant have been clear for years; the Food and Drug Administration, which is part of HHS, has been trying to restrict ephedra since 1997. Ephedra has been linked to some 155 deaths, including that of 23-year-old Baltimore Orioles pitcher Steve Bechler. It can cause heart attacks and strokes, even in healthy young adults.

But while the ban was a wise and necessary move, market forces had already largely worked in the case of ephedra. The combination of state laws banning or restricting ephedra sales, the threat of costly lawsuits, and bad publicity have all but killed the ephedra market -- though, sadly, not before the product killed some of its consumers. General Nutrition Corp., which runs the largest chain of dietary supplement stores, announced earlier this year that it would stop selling ephedra products, and Metabolife, the last major manufacturer of ephedra supplements, recently announced it would no longer sell ephedra. And so while we applaud the Bush administration's move, finally, to ban the product, the real questions raised by Tuesday's action are: What took so long? And, even more important, what can be done to safeguard the public from future ephedras, some of which are already on the market?

The answer to both those questions involves a truly terrible federal law, the 1994 Dietary Supplement Health and Education Act (DSHEA). The administration can be legitimately criticized for the unduly long time it took to get to yesterday's announcement, given the FDA's years-long effort to restrict ephedra. Even now, it will be months before the FDA's action takes effect. Mr. Thompson said he wanted to get the word out before dieters turned to ephedra to help fulfill their New Year's resolutions, but the new regulation won't be published for some weeks, and after that won't take effect for another 60 days -- and that's before the expected lawsuits from ephedra manufacturers.

But the fundamental fault lies with DSHEA. The law simultaneously makes it too easy to get dietary supplements on the market, and too hard to get them off. While manufacturers must show that ordinary drugs are safe and effective before they are allowed to sell them, dietary supplement makers face no such requirement before peddling their goods. If manufacturers develop information that calls into question their product's safety, they don't have to tell the FDA. And when there is an indication, as in the case of ephedra, that the product is dangerous, the law imposes a steep hurdle before the government can intervene: authorities must prove that the product presents a significant or unreasonable risk of injury.

Banning ephedra was a necessary step to protect the public, but not a sufficient one. The dietary supplement law is preventing government from fulfilling one of its bedrock functions: making sure unsafe products aren't foisted on unsuspecting consumers. It's time for Congress to stand up to the lavish contributions and relentless lobbying of the dietary supplement makers and fix this harmful law.

The New York Times

January 5, 2004

The Ephedra Ban Is Not Enough

It took an unconscionably long time, but the federal government has finally managed to ban an unsafe dietary supplement before it can harm or kill any more unwary users. The Bush administration's health regulators announced last week that they would soon ban ephedra, an herbal supplement used to promote weight loss and increase energy, on the grounds that it poses "an unreasonable risk of illness or injury." That was the only sensible response to mounting evidence that ephedra has been harming thousands of Americans. Yet the tortuous course of this regulatory crackdown underscores the dangerous weakness of a 1994 law that allows the supplement industry to market products whose safety and effectiveness have never been proved while making it extremely hard for health regulators to take them off the market if evidence of harm subsequently emerges.

Ephedra is an adrenaline-like stimulant, derived from plants, that excites the central nervous system, speeds metabolism and increases the rate at which a person burns calories. But it can also drive up blood pressure and stress the circulatory system. Ephedra has generated far more reports of adverse effects than any other supplement and has been linked to cases of heart attack, stroke and sudden death. Ephedra has been banned by three states, including New York, and by some athletic leagues though not others.

Some critics blame the Food and Drug Administration, which has been worried about ephedra for many years now, for moving too cautiously. There is some merit in that complaint, but the major culprit is clearly the 1994 dietary supplement law that requires the F.D.A. to prove that a supplement poses a significant or unreasonable risk of harm instead of requiring the manufacturer to prove that it is safe and effective, the standard used for prescription drugs. The law does not even require manufacturers to report adverse effects to the government.

This is a formula for covering up problems and ensuring regulatory inaction. It is no accident that ephedra will be the first supplement ever banned for safety reasons under the 1994 law. That sluggish response was precisely what the supplement industry and its more zealous customers wanted when they pressed Congress for protection against strict regulation.

When Congress returns for its next session, it needs to revise the ill-conceived 1994 legislation. At a minimum, Congress must require the industry to pass on any adverse health reports to the F.D.A. promptly. Even better, it should require the manufacturers to prove the safety and efficacy of their products before those products are allowed on the market. Under the current lax system, there is no guarantee that the substitutes for ephedra will be any safer.

The Salt Lake Tribune
Friday, January 2, 2004

By Any Other Name

Come March -- two years after it was banned in Canada, a year after it was implicated in the death of a professional baseball player and a few months after many of its biggest marketers had already stopped pushing it -- the United States government will ban the so-called diet supplement called ephedra.

We can expect that report on the structural integrity of the Titanic any day now.

As popular as it sometimes is to blame faceless federal bureaucrats for such a display of indolence, the fact is that it was an act of Congress that stood between the Food and Drug Administration's duty and its ability to do it.

Specifically, the 1994 Dietary Supplement Health and Education Act, pushed by Utah's Sen. Orrin Hatch, makes it nigh onto impossible for the FDA or any other federal agency to ban any diet aid, stimulant or other supposedly health-enhancing substance if its makers can claim it is a naturally occurring substance rather than a synthesized drug.

The law Hatch championed on behalf of his many friends and fellow Utahns in the industry places the burden on the government to prove a supplement is harmful before it can be banned. The law also gives the FDA no power to research diet supplements or to require that those who sell them record or report any problems connected to their products.

That's the polar opposite of what happens with the FDA and man-made drugs, the makers of which are required to prove their products both safe and effective before they can get to market, and keep scrupulous records of every sneeze and backache afterward.

The FDA tried to ban ephedra in 1997 but was told it didn't have enough evidence to meet the Hatch standard. Tuesday, after years more research linking the supplement to more than 100 deaths and a great many strokes and heart attacks, Health Secretary Tommy Thompson was finally confident that the ban, which won't officially kick in for more than two months, can stand up to any lawsuit.

In the meantime, Thompson urged everyone to avoid the stuff like a case of high blood pressure, which is basically what it is.

Neither Hatch's law nor Thompson's agencies are responsible for a society that wants to solve complicated health and lifestyle problems by taking a pill. But the added delay compounds the problem.

By the time the government has the proof it needs to ban a harmful substance, the pill has already built a loyal following of people who will look under the table or over the Internet to get it. So any such ban will be a day late and a dollar short.

Congress should let the FDA treat naturally occurring dietary supplements as the drugs they are. And Hatch, if he cannot lead such an effort, can at least take a pill and lie down for a while.

Los Angeles Times
latimes.com.
December 31, 2003

The Diet-Supplement Fiasco

The Bush administration's announcement that it plans to ban ephedra came several weeks after lawsuits forced Metabolife, the last major manufacturer of products containing the risky drug, to stop selling ephedra products. It's a classic case of closing the barn door long after the cows have ambled on.

Health and Human Services Secretary Tommy G. Thompson said he decided to announce the ban now — the government's first-ever on a dietary supplement — so that people making New Year's weight-loss resolutions wouldn't be tempted to try "speed"-like ephedra, long sold as an exercise and weight loss aid.

The obvious question is, why did he wait so long?

The administration should have banned ephedra in September 2001, when the group Public Citizen petitioned the Food and Drug Administration to do so. Numerous studies have proved it unsafe, and it has been linked to more than 155 deaths.

Another obvious prohibition point was five months ago, when the Army and Air Force took ephedra-containing products off commissary shelves. Thompson himself as far back as a year ago was publicly saying, "I wouldn't use it, would you?"

Ephedra is not the lucrative product it once was. Thompson's decision will barely ripple the industry's profits. And that's the problem. Federal regulation should have been exercised when ephedra use was thriving and people were dying of it. Thompson and FDA Commissioner Mark McClellan waited far beyond reason.

Legislators and the Bush administration should now confront the illogic in the way the FDA regulates the chemicals that Americans consume. If those chemicals are in products arbitrarily deemed "drugs," then the agency is required to prove they are safe before they can be sold. However, if those same chemicals are in "dietary supplements," the FDA has to do the opposite: prove that they are *un*safe before they can be taken off the market. In a Senate hearing in fall 2002, then-acting FDA Commissioner Lester M. Crawford conceded that if ephedra supplements were considered drugs they would be off the market.

Given the political clout of the supplement industry, it's unlikely that Congress will address the whole problem. At a minimum, however, it should pass two less ambitious reforms. The first, by Sen. Richard Durbin (D-Ill.) would require the makers of stimulants like ephedra to submit proof that their products were safe before they could be marketed. The second bill, by Rep. Susan A. Davis (D-San Diego), would require manufacturers or distributors to report negative health effects to the FDA within 15 days.

Until such basic safety regulations are in place, there will be more ephedra-type debacles in the dietary supplement industry.

RICHARD J. DURBIN
ILLINOIS

COMMITTEE ON APPROPRIATIONS

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www.senate.gov/~durbin

January 12, 2004

The Honorable Tommy Thompson
Secretary
Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Dear Secretary Thompson:

I am pleased you finally decided to remove ephedra-containing dietary supplements from the marketplace. Unfortunately, as the public grew more aware of the dangers of ephedra, supplement manufacturers have moved to selling other dangerous stimulants under the label "ephedra free." These products may pose the same risks as ephedra. As Dr. Paul Coates, director of the NIH's Office of Dietary Supplements, has stated, "The fact that a dietary supplement is ephedra-free is not an indication of its safety."[1]

In July, I wrote to seven companies that market "ephedra-free" supplements containing Citrus aurantium, also known as "bitter orange." Citrus aurantium contains the chemical synephrine, a substance very similar to ephedra that stimulates the central nervous system and can cause hypertension, heart attacks and strokes.

My letter requested data from studies conducted, either in-house or independently, on the safety and/or efficacy of Citrus aurantium. I also asked for information on the number of employees dedicated to monitoring product safety and/or effectiveness, and their qualifications.

Only four companies responded directly to my request, and their letters were distressing.

1. **Baywood International**
   Neil Reithinger of Baywood International, which sells ephedra-free "Metabolic Burn Tropin-EF," Meta-Tropin-EF" and "Thermogenic Burn Tropic-EF," answered none of the questions posed, either in part or in whole. Instead, in his one-page response, he stated merely: "As with all of the Company's dietary supplement products, we believe that the three products above lawfully may be sold as currently formulated and promoted."[2] There was no mention of the safety or efficacy of their products.

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[1] Jill Burcum, "Your Health: Ephedra-Free Products Loaded With New Herbs of Concern," Minneapolis Star Tribune, April 29, 2003.
[2] Letter from Neil Reithinger, President and CEO, Baywood International, to Senator Richard J. Durbin (Aug. 31, 2003).

2. **NVE Pharmaceuticals**
Robert Occhifinto, the president of NVE Pharmaceuticals and marketer of "Stacker 2 Ephedra Free," wrote that, "in our experience, it is unusual for companies to conduct in-house testing for nutraceutical compounds."[3] He went on to say that "the science [on Citrus aurantium] is sufficient enough for our company to forego in-house testing as it would be redundant."

On efficacy, he argues there is "ample" scientific evidence, but only cites one study. Conducted in Italy, the published results of the study contained no information on study design, study size, subjects or timeframe, all important factors in evaluating the study's validity. It is difficult to take any study seriously that contains the following statement: "For some products, this information was obtained by analogy."

On safety, Mr. Occhifinto cites one study that was conducted by highly regarded pharmacologists, but his claim is not substantiated by their results. Mr. Occhifinto said that a study entitled, "Seville (sour) Orange Juice: Synephrine Content and Cardiovascular Effects in Normotensive Adults" showed that the blood pressure and cardiac effects of Citrus aurantium were found to be "no different than water."[4] In fact, the study was not evaluating the safety of supplements containing Citrus aurantium, but examining whether orange juice, a natural source of synephrine, is safe to use in drug metabolism studies.[5] The orange juice used in the study did not even contain any octopamine, which is a key ingredient in Citrus aurantium. Furthermore, the whole reason this orange juice study was conducted was because Citrus aurantium has been shown to raise blood pressure in rats. The study concluded that glasses of Seville orange juice are safe for normal adults, but warned against use by people with high blood pressure, or people taking decongestants or MAOIs.

My staff wrote to one of the authors of this study to get his response to Mr. Occhifinto's assertion that this study proves the safety of Citrus aurantium. He responded: "I don't consider our study using Seville orange juice even remotely sufficient to assess the safety of synephrine-containing dietary supplements. If the industry is doing that then, in my opinion, they are committing an egregious error."[6]

Finally, Mr. Occhifinto says, "other studies have shown Citrus aurantium to have the effect of lowering the blood pressure in animals."[7] In fact, the Huang, et al study[8] he cites only suggests that synephrine can reduce surgically-induced elevated blood pressure within the livers of rats. The study does not address peripheral blood pressure, and any

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[3] Letter from Robert Occhifinto, President, NVE Pharmaceuticals, to Senator Richard J. Durbin (September 9, 2003)
[4] Letter from Robert Occhifinto, President, NVE Pharmaceuticals, to Senator Richard J. Durbin (September 9, 2003)
[5] Penzak, S; Jann, M.; Cold, J. "Seville (sour) Orange Juice: Synephrine Content and Cardiovascular Effects in Normotensive Adults," Journal of Clinical Pharmacology, 2001; 41:1059-1063
[6] E-mail from Dr. William Gurley, December 16, 2003
[7] Letter from Robert Occhifinto, President, NVE Pharmaceuticals, to Senator Richard J. Durbin (September 9, 2003)
[8] Huang YT, Lin HC, Chang YY, Yang YY, LEE SD, Hong CY, "Hemodynamic effects of synephrine treatment in portal hypertensive rats." Jpn J Pharmacol, 2201 Feb; 85(2):183-8

suggestion that this study indicates synephrine causes a reduction in peripheral blood pressure is erroneous.
In fact, a previous study by Huang, et al, published in 1995, indicated that both Fructus aurantii (the unripe fruits of Citrus aurantium) and synephrine elevated mean arterial blood pressure.[9]

Mr. Occhifinto conspicuously left out a study conducted in Italy in which Citrus aurantium was administered to rats. The three scientists involved in that study believe their results demonstrate that the substance "has lethal effects, probably due to the action of synephrine on the heart's physiology, as already well described in the literature...this is further example of medicinal plants [also] potentially dangerous to humans, especially when used for elderly, obese or cardiac patients, without any medical control."[10]

3. EAS
Earle Bellamy, general counsel for EAS, responded to my letter and wrote that "EAS typically conducts a thorough review of the available science of each component ingredient prior to formulating and marketing a product. EAS also relies on the prior safety determinations (including GRAS status) of the U.S. Food and Drug Administration (FDA) for component ingredients and food additives. "[11]

GRAS determinations for food/ food additives are useless in determining the safety of supplements, which contain vastly greater quantities and greater concentrations of ingredients. A teaspoon of bitter orange flavoring, which contains a small amount of bitter orange mixed with alcohol and sugar, is much different from a pill containing a concentrate of the substance mixed with other stimulants like green tea leaf extract and caffeine as EAS's product "BetaLean HP Ephedra Free" does.

Mr. Bellamy may have offered quite a few citations for the alleged safety and efficacy of Citrus aurantium, but if you look closely, you'll see none of the citations demonstrate the safety or efficacy of his product. He cites:

- The Physicians Desk Reference Guide for Herbal Medicine (PDR), A Physician's Guide to Herbal Medicine and the Encyclopedia of Common Natural Ingredients. The fact that a substance appears in these books says nothing about its safety and efficacy. In fact, they all say that safety and efficacy are not confirmed.

  The PDR for Herbal Medicine is made to appear just like the Physicians Desk Reference for prescription drugs, which is widely used. However, the two books are very different. The prescription drug PDR only lists FDA-approved drugs, meaning all drugs that appear in the book have undergone safety and efficacy testing. It lists all FDA-required information, including adverse events. The

[9] Huang YT, Wang GF, Chen CF, Chen CC, Hong CY, Yang MC, "Fructus aurantii reduced portal pressure in portal hypertensive rats," Life Sci. 1995 ; 57(22): 2011-20.
[10] Firenzoli F, Calapai, G, and Gori L, "Physicians discuss orange extract," (letter), Herbalgram Spring 1999; 46:76-77.
[11] Letter from Earle D. Bellamy II, General Counsel, EAS, to Senator Richard J. Durbin (August 28, 2003)

herbal medicine PDR has no requirement of safety or efficacy for a substance to be listed.

- The German E Commission Monograph, which the American supplements industry often cites in its claims of safety. The German monographs are disregarded by scientists in the U.S. and are not recognized by the FDA because they contain no references. We have no way of knowing if data was collected, and if it was, how it was analyzed. Without information about methodology, an assertion of safety is worthless.

- The same Seville orange juice study cited by Mr. Occhifinto, which does nothing to demonstrate the safety of supplements containing Citrus aurantium.

- The "Obesity and Medicinal Plants" study also cited by Mr. Occhifinto, which does not detail any kind of research methodology.

- The Pellati et al study, which has nothing to do with safety or efficacy. It is a study of a method of chemical extraction.

4. Twinlab Corporation

Richard Neuwirth, Twinlab's general counsel wrote to me saying that Twinlab did not conduct any in-house testing of the products I inquired about. He cited many of the same studies discussed above. The two studies that were not cited in the other letters were a study conducted by Penny Kendall-Reed, a practitioner of alternative medicine, and a study that was made possible by a grant from Twinlab Corporation.

Ms. Kendall-Reed's study has a myriad of problems. First and foremost, it is a study of efficacy rather than safety. While there was a physical examination of the participants at the beginning of the study, their vital signs were not monitored during the study. Second, the sample size is too small to reach concrete conclusions. Third, there are too many confounders; they didn't control for variables adequately. Fourth, the author offered no statistical analysis of her data. Finally, it appears this study didn't have an Institutional Review Board, which is in violation of federal law given that human subjects were used.

The second study Mr. Neuwirth cited, conducted by Colker, et al, does not contain any long-term safety data. It was a six week study, which is not sufficient to say one way or another that a substance is safe.

The responses I received from these companies suggest the industry does not have data showing Citrus aurantium is safe. Because this raises significant public health questions about "ephedra-free" products, I ask that you answer the following questions:

1. Are you aware of sound scientific evidence that shows that Citrus aurantium is safe in the amounts at which they are included in these products? If so, please provide me with that evidence.

2. Are you aware of evidence that proves that the combination of ingredients contained in "ephedra-free" formulations, or in any other dietary supplements that contain stimulants, can be safely used in combination with one another?

3. Of the "ephedra-free" products that have come on the market in recent years, how many has your agency evaluated or reviewed for safety?

4. Are you concerned that dietary supplements containing stimulants may pose risks to consumers?

5. What steps are you planning to take to protect consumers from the growing use of potentially dangerous stimulants in dietary supplements?

