

REGULATION OF DIETARY SUPPLEMENTS

HEARING

BEFORE THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

OCTOBER 28, 2003

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

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REGULATION OF DIETARY SUPPLEMENTS

TUESDAY, OCTOBER 28, 2003

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Committee met, pursuant to notice, at 9:30 a.m. in room SR-253, Russell Senate Office Building, Hon. John McCain, Chairman of the Committee, presiding.

OPENING STATEMENT OF HON. JOHN MCCAIN, U.S. SENATOR FROM ARIZONA

The CHAIRMAN. Good morning. I want to thank the witnesses for appearing before the Committee today, especially those who made special arrangements to be here.

The purpose of this hearing is to examine whether the current regulation of dietary supplements adequately informs and protects American consumers from the potential adverse health risks associated with the use of certain supplements. Dietary supplements, as the witnesses can attest, are readily available, from the malls to the Internet, to consumers of all ages, and often are promoted with questionable marketing practices.

I joined many of my colleagues, in 1994, in supporting the Dietary Supplements Health and Education Act, DSHEA, or “the Act.” The intent of the Act was to alleviate certain unnecessary pre-market approval regulations on vitamins, minerals, and herbs which are considered safe supplements to the human diet. At that time, the objective was to strike a balance between providing consumers with better access to supplements that could be used to improve their health, on the one hand, and maintaining minimum health and safety protection for such consumers, on the other.

While it is true that DSHEA succeeded in freeing many safe and useful supplements from unnecessary regulations, it is equally true that the Act appears to have provided a safe haven for substances that many experts believe pose potentially serious health risks. Of particular concern to many is the heavy use of supplements among teenagers.

A 2001 national survey of 785 teens by Blue Cross/Blue Shield estimated that of the one million American children between 12 to 17 years of age, roughly 4 percent of that age group take at least one performance-enhancing sports supplement. Members of school sports teams appear particularly vulnerable to the lure of performance-enhancing dietary supplements. For example, a 2001 study of 1,102 high school athletes in Westchester County, New York, found that 44 percent of the seniors, nearly all boys, had tried creatine.

This is not surprising, given that the supplement manufacturers appeared to target adolescent users through the use of enticing teen-friendly product names that incorporate terms like “extreme” and “Gen-X”.

While the long-term health consequences from the use of certain supplements are unknown, health experts warn that dietary supplements such as steroid precursors interfere with normal growth and bone development, cause hormonal imbalances, liver and kidney damage, and an increased risk of certain types of cancer. In fact, there is increasing concern in the medical community that today’s use of certain supplements could create a health crisis in the future.

The Committee will hear testimony today about whether American consumers are relying, to their detriment, on the notion that simply because supplements are so easily available and not illegal, they must be safe. I must tell my friends and colleagues that we obviously will, in some respect, refer to the recent reports in the media concerning allegations of a new type of steroid that has been uncovered recently. And I understand it’s the subject of an ongoing investigation.

I’d like to thank my two colleagues from the Senate, who have been heavily involved in this issue for a long period of time, and I’d like to begin with the distinguished Chairman of the Judiciary Committee, Senator Hatch.

Thank you, Senator Hatch, for being here, and thank you for the many years of work and effort you’ve put into this issue.

Please proceed.

**STATEMENT OF HON. ORRIN G. HATCH,
U.S. SENATOR FROM UTAH**

Senator HATCH. Well, thank you, Mr. Chairman. I appreciate you inviting us to this Committee, this important Committee, and I appreciate the opportunity to discuss a topic that’s very near and dear to my heart, and that is the regulation of dietary supplements.

There is no question that tens of millions of Americans rely daily on safe dietary supplements to maintain and improve their healthy lifestyles. The popularity of these products and the concern over their regulation are what led to the enactment of the Dietary Supplement Health and Education Act, or herein as I’ll call it, DSHEA, in 1994, a bill that Senator Harkin and I were proud to author with now-Governor Bill Richardson of New Mexico.

The message I’ll leave with you is simple. DSHEA is a strong law that will protect the interests of consumers, but, as with any law, to work, it must be implemented. Enactment of DSHEA, following literally decades of Food and Drug Administration animosity toward dietary supplement products, was one reason why we enacted it. This animosity and the lack of a clear regulatory structure for supplements were clearly demonstrated prior to the passage of DSHEA. That is why two-thirds of the Senate co-sponsored our bill. That is why a majority of the House co-sponsored our bill. And that is why it passed so overwhelmingly.

When we drafted DSHEA, safety was at the forefront of our efforts. The law gives FDA abundant tools to remove products that

are unsafe from the marketplace. There is no excuse for marketing products that are unsafe, or inaccurately labeled, or that make outlandish claims.

Unfortunately, a small number of irresponsible supplement companies are taking advantage of consumers. I contend that the law is adequate to deal with them if FDA implements and enforces it. Yet, in the nine-plus years since DSHEA was enacted, there has been too much talk that the law handicaps or handcuffs FDA, and too little effort to apply the law.

It is impossible for this law to protect consumers if it is not enforced. I've been pleased at the FTC's actions to challenge companies with inaccurate or deceptive advertising. While the FDA's record has not been as strong, it is notable that our new Commissioner, Mark McClellan, has stepped up enforcement efforts. I credit Commissioner McClellan for his commitment to implement the law fully. I truly believe he wants to make this law work, and I believe Congress must support him.