I would appreciate your responding to this letter by February 13, 2004. If you have any questions, please contact Krista Donahue of my staff at (202) 224-8464.

Sincerely,

Richard J. Durbin
United States Senator

Mr. BURTON. And some of the issues that you have raised today we will discuss with our other witnesses from the industry. We will ask them questions about that. And hopefully that will illuminate the issue further.

I don't have any questions further for the Senator. Do you have any, Ms. Watson?

Ms. WATSON. No, I don't.

Mr. BURTON. Ms. Davis?

Senator, thank you very much. It is nice to see you back. Thank you very much.

Our next panel consists of Dr. Robert Brackett, Ph.D., Director of the Center for Food Safety and Applied Nutrition from the Food and Drug Administration, the Department of Health and Human Services. And we will welcome you to the panel. A tough act to follow the Senator, but I am sure you are up to the task. We don't swear in our colleagues because they are liable to shoot us, but we like to swear in all of our other witnesses. So would you rise and be sworn, please.

[Witness sworn.]

Mr. BURTON. Do you have an opening statement, Dr. Brackett?

STATEMENT OF ROBERT BRACKETT, PH.D, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. BRACKETT. Good morning, Mr. Chairman and Congresswoman Davis and Congresswoman Watson. I am Dr. Robert Brackett, and Director of FDA's Center for Food Safety and Applied Nutrition. And I am very pleased to testify before the subcommittee on "10 Years After the Implementation of DSHEA and the Status of Dietary Supplements in the United States."

Many Americans take some type of dietary supplement, and in many cases there is either strong or suggestive evidence that many of these vitamins and minerals and other naturally occurring products have important benefits. The Dietary Supplement Health and Education Act of 1994, DSHEA, amended the Federal Food, Drug, and Cosmetic Act to set up A distinct regulatory framework for these products in an attempt to strike the right balance between providing consumers access to dietary supplements that they may be choosing to use to help maintain and improve their health, and giving the Food and Drug Administration regulatory authorities to take action against supplements or supplement ingredients that present safety problems, have false or misleading claims, or are otherwise adulterated or misbranded.

As with most foods, there are no premarket FDA approval of safety for dietary supplements. However, there is a 75-day premarket notification requirement for marketers of certain dietary supplements that contain so-called new dietary ingredients that were not marketed in the United States prior to October 15, 1994.

In the new dietary ingredient notification to FDA, the manufacturer or distributor of the supplement must submit information that provides the basis on which it includes that dietary supplements containing the new dietary ingredient will reasonably expect it to be safe. FDA regulates the safety of dietary supplements pri-

marily through a postmarket evaluation of whether the product is adulterated under the provision of the FD&C Act. And in developing a comprehensive postmarket safety evaluation of dietary supplement products, FDA collaborates with consumers and industry stakeholders, other Federal partners, and, of course, academic centers.

An important tool that FDA uses for developing a signal which may identify potential safety problems are adverse event reports. These reports are not mandatory and consist of voluntary reports from industry, health care providers, and consumers.

Under DSHEA, FDA was given the authority to promulgate regulations for dietary supplement current good manufacturing practices [CGMPs]. Such regulations could help ensure product quality and consistency, and FDA published a proposed rule on March 13, 2003, extended the comment period, and convened true satellite downreach—outreach meetings, and attended three outreach meetings organized by the industry. We are currently analyzing over 1,600 pages of comments from those, and publishing the final rule remains a high priority for FDA.

FDA uses three principles—direct health risk, indirect health risk, and economic harm—to guide the development of its risk-based enforcement strategy. Our highest priority is on products that have a potential for causing serious adverse effects or where there is risk of injury or death. FDA uses all available civil and administrative remedies to quickly remove such products from the market. FDA also uses publicity to warn consumers and health professionals about the products.

Products that are not themselves hazardous can still present an indirect health hazard, in that consumers may delay or forego proven medical treatments or drug therapies. Examples include unproven products promoted for the treatment of cancer, diabetes, arthritis, heart disease, and high blood pressure. Dietary supplements that present primarily an economic injury to consumers because they are promoted using unsubstantiated claims are also a key element in the agency's enforcement strategy. This strategy provides a basic outline of the agency's enforcement activities. However, we do continually reevaluate our actions and emphasis in light of emerging issues or products to ensure that our activities achieve compliance in a fair and balanced way through voluntary enforcement action.

Let me cite two recent examples. The first involves seasilver. In June 2003, U.S. Marshals seized $7 million worth of seasilver, a liquid dietary supplement. Seasilver USA was promoting seasilver on the Internet and in marketing materials as a safe and effective treatment for 650 serious diseases including AIDS, cancer, diabetes, hepatitis, and arthritis. On March 8, 2004 the producers and distributors of seasilver signed a consent decree of permanent injunction in which they agreed to stop manufacturing and distributing violative products, and agreed to destroy the sea products at their expense and pay liquidated damages of $10,000 per day for any future violation of the consent decree. Under a settlement with the Federal Trade Commission entered on March 4, 2004, the seasilver defendants and the individual distributors agreed to pay $4.5 million in consumer redress.

The second example involves coral calcium. In June 2003, FDA issued warning letters to 18 firms which operate 24 Web sites marketing multiple coral calcium products as effective treatments or cures for a variety of diseases and conditions including cancer, multiple sclerosis, lupus, and heart disease. One product called Calcium Supreme was promoted in nationally televised 30-minute infomercials. In June, on FDA's behalf, USDA Marshals seized $2.6 million of Coral Calcium Supreme, and in separate actions the Federal Trade Commission charged the marketers of Coral Calcium Supreme with making false and unsubstantiated claims that the product can treat or cure diseases.

In December 2003, a U.S. district court entered a consent decree of condemnation and permanent injunctions against the marketers of this product from promoting any products as a treatment for disease.

Mr. Chairman, thank you very much for this opportunity to testify today. And I will be happy to answer any of your questions.

Mr. BURTON. Thank you very much.

[The prepared statement of Mr. Brackett follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

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FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

UNITED STATES HOUSE OF REPRESENTATIVES

MARCH 24, 2004

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Thank you, Mr. Chairman for this opportunity to testify before your Subcommittee at this hearing entitled, "Ten Years After the Implementation of DSHEA: The Status of Dietary Supplements in the United States."

BACKGROUND ON REGULATION OF DIETARY SUPPLEMENTS

Many Americans take some type of dietary supplement, and in many cases, there is either strong or suggestive evidence that many of these vitamins and minerals and other naturally occurring products have important health benefits. The Dietary Supplement Health and Education Act of 1994 (DSHEA) (P.L. 103-417) amended the Federal Food, Drug, and Cosmetic (FD&C) Act to set up a distinct regulatory framework for these products in an attempt to strike the right balance between providing consumers access to dietary supplements that they may choose to use to help maintain and improve their health, and giving the Food and Drug Administration (FDA or the Agency) regulatory authorities to take action against supplements or supplement ingredients that present safety problems, have false or misleading claims, or are otherwise adulterated or misbranded. Although dietary supplements are regulated as foods, in that pre-market approval is not mandatory, DSHEA and FDA's implementing regulations establish special requirements for dietary supplements that differ in some respects from those covering "conventional" foods, and that also differ from those that apply to drug products (prescription and over-the-counter).

Congress defined the term "dietary supplement" as a product that, among other things, is intended for ingestion, is intended to supplement the diet, is labeled as a dietary supplement, is not represented as a conventional food or as a sole item of a meal or diet, and contains a "dietary ingredient." "Dietary ingredients" are defined as vitamins, minerals, amino acid, herbs or other botanicals, dietary substances (such as enzymes), and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients. Dietary supplements may be found in many forms, such as tablets, capsules, liquids, or bars.

LABELING OF DIETARY SUPPLEMENTS

Under the FD&C Act and FDA's implementing regulations, the label of a dietary supplement must bear a statement of identity (product name) that identifies the product as a dietary supplement; nutrition information in the form of a Supplement Facts panel; a list of any ingredients not listed in the Supplement Facts panel; the name and address of the manufacturer, packager, or distributor; and the net quantity of contents. In addition, if the labeling includes a claim to affect the structure or function of the body, a claim of general well-being, or a claim of a benefit related to a classical nutrient deficiency disease, the product must bear a disclaimer stating that FDA has not evaluated the claim and that the product is not intended to diagnose, treat, cure, or prevent any disease. Furthermore, a manufacturer of a dietary supplement making such a claim must have substantiation that the claim is truthful and not misleading and must notify FDA that its product bears such a claim within 30-days of marketing the product with the claim.

DIETARY SUPPLEMENT SAFETY

Statutory Framework

As with most foods, there is no requirement for manufacturers of most dietary supplements to provide evidence of product safety to FDA prior to marketing. Accordingly, FDA regulates the safety of dietary supplements primarily through a post-market evaluation of whether the product is adulterated under one of the provisions of the FD&C Act. However, there is a 75-day pre-market notification requirement for manufacturers or distributors of dietary supplements that contain "new dietary ingredients" that were not marketed in the U.S. before October 15, 1994, unless the supplement contains only ingredients that have been present without chemical alteration in the food supply as an article used for food. There must be a history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe when used as recommended in the labeling of the supplement. In its notification to FDA, the manufacturer or distributor of the supplement must submit information, including citation to published articles, that forms the basis for concluding that the dietary supplement containing the new dietary ingredient will reasonably be expected to be safe.

Scientific Research

In order to be informed about the safety of dietary supplements, in addition to assessing known reported adverse events, FDA evaluates published literature, evidence-based reports, and the known pharmacology of a compound in order to assist in the evaluation of dietary supplement products. Collaboration with academic centers such as the National Center for Natural Products Research (NCNPR), Federal partners such as the National Institutes of Health and the National

Center for Toxicological Research, and our consumer and industry stakeholders is important in developing a comprehensive safety evaluation of dietary supplement products. For example, the partnership that FDA has with NCNPR at the University of Mississippi is valuable in order to find practical solutions to practical scientific problems. For dietary supplements containing botanical ingredients, development of such a science-base can be especially difficult because of several unique factors, such as the complexity of the chemicals that make up these products and the variability between one product and another.

CFSAN Adverse Event Reporting System (CAERS)

Adverse event reports (AERs) are an important tool for developing a "signal" which can help FDA to identify potential safety problems with dietary supplements. Last year, FDA's Center for Food Safety and Applied Nutrition (CFSAN) put in place the CFSAN Adverse Event Reporting System (CAERS) to monitor adverse event reports on CFSAN-regulated products, i.e. food (including dietary supplements) and cosmetics. Adverse event reporting for dietary supplements is not mandatory and consists of voluntary reporting from industry, health care providers, and consumers. CAERS is a computerized system that records voluntarily received reports and separates them into product problems and adverse events. This system started collecting reports after June 15, 2003, and unifies CFSAN's adverse event reporting through one common portal. Future planned capabilities include transitioning data from older systems into the CAERS portal, developing a botanical thesaurus to enable sophisticated search strategies, and electronic links to other databases such as MedWatch and poison control centers.

DIETARY SUPPLEMENT CURRENT GOOD MANUFACTURING PRACTICES (CGMPs)

Under DSHEA, another important arm of FDA's regulatory and surveillance activities used to help ensure the safety of dietary supplement products is the Agency's authority to promulgate regulations for dietary supplement current good manufacturing practices (CGMPs). Such regulations will help ensure product quality and consistency. FDA published a proposed rule for dietary supplement CGMPs on March 13, 2003, which would establish standards to ensure that dietary supplements and dietary ingredients are not adulterated with contaminants or impurities, and are labeled to accurately reflect the active ingredients and other ingredients in the product.

Examples of product quality problems the proposed dietary supplement CGMPs would help prevent are: superpotent and subpotent products, wrong ingredients, presence of contaminants (e.g., bacteria, pesticide, glass, and lead), under-filled containers, foreign material in a dietary supplement container, improper packaging, and mislabeling. The publication of the final rule on dietary supplement CGMPs remains a high priority for FDA. A 90-day public comment period on the proposed rule was extended 60-days and closed on August 11, 2003. During the comment period, FDA staff participated in two outreach meetings and an FDA-sponsored satellite downlink, as well as three outreach meetings organized by industry groups to ensure that dietary supplement manufacturers (especially small manufacturers) and other interested parties were familiar with the proposal.

Due to the volume of comments and requests by commenters, FDA extended the time period in order to receive additional public comments. We are currently reviewing over 1600 pages of

comments, which include more than 400 substantive comments that are being carefully analyzed. We plan to publish a final rule once this evaluation is completed. We recognize the importance of having dietary supplement CGMPs in place and we are moving forward to complete this regulatory priority under DSHEA. This rule will give consumers greater confidence that the dietary supplements that they choose to use will have the identity, strength, purity and composition that they are represented to have.

CONSUMER HEALTH INFORMATION FOR BETTER NUTRITION INITIATIVE

As part of FDA's efforts on dietary supplements, the Agency has been working to inform consumers about these products and their uses. On December 18, 2002, the FDA Commissioner announced the Consumer Health Information for Better Nutrition Initiative. The focus of this effort is to make available more and better scientifically accurate information about foods and dietary supplements so Americans know the health consequences of what they consume. This Better Health initiative is designed to foster two complementary goals concerning the labeling of food and dietary supplements:

- encouraging makers of conventional foods and dietary supplements to make accurate, science-based claims about the health benefits of their products, and
- bringing enforcement actions against those dietary supplement marketers who make false or misleading claims.

In a July 10, 2003, status report on the Better Health Initiative, FDA unveiled a process to review health claims. In addition, the Agency announced enhanced enforcement activity against dietary supplement manufacturers and others who make misleading claims about health benefits that are not based on science. These enforcement activities are described below.

ENFORCEMENT ACTIONS

At the core of FDA's DSHEA enforcement efforts is our commitment to work with industry in order to enhance the legitimate manufacture, sale, and use of dietary supplements while enforcing the law aggressively against fraudulent product claims and other illegal practices. Dietary supplement enforcement actions include inspections that have resulted in voluntary compliance, voluntary recalls, warning letters, seizures and injunctions, criminal enforcement and joint enforcement actions with the Federal Trade Commission (FTC) and the Department of Justice.

FDA shares Federal oversight of dietary supplements with the FTC. FDA regulates the safety, manufacturing, and labeling of dietary supplements, while the FTC has primary responsibility for regulating the advertising of these products. Over the last few years, the FDA and the FTC have worked well together to ensure that there is a seamless assertion of our jurisdiction over these products. With the mutual goal of consumer protection, FDA and FTC chair an interagency health fraud steering committee that includes Federal agencies in the U.S., Canada, and Mexico. Also, as part of FDA's effort to curb Internet health fraud, the Agency has conducted several "surfs" to identify fraudulent marketing of health care products over the Internet. These actions

were carried out in partnership with the FTC and other law enforcement and public health authorities in the U.S. and abroad.

Since October 1, 2003, FDA has conducted 180 domestic inspections of dietary supplement manufacturers, issued 103 warning letters and "cyber letters" to marketers of dietary supplement products, seized products worth almost $9.65 million, supervised the voluntary destruction of almost $8 million worth of products promoted with unsubstantiated dietary supplement claims or that were unapproved drugs, and obtained permanent injunctions against 3 firms distributing misbranded or unapproved drugs.

FDA enforcement has extended to our nation's borders, where we have refused importation for 1171 foreign shipments of potentially unsafe or misbranded dietary supplements offered for entry in the U.S. The Agency's enforcement actions send a clear message that FDA will not tolerate fraudulent practices that victimize or endanger consumers.

As with all of FDA's activities, priorities are established based upon the direct impact upon public health. Products that present a direct health hazard to consumers are the Agency's highest priority. When the Agency encounters such products, FDA will use all available civil and administrative remedies to assure that the product is quickly removed from the market. We also aggressively publicize our actions to warn consumers and health professionals about such products. In some cases, the Agency may initiate a criminal prosecution against manufacturers or distributors of violative products.

HIGHLIGHTS OF RECENT ENFORCEMENT ACTIONS

Royal Tongan Limu

In October 2003, FDA witnessed the voluntary destruction of 90,000 bottles worth $2.7 million of Royal Tongan Limu, a liquid dietary supplement distributed by Dynamic Essentials, a subsidiary of NBTY, Inc. The firm was initially warned in a 2002 FDA "cyber letter" that website claims to treat various diseases such as cancer, arthritis, and Attention Deficit Disorder caused their products to be in violation of the law. Despite the warning, the product remained in distribution channels and, therefore, FDA recommended the seizure action. Dynamic Essentials ceased operation and no longer promotes or sells the products on its website.

Germanium Sesqioxide

In October 2003, FDA refused an entry of 20 kilograms of bulk germanium sesquioxide valued at $16,500, destined for use in human dietary supplements. Germanium has caused nephrotoxicity (kidney injury) and death when used chronically by humans, even at recommended levels of use.

Jean's Greens

In September 2003, at FDA's request, the U.S. Marshal seized herbal tea products known as Forticel and Forticel Mix from Jean's Greens in Norway, New York. The products claimed to treat and cure various life-threatening and serious illnesses such as cancer, thus causing the products to be unapproved drugs. FDA warned Jean's Greens in November 2001 to change its labeling for the products. The firm failed to comply. The value of the seized goods was more than $4000.

Seasilver

In June 2003, U.S. Marshals seized $7 million worth of Seasilver, a liquid multi-vitamin/mineral/amino acid dietary supplement. The marketer, SeasilverUSA, promoted Seasilver, on the Internet and in marketing materials, as a safe and effective treatment for 650 serious diseases, including AIDS, cancer, diabetes, hepatitis, and arthritis. On March 8, 2004, Seasilver USA, Inc., and Americaloe, Inc., of Carlsbad, California, and their principals, signed a consent decree of permanent injunction in which they agreed to stop manufacturing and distributing violative products, including "Seasilver." In addition, Seasilver USA, Inc. and Americaloe, Inc. will destroy the seized products at their expense and will pay liquidated damages for $10,000 per day for any future violation of the consent decree. Under a settlement with the FTC, entered on March 4, 2004, the Seasilver defendants and the individual distributors agreed to pay $4.5 million in consumer redress.

Coral Calcium

In June 2003, FDA issued warning letters to 18 firms, which operate 24 websites marketing multiple coral calcium products as effective treatments or cures for a variety of diseases and conditions including cancer, multiple sclerosis, lupus and heart disease. One product, Coral Calcium Supreme, was promoted in nationally televised 30-minute infomercials featuring Kevin Trudeau and Robert Barefoot. In June, on FDA's behalf, U.S. Marshals seized $2.6 million worth of Coral Calcium Supreme. In a separate action, FTC charged the marketers of Coral Calcium Supreme with making false and unsubstantiated claims that the product can treat or cure diseases and stipulated preliminary injunctions were entered against Trudeau, Barefoot, Shop America LLC and Deonna Enterprises, Inc. In December 2003, a U.S. District Court entered a

Consent Decree of Condemnation and Permanent Injunction against Shop America prohibiting Shop America and its directors, officers, agents, representatives from promoting any products as a treatment for disease.