That is why I have joined with Senator Harkin to introduce the DSHEA Full Implementation and Enforcement Act of 2001. That's S. 1538. Yes, there are a small number of products that do raise serious concerns. Ephedra is one. As I have done for many years, I urged the FDA to act definitively on this issue, based on the best available science, not politics. This has gone on far too long.

Frankly, resources are a large issue here. The FDA simply does not have the staff or money it needs to do the job, and I think we ought to remedy that here in Congress. That is the only reason I can see that the safety standard we enacted has never been invoked. Never. That has to be the reason it has taken almost a decade to promulgate good manufacturing practice standards that can help guarantee the safety, the purity, and the accurate labeling of products. And we provided in that bill for these good manufacturing standards that should be set by FDA, but still we're waiting for them, although I believe they're doing that now.

And that must be the reason a product like androstenedione, which I believe is not even a dietary supplement, continues to be marketed in this country. I've been very concerned about the safety, as you are, Mr. Chairman, of steroid precursor products like andro, and especially when they fall into the hands of our youth. That is why I've joined with Senator Biden, Senator Harkin, and Senator Grassley to cosponsor the Anabolic Steroid Control Act—that's S. 1780—that will add andro and other steroid precursors, as well THG, to the list of controlled substances.

I intend for the Judiciary Committee to make adoption of S. 1780 a priority, and hope that our colleagues will join me in supporting both S. 1780 and S. 1538.

Now, Mr. Chairman, you've been generous with your time, so I will close here. The thought I wish to leave with my colleagues is that we have a solid law, which can deal with the problems witnesses will discuss today, but the FDA must use that law for it to be effective, and Congress must support the agency in that effort.

And I just want to thank you for holding this hearing and allowing me to say a few words.

[The prepared statement of Senator Hatch follows:]

PREPARED STATEMENT OF ORRIN G. HATCH, U.S. SENATOR FROM UTAH

Mr. Chairman and Members of the Committee:

I appreciate the opportunity to testify before you today and to discuss a topic very near and dear to my heart: the regulation of dietary supplements.

There is no question that tens of millions of Americans rely daily on safe dietary supplements to maintain and improve their healthy lifestyles. The popularity of these products and the concern over their regulation are what led to enactment of the Dietary Supplement Health and Education Act (DSHEA) in 1994, a bill that Senator Harkin and I were proud to author with now-Governor of New Mexico Bill Richardson.

The message I wish to leave with you is simple: DSHEA is a strong law that properly implemented will protect the interests of consumers. But, as with any law, it has to be implemented for it to work.

Enactment of DSHEA followed literally decades of Food and Drug Administration animosity toward dietary supplement products. 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 cosponsored our bill.

That is why a majority of the House cosponsored the bill.

And that is why it passed so overwhelmingly.

The basic structure of DSHEA allowed all products marketed as dietary supplements when the bill was enacted to stay on the market unless the FDA could show safety problems with a particular product or line of products—this is the so-called “grandfather” provision; manufacturers must notify the FDA before any new ingredients are marketed. At the same time, we provided the FDA with the full range of enforcement mechanisms to act against unsafe or misbranded supplements, including seizure, injunction, civil monetary penalties and even criminal penalties.

And, when Chairman Dingell and Chairman Waxman expressed lingering concerns that an unsafe product might be marketed and FDA would not have adequate authority to act against it, we added a new tool—imminent hazard—so that the Secretary could take immediate action against a product that he believed poses an imminent hazard to public health. I might add, the definition as to what constitutes an “imminent hazard” is entirely up to the Department of Health and Human Services, so this is a very broad authority.

Even so, there are some who believe that dietary supplements should not be marketed in the United States without a preclearance similar to that for pharmaceuticals. We who drafted and passed DSHEA along with millions of Americans were persuaded that was not necessary.

First, most supplements cannot be patented, so there is little incentive for manufacturers to undergo the expensive and time-consuming FDA approval process.

Second, many, many supplements have been used safely for literally centuries, if not millennia, so it is not necessary to subject them to the approval process. That was why even the most liberal members felt comfortable with the grandfather structure.

Finally, we added a provision so that FDA would have the time to examine any ingredient not previously marketed and the evidence of its safety before that product actually reached the stores.

When we drafted DSHEA, ensuring the safety of products was at the forefront of our efforts. The law gives the FDA abundant tools to remove products that are unsafe from the market. It includes a safety standard that was carefully crafted with Senator Kennedy and Representatives Dingell and Waxman, the chairs of FDA-related panels in 1994.

There is no excuse for a supplement manufacturer to market products that are unsafe or inaccurately labeled or that make outlandish claims. Unfortunately, a small number of irresponsible supplement companies are taking advantage of consumers.

I contend that the law is adequate to deal with them if FDA implements and enforces it.

Yet, in the nine-plus years since DSHEA was enacted, there has been too much talk that the law handcuffs FDA and too little effort to apply the law.

It is impossible for this law to protect consumers if it is not enforced.

I have been pleased at the FTC’s actions to challenge companies with inaccurate or deceptive advertising.

The FDA’s record has not been as strong.

I am not here to criticize the FDA or throw barbs. Frankly, the FDA under Commissioner Mark McClellan has done more to enforce DSHEA than the previous administration had. I credit Commissioner McClellan for his commitment to imple-

ment the law fully. I truly believe he wants to make this law work. Congress must support him.

That is why I have joined with Senator Harkin to introduce the DSHEA Full Implementation and Enforcement Act of 2003 (S. 1538).

Yes, there is a small number of products that do raise serious concerns.

Ephedra is one. As I have done for many years, I urge the FDA to act definitively on this issue based on the best available science, not politics. If the agency deems that ephedra poses a significant or unreasonable risk of illness or injury when used as labeled, then the agency can—and must—move to take the product off the market. This has gone on for too long.

Frankly, resources are a large issue here. The FDA simply does not have the staff or money it needs to do the job.

While FDA is constrained by the President's budget in not seeking new funding for DSHEA, I predict that members of the Committee who inquire of the FDA witness may receive support for my contention that the agency is woefully underfunded, especially in this area.

That is the only reason I can see that the safety standard we enacted has never been invoked.

That has to be the reason that it has taken almost a decade to promulgate the good manufacturing practice standards that can help guarantee the safety, the purity, and the accurate labeling of products.

And that must be the reason that a product like androstenedione, which I believe is not even a dietary supplement, continues to be marketed in this country.

I have been very concerned about the safety of steroid precursor products like andro—and especially when they fall into the hands of our youth.

That is why I have joined with Senator Biden, Senator Harkin and Senator Grassley to cosponsor the Anabolic Steroid Control Act (S. 1780) that will add andro and other steroid precursors, as well as THG, to the list of controlled substances. I intend for the Judiciary Committee to make adoption of S. 1780 a priority and I hope my colleagues will join me in supporting both S. 1780 and S. 1538.

Mr. Chairman, you have been very generous with your time, so I will close here. The thought I wish to leave with my colleagues is that we have a solid law which can deal with the problems witnesses will discuss today. But the FDA must use that law for it to be effective, and Congress must support the agency in that effort.

The CHAIRMAN. Thank you, Senator Hatch. And before you go, and I know you have to leave, and this is a little unusual, but maybe I could just engage you in a little conversation—

Senator HATCH. Sure.

The CHAIRMAN.—for my own benefit, with you and Senator Durbin.

Senator HATCH. I'd be glad to.

The CHAIRMAN. As you know, we have oversight of professional sports, and we had a reform of the Olympic Committee. During those hearings, this issue of anabolic steroids, other performance-enhancing drugs used by Olympic athletes and in professional baseball, came into being. As you know, there was a big *Sports Illustrated* story about the abuse—the alleged abuse—of these substances by professional athletes. And the concern that all of us share is that young people will be tempted to make use of the same kind of supplements as steroids, whatever you want—performance-enhancing substances in order to succeed.

Now, one of the things that the Major League Baseball Players Representative said to me, he said, “Well, it's hard for us to outlaw certain substances that are available over the counter.” How are you going to say that professional baseball players shouldn't use it, but it's available over the counter?

Also, isn't there a problem here—and I'm asking you to think out loud—of development of new kinds of performance-enhancing substances, as alleged in the newspaper about some outfit in San Francisco which has developed a performance-enhancing substance

which has recently been detected by new measures, as we'll hear from the Anti-Doping Agency as we move forward.

I'd just like both your thoughts on that issue, because I think it is a problem here with young people. I'm not so concerned—I don't think all of us are so concerned about professional athletes destroying themselves, although that's certainly an issue, but I think we're much more concerned about young people imitating that, because they see that as their only way to become a successful professional athlete.

Maybe I could begin with Senator Hatch and then with you, Senator Durbin, before you make your statement.

Senator HATCH. Well, as you know, over a hundred million people take dietary supplements every day, which are totally safe and very beneficial to mankind. I personally take them. I think most members of the U.S. Senate take them. But where this really comes up is in the androstenedione and other steroid precursors that are deleterious to the human body, and we know they are.

Now, we've been—Senator Harkin and I have been after the FDA for years to do something about that. They have the power to take—under DSHEA, they have the power to take anything off the marketplace that is detrimental or harmful to the human being. But, in all honesty, it's not all their fault that they haven't done it, although I think they are at fault. We should give them the monies to be able to do the investigation that they need of these steroid precursors and anything else that might be not a true dietary supplement.

In the case of ephedra, there are—both sides of that argument have good arguments with regard to ephedra, but the FDA should make some determinations there. They do have the authority to do that.

With regard to our young people, there's no question we should be protecting them. I appreciate your comments, and I appreciate your efforts and your desire to be able to do that, and I will join arms with you and help get that done.

But, I think one of the problems is that we, in the Congress, have not given the help to the FDA that they need to be able to do the job that they really should do.

Now, it's also complicated by the fact that there are a number of current bureaucrats at the FDA who hate dietary supplements and want to get pre-market approval, which would drive the cost of vitamins, and minerals, and even herbal products out of sight. Well, that would cause a tremendous reaction in this country, as you know. And we've got to have them use the bill, enforce the bill. If they would do that, they could solve every one of these problems, but we ought to make sure that they have enough support from the Congress, money and other support from the Congress, to be able to do it.

We've come up with these two bills that would help, I think, alleviate virtually every problem that we must be concerned about in these areas, and I think these hearings today will also help us to understand this better.

The CHAIRMAN. Thank you, Senator Hatch. Senator, I know you have to leave, Senator Hatch, and I know you have a very busy

schedule, and I appreciate you being here, and all of us look forward to working together. I think it's a growing problem.