SIGRA

In June 2003, FDA warned consumers not to purchase or consume SIGRA, STAMINA Rx and STAMINA Rx for Women, Y-Y, Spontane ES and Uroprin, manufactured by NVE Pharmaceuticals, Inc., in Newton, New Jersey and distributed by Hi-Tech in Norcross, Georgia. These products, which were marketed as dietary supplements for sexual enhancement, were found to contain the prescription drug ingredient tadalafil, which could cause a drastic lowering of blood pressure when combined with prescription drugs containing nitrates. Tadalafil is the active ingredient in Cialis, an Eli Lilly product approved in Europe to treat male erectile dysfunction. Despite FDA's warnings, the defendant and his related businesses repeatedly sold dietary supplements that claimed to treat obesity and erectile dysfunction. Hi-Tech recalled the products and in September 2003, a U.S. District Court Judge entered a Consent Decree of Permanent Injunction enjoining Hi-Tech Pharmaceuticals, National Urological Group, National Institute for Clinical Weight Loss, American Weight Loss Clinic, United Metabolic Research Center, and the President of these corporations, from distributing unapproved new drugs and misbranded drugs.

Global Source and Consulting, Inc.

In June 2003, a U.S. District Court entered a Consent Decree of Condemnation and Destruction for the seized products from Global Source and Consulting, Inc., which included 450 bottles and 57,000 bulk capsules of 20 dietary supplement products worth $19,000. Global Source agreed to destroy the products and to cease manufacture and marketing of "Vitamin Hut Scientific Cholesterol Support Program" or any similar red yeast rice product containing lovastatin, or any other drug product that is a new drug unless and until an approved new drug application is in effect for such product.

Severe Acute Respiratory Syndrome (SARS)

In May 2003, in an immediate response, FDA and FTC warned website operators, manufacturers and distributors to remove misleading or deceptive Internet claims that their products may prevent, treat or cure SARS. An internet "surf"" conducted by FTC, FDA and the Ontario Consumer and Business Services, found over 40 sites promoting a variety of SARS treatment and/or prevention products. The products include dietary supplements containing ingredients such as colloidal silver, ascorbic acid, beta glucan, pycnogenol, and oregano oil. FDA sent warning letters to 8 Internet firms promoting dietary supplement products to treat or prevent SARS. FTC also notified violative firms that they were subject to possible civil or criminal actions under the FTC Act.

Gero-Vita International, Inc.

In May 2003, the FTC filed a complaint against Glenn Braswell and four of his corporations for making false and unsubstantiated claims that several products marketed as dietary supplements are "scientific breakthroughs" to treat or cure numerous serious medical conditions. FDA

provided technical assistance and scientific support to FTC for this action. Products identified in the complaint were: Lung Support Formula, which claimed to cure or ameliorate asthma, emphysema, smoking damage and other respiratory problems; Antibetic Pancreas Tonic, which claimed to treat or cure diabetes and to lower blood sugar levels; and GH3 and GH3 Romanian Youth Formula, which claimed to extend life and prevent or treat Alzheimer's disease and other forms of dementia; Chitoplex to promote weight loss and reverse obesity without diet or exercise; and Testerex, which claimed to treat erectile dysfunction.

Nature's Youth

In April 2003, FDA announced that Nature's Youth, LLC, of Centerville, Massachusetts, voluntarily destroyed approximately 5700 boxes of its misbranded product, "Nature's Youth hGH" worth $515,000. The action followed FDA's advisory that the products appeared to be misbranded by labeling that included unsubstantiated "structure and function" claims that the product would, among other things, "improve physical performance, speed recovery from training, increase cardiac output, and increase immune functions."

Street Drug Alternatives

On March 31, 2003, FDA sent Warning Letters to 8 firms after an investigation revealed that the firms sold "street drug alternative" products marketed for "recreational" purposes with claims that they would produce such effects as euphoria, a "high", or hallucinations. These street drug alternatives cannot meet the legal definition of a dietary supplement because they are not intended to supplement the diet, to promote health or to reduce the risk of disease. The 8 letters

were targeted primarily to manufacturers of products that contained ephedrine or norephedrine hydrochloride.

In 2001, FDA brought a seizure and injunction action against a purported supplement manufacturer that marketed its products as illegal street drugs. The case, *U.S.* v. *Undetermined Quantities of Articles of Drug, Street Drug Alternatives . . . et al.* showed that Hit Products, Inc., and Organic Diversions, Inc., marketed products made from a mixture of herbs that promised users effects comparable to illegal street drugs. FDA categorized these products as "street drug alternatives" and seized them as misbranded and unapproved new drugs in violation of the FD&C Act. FDA sought the destruction of the seized goods and an injunction barring defendants from future FD &C Act violations. In granting this relief, the court found FDA's position on street drug alternatives "highly persuasive" and criticized the defendants' characterization of the products as dietary supplements as a "veiled attempt to circumvent" the FD&C Act. The court "declined to carve out a statutory loophole for drug manufacturers attempting to profit from the illegal drug epidemic by masquerading potentially dangerous substances as legitimate dietary supplements."

Ancom Anti-Hypertensive

In February 2003, FDA investigators found that Ancom Anti-Hypertensive Compound tablets, which were marketed on the Internet and in retail stores as dietary supplements, contained several prescription drug ingredients, including reserpine, diazepam (Valium), promethazine, and hydrochlorothiazide. Best Life International, the manufacturer, ceased distribution and recalled the product. Subsequently in May 2003, Best Life International issued a voluntary recall and warned consumers not to buy or consume its product called, Viga. Viga, marketed as a dietary

supplement, was found to contain sildenafil, the active ingredient in Pfizer's Viagra. Sildenafil can cause life-threatening lowering of blood pressure when taken with nitrates.

Unsubstantiated Claims for Enhanced Athletic Performance

In February 2003, based upon the conclusions of the RAND study, FDA warned 26 firms to cease making unproven claims that ephedrine-containing dietary supplements enhance athletic performance. Since performance enhancement was one of the two principal ways in which ephedra products have been marketed, the impact of these warning letters was substantial. On February 5, 2004, FDA officials accompanied U.S. Marshals in a seizure of ephedra-containing dietary supplements Betatrim, Thermbuterol, and Stacker 2, from *Musclemaster.com* in Northboro, Massachusetts. The firm failed to comply with FDA's warning to stop making unsubstantiated athletic performance claims on its websites. The value of the 900 bottles of seized goods was approximately $19,308.

Yellow Jackets and Black Beauties

In January 2003, FDA and the U.S. Marshal's Service served an inspection warrant that would allow FDA to witness the voluntary destruction of $4 - 5 million worth of products known as "Yellow Jackets" and "Black Beauties." The warrant was served at NVE Pharmaceuticals, Inc., the manufacturer of the products, located in New Jersey. A distributor in the Netherlands promoted the products on the Internet as alternatives to street drugs. Yellow Jackets and Black Beauties are "street terms" for controlled substances and were sold as herbal street drug alternatives. In September 2002, FDA became aware of the tragic death of a 16-year old high school football player who had taken Yellow Jackets. FDA placed the products on Import Alert on October 7, 2002.

EverCLR

On December 16, 2002, U.S. Marshals seized approximately 3,000 bottles of EverCLR, a dietary supplement, valued at more than $100,000. EverCLR was marketed by Halo Supply Company of San Diego, California, a "natural" treatment for viruses such as the herpes virus and "cold and flu protection." None of these claims were substantiated. FDA charged that EverCLR was an unapproved and therefore, illegal, new drug because it was promoted to treat and prevent specific diseases and conditions. Because EverCLR's labeling lacked adequate directions for use, FDA also charged that it was misbranded

Calm Focus

In August 2002, FDA issued a Warning Letter to Better Way Kids. This firm distributed "Calm Focus," a product promoted to treat Attention Deficit Disorder and Hyperactivity Disorder. The firm characterized its product as a "natural alternative to Ritalin" and claimed that it was "formulated to energize neurotransmitters in the brain." The Warning Letter made clear that dietary supplements may not make disease claims or unsubstantiated structure/function claims. The firm corrected its product claims.

U.S. v. Syntrax Innovations, Inc., et. al

U.S. v. *Syntrax Innovations, Inc., et al*, involved a substance called Triax, marketed by Syntrax as a dietary supplement for the treatment of obesity and to promote weight loss. FDA scientists determined that the product contained a potent thyroid hormone called, tiratricol, that if taken in sufficient quantity can cause heart attacks and strokes. FDA alleged that Triax could not be a dietary supplement because it was promoted to treat a disease (obesity) and because it did not

contain any of the dietary ingredients identified in DSHEA. In February 2001, the court entered an injunction barring the distribution of Triax.

U.S. v. Lane Labs USA, Inc. and Andrew Lane

FDA brought an injunction action against Lane Labs USA, Inc., Andrew Lane and against three of Lane Labs' products, including its shark cartilage product, BeneFin. Lane Labs claimed that two of these products were dietary supplements, but the company promoted those products for the treatment of cancer and HIV. The third product is a skin cream promoted for the treatment of skin cancer. FDA contended that the disease claims caused all three of these products to be an unapproved, and therefore illegal, new drugs and misbranded drugs.

Brain Nutrient Capsule

United States v. *Undetermined Quantities of Cases of an Article of Food and Drug Labeled in Part: Brain Nutrient Capsule*, involved a dietary supplement product offered as a supplementary treatment for mental retardation, cerebral palsy, and epilepsy. The product's distributor claimed that it "has the function of increasing the intelligence, elevat[ing] the intelligence quotient (IQ) and promoting growth." FDA alleged that these claims were baseless.

RULE REMOVING DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS (EPHEDRA) FROM THE MARKET

Under DSHEA, a dietary supplement is adulterated if, among other reasons, it presents a significant or unreasonable risk of illness or injury under the conditions of use recommended in the labeling, or if the labeling is silent, under ordinary conditions of use.

On February 11, 2004, FDA applied DSHEA's unreasonable risk standard and issued a final rule declaring dietary supplements containing ephedrine alkaloids (ephedra) adulterated. The rule will have the effect of removing dietary supplements containing ephedrine alkaloids from the marketplace and will become effective April 12, 2004.

Last winter, FDA issued letters to manufacturers of dietary supplement containing ephedra to notify them of its planned action. The Agency's history in reviewing ephedra under DSHEA is substantial. FDA has had long-standing concerns about potential risks associated with dietary supplements containing ephedra.

FDA ACTION ON SUPPLEMENTS CONTAINING ANDROSTENEDIONE

On March 11, 2004, FDA announced action on androstenedione ("andro"), as a result of the Agency's concerns about its safety. Andro acts like a steroid once it is metabolized by the body and therefore can pose similar kinds of health risks as steroids. These products are generally marketed as dietary supplements to enhance athletic performance based on their claimed anabolic and androgenic properties to stimulate muscle growth and increase production of testosterone.

FDA sent warning letters to 23 companies asking them to cease distributing products sold as dietary supplements that contain androstenedione and warning them that they could face

enforcement action if they do not take appropriate actions. The letters stated that FDA is not aware of any information demonstrating that androstenedione was lawfully marketed as a dietary ingredient in the U.S. before October 15, 1994, nor is FDA aware of any information demonstrating that this ingredient has been present in the food supply as an article used for food in a form in which the food has not been chemically altered. In the absence of such information, dietary supplements containing "andro" are subject to the pre-market notification requirement for a new dietary ingredient. Because no notification was submitted for "andro", dietary supplements containing "andro" are considered adulterated.

The warning letters further state that, based on what FDA knows now, the Agency is aware of no history of use or other information establishing that a dietary supplement containing androstenedione will reasonably be expected to be safe. There is existing evidence that the use of androgenic steroid precursors such as androstenedione may have long-term adverse health consequences. If a manufacturer files a new dietary ingredient notification to the Agency, FDA will evaluate whether specific products are adulterated.

Mr. Chairman, thank you for this opportunity to testify. I am happy to answer your questions.

Mr. BURTON. Does the FDA have the authority under DSHEA to eliminate products that they think are a risk to public health?

Mr. BRACKETT. Well, as indicated by the fact that we have taken enforcement on products such as this, we do have the authority and we are in the process of trying to completely implement DSHEA to give us all of the tools that we need.

Mr. BURTON. And when DSHEA is fully implemented, you will have the tools to do what is necessary to protect the public health from a product that you feel is not safe?

Mr. BRACKETT. We think that we will have the tools that we need, using the existing authority that we have. However, taking into account that these have not yet been tested in courts, and that will be the final event that will see how thoroughly we can regulate these products.

Mr. BURTON. I understand. But we have studied the DSHEA law pretty thoroughly, as has the industry. And there are a number of us in Congress that feel like if there is a threat to public health, the FDA and our health agencies do have the authority under DSHEA to get those products off the market.

Mr. BRACKETT. Right. And at this time the administration has no indications that we are going to seek additional legislative action on DSHEA.

Mr. BURTON. Well, Senator Durbin, a good friend of ours, has legislation that he is supporting, and others like Ms. Davis, that would add additional regulation and authority, I guess, to DSHEA. But under the current law, you do have the tools necessary in order to get any threat to the public health off the market?

Mr. BRACKETT. Of everything that we have tested, we do have the authority to make those seizures and those types of actions against unsafe products.

Mr. BURTON. Thank you. And one of the issues that I have been concerned about, a product like ephedra. Now there is a synthetic ephedra and then there is a natural ephedra. Do they both react the same? Or have you ever tested that? I mean, have you ever checked that out? Because in China they have used ephedra products for thousands of years, and they do it to this day. But there is a synthetic ephedra that has caused a number of problems. And I just wonder are they similar?

Mr. BRACKETT. Well, they may be similar. In terms of our rule against ephedra, that would specifically exclude those that are used in traditional Chinese medicine or teas, the natural form of ephedra.

Mr. BURTON. It would exclude them as well.

Mr. BRACKETT. Correct.

Mr. BURTON. So all forms of ephedra would be excluded.

The labeling on the various bottles of products like ephedra, when the FDA looked into that, did they find that the people who suffered adverse events from the ephedra products, that they had followed the labeling on those products?

Mr. BRACKETT. It is my understanding in many of those cases that in fact they did follow the recommendation on those products.

Mr. BURTON. They did.

Mr. BRACKETT. That is correct.

Mr. BURTON. I would like to see some of those cases if you have those, because a number of the cases that I followed very closely in the newspaper, like the baseball player that died—and it was a highly publicized event. And I don't know about the young man that Ms. Davis and Senator Durbin talked about, but they were overweight and had high blood pressure and had other health problems already, and the ephedra specifically should not have been used by them, and I think it said so; it so stated on the directions on the bottle. And that was one of the things that was troubling. Had they read that, they might have not had that horrible experience that occurred.

So the bottom line is that you believe that the DSHEA law as is currently written gives you the tools necessary to get potentially hazardous products off of the market?

Mr. BRACKETT. That is correct. As indicated by the two examples that I shared in my oral testimony. In addition, in my written testimony there are a number of other actions that we took, some of which were against small companies, large companies, that we did take on the various conditions that I had mentioned earlier.

Mr. BURTON. And FDA and HHS and the administration at this time are not seeking additional legislation to alter or change DSHEA?

Mr. BRACKETT. That is correct.

Mr. BURTON. Thank you.

Ms. Watson.

Ms. WATSON. Thank you very much for your testimony. And my question is, under DSHEA, is there—if you order a product taken off of the market, that would be the extreme. Correct?

Mr. BRACKETT. That would be the case where we would have sufficient scientific evidence to show that there would be cause for human health problems, yes.

Ms. WATSON. What are the options that you have, less taking it off of the market? Are you considering more on the labels, warnings on the labels like we do on packages of cigarettes? What are the options that you would have under the law?

Mr. BRACKETT. Well, some of the options that we have, for instance, is to send letters to the manufacturers of these products that they are in violation, and in many cases they voluntarily withdraw it from the market. In other cases, we would have to go back to the science, with the ingredients, find out exactly which ingredients are in those products, and develop the scientific evidence, the pharmacology, and then go back and review and see if that meets the standard that we need to remove that product.

Ms. WATSON. Since many of these natural supplements have been used by other cultures for hundreds of thousands of years, what have you been able to identify is the current void or lack on the part of the manufacturers of these supplements? Is it that they are not doing extensive scientific testing on humans? What have you been able to identify, or have you been able to identify at this point what the problem might be?

Mr. BRACKETT. Well, the two main reasons why they may be denied in a letter is, first of all, because they have not shown that they provided sufficient evidence that the product is safe. The second one is that they have not identified the ingredients in the prod-

uct itself. So those are two of the provisions under DSHEA that we have used to either—looking at new dietary ingredients, on whether they meet the bar or not.

Ms. WATSON. Thank you.

Mr. BURTON. Ms. Davis.

Mrs. DAVIS OF CALIFORNIA. Thank you, Mr. Chairman.

Thank you, Dr. Brackett, for being here.

You know, we know that ephedra was taken off the market because of safety concerns. But it has been replaced, as Senator Durbin mentioned and I had mentioned also that, replaced by new stimulant combinations. And I am wondering if FDA has evidence that these products are significantly safer——

Mr. BRACKETT. No.

Mrs. DAVIS OF CALIFORNIA [continuing]. Than the products that were taken off the market.

Mr. BRACKETT. Sorry. No, we don't have that evidence. We are replacing something with a known pharmacology, that is ephedra, with perhaps items for which we know a lot less. And so in response to that, we are working very closely with the National Institutes of Health and University of Mississippi, National Center for Natural Products Research, to try to find as much information about those products as we can to make sure that they do not have the same risks as ephedra does.

Mrs. DAVIS OF CALIFORNIA. And you are looking at that from what—I guess what would—what kind of information would satisfy you that you have the appropriate information?

Mr. BRACKETT. Well, we are looking mostly at the scientific evidence, both the pharmacology of the products. And first of all, in many of these products we have to identify exactly what is the ingredient in that we need to be concerned about. Identify the products is the first thing.

The second thing is identify what pharmacological properties that ingredient may have, look at the scientific literature to see what published information we have about that, together with such things as adverse events that we may hear about. All of that together needs to take it so that each individual ingredient or compound needs to be looked at on a case-by-case basis.

Mrs. DAVIS OF CALIFORNIA. And you mentioned the adverse event reports. I think my concern is that we know that at least one company had a number of adverse event reports that they were sitting on, basically. And that there was nothing in law, nothing in DSHEA, to mandate that they turn those over. If nothing changes then, how will you necessarily have those AERs to be able to make an assessment about the way that they are actually influencing people in the real world?