Senator HATCH. I do, too.

The CHAIRMAN. So I think I understand, from the media—and I have no direct communications with anyone—that there now is a grand jury impaneled on this particular issue, and some people say it could be a major scandal brewing. I don't know if that's true or not, but certainly some very large names have been mentioned there. So, I think it's going to deserve our attention in the months ahead. Maybe next year, I don't know, but I certainly would support passage of you and Senator Harkin's legislation, since you were certainly the trailblazer on this issue.

Did you want to make an additional comment, Senator Hatch?

Senator HATCH. I'll just make one more additional comment, and that is, when we did the DSHEA, the purpose was to give FDA additional tools, which we did. They actually have more tools now than they had pre-DSHEA.

Now, the structure of DSHEA, new products not marketed in the United States before 1994, the date we enacted DSHEA, as a supplement, they have to submit a petition to the FDA 75 days before selling. Now, FDA would have the information to go after anything that would not meet true dietary supplement standards and would be deleterious to the human being.

S. 1780, the Anabolic Steroid Control Act of 2003, which we would like to pass, takes care of andro, THG, and other similar products by subjecting them to the Controlled Substance Act so that they have to be taken off the market. We believe that really ought to be done, and we believe FDA has the power to take them off the market. But if they don't, we ought to pass that legislation and get them taken off the market by force of law.

But we actually gave more authority to FDA than they ever had before, in the 1994 Act. And if they would use that authority, I think they could solve most every problem that the distinguished Chairman and I are concerned about.

The CHAIRMAN. Thank you very much, Senator Hatch. Senator Durbin?

**STATEMENT OF HON. RICHARD J. DURBIN,
U.S. SENATOR FROM ILLINOIS**

Senator DURBIN. Thank you very much, Senator McCain, for chairing this hearing. I share your concern about the dangers of dietary supplements, and I appreciate this opportunity to share my views.

As has been said, dietary supplements are used by millions of Americans every day. I took my vitamin this morning. The vast majority of these supplements don't result in any harm to the consumer. In fact, there's scientific evidence that they are very helpful.

Unfortunately, it's not the case for all supplements. Some cause dangerous health problems—increased blood pressure, heart attack, stroke, seizures, and liver failure. Ephedra is the most well-known among these, but there are others, such as synephrine, usnic acid, kava-kava, and yohimbe.

Let me touch briefly on ephedra, because I think it tells the story about DSHEA. The hearings I chaired last year in the Govern-

mental Affairs Committee finally made a public record of the danger of ephedra. The FDA has received thousands of reports of adverse health events from consumers who have used dietary supplements containing ephedra, including 117 deaths and 2,000 significant incidents of cardiac, neurologic, and psychiatric problems. The National Football League, the NCAA, Minor League Baseball, Professional Soccer, and the International Olympic Committee have all banned ephedra for their athletes. The American Medical Association called on our Government to ban ephedra products on June 19 last year. All of the Nation's major drugstores, including Walgreen's, Rite Aid, CVS, Eckerd, and Wal-Mart, have pulled dietary supplements containing ephedra from their shelves to protect their consumers. Three states—my own, of Illinois, California, and New York—have banned them. And Health Canada, that nation's equivalent to our FDA, recalled all products containing ephedra from Canada's drugstore shelves, and banned the sale of ephedra products almost 2 years ago.

The CHAIRMAN. But, can't you still get it over the Internet?

Senator DURBIN. Well, that's entirely possible. I'm saying we're not closing all the gaps, but the fact is, Canada, as a nation, banned it, and it makes it more difficult, particularly for young people, not that they don't use the Internet, but it makes it a little more difficult.

Unfortunately, the FDA, our government watchdog for consumers, has failed to respond, even as of today. They have failed to protect American families from ephedra, which Senator Hatch concedes, and I concede, I think virtually every person concedes, is a dangerous dietary supplement.

This is proof positive that we need to revisit DSHEA. The law doesn't adequately protect the health of the American public.

Under DSHEA, supplement manufacturers are not required to prove their products are safe or effective before they are marketed. Supplements are assumed safe until the FDA proves them unsafe. Unlike prescription drugs and food, the burden of proving a product is dangerous falls, not on the maker of the product, but on the Government. Think about that. The thousands of products coming on the market, and we are saying the FDA has to prove each and every one of them that might be unsafe, to be unsafe. And what is even worse, supplement manufacturers do not even have to notify the FDA when they receive reports of adverse health reactions caused by their products.

Mr. Chairman, I don't think the average American walking into a drugstore understands the different standards of care that are being applied to the products that you buy in a drugstore. As you walk into your drugstore to fill a prescription, you can be certain that this drug has gone through clinical trials, that it has been proven to be safe and effective. Is it a hundred-percent safe? No. There are tragic incidents when, after a long period of time, even these clinical trials don't prove to be a hundred-percent accurate. But you know, going in, that your prescription drugs have been established to be safe and effective.

You also buy over-the-counter drugs, and you know when you buy these over-the-counter drugs, that the companies that make them are obliged to find out not only whether they're safe, but to

report, in every instance, if they had an adverse health effect on a person so that the FDA can accumulate the evidence. And I'm not pointing to this drug or any, in particular, over-the-counter drugs, but at least all of the evidence is being accumulated so that if something is wrong, if it's dangerous in any way, the FDA has the information. But that is not true when it comes to these supplements.

Yellow Jackets, for example. There is no—this is an ephedra product which I'd like to speak to for a moment. This is a product that was never tested before it was sold to the American people. It is being tested today on American consumers to see what the results are. And I want to tell you about this particular product that was tested on a constituent of mine.

A 16-year-old high school football player in Lincoln, Illinois—a healthy young kid getting ready for the big game—went into a gas station and bought Yellow Jackets. He took the Yellow Jackets, because it said it was going to give him more strength for performance at the football game, washed them down with a Mountain Dew, and, as a result of it, had a heart attack and died. This product had never been tested before it was being sold. There was no reporting by this company of adverse health events.

Now, I've introduced a bill that's going to deal with, I think, some of the obvious weaknesses in DSHEA. The bill would require supplement manufacturers to report adverse events to the FDA. If we are requiring no pre-market safety data, adverse event reports are the only way that we can learn if a supplement is dangerous. To think that we're in a position here where these companies that make things, like Yellow Jackets, don't even have to report these adverse events when they are given to them.

A good example is Metabolife, and I have one of their products here, 356, which is one of the most popular dietary supplements to be sold. This company lied to the Federal Drug Administration and the American public for years, stating they had never been informed of any adverse health events caused by their products. The company claims their product, Metabolife, was absolutely safe. Finally, after pressure from class action lawsuits and other lawsuits brought by ephedra victims, Metabolife admitted to the following: 18,000 adverse event reports—18,000—including almost 2,000 cases of significant cardiac, neurological, and psychiatric problems.

The bill I have introduced would also give the FDA the power to conduct a clinical evaluation of the supplement that receives one or more serious adverse event reports. And I underline "serious." If, and only if, the clinical evaluation shows the supplement presents an unreasonable risk of illness, and the company can't demonstrate the product safe, the Secretary has the authority to stop the continued marketing of the supplement. Given that most supplements, such as vitamins and minerals, are inherently safe, this provision is no threat to their continued sales.

Mr. Chairman, you remember when DSHEA was being debated, and I do, too. We talked about Vitamin C and multiple vitamins, garlic and the basic things that, frankly, cause no problems to anyone. Did anyone in the course of that debate imagine we'd be reaching a point where we'd be selling, under the name of dietary supplements, these witch's brews of chemicals that no one has ever

tested, in terms of their safety and efficacy? Did anyone imagine that we were going to put these on the market so that kids could buy them at gas stations, and say that's the same thing as your Vitamin C that you take every morning, or the Flintstones vitamins you give your children? I don't think so. That's not what we had in mind when we passed DSHEA. But that is what has happened.

Now, the second major provision of my bill—

The CHAIRMAN. Let me just interrupt you.

Senator DURBIN. Sure.

The CHAIRMAN. I'm sure that there will be a witness or someone who supports DSHEA who will say, "What Senator Durbin is trying to do is ban the garlic, other natural products, and it'll drive up the costs, and, therefore, not be available to consumers." How do you respond? Where do you draw the line?

Senator DURBIN. I'll tell you where I draw the line. And I think we've identified. Clearly, Senator Hatch, I think from what you've said in your question, and I would draw the line to say take steroids off the table. Steroids are not a dietary supplement that should just be sold without any testing, without the monitoring that we expect of over-the-counter drugs, for example. So steroids are one.

The second category would be stimulants, and that's what we're talking about with ephedra. We're dealing with stimulants here that, unfortunately, have had adverse health effects, like ephedra has had.

Now, beyond that, the only thing that I would ask in my bill is that if a product that you're selling as a dietary supplement does create an adverse health event—a seizure, a stroke, a heart attack, or death—you at least have to report that to the government. Is that going to happen with a Flintstones vitamin? I don't think so. These products are inherently safe. We know they are. They've been used over and over again.

I think we ought to draw clear lines when it comes to steroids and stimulants.

And if I can say, when it comes to my bill, we preserved DSHEA's assumption that dietary supplements are safe, except for stimulants. A product that speeds your heart rate, constricts your blood vessels, or interacts with your central nervous system should be checked for safety before being marketed.

Now, I'm not talking about caffeine, I see, as you drink your cup of coffee. In fact, my bill specifically exempts caffeine. We know, by human experience, the difference between decaf and regular coffee, regular coffee and espresso, caffeine-free Coke and regular Coke. But the average consumer walking into the drugstore won't know that the diet pill, Zantrex-3, contains the equivalent stimulant of a six-pack of Coke in each pill. It's reasonable to require safety data before these pills are marketed.

What I do with steroids is basically what Senator Hatch and Senator Biden would accomplish in their bills, so I won't go into that.

Let me just close by saying this. I believe fixing DSHEA and keeping dietary supplements safe is a challenging task and no assignment for the politically timid. You've never been accused of

that, Mr. Chairman. The supplement industry is a multibillion dollar operation with an army of lobbyists, friends in the highest places in Washington, and attack dogs straining at the leash. I know this, because they've unleashed this avalanche of faxes at me, saying, "Durbin wants to take your vitamins away." Be prepared, Mr. Chairman. If you get into this issue, they are going to distort your position on it.