Mr. BRACKETT. Well, adverse events are just one tool among a number that we will use to evaluate the safety of the a product. But in the meantime, FDA's Center for Food Safety and Applied Nutrition has developed an adverse event reporting system, CARES, which is meant to tabulate all of these regulated products to try to develop a signal that something may rise to the point where we need to take a closer look at it.

Mrs. DAVIS OF CALIFORNIA. So is it a standardization of those reports that has changed? What has changed, I guess, from prior to? There was no system in place before?

Mr. BRACKETT. There were a number of different systems, but no one portal for which all the information would come in. And I think that is the main thing that has changed. So we have better information for a broader set of sources.

Mr. DAVIS. What kind of changes has that made in terms of personnel and the ability of people to actually monitor that? Has the number of employees in that area changed? What have you done specifically within FDA to bring about perhaps greater monitoring, then?

Mr. BRACKETT. We have hired a number of people specifically to look at the adverse events reports, decide which are more qualitative, or complaints about product versus those that may actually involve human health; and, of course, prioritize those based on those that might rise to the level of a serious adverse health effect.

Mrs. DAVIS OF CALIFORNIA. And how do you get those if it is not mandatory? How do you know whether people or the companies are actually responding?

Mr. BRACKETT. Well, we don't know. We rely a lot on consumers, a lot on the medical profession to provide some of those to us.

Mrs. DAVIS OF CALIFORNIA. If we are relying on the consumers, then how are you necessarily getting that information? Are most consumers giving out information to the companies, or are they calling the companies or are they calling FDA?

Mr. BRACKETT. Well, I would hate to speculate on what specific consumers would do. They will do all of the above. They will make reports to the companies, to their physicians, to FDA.

Mrs. DAVIS OF CALIFORNIA. OK. I appreciate the changes that you see that are being made. But it really does concern me that we were aware of the fact that these reports are not necessarily turned over, and yet you are relying on those. And I think that if there is any change, I certainly believe that we need to find a way to make at least those adverse event reports that are very substantive, and I think that we all recognize the difference between somebody perhaps once responding, but then there are others that are really quite serious.

One of the concerns that I had in talking to people over the years is that people are quite embarrassed sometimes, at they should have known better, and so we need to—part of it is education, of course, but then I think it is also the experience that people have that if they do report, that something will happen to that information. And we need to find a better way, I think, perhaps to make sure that people have that confidence.

Mr. BRACKETT. I agree.

Mrs. DAVIS OF CALIFORNIA. I have, Mr. Chairman, one or two just other quick questions.

You know, the burden is on the FDA to have knowledge of the products and the ingredients, and you mentioned that, to know better. I know that when we had our hearing here it did surprise us that when we asked the companies what was contained in their products, they really didn't know. That is an important element, and I think that needs to be followed up.

One of the questions would be whether the authority that you have is adequate to make sure that supplements containing aristocholic acid, which can and has caused severe kidney toxicity and which is a potent carcinogen, that those are not on the market. Do you have that kind of authority to be able to look at those kind of supplements as well?

Mr. BRACKETT. Yes, we do have that kind of authority. And that is another one of the instances where we are very hurriedly trying to obtain as much good scientific proven evidence or characteristics of the compound and its pharmacology that could be used in making those judgments.

Mrs. DAVIS OF CALIFORNIA. OK. Thank you very much, Dr. Brackett. I appreciate it.

Mr. BURTON. Let me just followup on a couple of questions. You know, in 1994, Congress passed this law, and it wasn't until 18 months ago, 9 years after passage, that the FDA passed the good manufacturing practices. Why did it take 9 years? I mean, we gave FDA the authority to do that so that they could followup on this, and a lot of this criticism would have been avoided if FDA had gotten on the ball and used the authority that it had to come up with these good manufacturing practices. Why did it take 9 years? And you weren't there all that time, so I am not beating on you. Just, why did it take so long?

Mr. BRACKETT. The first thing I want to reemphasize is getting that particular rule out is one of the highest priorities we have in the center.

Mr. BURTON. Excuse me. I know it is one of your highest priorities, but you have had almost 10 years. Why did it take that long? Because some of the things that Senator Durbin is talking about and Congresswoman Davis is talking about, I think could have been avoided had the FDA said, OK, we have the authority, let us get with it. Why did they take 10 years?

Mr. BRACKETT. Well, it wasn't because things weren't happening. There was a lot going on in the background. Not long after DSHEA was implemented, we met with the industry at their request to try to learn from them what the appropriate framework for the dietary supplement good manufacturing practices would be, and from that developed advanced notice of proposed rulemaking for which we took comments from the industry, met with them. And it was during that time where we were formulating what we thought the framework for the GMP would look like.

And that resulted in what we saw last March when we proposed the dietary supplement GMP rule from that time we got many substantive comments. We wanted to make sure we got this rule right. We wanted to make sure it wasn't overly burdensome on the industry. And so a lot of it was doing our homework beforehand and since that time.

Mr. BURTON. Thank you, Director Brackett. But 10 years is a long time to get it right, I mean. So I think the FDA bears some of the responsibility for not getting on the ball a little bit quicker.

Critics of DSHEA say that the regulations placed on dietary supplements under the law are too flexible to provide for the safety of the products. In your opinion, do you believe that the FDA should

take more stringent actions toward supplements, or do you think the law as presently written is sufficient?

Mr. BRACKETT. I think we should use the existing law to its fullest extent, which is why the administration is not proposing any legislative changes at this time.

Mr. BURTON. So, in effect, you think it is sufficient.

Mr. BRACKETT. We have no changes to make to it.

Mr. BURTON. It has come to my attention that the FDA created a new process for reporting adverse events in regard to dietary supplements. And as was talked about, this new reporting system is different than its predecessor.

And you believe this new system is going to provide more accurate data and will get the job done.

Mr. BRACKETT. We think it will be a vast improvement to what we had previously, again, because it is bringing multiple sources of information in through one portal that we can use to generate the signal that would tell us that something may be happening.

Mr. BURTON. OK. And what measures do you believe the FDA could take to improve the existing policies on dietary supplements?

Mr. BRACKETT. Well, the best thing that FDA could do is again use DSHEA to its fullest, and we are committed to implementing it to its fullest, taking the appropriate actions that we need to, enforcement actions, getting our dietary supplement GMP that creates a level playing field for the industry and consumers and using the existing authority that we have.

Mr. BURTON. You have been over there in this capacity for how long now?

Mr. BRACKETT. Two months.

Mr. BURTON. Well, it is nice to have you there. I am sorry the FDA took 10 years to get you there, but it sounds like you are a pretty sharp guy, and we will look forward to working with you to make sure we solve some of these problems.

Do you have any further questions or statements for this gentleman, Mrs. Davis?

Mrs. DAVIS OF CALIFORNIA. No, thank you, Mr. Chairman.

Mr. BURTON. Thank you very much, and good luck in your new position. And if we can help you at all, you contact us, because we are very concerned about this issue.

Mr. BRACKETT. I will do that.

Thank you very much, Mr. Chairman.

Mr. BURTON. Our next panel is Marc Micozzi, M.D., Ph.D. With the Policy Institute for Integrative Medicine from the Thomas Jefferson University Hospital; my good friend David Seckman, executive director and CEO of the National Natural Foods Association; Annette Dickinson, president of the Council for Responsible Nutrition; and Doug Rose, dietary supplement consumer, a good friend of mine from Indianapolis, IN, and, Doug, it is good to see you, Buddy; and Alan Dumoff, J.D., MSW, for the American Association For Health Freedom.

Would you all stand?

[Witnesses sworn.]

Mr. BURTON. I think we will just start and go right down the line.

We will start with you, Dr. Micozzi.

STATEMENTS OF MARC MICOZZI, M.D., PH.D., DIRECTOR, POLICY INSTITUTE FOR INTEGRATIVE MEDICINE, THOMAS JEFFERSON UNIVERSITY HOSPITAL; DAVID SECKMAN, EXECUTIVE DIRECTOR AND CEO, NATIONAL NATURAL FOODS ASSOCIATION; ANNETTE DICKINSON, PH.D., PRESIDENT, COUNCIL FOR RESPONSIBLE NUTRITION; DOUGLAS C. ROSE, PRESIDENT, IRWIN R. ROSE AND CO., INC.; AND ALAN DUMOFF, J.D., M.S.W., AMERICAN ASSOCIATION FOR HEALTH

Mr. MICOZZI. Good morning, Mr. Chairman, Mrs. Davis, thank you for the opportunity to be here. Appreciate your efforts on behalf of dietary supplement safety and information.

Over the past decade, under DSHEA, improved information about the structure and activity of dietary supplements has helped many health practitioners make judgments and provide recommendations to their patients about the use of herbs and nutrients.

In addition, DSHEA has helped facilitate integration of dietary supplements into medical practice.

Further, over the past decade, much third-party research, that is research not done by the university but by medical and scientific institutions, has been conducted and, in fact, demonstrates the benefits of dietary supplements in the management of many medical conditions. In addition, this type of research has shed light on interactions between herbs and pharmaceuticals as well as medical procedures and anesthetic agents.

These developments are important in light of increasing use of CAM, complimentary alternative medicine, and dietary supplements among U.S. adults. A current survey, which we published in Seminars and Integrative Medicine last year, shows that two-thirds of adults demonstrate lifetime use by age 33. Further use is actually highest among post baby boomers, 7 out of 10, with only 5 out of 10 boomers and 3 out of 10 pre-boomers.

These trends may, indeed, indicate that utilization is related to managing medical conditions, which are more common among older Americans. In addition, two-thirds of HMOs offered at least one type of alternative therapy as of 1999, with acupuncture, massage and nutritional therapy as the three most likely modalities to be offered.

The best single predictor of the use of CAM and dietary supplements is higher educational status, perhaps reflecting disposable income, as well as knowledge, awareness, and attitudes. Unfortunately, up to half of all patients do not tell their physicians about their use of CAM and dietary supplements, indicating much additional work is needed on integration and good continuum of care.

A higher proportion of adults with cancer utilize CAM. Several surveys found rates 80 percent or higher. CAM use is also marked in neurological diseases, phychiatric disorders, physical disabilities, psoriasis, diabetes and other disorders.

In addition to the management of medical conditions, CAM and dietary supplement therapies have gained increasing attention in the prevention of chronic disease. The 2002 article in the Journal of the American Medical Association on vitamins for chronic disease prevention in adults provided clear substantiation for the im-

portant role of dietary supplementation in light of the typical U.S. diet as well as limitations in the nutrient composition of foods.

Dietary supplement use is already prevalent among older Americans. In addition, efforts are underway to provide older Americans with dietary supplementation by the Healthy Foundation, for example, with support from U.S. Senator Tom Harkin, Senate co-chair of the Congressional Caucus on CAM and the Dietary Supplements for Senior Health program based in Idaho, has been seeking support from Senator Larry Craig, who chairs the Senate's Special Committee on Aging.

In 2001, this Committee on Aging commissioned a report by the General Accounting Office on the use of dietary supplements in older Americans. The GAO report documented the many problems associated with this practice but did not address the evidence of benefits. Senator Craig has indicated to us interest in revisiting this issue.

Under DSHEA, physicians and other health professionals have been able to incorporate the use of dietary supplements in integrative medicine, combining the best of mainstream and alternative approaches. At the Jefferson-Myrna Brind Center for Integrative Medicine in Philadelphia, we provide over 500 different dietary supplements to 7,500 patients who visit us each year with a very high rate of patient satisfaction.

Under DSHEA, licensed physicians and pharmacists in the hospital recommend dietary supplements based upon scientific evidence, published evidence, in appropriate doses, forms and combinations. This experience is shared with a nationwide clinical network of seven leading integrative medicine centers and also among 22 members of the Consortium of Academic Health Centers For Integrative Medicine, potentially reaching millions of patients.

One answer to improved and more effective use of dietary supplements and other CAM modalities lies in the continued integration of herbal and nutritional therapy into medical practice through the active involvement of physicians, pharmacists, other health care professionals and the health care system. In this manner, medical science and practice will continue to learn and apply optimal utilization of dietary supplements and provide collective and individual guidance to consumers.

This goal is already being achieved through integrative medicine, and the current DSHEA provides regulatory authority, as we have heard. What is missing from the present formula can best be provided by the continued expansion of the integration of herbs, nutrition and dietary supplements into medical education, science and practice.

Thank you.

[The prepared statement of Mr. Micozzi follows:]

Committee on Government Reform

House of Representatives

Congress of the United States

"Ten Years After the Implementation of DSHEA: The Status of Dietary Supplements in the United States"

Testimony of Marc S. Micozzi, MD, PhD

Executive Director, Jefferson-Myrna Brind Center for Integrative Medicine

Thomas Jefferson University Hospital, Philadelphia PA 19107

March 24, 2004

Over the past decade under DSHEA, improved information about the structure and activity of dietary supplements has helped many health practitioners make judgments and provide recommendations to their patients about the use of herbs and nutrients. In addition,

DSHEA has helped facilitate integration of dietary supplements into medical practice. Further, over the past decade, much third party research has been conducted that demonstrates the benefits of dietary supplements in the management of many medical conditions, as well as interactions between herbs and pharmaceuticals, medical procedures and anesthetic agents.

These developments are important in light of increasing utilization of CAM (complementary and alternative medicine) and dietary supplements among US adults. A current survey shows that two-thirds of adults demonstrate lifetime use by age 33 as published last year in the medical journal, Seminars in Integrative Medicine, for which I serve as editor. Further, use is highest among post-baby-boomer (7 out of 10), with only 5 out of 10 boomers, and 3 out of 10 pre-boomers. These trends may indicate that utilization is related to managing medical conditions more common among older Americans.

In addition, two-thirds of HMOs offered at least one type of alternative therapy as of 1999, with acupuncture, massage and nutritional therapy the most likely modalities to be added. The best single predictor of CAM and dietary supplement use is higher educational status, perhaps reflecting disposable income as well as knowledge, awareness and attitudes.

Up to half of all clients do not tell their physicians, indicating that much additional work on integration into the continuum of care is needed.

A high proportion of adults with cancer utilize CAM. Several surveys found rates of 80% or higher. CAM use is also marked in neurological diseases, psychiatric disorders, physical disabilities, psoriasis, diabetes and other disorders.

In addition to the management of medical conditions, CAM and dietary supplement therapies have gained increasing attention in the prevention of chronic disease.

The 2002 article in the Journal of the American Medical Association on "Vitamins for Chronic Disease Prevention in Adults" provided clear substantiation for the important role of dietary supplementation in light of the typical US diet and nutrient composition foods.

Dietary supplement use is already prevalent among older Americans. In addition, efforts are underway to provide older Americans with dietary supplementation by the Healthy Foundation, with support from US Senator Tom Harkin (D-Iowa), Senate Co-Chair of the Congressional Caucus on CAM and Dietary Supplements. The Dietary Supplements for Senior Health Program, based in Idaho, is also seeking support from US Senator

Larry Craig (R-Idaho) who chairs the Senate Special Committee on Aging. In 2001, the Committee on Aging commissioned a report on the use of dietary supplements in older Americans by the General Accounting Office. The GAO Report documented the problems associated with this practice but did not address the evidence of benefits; Senator Craig has indicated to us interest in revisiting this issue.

Under the Dietary Supplement Health and Education Act, physicians and other health professionals have been able to incorporate the use of dietary supplements in integrative medicine, combining the best of mainstream medical and alternative approaches. At the

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licensed physicians and pharmacists recommend dietary supplements in appropriate forms, dosages and combinations from appropriate sources.

Our experience is shared with a nationwide clinical network of seven leading integrative medicine centers, and among 22 members of the Consortium of Academic Health Centers for Integrative Medicine, potentially reaching millions of patients.

In my opinion, one answer to improved and more effective utilization of dietary supplements and other CAM modalities lies in the continued integration of herbal and nutritional therapy into medical practice through the active involvement of physicians, pharmacists, other health care professionals and the health care system. In this manner medical science and practice will continue to learn and apply optimal utilization of dietary supplements and provide collective and individual guidance to consumers. This

goal is already being achieved through integrative medicine. The current DSHEA in my opinion provides appropriate regulatory authority without the need for further legislation. What is missing from the present formula can best be provided by the continued integration of herbs, nutrition and dietary supplements into medical education, science and practice.

Mr. BURTON. Thank you, Doctor.

Mr. Seckman.

Mr. SECKMAN. Chairman Burton and Congresswoman Davis, thanks for the opportunity to address you today as a representative of the dietary supplement industry.

I am David Seckman, executive director and CEO of the National Natural Foods Association. We represent the interests of more than 5,000 retailers, manufacturers, suppliers and distributors of health foods, dietary supplements and related items.

The committee has asked that I address the status of dietary supplements in the United States as we reach the 10-year milestone of the law that governs these diverse products, the Dietary Supplement Health and Education Act of 1994.

Although DSHEA was enacted 10 years ago, much of its key implementation has only happened within the past 18 months. Because dietary supplements are often viewed in regard to their safety, quality and efficacy, my testimony today will address how these and how well the law is supported and is being applied in these three broad categories. Since the law underlies all that we have discussed and will be discussing here today, let me start with DSHEA.

DSHEA is often wrongly characterized as taking away from the Food and Drug Administration their ability to regulate supplements. In fact, DSHEA increased FDA's enforcement powers. These powers include, but are not limited to, stopping the sale of an entire class of dietary supplements if they pose an imminent public health hazard, seizing dietary supplements that pose a significant or unreasonable risk of illness or injury, or keeping a new dietary ingredient from being marketed if not enough safety data is received.

In evaluating the effectiveness of any law there are a couple of critical steps that must be followed for their enactment. First is implementation and enforcement. Laws only work when their provisions are put into practice and the failure to abide by them punished. In regard to DSHEA, and for a number of reasons, this law has never been fully implemented or adequately enforced.

Although I will highlight specific instances where DSHEA has not been fully implemented, let me say that the FDA, under the leadership of its most recent commissioner, has made progress, particularly in regard to enforcement. But there is still much more to be done.

Quality: Having standards in place that help to ensure that what is on the product label is actually in the product is essential. DSHEA provides for the establishment of good manufacturing practices [GMPs], tailored to the dietary supplements. A regulation for GMPs was just introduced last year, more than 9 years after the law was enacted. Under the rule, manufacturers would be required to identify the purity, quality, strength, and composition of the dietary ingredients and dietary supplements.

The industry supports the introduction of this regulation, and we encourage its swift finalization, implementation and enforcement.

Safety: While I want to discuss specific examples of how DSHEA has been applied when an issue of safety has arisen, I would like to put it in perspective. Dietary supplements are far more safer

than most common foods and drugs. For instance, the common pain reliever, ibuprofen, is responsible for more than 17,000 deaths annually. Prescription drugs, for all the testing they go through and copious usage directions that are issued with them, are estimated to be one of the top five leading causes of death in the United States at more than 106,000 annually. Illnesses from tainted foods kill 5,000 Americans each year.

One reason dietary supplement safety is questioned is because few can agree on accurate sources of statistical information about their use. Even so, the FDA's most recent adverse event estimates for dietary supplements are at 1,214 in a given year. Comparatively, the FDA received more than 300,000 adverse event reports about drugs over the same 12-month period.

Critics of DSHEA claim that the number of adverse event reports would be much higher were a different reporting system in place. The FDA has just begun implementing an extensive revamped reporting system for dietary supplements that should yield more accurate data and information and provide us with more information about problems we have with products. This new system should be given a chance to work.

The industry supports continuing efforts that will provide a constructive and impartial representation of dietary supplement safety. In the rare instances that a safety issue does arise, the FDA has all the authority it needs to either prevent a dietary supplement from reaching the marketplace or recovering it once it has.

Recent FDA actions regarding ephedra and androstenedione, or Andro, proved this point. In the instance of ephedra, the product was banned because the agency deemed it a health hazard. In the case of Andro, the FDA determined that it had not received the pre-market notification necessary under DSHEA for new dietary ingredients.

These examples, again, illustrate that the law works. But it also begs the question of what and why it took the FDA so long to take its action.

Efficacy: In passing DSHEA, Congress recognized that there may be a positive relationship between sound dietary practices and good health. While conceding that further scientific research is needed, Congress also recognized the potential between dietary safety and dietary supplement usage in reduced health care expense and disease prevention. The Office of Dietary Supplements [ODS], was established as a result of DSHEA to stimulate, coordinate and disseminate the results of science and research on the benefits and safety of dietary supplements in the treatment and prevention of chronic disease.

ODS has begun funding research on botanical supplements at university-based research centers that promote scientific discourse and provide the critical scientific mass necessary for sound science on the efficacy and safety of botanical supplements. With the support of the NNFA and other industry associations, the ODS budget has grown from $69,000, when it was first created in the mid 1990's, to $20 million in fiscal year 2003. NNFA supports future increases in funding.

Thanks to ODS and others, each year, more and more studies are published in major medical journals that support the use of supple-

ments for the treatment of specific conditions, prevention of diseases or for general nutritional enhancements. Examples of notable dietary supplement research includes an article published in the Journal of the American Medical Association where researchers concluded that every child and adult would benefit from taking vitamins daily. Other landmark studies include two others published in JAMA relating to the delay and lessening of symptoms of Alzheimer's disease by patients who took the herb ginkgo and vitamins C and E.

Not only has research demonstrated the health benefits of dietary supplements, it has also shown they can reduce health care costs by billions of dollars. For instance, a study published late last year reported that if seniors took a multivitamin daily, it could reduce health care costs by $1.6 billion annually.

Another study in a major medical journal reported that increased intakes of vitamin E, folic acid, and zinc could save $20 billion annually in hospital costs.

Let me add that while science increasingly validates the role dietary supplements play in maintaining health and preventing illness, it makes sense that these products receive the same favorable treatment the IRS provides for drugs in recognizing their costs for those. To that end, we support passage of a bill introduced by you, Mr. Chairman, that would do just that, H.R. 2627, the Dietary Supplement Tax Fairness Act.

In summary, DSHEA increased the FDA's enforcement authority, preserved consumer safety and mandated higher product standards. It also provided for more funding for supplement research that would make and validate their efficacy. The result is an increased ability by consumers to make informed personal health decisions.

But to be effective, like any law, it needs to be implemented and enforced. The bottom line is that there is no issue with dietary supplements, be it quality, safety or efficacy, which cannot be addressed under the current regulatory and legal framework.

Finally, I leave the committee with three recommendations to improve the effectiveness of DSHEA. The first is to give the FDA the resources it needs to fully implement this law. This can be done through the appropriation process and through passage of a new bill introduced in the Senate by Senators Tom Harkin and Orrin Hatch, Senate bill 1538, the DSHEA Full Implementation Enforcement Act. This bill would provide the FDA with the funding it needs to ensure the FDA is carrying out its congressional intent. It would also increase funding for the National Institute of Health's Office of Dietary Supplements. I understand there is a companion bill likely to be introduced in the House soon.

The second recommendation I have is for the FDA to quickly finalize and begin enforcement of good manufacturing practices for dietary supplements. Although I believe the vast majority of dietary supplement manufacturers have implemented production procedures that meet or exceed what is currently accorded by law, a Federal GMP regulation would bring others into line as well.

My final recommendation is this: Stop seeking legislative solutions to regulatory problems when it comes to DSHEA. Currently, there are six bills in Congress that would amend, augment or oth-

erwise modify DSHEA in an attempt to fix perceived weaknesses in the law. Although we support the intent of some, I believe most would not have been introduced if the FDA would have used its authority in a more timely manner to fully implement and enforce DSHEA.

Congressional hearings such as this one make strong impressions on the minds of Americans about the issues they cover. Often these issues are negative, and they focus on what went wrong and how it can be fixed.

I want to thank Congressman Burton and members of the subcommittee for taking time to examine what is right with dietary supplements.

[The prepared statement of Mr. Seckman follows:]

TESTIMONY OF DAVID R. SECKMAN
BEFORE
The Subcommittee on Human Rights & Wellness
of the House Government Reform Committee
U. S. HOUSE OF REPRESENTATIVES
March 24, 2004

Chairman Burton and Honorable Members of the Subcommittee on Human Rights & Wellness, thank you for the opportunity to address you as a representative of the dietary supplement industry. I am David Seckman, executive director and CEO of the National Nutritional Foods Association (NNFA). NNFA was founded in 1936 and is the oldest and largest trade association in the natural products industry. We represent the interests of more than 5,000 retailers, manufacturers, suppliers and distributors of health foods, dietary supplements and related items.

The Committee has asked that I address the status of dietary supplements in the U.S. as we reach the 10-year milestone of the law that governs these diverse products, the Dietary Supplement Health and Education Act (DSHEA) of 1994. I think the Committee has chosen an appropriate anniversary to revisit the law. In my experience, when a law has been on the books for 10 years ample evidence accumulates as to what is working and what is not. In regard to DSHEA, its enactment may have occurred 10 years ago, but much of its key implementation has only happened within the past 18 months.

Because dietary supplements are often viewed in regard to their safety, quality and efficacy, my testimony today will address how well the law has supported and is being applied in these three broad categories. Since the law underlies all that we will discuss here today, let me start with DSHEA.

The Dietary Supplement Health and Education Act was unanimously passed in 1994 to balance the American consumer's growing interest in health maintenance with the preservation of public safety. This legislation improved consumer access to dietary supplements and information about these products. It also increased consumer protection against unsafe products and false and misleading claims. In addition, it required supplement manufacturers to submit evidence of the safety of their products and the scientific basis for claims.

DSHEA is often mischaracterized as lessening the Food and Drug Administration's ability to regulate supplements. In fact, the enactment of DSHEA provided the FDA, the primary

agency that regulates supplements, with increased enforcement powers by establishing new labeling and potency standards. Briefly, under DSHEA, the FDA has the power to:

- Seize dietary supplements that pose an "unreasonable or significant risk of illness or injury" [Section 402 (f)].
- 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 guidelines (Good Manufacturing Practices), including potency, cleanliness, and stability [Section 402 (g)].
- Stop a new dietary ingredient from being marketed if the FDA does not receive enough safety data in advance [Section 413].
- 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)].

In evaluating the effectiveness of any law, there are two critical steps that must follow its enactment: implementation and enforcement. Laws only work if their provisions are put into practice and the failure to abide by them is monitored and punished. In regard to DSHEA specifically, and for a number of reasons, this law has never been fully implemented or adequately enforced.

Although I will highlight specific instances where the FDA has not fully implemented DSHEA, let me say that the agency, under the leadership of Commissioner McClellan, has made progress, particularly in regard to enforcement. But there is still much more to be done.

Quality

Having standards in place that help to ensure that what is on a product label is actually in the product is essential. Although manufacturers of dietary supplements are currently required to adhere to standards developed for foods, DSHEA provided for the establishment standards tailored to dietary supplements. Such standards are called good manufacturing practices, or GMPs. GMP standards would require manufacturers to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. And in fact the FDA has proposed a regulation for dietary supplement GMPs that would do just that. However, the publication of this rule last year took more than nine years from the passage of the law that allowed for it. I do not have an answer as to why this took so long, nor have I heard an explanation from the FDA. In fact, I testified last year at a Senate hearing where an FDA panelist was asked and had no answer to explain the delay.

Certainly, the dietary supplement industry did not present an obstacle to establishing a GMP regulation. Quite the opposite. The leading trade associations and their members actually

encouraged and welcomed its release. Further, in a substantive demonstration of industry support for a good manufacturing practices framework for dietary supplements, my organization created its own certification program five years ago.

I understand that the FDA is reviewing comments regarding the proposed rule in order to finalize it. While industry, including NNFA, has some concerns with it, such as unrealistic costs for to implement the rule and its lack of flexibility, we believe these can be addressed while still maintaining the integrity of the final regulation. We trust that the FDA finds merit in our comments and will address our areas of concern when it issues a final regulation, hopefully this year.

Safety

While I want to discuss specific examples of how DSHEA has been applied when an issue of safety has arisen, I would first like to put this issue in perspective. Dietary supplements are far safer than most common foods and drugs that consumers use without a second thought. For instance, the common pain reliever ibuprofen is responsible for more than 17,000 deaths annually[1]. Prescription drugs, for all the testing they go through and copious usage directions that are issued with them, are estimated to be one of the top five leading causes of death in the U.S. at more than 106,000 annually [2]. Illnesses from tainted foods kill 5,000 Americans killed each year[3].

One reason that supplement safety is questioned is because few can agree on accurate sources for statistical information about their use. Even so, the FDA's most recent adverse event estimates for dietary supplements are 1,214 in a given year[4]. Comparatively, the FDA received more than 300,000 adverse reports about drugs [5] over the same 12 month period. So, using the FDA's own data, adverse events related to supplements represent less than half-of-one percent of drug adverse events.

Critics of DSHEA claim the number of adverse events reported would be much higher were a different reporting system in place. The FDA has just begun implementing an extensively revamped reporting system for dietary supplements that should yield more accurate data about potential problems with these products and others. This new system should be given a chance to work. The industry supports continuing efforts that will provide a constructive and impartial representation of dietary supplement safety.

As I mentioned earlier, there are several provisions in DSHEA that grant the FDA the authority to ensure that only safe products stay on the market or reach it in the first place. In regard to the former, for a number of years, the agency has questioned its ability under DSHEA to effectively remove a product it believes presents a safety risk. Now, for the first time since DSHEA was passed, the FDA has exercised such authority under this law by banning a product it believes presents an "unreasonable risk of illness or injury" to consumers. I am talking of course about ephedra.

The FDA took literally years to weigh the considerable safety evidence for and against removing ephedra from the marketplace. Keep in mind that banning a product is not the

agency's only option. The FDA could have also regulated dosage and mandated warning labels on these products. Although critics of DSHEA have claimed it eviscerated the FDA's enforcement powers, the agency's most recent actions in regard to ephedra prove otherwise.

Another provision of DSHEA which the agency has just implemented is in regard to pre-market approval for a new dietary ingredient. This very recent action involves androstenedione or "andro." The FDA defines a new dietary ingredient as one not marketed in the U.S. prior to DSHEA's passage in October of 1994. In most cases, the law requires that at least 75 days prior to selling any product containing a new dietary ingredient, manufacturers or distributors must submit to the FDA information that indicates the ingredient is "reasonably" expected to be safe. The FDA contends that no such notification was received in the case of andro and that products containing it are adulterated and their marketing prohibited under DSHEA.

This example illustrates again that the law works. But it also again begs the question of what took the FDA so long to take action. It was not because they were unaware that some had questioned andro's dietary supplement status. FDA has been asked for several years by both industry and lawmakers to determine whether andro products are actually dietary supplements as defined by DSHEA, but received no response.

In summary, what both theses actions, which pertained to different provisions in DSHEA, demonstrate is that the law does not prevent the FDA from taking action it deems necessary.

Efficacy

In passing DSHEA Congress acknowledged that there may be a positive relationship between sound dietary practice and good health, and that, although further scientific research is needed, there may be a connection between dietary supplement use, reduced health-care expenses, and disease prevention. The Office of Dietary Supplements was established as a result of DSHEA to stimulate, coordinate and disseminate the results of research on the benefits and safety of dietary supplements in the treatment and prevention of chronic disease. NNFA agrees with the President's Commission on Dietary Supplement Labels that if fully-funded, "...ODS could play a valuable role in providing consumers with information about dietary supplements ...including [the] promotion of scientific studies on potential roles of dietary supplements in health promotion and disease prevention. Appropriations as authorized by DSHEA are essential if ODS is to meet [the] mandates of the Act."

The office, with NNFA's support, has begun funding research on botanical supplements through university-based research centers. Each of the ODS-funded centers will promote scientific discourse and provide the critical scientific mass necessary for sound studies on the efficacy and safety of botanical supplements. With the support of NNFA and other industry associations, the ODS' budget has grown from $69,000 when it was first created in the mid 1990s to $20 million in Fiscal Year 2003. NNFA supports future increases for funding.

Clearly, dietary supplements as a whole – not just vitamins and minerals – are beginning to get the research attention they deserve. Each year, more and more studies are published in

major medical journals that support the use of supplements for the treatment of specific conditions, prevention of diseases or for general nutritional enhancement. This is due, to an increasing extent, to funding from government agencies and offices, like ODS.

Examples of notable dietary supplement research include an article published in the *Journal of the American Medical Association (JAMA)*, where researchers concluded that every child and adult would benefit from taking vitamins daily [6]. A report in the journal *Nutrition* also recommended a daily vitamin for older adults, who often don't get proper nutrition from food [7]. These studies are particularly important because our research indicates that physicians often do not discuss supplementation with their older patients [8]. Other landmark studies include two published in *JAMA* relating to the delay and lessening of symptoms of Alzheimer's disease by patients who took the herb ginkgo and vitamins C and E [9, 10].

Not only has research demonstrated the health benefits of dietary supplements, it has also shown that they can reduce health-care costs by the billions of dollars. For instance, researchers at the University of California in San Francisco estimate that 310,000 fewer people would die from heart disease over a ten-year period if they ate folate-fortified foods and supplemented with B vitamins vs. eating only fortified foods [11]. Another study in a major medical journal reported that increased intakes of vitamin E, folic acid and zinc could save $20 billion annually in hospital costs by reducing heart disease, birth defects and premature death [12]. Another study published late last year that reported that if seniors took a multivitamin daily it could reduce health care costs by $1.6 billion annually [13]. Earlier I mentioned two studies showing the positive affect dietary supplements can have on Alzheimer's disease. This illness costs Americans $61 billion a year, in lost productivity from absenteeism of employees who care for family members with Alzheimer's and businesses that share health and long-term care costs [14]. Even a modest reduction in symptoms and delay of onset of this destructive disease can save billions of dollars.

Let me add that with Science increasingly validating the role dietary supplements play in maintaining health and preventing illness, that it makes sense that these products receive the same favorable IRS treatment as other recognized health expenses. To that end, we support passage of a bill introduced by Chairman Burton that would do just that, H.R. 2627, the Dietary Supplement Tax Fairness Act.

Additional Implementation and Enforcement

The FDA is not alone in enforcing and implementing DSHEA. The Federal Trade Commission also has regulatory authority over what supplement manufacturers can say about their products in advertising or on the Internet. For example, in recent years the FTC has invested substantial time and resources in cracking down on online supplement advertisers who disobey the law. While the industry applauds and supports these efforts, I would like to point out that supplements sold over the Internet account for only one percent of total dietary supplement sales. Attention paid to a small fraction of Internet supplement marketers who break the law is disproportionate to the actual problem. Nevertheless, the industry has been vocal in its support of the FTC's Internet sweeps and encourages their continuation.

In summary, DSHEA increased FDA enforcement authority to preserve consumer safety and mandated higher product standards. It also provided for more funding for supplement research that would validate their efficacy. The result is an increased ability by consumers to make informed personal health choices.

But to be effective, like any law, it needs to be implemented and enforced. The bottom line is that there is no issue with dietary supplements, be it quality, safety or efficacy, which cannot be addressed under the current regulatory and legal framework.

Finally, I will leave the Committee with three recommendations to improve the effectiveness of DSHEA. The first is to give the FDA the resources it needs to fully implement the law. This can be done through the appropriations process and through Passage of a new bill introduced in the Senate by Sens. Tom Harkin and Orrin Hatch, S. 1538, "The DSHEA Full Implementation and Enforcement Act." This bill would provide the FDA with the funding it needs to ensure that DSHEA is carried out as Congress intended. It would also increase funding for the National Institutes of Health's Office of Dietary Supplements. I understand that a companion bill is likely in the House and hope it you will support it.

The second is for the FDA to quickly finalize and begin enforcement of good manufacturing practices for dietary supplements. Although I believe the vast majority of dietary supplement manufacturers have implemented production procedures that meet or exceed what is currently required by law, a federal GMP regulation would bring all others into line, as well.

My final recommendation is this: Stop seeking legislative solutions to regulatory problems when it comes to DSHEA. Currently, there are six bills in Congress that will amend, augment or otherwise modify DSHEA in an attempt to fix perceived weaknesses in the law. Although we support the intent of some, I believe most would not have been introduced if the Food and Drug Administration had used its authority in a more timely manner to fully implement and enforce DSHEA.

* * * * *

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Mr. BURTON. Thank you, Mr. Seckman.

Ms. Dickinson.

Ms. DICKINSON. Thank you, Mr. Chairman. I am president of the Council for Responsible Nutrition, which is a trade association representing what we have referred to as the mainstream core of the dietary supplement industry, the products that are used by millions of Americans who purchase them through natural food stores, through the mass market, through direct sales and through mail order.

DSHEA was passed in 1994 because, in 1993, FDA had floated a notion that would have led to restriction of a number of dietary supplements, restricting dosage of vitamins and minerals, restricting herbs and botanicals and not permitting the sale of supplements containing amino acids.

DSHEA had two purposes: One was to assure consumers access to a wide variety of products. The other was to increase the information available to consumers about how to use those products. The growth of the market since the passage of DSHEA and, in fact, before the passage of DSHEA indicates that it was successful with regard to maintaining access to products.

With regard to access to information, one of the new tools that DSHEA provided for consumers were statements of nutritional support, also known as structure/function statements. To date, FDA has been fully implementing the requirement of the law regarding structure/function statements. There have been more than 10,000 letters of notification submitted to FDA for these statements, as required under DSHEA.

FDA has been reviewing those statements and has, in fact, sent courtesy letters back to about 10 percent of the notifiers indicating their claims actually went over into disease claims and, therefore, would not be permitted. So this is an area in which DSHEA is working, as it was intended.