I am not opposed to people buying vitamins without a prescription. I think that should be preserved. We should be able to buy these over the counter. But when it comes to these exotic mixtures, Metabolife with ephedra, Yellow Jackets with ephedra, it's a different ball game.

I'm glad this Committee has the political nerve to take on this issue. I can only hope that responsible vitamin and supplement manufacturers will not defend and harbor the worst among them in the name of solidarity. Regardless, our responsibility to protect the health of the American consumer is clear.

Thank you very much.

The CHAIRMAN. Where's the pharmaceutical industry on this?

Senator DURBIN. I don't know. I can't tell you where they stand, but I can tell you when I went to the largest pharmaceutical company in my state, Walgreen's, and sat down with them and said, "Are you selling ephedra products," "No way," they said, "We've taken them off the shelf long ago. We realized they weren't safe for our customers, and there were lawsuits flying in every direction." So they made that conscious marketing decision not to sell these dangerous products. But how can they keep up with this combination process?

First, let me tell you, Mr. Chairman, it's been 9 years since we passed DSHEA. FDA still hasn't promulgated the rules about the purity of what's included in these products. We don't know even—

The CHAIRMAN. Why not?

Senator DURBIN. Well, because they've been caught up in a bureaucratic tangle, challenged by the industry, and they have fallen down on the job. They haven't done it.

They've finally come out with a proposed rule, after 9 years, to talk about the fact that when they say ephedra is in here, it's actually in here. Now, you know that's going to be the case when it comes to over-the-counter drugs and prescription drugs, in terms of purity. That is not the case when it comes to dietary supplements. And so, frankly, we haven't even reached the threshold level to say that what we're saying to the public is in the dietary supplement is actually there.

And, furthermore, obviously we haven't the resources at the FDA to deal with the issues Senator Hatch alluded to. You and I know that with the deficit we're facing in this country, the fact that we're going to—or the possibility that we would dramatically increase the surveillance of the dietary supplement industry under existing law, with DSHEA, by the FDA, is a long shot, not likely to occur. In the meantime, these products are being tested on Americans, unsuspecting Americans, every single day, with tragic results, as we've seen with ephedra.

The last point I'll make is this. It is little comfort to hear that they're now selling this product, Metabolife, ephedra-free. The obvious question is, what have they replaced ephedra with, and what does it do to you? Has it been tested? Does anybody know whether it's safe? There are still unanswered questions based on the law that we have on the books today.

The CHAIRMAN. And your legislation, basically, would simply ban or require FDA approval for any product that contains steroids or stimulants.

Senator DURBIN. Steroids, clearly, as I said, we've put that at a different class. And when it comes to stimulants, we say these are products which, sold as dietary supplements, pose such a risk that they ought to be in a special category. And, generically speaking, or generally speaking—I won't use the word "generically"—but, generally speaking, all makers of dietary supplements would have to report to the government if there are adverse health events so we can see that red flag starting to wave, that something's on the market out there that's causing a problem.

The CHAIRMAN. Thank you very much, Senator Durbin.

Senator DURBIN. Thank you, Mr. Chairman.

The CHAIRMAN. You've been very informative.

Our first panel of witnesses, Mr. John M. Taylor, Associate Commissioner for Regulatory Affairs, the U.S. Food and Drug Administration, Mr. Howard Beales, the Director of the Bureau of Consumer Protection in the Federal Trade Commission. I'd like to welcome both of you here today.

And, Mr. Taylor, we'd like to begin with you, if you are prepared. And thank you for appearing today, both of you.

**STATEMENT OF JOHN M. TAYLOR,
ASSOCIATE COMMISSIONER, REGULATORY AFFAIRS,
FOOD AND DRUG ADMINISTRATION**

Mr. TAYLOR. Good morning, Mr. Chairman. Thank you for the opportunity to testify at this hearing about dietary supplements.

FDA regulates the safety, manufacturing, and labeling of dietary supplements, while our partners in the Federal Trade Commission have primary responsibility for regulating the advertising of these products. I am pleased to be here with Howard Beales, of the FTC. The partnership between our agencies is essential to protecting the public from health fraud.

Let me begin by discussing tetrahydrogestrinone, or THG. FDA considers THG to be a new unapproved drug within the meaning of the Federal Food Drug and Cosmetic Act. THG is a highly potent anabolic steroid. It is purely synthetic and does not occur naturally. THG is a designer steroid in the truest sense. It is directly derived from an anabolic drug that's banned by the U.S. Anti-Doping Agency. Furthermore, THG is structurally related to trenbolone, a veterinary anabolic steroid listed as a controlled substance.

FDA is aggressively working with other Federal law-enforcement agencies to prosecute the manufacturer of THG. We will also take swift action in the future against anyone who manufactures, distributes, or markets this potentially unsafe product.

In a statement that we'll issue later today, FDA will announce its conclusion that THG is an unapproved new drug. We also will

warn customers that while—or consumers—that while little is formally known about the safety of THG, its structure and relationship to other anabolic steroids leads FDA to believe that its use may pose considerable health risks. Anabolic steroids can have serious long-term health consequences in men, women, and children.

Now, let me speak more generally about FDA's regulatory approach and enforcement actions in dietary supplements. Under the Dietary Supplement and Health Education Act, the regulatory framework for dietary supplements is primarily a post-market program, as is the case for foods.