It is sometimes forgotten that DSHEA also had an impact on nutrition labeling. At the time DSHEA was passed, FDA would have required nutrition labels for supplements to be basically the same as those for conventional foods, allowing them only to mention in the facts box, which you see on these products, vitamins, minerals and other macro nutrients; not allowing them to mention the identity of the herbs, the active components of those herbs or substances such as echinacea, substances such as SAMe, for example, that might have been in the product. DSHEA actually required FDA to revisit that nutritional labeling information and revise it so that it was appropriate for dietary supplements.

We have provided the committee with examples of a product that is made by one of our member companies, a product containing echinacea, which demonstrates not only the appropriateness of the nutrition label to this type of product but illustrates that this company, like many other companies in the industry, are going way beyond basic nutrition labeling and providing additional information to consumers.

This particular label opens out, if you pull this little red tab, and actually has a three-page little document inside, which was prepared by the company in conjunction with the American Botanical Council and provides more information on the safety, the benefits

and the research regarding this ingredient. This is an example of ways in which the industry is moving to increase consumer information about these products.

The Council for Responsible Nutrition took the lead in helping FDA develop good manufacturing practices. We organized a working group involving the other associations as well and submitted to FDA, within a year after DSHEA was passed, a draft document on GMPs, which has been working its way through the system and, as you indicate, is just now about to become final. And we are with you in full support of that.

The area of new ingredients is another area where FDA has, in fact, been implementing the law as it was intended, and it has been working effectively. Companies are required to notify FDA 75 days in advance about new ingredients that are marketed. FDA has been carefully reviewing those notifications and has, in fact, rejected approximately half of them because they either did not establish adequate information to demonstrate safety or because they did not provide sufficient information on the identity of the ingredient. This is an area we believe is working appropriately, but it needs more implementation yet.

One of the areas that we think need more attention, both from the industry and from FDA, is whether all of the companies that are supposed to be submitting these notices are in fact submitting them for certain ingredients or whether there are ingredients being marketed without these appropriate notices. This is an area that we would flag as requiring additional implementation.

During the time since DSHEA has passed, we have had two issues that have plagued both the industry and the FDA and that have led to an actual undermining, in our view, of consumer confidence in the entire category of dietary supplements. That has been our failure to resolve the ephedra issue during the years it has been pending and the absence of action restricting the marketing of Andro, which has led to ongoing controversy.

We are pleased in the Council for Responsible Nutrition that FDA has taken actions in the past few months that we believe are going to bring both those controversial issues to closure. And we are very hopeful that having brought these issues to closure, that we can move on to what should be our appropriate business, which is to provide more information to consumers about the safety and benefits of the wide variety of dietary supplements that are available, to assure that they are manufactured to high-quality standards and to ensure that the information about them, both in labeling and advertising, is truthful and not misleading.

We fully support FDA and FTC enforcement with regard to all of these requirements, because we do believe that safe and beneficial dietary supplements are an important and very positive component of a healthy lifestyle for Americans.

[The prepared statement of Ms. Dickinson follows:]

TESTIMONY for the March 24, 2004 HEARING:

"10 Years after the Implementation of DSHEA: The Status of Dietary Supplements in the United States"

Subcommittee on Human Rights and Wellness
Committee on Government Reform
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Hearing Testimony
"10 Years after the Implementation of DSHEA: The Status of Dietary Supplements in the United States"
Prepared by Annette Dickinson, President, Council for Responsible Nutrition

Mr. Chairman and members of the Committee, thank you for the opportunity to testify before the Committee on Government Reform, Subcommittee on Human Rights and Wellness - 10 Years After the Implementation of DSHEA: The Status of Dietary Supplements in the United States. My name is Annette Dickinson and I am the president of the Council for Responsible Nutrition (CRN).

CRN represents the mainstream core of the dietary supplement industry, including suppliers of dietary supplement ingredients as well as manufacturers and marketers of branded and private label products available to consumers through all distribution channels -- mass market, health food stores, mail order, and direct sales. CRN members adhere to a strong code of ethics, comply with dosage limits and manufacture dietary supplements to high quality standards under good manufacturing practices.

Introduction

The Dietary Supplement Health and Education Act was passed in 1994 for two primary reasons: to ensure that consumers would continue to have access to a wide variety of safe dietary supplements and to provide consumers with more information about the dietary supplements they purchase.

The past 10 years have demonstrated that these purposes are being fulfilled, as are other goals established by the law.

Access to Products

In 1993, FDA published an Advance Notice of Proposed Rulemaking suggesting numerous restrictions that might be placed on dietary supplements, including

- Limiting the dosage of vitamins and minerals to a small multiple of the RDA,
- Not permitting the sale of dietary supplements containing amino acids,
- Treating most herbs and botanicals as inherently therapeutic and restricting them to sale as drugs.

DSHEA was passed in part to avoid these arbitrary restrictions, by establishing a broad and specific definition listing several classes of permissible dietary supplement ingredients. Today, consumers have access to a wide variety of safe dietary supplements, and category sales have continued the steady rate of increase they have enjoyed since at least the 1970s. Thus, DSHEA has been successful in assuring broad consumer access.

Access to Information

In order to provide consumers with more information about the uses of dietary supplements, DSHEA permitted marketers to make Statements of Nutritional Support, including structure/function statements -- that is, statements describing how a product affects the structure or function of the body. These statements may be used in labeling, subject to the following provisions:

- The marketer must have substantiation that the statement is truthful and not misleading.
- FDA must be notified within 30 days that the statement is being made.

- The product label must include a disclaimer that distinguishes the statement from FDA-approved health claims and from FDA-approved drug claims.

Companies began using Statements of Nutritional Support as soon as DSHEA was passed, and FDA issued extensive rules on structure/function statements in January 2000. As of today, more than 10,000 letters of notification have been submitted to FDA, and the agency has responded to about 10% of the statements with "courtesy letters" advising companies that the claim submitted was not appropriate, either because FDA viewed it as a disease claim or because the product involved was not in fact a dietary supplement.

The ten most commonly utilized types of structure/function statements in the marketplace have to do with immune function, heart health, antioxidant effects, gastrointestinal function, healthy joints, cognitive function, men's health issues, weight loss or metabolism, energy or endurance, and women's health issues. Consumers have a vital interest in receiving more information about these topics, and DSHEA was successful in devising a means of providing that information in product labeling.

Nutrition Labeling

In its implementation of the Nutrition Labeling and Education Act, FDA initially proposed to require companies to label dietary supplements as though they were conventional foods. Under this proposal, herbal products for example would have been required to show the amount of protein, fat, and carbohydrate in the product, even though all three values would almost always be zero. Further, those herbal products would not

have been permitted to list any of their active components, but would have been required to show the amount of vitamins A and C and the amount of calcium and iron they contained. A product like glucosamine and chondroitin sulfate would have been subject to similar requirements. Since this approach would not have provided consumers with useful information about dietary supplements other than vitamin and mineral products, DSHEA required FDA to reconsider its approach to nutrition labeling for dietary supplements and to develop a more appropriate system. DSHEA further specified that the new system must permit the inclusion in the Facts Box of components other than vitamins and minerals.

FDA developed a revised approach, as required by DSHEA, and published final regulations on nutrition labeling for dietary supplements in September 1997. These regulations permit all relevant components to be listed in the "Supplement Facts" box, following the list of macronutrients and micronutrients, if any are present. Thus, DSHEA succeeded in the goal of creating a nutrition labeling format appropriate to the types of ingredients and components utilized in dietary supplements.

Good Manufacturing Practices

DSHEA authorized FDA to establish Good Manufacturing Practices (GMPs) for dietary supplements, modeled after GMP regulations for foods. Until such regulations are finalized, dietary supplements are subject to the same GMPs that apply to conventional foods. The Council for Responsible Nutrition (CRN) had earlier established GMP guidelines for its membership, and those GMPs had formed the basis for the guidelines adopted by the U.S. Pharmacopeia for nutritional supplements. After the

passage of DSHEA, CRN approached FDA officials and inquired whether they intended to establish dietary supplement GMPs. They indicated they would like to do so, but lacked in-house expertise and would appreciate input from the industry. CRN convened a working group to draft appropriate GMPs and invited other trade associations to join in this effort. In November 1995, just over a year after the passage of DSHEA, the trade associations submitted a comprehensive draft that FDA published in February 1997 as an Advance Notice of Proposed Rulemaking. The proposal languished until the current administration published an extensive and problematic Proposed Rule in March 2003. Numerous comments were submitted during the official comment period, and even after the comment period several trade associations continued to work toward GMP language that could be jointly supported. On January 30, 2004, CRN, the American Herbal Products Association, and the National Nutritional Foods Association submitted a joint proposal that included specific recommended language for the GMPs. This document was also endorsed by the Consumer Healthcare Products Association. FDA is currently evaluating all the comments and is expected to issue a final rule in the near future. The new GMPs will provide a strong framework for ensuring the purity, identity, quality, strength and composition of dietary supplements, and CRN is pleased to have been able to contribute to this outcome by getting the ball rolling in 1995 and by submitting extensive comments and participating in development of the joint submission in 2003 and 2004.

New Ingredients

DSHEA "grandfathered" dietary supplement ingredients already on the market as of October 1994, in the same way the 1958 food additive amendments to the Food, Drug and Cosmetic Act "grandfathered" hundreds of substances already being used in foods at the time those amendments were adopted. DSHEA established a procedure that would be required for new ingredients used in dietary supplements in the future. Companies are now required to provide a notification to FDA regarding any new ingredient at least 75 days before marketing it, setting forth the basis for considering the ingredient to be "reasonably expected to be safe." FDA has been receiving these notifications on a regular basis since the passage of DSHEA and has been giving them serious attention. A recent analysis by the American Herbal Products Association indicated that there have been 138 unique notifications filed, of which FDA has rejected 65, or almost half. The rejections are generally due to a company's failure to sufficiently establish the identity of the ingredient or a failure to provide sufficient information to provide a basis for concluding that the ingredient is reasonably expected to be safe.

Commission on Dietary Supplement Labels

DSHEA mandated the appointment by the President of a Commission on Dietary Supplement Labels, to provide advice to FDA on a number of issues. The Commission was appointed in 1995, met for a period of two years, and published its final report in November 1997. That report, unfortunately, has been largely ignored but it provides useful guidance that could still be helpful in defining, for example, the level of substantiation that should be required for structure/function statements. Among the seven

members of the Commission were two highly respected professors of nutrition (including the Chairman), the country's leading professor of pharmacognosy, a prominent professor of law who had previously served as an FDA counsel, and three persons directly or indirectly associated with the industry, including myself.

NIH Office of Dietary Supplements

DSHEA required the establishment within the National Institutes of Health of an Office of Dietary Supplements (ODS), to encourage additional research and to serve as a source of expertise for FDA on issues relating to dietary supplements. This year, under the leadership of Dr. Paul Coates, ODS has a budget of $20 million to support an aggressive research agenda relating to safety, benefits, and analytical methods. ODS also supports six botanical research centers at leading academic institutions and has sponsored numerous research conferences highlighting the evidence available regarding dietary supplements for specific populations such as women or the elderly or for particular purposes such as performance enhancement. Thus, DSHEA succeeded in creating a powerful mechanism within NIH for increasing research attention to dietary supplements and for engaging leading academic institutions in the task.

Problem Ingredients

The biggest problems for the industry in the decade since the passage of DSHEA are only two in number, but these two have led to criticism so widespread as to undermine consumer confidence in the dietary supplement category as a whole. These are:

- The failure to resolve the issues surrounding ephedra until just this year, and
- The absence of action restricting the marketing of steroid hormone precursors until just this year.

FDA has recently finalized a regulation declaring ephedra products to be adulterated, using new authority provided under DSHEA to declare a product adulterated if it poses a "significant or unreasonable" risk of illness or injury. A legal challenge has been filed against the rule, and the courts will soon decide whether FDA's rule is appropriate. Also, legislation has been introduced in both the Senate and the House that is expected to pass this year and that will classify androstenedione and a number of related substances as controlled substances. It is to be hoped that these actions will bring these issues to a resolution.

What Remains to be Done?

DSHEA brought about a meaningful change in the way dietary supplements were regulated. Dietary supplements have always been regulated as a subcategory of foods, and DSHEA reaffirmed the appropriateness of this classification, but within the food category specific provisions were created for dealing with the unique aspects of dietary supplement regulation. FDA has implemented some of the provisions of DSHEA through extensive regulations on nutrition labeling for dietary supplements, on structure/function statements used for dietary supplements, and on GMPs for dietary

supplements. It cannot be said, however, that DSHEA has been fully implemented as of this tenth year following its passage.

DSHEA requires that companies submit notifications before marketing new ingredients, and those notifications must include information about the safety of the ingredients. FDA has been evaluating these submissions in a meaningful way, but there is no indication that the agency is monitoring the marketplace to ensure that new ingredients are not introduced without the filing of such notifications. This is an area that needs additional attention.

DSHEA permits marketers to use structure/function statements to describe the effects of dietary supplements, but also requires the companies to have substantiation that the statements are truthful and not misleading. The industry and the agency need to pay more attention to establishing guidance about the kind of substantiation needed. The Commission on Dietary Supplement Labels suggested that the substantiation be made public, in order to provide health professionals and consumers with more information about the basis of the claims, and this is a proposal worthy of further consideration.

One serious remaining challenge for the industry and for FDA is to put a stop to the marketing of street-drug knockoffs masquerading as dietary supplements. The agency has taken a number of actions against such products, but no sooner is one challenged than another emerges. There is a need for the industry and the agency to develop a highly visible partnership to attack this problem, in order to protect young people from unscrupulous marketers.

It is to be ardently hoped that the industry's second decade under DSHEA will be more peaceful than the first. With a few very difficult issues now resolved or about to be

brought to closure, the industry should have an opportunity as it moves forward to focus on the good news about the safety and benefits of most dietary supplements as positive components of a healthy lifestyle.

Mr. BURTON. Thank you, Ms. Dickinson.

Mr. DUMOFF. Thank you, Mr. Chairman, members of the committee. My name is Alan Dumoff, and I am here on behalf of the American Association for Health Freedom. We appreciate this opportunity to present our views on DSHEA, 10 years after its enactment.

We would first like to take a brief moment to thank the chairman for his sponsorship and active support for H.R. 2085, the Access to Medical Treatment Act. This is legislation we strongly care about.

The AHF is composed of physicians, distributors and Americans dedicated to health freedom and access to the full range of health promotion and treatment options. The organization works toward a health care system which freely uses integrative therapies, including support for the 158 million consumers who want access to these products and information that will help them make constructive choices about their care. DSHEA is a vital part of that ability.

Since enactment of DSHEA, the AHF has had the opportunity to testify on DSHEA implementation issues, that you, Mr. Chairman, have already been willing to address. The AHF has also played a major role in trying to ensure that FDA regulatory interpretations comply with congressional intent. This effort has compelled us to take judicial action, starting with the Pearson v. Shalala matter. Since our successful outcome with Pearson, we have needed to challenge FDA's interpretation of allowed health claims in a number of other suits.

We agree with the FDA that the enforcement mechanisms for ensuring public safety available to them, for the most part, have and are working. We believe the problems are elsewhere. There are three specific matters we believe deserve the committee's attention and may be candidates for future congressional oversight or legislative action.

First, with regard to the FDA's proposed GMP regulations, our concern is that, after 10 years, the FDA does not have it right. It was our hope that, after 10 years, consumers would have the confidence that what is on the label is what is in the bottle. That was really the point for effective GMP regulations.

The FDA's delay is, in large part, due to its effort to apply pharmaceutical standards to the supplement industry, which has delayed this critical goal. This approach will have a severe impact on small manufacturers and distributors who cannot bear these overly stringent and unnecessary requirements.

While there is a 3-year implementation period for small companies, many of these requirements are ones they should never have to meet and cannot afford, such as batch testing or repetitive certificate-of-analysis requirements. The chilling effect of these excessive regulations would not only affect access to supplements but could cause lost businesses and lost jobs.

Second, we are concerned about the manner in which the FDA has entered this arena. While we recognize the FDA has a legitimate role to play in preventing misleading advertising, the standards applied by the FTC are different than the scheme Congress intended in enacting the DSHEA. These actions are creating confusion for manufacturers as to what claims can be made.

We applaud recent actions against marketers of Focus Factor and Seasilver, but the standards imposing these actions are based upon unreasonable levels of scientific evidence, such as their production of multi-center studies in which the advertised product itself must be tested rather than simply studies supporting the ingredients of which they are made. Such requirements have no scientific basis.

It appears as if the FTC is attempting not just to regulate advertising but to indirectly regulate the dietary supplement industry. Dietary supplement manufacturers that meet the standards of evidence, worked out over years of congressional and judicial action, should not have to meet an additional uncertain burden placed upon them by the FTC.

Third, we bring to the committee's attention concerns about the FDA's methods of implementing the Qualified Health Claims requirement under Pearson. The interim approach currently used has not been adequate to assess and inform consumers about the level of scientific support for a claim. There are two significant problems: First, FDA reviewers do not have the expertise in the fields of botanical and nutritional medicine to fairly and efficiently evaluate claims. And second, the juxtaposition of the manufacturer's claim with the FDA disclaimer creates a label you might consider bipolar. There is a glowing claim by the manufacturer countered by an up-to-date disclaimer that greatly limits it. And it reflects, perhaps, more the schism and the politics of dietary supplements than actual useful information for the consumers.

There are numerous claims, for example, the saw palmetto claim in the treatment of BPH for which the evidence is very clear to experts in the field. While the FDA review panel members are respected in their scientific endeavors, they lack the expertise in the arena to recognize where the evidence lie. The FDA should seek those with specific knowledge about these issues to expedite review of these claims.

While the evidence-based ranking system sounds promising, we suggest that the inclusion of scientists specifically experienced in these areas on supplements could better evaluate and tailor decisions and language that would be useful to consumers. Recently, H.R. 4004 was introduced, which we believe correctly addresses some of these issues.

In conclusion, I would like to comment that the prevailing FDA regulatory philosophy too often continues to seek to regulate supplements like drugs. We are opposed to any FDA regulatory or congressional legislative proposals to substantially change DSHEA in this fashion. Under one pending bill, H.R. 3377, our analysis shows that two-thirds of current dietary supplement products could be subject to FDA drug-like regulation, effectively repealing much of DSHEA.

When I was asked to testify, I recalled an interesting experience I had a few years ago when I was called to testify in Cairo at a conference on integrative medicine. It was cosponsored by WHO. Many of the speakers at that conference addressed methods of restricting access in countries in Europe and the Arabic states to access to dietary supplements.

I took the opportunity in my presentation to review the four decades of history in which consumers have repetitively asked Congress to restrict the FDA's ability to restrict their access to dietary supplements. It is important we remember this 10-year anniversary, the important choice for health freedom that DSHEA represents and how it reflects the U.S. experiment of freedom that is unique in the world.

Ten years after DSHEA, the law has greatly benefited millions of Americans. We appreciate the attention of the committee as well as this opportunity to express our views, and we welcome any questions.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Dumoff follows:]

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TEN YEARS AFTER THE IMPLEMENTATION OF DSHEA: THE STATUS OF DIETARY SUPPLEMENTS IN THE UNITED STATES

STATEMENT OF

ALAN DUMOFF, J.D., M.S.W.
AMERICAN ASSOCIATION FOR HEALTH FREEDOM

BEFORE THE SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS
COMMITTEE ON GOVERNMENT REFORM
US HOUSE OF REPRESENTATIVES

MARCH 24, 2004

Mr. Chairman and members of the committee, my name is Alan Dumoff and I am here on behalf of the American Association for Health Freedom (AAHF). We appreciate the opportunity to present our views on the implementation of the Dietary Supplement Health Education Act (DSHEA), and status of supplements ten years after its enactment.

We would also like to take this opportunity to thank the Chairman for his sponsorship and active support for H.R. 2085, the Access To Medical Treatment Act. This is legislation that we strongly care about.

The AAHF is composed of medical practioners, small distributors, and average Americans dedicated to ensuring medical choice freedoms and access to the full range of health promotion and medical treatment options. The organization works with other groups to achieve a health care system at the federal and state levels of government in which practitioners and citizens can freely use integrative medical therapies, including dietary supplements, without fear of recrimination, with the well being of patients foremost in mind.

Our physician members are seeing more and more patients seeking professional help with incorporating integrative complementary and alternative medical (CAM) treatment options, including the use of dietary supplements, into their lifestyles, and as medical treatment options for diseases or terminal illnesses for which conventional medical treatments have not worked. It is well recognized that there are 158 million consumers of dietary supplements in our country. Estimates also show that frustrated by the inability of mainstream medicine to meet all their health care expectations and needs, as many as 42 percent of Americans are adopting integrative medicine approaches to satisfy their health care needs.

Since enactment of DSHEA, and its subsequent execution by the Food and Drug Administration (FDA), the AAHF has had the opportunity to testify on DSHEA implementation issues that you, Mr. Chairman, have already been willing to address. The AAHF has played a major role in trying to ensure that FDA regulatory interpretations and decisions comply with the Congressional intent for the DSHEA. Aside from the normal regulatory participation avenues, the AAHF has, unfortunately, been compelled to go the route of federal judicial action, starting with *Pearson v. Shalala,* 64 F.3d 650 (D.C. Cir. 1999). Since the successful outcome with *Pearson*, we have also been compelled and have been successful in challenging the FDA's interpretation of allowed health claims for dietary supplements in a number of other DSHEA related federal suits. In general, these federal actions have been motivated by the FDA's efforts to limit the reach of *Pearson*, and refusal to recognize the changing scientific evidence and public demand for access to the therapeutic benefits of dietary supplements.

There have been many bumps in the road over the past ten years with the implementation of DSHEA. In our view, the FDA's intrinsic resistance to implementing the federal regulatory framework created by the DSHEA still requires the continuing oversight of the Congress. Medical practitioners and consumers are still wondering if the FDA has accepted the public's reasonable desire and the clear mandate of Congress that consumers have access to health information regarding dietary supplements. In our view, the answer too often has been no.

This is not to say that all of the FDA's DSHEA implementation actions have been misdirected. The enforcement mechanisms for ensuring the public safety of dietary supplements, available to the FDA under the DSHEA, for the most part, have and are working. There are three specific and one broad implementation matters we believe deserve the committee's attention. These may be candidates for future committee oversight or Congressional action. These are briefly discussed as follows.

Proposed FDA Good Manufacturing Practices Regulation

We support having a Good Manufacturing Practices (GMP) regulation on the books. After ten years, we would have hoped that consumers could have confidence that what's on the label is what's in the bottle. The FDA's effort to apply pharmaceutical standards to the supplement industry has delayed meeting this critical goal. As the FDA moves toward implementing GMPs, our concern is its severe impact on small manufacturers and distributors, who cannot bear these overly stringent and unnecessary requirements. The FDA's regulatory proposal does grant a three-year implementation period for small companies. However, the proposed mandated requirements, no matter how long the period is for a transition, are ones that many of our small distributor members simply cannot financially afford. Many of these provide specialty products that are simply unavailable from any other source. The FDA is essentially proposing to impose a pharmaceutical drug GMP model on small dietary supplement manufacturers and distributors. Options such as limiting the proposed GMP requirements to companies that produce high-risk products need to be explored further. The chilling effect of excessive FDA regulation would not only affects consumer access to supplements but also, in this case, lost jobs for hundreds if not thousands of Americans.

Federal Trade Commission Requirements Run Counter to the DSHEA

The responsibility for ensuring the validity of dietary supplement health claims under DSHEA rests with the FDA. Yet the FTC has actively imposed its own views about what health statements may be made in certain non-manufacturer sponsored commercial advertising venues that have included dietary supplements. While we recognize that the FTC has a legitimate role to play in preventing misleading advertising, the standards applied by the FTC are, however, sufficiently different from the scheme Congress intended in enacting the DSHEA. These actions have and are creating

confusion among manufacturers and representatives, and with commercial broadcasters, about what claims may be made. On the other hand, recent actions taken against the marketers of "Focus Factor," a dietary supplement purported to improve concentration, "V-Factor", a supplement purported to enhance sexual performance, and marketers of "Seasilver", a supplement purported to be clinically proven to treat or cure 650 diseases, including cancer and AIDS, in consumer "infomercials" should be applauded.

But, the standards imposed in these actions have set forth levels of scientific evidence, to the point that manufacturers are required to produce multi-center studies in which their product was used, rather than studies supporting the generic ingredients upon which they are based. There is no scientific basis for such requirements and the impression these actions give is that FTC is attempting, not just to regulate advertising, but also to regulate the content of information that can be available to consumers of dietary supplements. This is contrary to the intent of Congress that the industry be regulated under the standards of DSHEA. Dietary supplement manufacturers that meet the standards of evidence worked out over years of Congressional and judicial action should not have to meet an additional, and uncertain, burden placed upon them by the FTC. The result of this co-agency implementation problem has had a serious impact on helping to educate consumers.

The Struggle of the FDA to Properly Implement Qualified Health Claims Under *Pearson*

The FDA's response to the requirement in the *Pearson* case to develop a reasonable approach to qualified health claims occurred a year after the mandate. The interim approach has not been adequate to assess and inform consumers about the level of scientific support for a claim. There are two significant problems with the current interim FDA approach: (1) the FDA reviewers do not have the specialized expertise in the fields of botanical, herbal, and nutritional medicine to fairly and efficiently evaluate

claims; and (2) the juxtaposition of the manufacturer's claim with the FDA disclaimer creates a label that appears "bipolar", reflecting the schism in the politics of dietary supplements rather than useful information for the consumer.

For example, with regard to scientific review, there are numerous claims, such as saw palmetto in the treatment of benign prostatic hypertropthy (BPH), for which the evidence is very clear to experts in the field. But while the FDA review panel members are respected in their scientific endeavors, they lack the expertise in the area to recognize this. The FDA should seek the expertise of those with specific knowledge about these issues to expedite a knowledgeable review of the claims.

Secondly, glowing claims by manufacturers set next to language that "very limited and preliminary scientific research suggests . . . there is little scientific evidence for this claim" does not provide useful consumer information. Under a proposed FDA regulation, the agency is seeking to establish an "evidence-based ranking system." Under this system, the agency would review the science submitted in support of a claim, assesses the science and rank structure and function claims with a letter (A, B, C, or D) corresponding to the level of support for a supplement health claim. While this sounds promising, we continue to have concerns with the "evidenced based" approach being propositioned. In comments filed by the Federal Trade Commission (FTC) with the FDA on this proposed rule, the FTC's own consumer research suggested that consumers could distinguish between levels of scientific support for health claims. We are concerned and suggest that the inclusion of scientists experienced in the level of research could better evaluate and tailor decisions and language that would be useful to consumers.

Regulating Supplements Like Prescription Drugs

Taking a forward looking public policy point of view, we have had and continue to have concerns with the prevailing overall FDA regulatory philosophy toward dietary supplements. Almost since the beginning of DSHEA, the policy and legal positions of the FDA have been to regulate supplements more like prescription drugs. We are opposed to any FDA regulatory or Congressional legislative proposals to substantially change, if not repeal, DSHEA in this fashion. Doing so goes against the original intent of DSHEA. Doing so would lead to higher costs for consumers and/or patients wanting to help reduce health care costs by their own taking of responsibility for improving their health status and/or using less expensive and equally effective complementary and alternative integrative medical treatment options.

Adopting this approach, either by federal administrative law or via federal legislation is not needed. Under one pending Congressional bill, H.R. 3377, our analysis shows that two-thirds of current dietary supplement products could be subject to FDA prescription drug like regulation. If enacted, it could effectively repeal two-thirds of the DSHEA. To paraphrase a slogan used on a civil rights discrimination issue during the Clinton Administration, there may be implementation problems with DSHEA, but Congress should "Amend it, and not end it".

Finally, when I was asked to testify, I recalled an incredible experience I had at a meeting co-sponsored by the World Health Organization (WHO) at a conference on integrative medicine. I discovered that many of the international speakers addressed methods of restricting access to dietary supplements. I took the opportunity to describe the history of efforts by the FDA to restrict reasonable access to dietary supplements - restrictions rejected by U.S. consumers who have clearly voiced their desire to make their own choices in this regard. These voices have been heeded by Congress in the DSHEA. It is important that we remember and maintain the important

choice for health freedom that the DSHEA represents, and how it reflects the U.S. experiment in freedom that is unique in the world.

Ten years after DSHEA, the law has, in our view, greatly benefited millions of Americans who use supplements on a regular basis, and Americans seeking professional help with integrating complementary and alternative medical treatment options, including the use of dietary supplements, into their lifestyles and as part of medical treatment options. We realize that these are complex issues. We believe that they deserve consideration in light of all of the known and published scientific evidence and advances taking place in the day-to-day use of integrative medical treatment alternatives and growing public demand.

Again, thank you for the opportunity to express our views on DSHEA implementation. We hope that we have been able to highlight our public policy concerns. I would welcome any questions members of the committee may have.

Mr. BURTON. Thank you, Mr. Dumoff.

Mr. Rose.

Mr. ROSE. Mr. Chairman, members of the committee, thank you very much for the privilege and the honor to speak with you here this morning.

My name is Doug Rose. My wife, Michelle, joins me today.

Thank you, Michelle.

I am president of Irwin R. Rose & Co., Inc. We are an Indianapolis, IN, based commercial real estate firm. We specialize in multifamily housing, own and manage apartment communities across a five-state region. We have no financial interest in the dietary supplement industry. We do not receive any Government grants or funding. We are here at our own expense.

We have an interest in supplements because they have been shown conclusively to prevent some of the most severe birth defects faced by children. We are the proud parents of two daughters. Our youngest daughter, Emily, age 4, was diagnosed at birth with permanent birth defects. She was diagnosed with a condition called achondroplasia, which if you are like me, I did not know what that was. It is a form of dwarfism.

Fortunately, medical science knows quite a bit about her condition. However, the prevention science is not in place or anywhere near discovery.

Fortunately, that is not the case with two of the most severe and common birth defects seen in America and across the world. And I am speaking of spina bifida and anencephaly. My family knows firsthand how the birth of a child with a permanent birth defect is a life-altering experience that should not occur if it can be prevented. A family without a child with birth defects is a family helped.

We are interested in seeing our country declare war on birth defects and conduct the research and implement prevention programs so that not a single baby anywhere develops any birth defects.

Since our daughter was born, we have learned that folic acid, a simple B vitamin that is in multivitamin supplement pills, has been proven in randomized controlled trials to prevent two of the most common and severe birth defects, spina bifida and anencephaly. This has been known since 1991.

In the mid 1970's, FDA regulations permitted multivitamins in servings of cold breakfast cereals to have 400 micrograms of B vitamin folic acid in them. Americans who consumed these products have had many fewer babies develop birth defects, and they themselves have been reported to have less cancer and less cardiovascular disease.

The U.S. Public Health Service, including the Centers for Disease Control and Prevention and the Food and Drug Administration, recommended in the summer of 1992 that all women assume 400 micrograms of folic acid a day to reduce the risk of birth defects. In 1998, the Institute of Medicine clarified by recommending that all women capable of pregnancy consume 400 micrograms of synthetic folic acid a day. The FDA required, beginning on January 1, 1998, that synthetic folic acid be added to all enriched grain products at a rate that would add 100 micrograms to the average woman's diet.

The folic acid fortification of enriched grains has been remarkably successful. It has raised blood folics, and it has prevented approximately 1,000 of the 4,000 cases of spina bifida or anencephaly that develop each year in this country. Recently presented research from the Centers for Disease Control and Prevention suggests that the fortifications may have also prevented, each year, 50,000 fewer people dying from heart attacks and strokes.

In spite of this significant progress, much work remains to be done. The current estimate is that if folic acid fortification were increased to the levels that CDC, the American Academy of Pediatrics and the March of Dimes recommended, then nearly two to three times as many birth defects could be prevented. The FDA has shown no indication that it will be requiring more folic acid be put into enriched grain products. Thus, if we are to prevent all folic acid birth defects that are preventable, we must find additional ways to get American women capable of becoming pregnant to consume at least 400 micrograms of synthetic folic acid recommended by authoritative sources.

Furthermore, the FDA should raise the concentration of folic acid currently required in enriched grain products by 150 percent, to the level that the CDC, the American Academy of Pediatrics, the March of Dimes, the Spina Bifida Association of America, the Teratology Society, and other organizations have recommended. If we are to prevent all of the folic-acid-preventable birth defects that we can prevent, this change in the FDA regulation is a necessary complement to the proposed CDC program.

There are two current ways and a third way in progress that can increase the amount of folic acid women consume. Vitamin supplement pills with 400 micrograms are widely available in the usual multivitamin and in the servings of a large number of breakfast cereals. With respect to multivitamins, I want to point out that if you were to go to your neighborhood chain drugstore or to one of the large discount stores—and I won't name any—you can purchase a year's supply of multivitamins containing the daily recommended dose of synthetic folic acid, 400 micrograms, generic product, for approximately $7, for a 1-year's supply. I have checked it. I have shopped. And that is equivalent to about 2 cents a day for women to receive the full prevention benefits afforded by this vitamin supplement.

Now, if you contrast that with, for example, Mr. Chairman, Wishard Hospital's cost, which is the public hospital in our community, to treat one spina bifida baby, it is remarkable. And it is why my wife and I are here, because there are babies in Indiana and across the United States and around the world that are being born with birth defects that could be prevented, that should have been prevented.

Since 1991, Mr. Chairman, 3,000 to 4,000 babies a year in the United States have been born with spina bifida or were diagnosed with anencephaly, which results in certain death. These figures do not take into account the number of voluntary terminations of pregnancies that result from prenatal diagnoses of these conditions.

So these are pro-family issues. These are issues that I believe can make a substantial contribution to public health in America, and I salute you, Mr. Chairman, and your colleagues on the sub-

committee for your leadership in these areas and in public health in general.

Access to multivitamin products in the last 40 years has prevented thousands of American families from having children with severe birth defects and is likely to have prevented tens of thousands of adults from dying of heart attacks, strokes, and colon cancer.

Johnson & Johnson are working with the FDA to bring oral contraceptive products to market that will include 400 micrograms of folic acid so that women will not need to take two pills. I was struck when I found out that there are approximately a million women in America who become pregnant each year while taking oral contraceptives or within the first 3 months of having stopped taking oral contraceptives. And the studies have shown that this group of women are the most likely not to be receiving the daily recommended requirement of B vitamin folic acid to receive the full prevention benefits.

So it is our hope that not only will Johnson & Johnson be able to bring their product to market expeditiously, but we would hope that FDA will require all oral contraceptives to contain folic acid. This is, I think, an ingenious delivery system for the prevention benefits. Perhaps the committee can help see that these products get to market more rapidly.

According to the March of Dimes' supported Gallop polls, only 30 percent of American women of reproductive age consume enough folic acid. It is critical, of course, that vitamin supplements and breakfast cereals sold in this country continue to have 400 micrograms of folic acid in a pill or in a serving. Given that it has been nearly 13 years since science proved that folic acid will prevent severe birth defects and given that only 30 percent of our young women are adequately protected from having a baby with these birth defects, there must be better programs implemented to increase the proportion of young women consuming enough folic acid.

The Centers for Disease Control and Prevention would be the agency to lead the campaign for the total prevention of folic-acid-preventable birth defects. So far, their appropriations have fallen far short of what is needed to get the job done. As I understand it, it would take approximately $2 million a year per State to implement successful education programs or a national program requiring $100 million. Currently, the CDC spends less than $10 million on folic-acid-prevention programs each year.

While I know this is not an appropriation hearing, I trust that you can encourage your colleagues on the Committee on Appropriations to increase CDC appropriations to this level to build an effective program that will prevent all folic-acid-preventable birth defects. With the necessary resources, CDC, working with the supplement industry, can substantially increase the likelihood that our babies will not develop preventable birth defects.

Mr. Chairman and members of the subcommittee, I want to thank you for your attention to this matter and your leadership on public health issues. This concludes my statement. I would be happy to answer any questions.

[The prepared statement of Mr. Rose follows:]

ORAL STATEMENT OF: DOUGLAS C. ROSE

CONGRESS OF THE UNITED STATES -HOUSE OF REPRESENTATIVES

COMMITTEE ON GOVERNMENT REFORM

"10 Years after the Implementation of DSHEA: The Status of Dietary Supplements in the United States."

March 24, 2004, at 10:00A.M.
2154 Rayburn House Office Building

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TESTIMONY OF DOUGLAS C. ROSE:

Mr. Chairman, Members of the Committee, thank you very much for the privilege and honor to address this committee today.

My name is Doug Rose. My wife, Michelle, joins me today. I am President of Irwin R. Rose & Co., Inc., an Indianapolis, Indiana based commercial real estate firm. We own and operate multi-family apartment communities, operating in five states. We have no financial interest in the dietary supplement industry. We do not receive any government grants or funding. We have an interest in supplements because they have been shown to prevent some of the most severe birth defects.

We are the proud parents of a daughter who was born with birth defects. Our youngest daughter, Emily, age 4, was diagnosed at birth with achondroplasia, a form of dwarfism, which is a birth defect caused by a genetic mutation. While medical science knows a great deal about her condition, it is not yet known how to prevent her condition. Fortunately, this is not the case, as it relates to two of the most common, and devastating birth defects… spina bifida, and anencephaly.

My family knows how the birth of a child with a permanent birth defect is a life altering experience that should not occur if it could be prevented. A family with a child, without birth defects, is a family helped. We are interested

in seeing our country declare war on birth defects, and conduct the research and implement prevention programs so that not a single baby anywhere develops any birth defects.