If safety problems arise after marketing, FDA bears the burden of proving there is a safety risk. Most dietary supplements do not raise significant safety concerns, and, in certain cases, have demonstrated health benefits. However, when false or misleading claims endanger the public health and undermine the goals of the FDA, we take action to ensure that consumers have access to truthful, non-misleading health information.

FDA's enforcement focus gives highest priority to products that have a potential for causing serious adverse effects or where there is a risk of injury or death. FDA uses all available civil, administrative, or criminal remedies to quickly remove such products from the market.

The appendix to my testimony chronicles FDA's recent dietary supplement enforcement actions in more detail. However, in the past year these enforcement actions have included witnessing the voluntary description of almost \$8 million worth of dietary supplements, bringing injunctions and seizure actions against fraudulent dietary supplements, and in some cases those seizures were done in conjunction with the FTC. We've sent numerous warning letters to firms who have made drug claims in association with the dietary supplements. We've also sent warning letters to firms marketing dietary supplements as street-drug alternatives. And, in addition, we've sent warning letters to firms making unproven claims for ephedra-containing dietary supplements. As I said earlier, many of these enforcement activities were joint FDA/FTC actions.

Turning to the herbal dietary supplement, ephedra, this product, as we've noted today, has been marketed for weight control, to enhance athletic performance, and as an illicit street-drug alternative. Many ephedra products contain other stimulants, such as caffeine, that may increase the potential for adverse events.

In the past year, FDA compiled the most comprehensive scientific information to date about the risks and benefits of ephedra products when we gained access to significant additional adverse event information from manufacturers of ephedra.

FDA provides these adverse event reports to the RAND Corporation, along with all other recent scientific evidence on ephedra. Last February, the Department and FDA announced the results of the RAND review. In evaluating the potential benefits of ephedra, the RAND report found only limited evidence of ephedra's effect on short-term weight loss, and minimal evidence of an effect on sports performance enhancement. The RAND review of some 16,000 adverse event reports revealed two deaths, three heart attacks, nine strokes, three seizures, and five psychiatric cases involving ephedra.

When we announced the results of the RAND review, we also announced that we would reopen the comment period on an ephedra regulation that we proposed, but withdrew, in 1997. Also, we sought additional evidence on ephedra safety and comments on whether ephedra should be considered adulterated in the event it presents a significant or unreasonable risk of injury at the recommended level of use.

We are currently analyzing approximately 30,000 public comments that we have received this summer in the wake of that *Federal Register* announcement. Because we are engaged in a deliberative review, I cannot discuss the specifics of the process or the anticipated outcome. However, I do want to be clear about one thing. We are working expeditiously to take effective action in the interest of the public health, based on the best possible scientific evidence, and authorities available to us under DSHEA.

Mr. Chairman, thank you very much for this opportunity to appear at this hearing, and I'm happy to take any questions.

[The prepared statement of Mr. Taylor follows:]

PREPARED STATEMENT OF JOHN M. TAYLOR, ASSOCIATE COMMISSIONER, REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION

Introduction

Thank you, Mr. Chairman, for this opportunity to testify at this hearing on dietary supplements and the current regulations to protect American consumers from the potential adverse health risks associated with the use of certain supplements. I am John M. Taylor, Associate Commissioner for Regulatory Affairs at the Food and Drug Administration (FDA or the Agency). In my statement today, I will address FDA actions to implement DSHEA, especially our regulations development, adverse event monitoring, and enforcement posture. I will also address FDA actions on two major types of dietary supplements that are of current concern, ephedra and steroid precursors. But first, let me provide you a short background on dietary supplements.

Background on Regulation of Dietary Supplements

Nearly half of the population of the United States uses "dietary supplements."¹ The Dietary Supplement Health and Education Act of 1994 (DSHEA) established a unique regulatory framework in an attempt to strike the right balance between providing consumers access to dietary supplements that they choose to use to help maintain and improve their health, and giving the FDA the necessary regulatory authority to take action against supplements or supplement ingredients that present safety problems, make false or misleading claims, or are otherwise adulterated or misbranded. Although dietary supplements are generally regulated as foods, there are special statutory provisions and implementing regulations for dietary supplements that differ in some respects from those covering conventional foods. Moreover, the regulatory requirements for dietary supplements also differ from those that apply to prescription and over-the-counter (OTC) drug products.

Congress defined the term dietary supplement as a product that, among other things, is ingested, 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 the diet, and that contains at least one dietary ingredient. The dietary ingredients in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and dietary substances such as enzymes. Dietary ingredients also can be metabolites, constituents, extracts, concentrates, or combinations of the preceding types of ingredients. Dietary supplements may be found in many forms, such as tablets, capsules, liquids, or bars. DSHEA placed dietary supplements in a special subcategory under the general umbrella of foods, but products that meet the drug definition are subject to regulation as drugs.

¹Bennett, J. and CM Brown. 2000. "Use of Herbal Remedies by Patients in a Health Maintenance Organization." *Journal of the American Pharmaceutical Association*. Volume 40, Number 3: 353-358.

Labeling of Dietary Supplements

Under the Federal Food, Drug, and Cosmetic (FD&C) Act and FDA's implementing regulations, the label of a dietary supplement must include:

- 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, packer, or distributor.
- the net quantity of contents.

In addition, if the labeling includes a claim that the product affects 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 also 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. If a product that is marketed as a dietary supplement includes claims that the product is intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of a disease, it is considered a drug within the meaning of the Act.