Since our daughter was born, we have learned that folic acid, a simple B vitamin that is in multivitamin supplement pills, has been proven in randomized controlled trials, to prevent two of the most common and severe birth defects—spina bifida and anencephaly. This has been known since 1991. In the mid 1970s, FDA regulations permitted multivitamins and servings of cold breakfast cereals to have 400 micrograms of folic acid in them. Americans who consumed these products had many fewer babies develop birth defects and they themselves have been reported to have less cancer and less cardiovascular disease.

The United States Public Health Service, including the Centers for Disease Control and Prevention and the Food and Drug Administration recommended in summer of 1992 that all women consume 400 micrograms of folic acid a day to reduce the risk of birth defects. In 1998, the Institute of Medicine clarified by recommending that all women capable of pregnancy consume 400 micrograms of synthetic folic acid a day. The FDA required, beginning on January 1, 1998, that synthetic folic acid be added to all "enriched" grain products at a rate that would add 100 micrograms to the average woman's diet.

The folic acid fortification of enriched grains has been remarkably successful. It has raised blood folates and has

prevented about 1000 of the 4000 cases of spina bifida or anencephaly that develop each year in this country. Recently presented research from CDC suggests that the fortifications may have also prevented each year 50,000 fewer people from dying from heart attacks and strokes.

In spite of the progress, we still have more work to do. The current estimate is that if folic acid fortification were increased to the levels that CDC, the American Academy of Pediatrics, the March of Dimes recommended, then nearly two to three times as many birth defects could be prevented. The FDA has shown no indication that it will be requiring more folic acid to be put into enriched grain products. Thus, if we are to prevent all the folic acid birth defects that are preventable, we must find additional ways to get American women capable of becoming pregnant to consume at least the 400 micrograms of synthetic folic acid recommended by authoritative sources.

The FDA should raise the concentration of folic acid currently required in enriched grain products by 150%-- to the level that the CDC, the American Academy of Pediatrics, the March of Dimes, the Spina Bifida Association of America, the Teratology Society and other organizations have recommended. If we are to prevent all the folic acid-preventable birth defects that we can prevent, this change in the FDA regulation is a necessary complement to the proposed CDC program.

There are two current ways, and a third way in progress, that can increase the amount of folic acid women consume.

Vitamin supplement pills with 400 micrograms are widely available in the usual multivitamin and in the servings of a large number of breakfast cereals. Supplements with 400 micrograms of synthetic folic acid should be readily available to Americans as multivitamin or single vitamin supplements and in single servings of cold breakfast cereal. Access to these products in the last 40 years has prevented thousands of American families from having children with severe birth defects and is likely to have prevented tens of thousands of adults from dying of heart attacks, strokes and colon cancer.

Johnson and Johnson are working with FDA to bring oral contraceptive products to market that will include 400 micrograms of folic acid so that women will not need to take two pills. I hope that this product is on an expedited path as it could almost instantaneously result in 20 million American women consuming the recommended amount of folic acid. Perhaps the committee can help see that these products get to the market rapidly.

According to the March of Dimes supported Gallup poles, only 30% of American women of reproductive age consume enough folic acid. It is critical, of course, that vitamin supplements and breakfast cereals sold in this country continue to have 400 micrograms of folic acid in a pill or a serving. Given that it has been nearly 13 years since science proved that folic acid will prevent severe birth defects and given that only 30% of our young women are adequately protected from having a baby with these birth defects, there must be better programs implemented to

increase the proportion of young women consuming enough folic acid. The Centers for Disease Control and Prevention would be the agency to lead the campaign for the total prevention of folic acid-preventable birth defects. So far their appropriations have fallen far short of what is needed to get the job done. As I understand it, it would take about $2.0 million a year, per state, to implement successful programs or a national program requiring $100 million. Currently the CDC spends less than $10.0 million on folic acid prevention programs. While I know this is not an appropriation hearing, I trust that you can encourage your colleagues on the appropriations committee to increase CDC's appropriations to this level, to build an effective program that will prevent all folic acid preventable birth defects. With the necessary resources, CDC, working with the supplement industry, can substantially increase the likelihood that that our babies will not develop preventable birth defects.

Mr. Chairman, thank you for the Committee's attention and interest. I would be happy to answer any questions.

Mr. BURTON. Let me start with you, Mr. Rose.

You know, my grandson became autistic after having nine shots in 1 day, seven of which contained mercury, and I was not even aware of what autism was until that happened. Evidently, you and your wife have experienced a similar situation with your daughter.

Mr. ROSE. Yes, sir.

Mr. BURTON. I guess it was when your daughter was born and you realized that folic acid and other supplements could have prevented a lot of these other childhood problems. So you are to be commended. I just wish we all knew about these things before they occurred.

What I would like to do is—and I would be happy and I hope I will get my colleagues to join me in writing a letter not only to CDC but FDA with the recommendations you have made regarding folic acid. So we want to do that and ask them to try to include this, I think you said the birth control pills and anything else that will help.

As far as the advertising is concerned and the budgetary concerns you mentioned, this is probably not the best year to start asking for more money, but at least, we can talk to our health agencies about that. They get billions of dollars anyhow, and they can move that money around without an additional supplemental appropriation. So we will do that.

What I would like to do is to have the high points of his testimony put into a letter to both the CDC and the FDA.

Mr. ROSE. May I make one more comment, Mr. Chairman?

Mr. BURTON. Sure.

Mr. ROSE. I was working on this issue during the last Congress, and during the last Congress, the Senate Committee on Agriculture passed language which amended the Food Stamp Act for the first time. That amended language would have permitted food-stamp recipients to purchase multivitamin products containing folic acid. That language was omitted from the bill in conference, and I believe this is something that could be handled by administrative order in the Department of Agriculture. But it seems to me to be most unjust that poor Americans are denied these prevention benefits.

Mr. BURTON. Well, Doug, I have sponsored legislation that would do essentially the same thing, that would allow people to be able to get these supplements that are necessary through some assistance.

Mr. ROSE. Thank you, sir.

Mr. BURTON. So we will check that. We will check that out. And make a note to talk to them about that food stamp as well.

Dr. Micozzi, in your testimony, you cited a 2002 article in the Journal of the American Medical Association on vitamins for chronic disease prevention in adults. Can you tell me a little more about that article? I am not familiar with that.

Mr. MICOZZI. The article was by a group of investigators at Harvard, the Nutritional Epidemiology Program, which is led by Walt Willet there, and it was Fairfield and Fletcher who wrote the article.

They basically surveyed the biological evidence regarding optimal levels of a whole series of nutrients relative to a typical dietary in-

take, pointing out that the information that we use for recommended daily allowances is really to avoid deficiency states, to avoid the nutritional deficiencies that have been well documented medically.

We have been learning in scientific research that optimal levels of nutrients for the prevention of disease are higher than are usually reflected in the recommended daily allowances. So their main point of the article was to summarize the evidence that has accumulated now to show that Americans really should, for many nutrients, have higher intakes than are presently reflected in the RDAs.

Mr. BURTON. We have had a lot of people say that there is no direct link between dietary supplements and the well-being of Americans. Does that article or any information that you have indicate to the contrary?

Mr. MICOZZI. To me, Mr. Chairman, that article in the Journal of the American Medical Association, because of its breadth and scope, its publication in a leading medical journal that reaches American medical practitioners, its origin from a distinguished group of investigators at the Harvard Nutritional Epidemiology Program, all those things together, to me, marked it as a somewhat seminal event in mustering the evidence, where certainly those who read the article in the medical profession can no longer say that Americans cannot benefit from dietary supplementation.

Mr. BURTON. Mr. Seckman, in 1994, NNFA supported DSHEA, and I think you have already addressed this question, the FDA has not really been on the ball in getting that thing implemented. With their new director, do you think they are moving rapidly enough now?

Mr. SECKMAN. We think under Commissioner McClellan, who recently just left the FDA and moved over to a different agency under HHS, we think under his leadership in the last 18 months we did see very much progress. He took on the issue of ephedra and dealt with that. He also got the long-awaited GMP regulations out. So we see the agency in the last 18 months headed in the right direction with the implementation that was mandated in 1994.

Mr. BURTON. Well, if there are additional things we can do to speed up the process, to make sure that DSHEA is fully implemented, I wish you would let me know about it. Because there are a number of pieces of legislation that would alter DSHEA, as you know, and that is one of the things we have talked about in the past.

If we can make sure that everybody in Congress knows that everything is being done by FDA to fully implement DSHEA, that would probably discourage a lot of that legislation because they would see it is not necessary.

So we need to know what kind of progress is being made over there, and on a day-to-day basis, I cannot keep up with it. So I need you guys to keep us informed.

Mr. SECKMAN. We will do so. And that is why I mentioned in my testimony Senate bill 1538, which, as you indicated, this might not be a good year for additional appropriations. Although with the additional appropriations to the FDA to actually implement DSHEA, it specifically spelled out that the FDA would have to report back

to Congress on their schedule of the implementations of the act itself.

Mr. BURTON. Well, like I said before, our health agencies are getting billions and billions and billions of dollars. You could move that money around in a lot of ways. I am not sure an additional appropriation is necessary. We just need to have them prioritize a little bit differently.

Ms. Dickinson, as a representative of the mainstream core of the dietary supplement industry, how has DSHEA affected your council, the implementation of it or the lack of implementation of it affected your council?

Ms. DICKINSON. The lack of implementation of DSHEA, I think, has put a cloud over the entire industry. We feel that the ongoing problems that we have had over the last 10 years in resolving some of the issues that we recognize to be very troublesome issues have led to the impression that FDA cannot act.

So we are very pleased, and I share with Mr. Seckman the view that, under the leadership of Commissioner McClellan, FDA has made a commitment to act, has in fact been acting and we feel that is to the benefit of both consumers and the industry, because it demonstrates that the appropriate regulation can work when FDA decides to make it work.

We believe that, once FDA has started down this track, that Dr. Crawford and others, who will still be there leading the agency after Dr. McClellan leaves, we hope and expect that they will continue on that track.

Mr. BURTON. Well, I'm glad to hear that Dr. McClellan has done some positive things over there. We had a little difficulty getting him to testify before Congress, but I think that issue has finally been resolved.

Mrs. Davis, do you have some questions?

Mrs. DAVIS OF CALIFORNIA. Thank you, Mr. Chairman, I appreciate all of you being here. I wonder if we could talk a little bit more about the self-policing issue. Because one of the things you suggested—and I think Mr. Seckman was critical of the FDA because they did not act sooner, and yet in many ways the legislation left it up to the industry to self-police. But we know that they did not do that or we would have had adverse event reports that had been reported to the FDA.

Could you share with me, then, why do you think they should have acted sooner? On what basis would they have acted?

Mr. SECKMAN. I think it is required under the act. There is a new dietary ingredient provision in there for any new dietary ingredients that were not grandfathered in prior to 1994. So, in fact, the FDA, I think, on that has indicated there has been about 190 new dietary ingredient submissions in that time where they have gone ahead and made some kind of action.

On the existing products out there, it is up to the FDA to make their prioritization on products like ephedra, where they had a proposed rule, I believe in 1997, on some requirements to come to closure on that. Commissioner McClellan finally did take some sort of action on that.

So they have the authority, clearly, and they have indicated that, to take action on products if they so choose. And I think that is up to the agency to go ahead and make those kinds of determinations.

Mrs. DAVIS OF CALIFORNIA. Can we count on the industry, then, to basically self-police, to be sure that those adverse event reports get to the industry? And I am talking more about really the weight-loss supplements or those supplements that people take to get more energy, not necessarily going as far as steroids, but some of the other ingredients that we are aware of, because that really did not work before.

Ms. DICKINSON. The industry recognizes the need for an improvement in the adverse event reporting system and is interested in working both with Congress and with FDA to develop a system that is appropriate for this category.

I think it is important to recognize, though, that the long period that it took FDA to act on this was not for lack of information and was not for lack of adverse event reports that it began to receive actually as early as 1992.

I would even suggest, and I know it is a controversial thing to suggest, that the adverse event reports that were obtained from Metabolife, as offended as everybody is by the fact they said they didn't have them and then they had an awful lot, I think substantively the information in those adverse event reports did not add a lot to the information the FDA already had from the adverse event reports it had received.

I think we have seen in other areas, for example, with FDA's action against GHB, that when they receive adverse event reports that have a very clear signal, they have, in the past, been able to act very quickly on those events and did appropriately act.

I think the situation with ephedra indicates, in fact their current action is based on scientific information, the adverse event reports that they had even quite a long time ago and the known pharmacology of ephedra, all of which information was available to them before now.

So I would not blame the failure of adverse event reporting or mandatory adverse event reporting for the delay. Yes, a company, a responsible company should be reporting serious adverse events. Yes, it may add to the volume of reports FDA receives.

But in terms of the meaningful information to be drawn from those reports, I believe FDA had that information and has had it for some time.

Mrs. DAVIS OF CALIFORNIA. Is the industry encouraging companies, then, to produce those adverse event reports?

Ms. DICKINSON. As you well know, under the food provisions of the act, companies are not required to submit adverse event reports, even serious adverse event reports, either for foods or for supplements or for OTC drugs that are subject to monograph approval. So supplements are not the only area where adverse event reporting is not mandatory.

We do recognize that, because of this ephedra event and because of other events surrounding our industry, we are under extra pressure to do that, and we have made a determination to support mandatory adverse event reporting. The devil is in the details, as you well know, about exactly how that system is going to operate.

Mrs. DAVIS OF CALIFORNIA. So you are saying that you are supporting the mandatory reporting?

Ms. DICKINSON. We are in support of mandatory adverse event reporting. We have not yet reached, and I do not think anyone has reached, the full picture of what the details are that would surround that system.

We are also exploring with some poison control centers some alternatives that would involve a voluntary system.

Mrs. DAVIS OF CALIFORNIA. Thank you, I appreciate that.

Mr. Chairman, I just wanted to make certain that people understood I am not personally here to restrict access to vitamins or minerals. I think that is important, that people have access to those.

What is really critical is that they have good information about it. So I look forward to working with the industry on that.

I just wanted to make it clear, as well, that I think that Mr. Dumoff's testimony suggested that, in the legislation H.R. 3377, that, in fact, what we are trying to do is regulate supplements like prescription drugs. And I hope you will take another look at that legislation and tell me where you think that is there, because that is certainly not the intent.

I do not think you can read that into the legislation. What is a part of that, of course, is the forwarding of adverse event reports.

That is what we are interested in, and I appreciate the fact that the industry also sees that there is a need to do that. And we look forward to working with them on that.

Mr. DUMOFF. Thank you for that comment. We certainly look forward to having that conversation with you.

Mrs. DAVIS OF CALIFORNIA. Great. Thank you.

Thank you, Mr. Chairman. One further comment.

Mr. BURTON. Sure.

Mrs. DAVIS OF CALIFORNIA. I know that Dr. Brackett mentioned that there had been an effort to reach out to the community, to reach out to the supplement community and to get some information so that they could promulgate their regulations. I wonder if it's possible to get some more detailed information from him about that outreach so we can understand fully who all was involved in that and whether in fact there are other medical groups or other consumer groups that might have been contacted as well.

Mr. BURTON. I do not know to whom you are addressing that, but, David, could we get information like that? We would like to have it, if we can get it.

Mr. SECKMAN. I think we could help you get that information, yes.

Mrs. DAVIS OF CALIFORNIA. Thank you very much.

Mr. BURTON. One more thing I want to ask you, Mr. Seckman, David, is, you quoted some statistics there that I think are not widely known. Can you go through those real quickly one more time?

For instance, ibuprofen, I take that all the time because I get terrible headaches and backaches. At my age, those things happen.

Don't laugh at me out there, young lady.

Mr. SECKMAN. Ibuprofen is responsible for more than 17,000 deaths annually.

Mr. BURTON. 17,000 deaths annually.

Mr. SECKMAN. Right. Prescription medications are among the top five leading causes of death, about 106,000 annually.

Mr. BURTON. And I take Lipitor, and they check my liver every 3 months to make sure I don't have liver damage.

So I guess, the one point I would like to make is that the supplement industry has had so few, comparatively speaking, adverse events compared to what we do on a daily basis regarding ibuprofen. And people die from aspirin and Lipitor and Zocor, and all the other things we take, atenolol for our blood pressure and all those things. I am mentioning some of the things I take from time to time.

So I think you need to keep that in perspective. There is no question DSHEA needs to be fully implemented and that the health agencies need to be vigilant in making sure that we don't have supplements causing people severe side effects. But any time you put something in your body, whether it is too many tomatoes, so you get rashes, you are going to run the risk of some kind of problem like that.

Anyhow, thank you very much to this panel, we really appreciate it.

We stand adjourned.

[Whereupon, at 11:57 a.m., the subcommittee was adjourned.]

[The prepared statement of Hon. Elijah E. Cummings follows:]

Statement of Congressman Elijah E. Cummings
House Government Reform
Subcommittee on Human Rights and Wellness Hearing
On
"10 Years After the Implementation of DSHEA: The Status of Dietary Supplements in the United States"
March 24, 2004 at 10:00 a.m.

Thank you, Mr. Chairman for holding this hearing to consider Federal government research and implementation of the Dietary Supplement Health Education Act (DSHEA) of 1994 (Public Law 103-417).

DSHEA was implemented ten years ago in an effort to fully define dietary supplements and dietary ingredients. Before its passage, this legislation, dietary supplements were given the same pre-market safety evaluations as food ingredients. DSHEA outlined new rules specific to diet supplements, and more importantly, it established a framework for assuring product safety through the use of labeling as well as a process for determining whether a product is safe for consumption.

Today, many medical doctors in the United States often advise their patients to incorporate dietary supplements into their health regimen, as credible scientific study has shown that these supplements can promote wellness.

However, there have been several alerts issued by the Food and Drug Administration (FDA) on dietary supplements since the enactment of DSHEA. Most recently in December 2003, the FDA ban on ephedra (a supplement used in many weight loss and energy booster supplements), reportedly caused severe adverse reactions, such as deaths, heart attacks and strokes. These alerts are important and further measures must be undertaken to ensure that users of dietary supplements understand the risks associated with specific supplements through proper labeling and alerts when necessary.

For example, recently preliminary research has shown that, dietary supplements, such as Black Cohosh, which has been shown to relieve menopausal symptoms, may also increase the risk of breast cancer metastasis and liver failure. It is important to American women, that the FDA investigate and properly address these serious concerns through proper labeling. The DSHEA has opened the door for this type of enforcement through its ten-year strategic plan for regulation of dietary supplements.

I am eager to hear of the challenges and successes the FDA has had in its implementation of this law. The provisions the FDA plans to address:

safety, labeling, definition of product categories, enforcement, science-based decision-making, and stakeholder outreach, along with its joint work with the Academy of Sciences to study a protocol for reviewing supplement safety, should provide much greater health assurances for American consumers.

I look forward to hearing from today's witnesses as they discuss the impact of this law. Once again, thank you Mr. Chairman for holding this hearing.

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