Dietary Supplements Containing Steroid Precursors

Because of the Committee's interest in steroid precursors, let me discuss them now. FDA is aware of a wide variety of products that contain steroid precursors. Some consumers ingest steroid precursors because they believe these products boost testosterone levels and speed muscle growth.

Use of these products has grown dramatically in popularity in the United States. We have heard from athletic organizations, health care professionals and health organizations, and anti-drug abuse authorities about potential health risks that may be associated with their use. However, the scientific evidence about the benefits or adverse consequences of steroid precursors appears to be inconclusive at this time. These products are generally marketed as dietary supplements and targeted to athletes and body builders as performance enhancers. Some of these products are marketed for weight loss or as anti-aging products. While the majority of products containing steroid precursors are not promoted for disease treatment or prevention purposes, a minority of products may be promoted for therapeutic purposes and therefore are subject to regulation as drugs.

In addition, some steroid precursors are clearly outside the scope of the dietary supplement definition and are subject to regulation as drugs because they are intended to affect the structure or function of the body. For example, FDA considers tetrahydrogestrinone, or THG, the subject of what is rapidly becoming a major sports controversy, a new drug under FD&C. Our analysis demonstrates that this is a purely synthetic, non-naturally occurring, highly potent anabolic steroid. It is a designer steroid in the truest sense. It is directly derived, by simple chemical modification, from an anabolic drug that is explicitly banned by the U.S. Anti-Doping Agency. That drug, gestrinone, a synthetic product, is approved in Europe for the treatment of endometriosis, a painful condition of pre-menopausal women. Furthermore, THG is closely related, structurally, to trenbolone, a strong veterinary anabolic steroid approved in the U.S. to increase rate of weight gain and/or improved feed efficiency in beef cattle. Trenbolone is a controlled substance.

Steroid precursors marketed as dietary supplements present complex regulatory issues for FDA regarding the scope of the dietary supplement and drug definitions. FDA is still examining these issues and has not reached any formal conclusion about the status of steroid precursors as dietary supplements under the FD&C Act. Nevertheless, we understand that this is a public health issue that warrants our close attention. FDA is currently pursuing an evaluation of the legal and scientific uses that bear on the status of these kinds of substances and we hope to be able to address this matter more authoritatively in the future.

Adverse Event Reporting

Now, let me turn to our discussion of dietary supplements. DSHEA's regulatory framework is primarily a post-market program, like much of food regulation. There is no pre-market approval requirement for dietary supplements. Further, there is no requirement for manufacturers to provide evidence of product safety to FDA prior to marketing a dietary supplement, unless the supplement contains a "new dietary ingredient" (a dietary ingredient that was not marketed in the United States before October 15, 1994) that has not been "present in the food supply as an article used for food in a form in which the food has not been chemically altered" (21 U.S.C. 350b(a)). In contrast, drug regulation involves an extensive pre-market evaluation

of safety and effectiveness with explicit standards of evidence. This evidence provides a basis to guide not only approval decisions but also conditions of use to manage benefits and risks. In addition, there are post-market reporting requirements for drugs to support product safety monitoring. These requirements do not exist for dietary supplements.

As a result, voluntary adverse event reports (AERs) are the primary means FDA has for identifying potential safety problems with dietary supplements. Under DSHEA, FDA must rely on AERs as a major component of its post-market regulatory surveillance efforts. Also, unlike drug regulation, FDA cannot compel reporting of adverse events by dietary supplement manufacturers.

In June 2003, 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 for foods, cosmetics, and dietary supplements. This state-of-the-art system compiles and analyzes any reports of consumer complaints and adverse events related to CFSAN-regulated products presented to FDA. Health care professionals and consumers voluntarily send submissions to CAERS. While voluntary reporting systems are estimated to capture only one percent of adverse events, they provide valuable signals of potential problems.

Enforcement

Protecting the public health has always been the Agency's first responsibility. Consumers need to have confidence in the safety and effectiveness of the products they use. Therefore, unsafe, ineffective, or fraudulent products are a threat to the public health.

FDA is serious about its responsibility of ensuring that there is access to effective, safe, scientifically-based health products for our Nation's citizens. U.S. citizens must have access to truthfully labeled, safe, effective, and non-misleading health products.

At the core of FDA's enforcement efforts is our commitment to enhance the legitimate manufacture, sale, and use of dietary supplements while protecting consumers against unsafe products, fraudulent labeling claims, and other illegal practices. Achieving these goals utilizes a number of strategies, including cooperation and coordination with other state, Federal, and international law enforcement agencies in protecting consumers against unapproved and potentially harmful products offered by Internet outlets, some of which are based abroad.

On December 18, 2002, FDA announced its "Better Health Information for Better Nutrition" initiative. The purpose of the initiative is to improve the health of consumers by providing them with scientifically accurate, FDA-approved information about the health effects of foods and dietary supplements. In undertaking this initiative, FDA recognized that false claims that mislead Americans both endanger the public health and undermine the goals of the FDA. Because FDA recognizes that efficient, effective enforcement is an essential component to ensure that such false and misleading claims do not take root in commercial distribution channels, FDA is prepared to take aggressive enforcement action to ensure that consumers have access to truthful and non-misleading information about products related to their health.

FDA's commitment to continue its efforts to ensure that there is access to safe, scientifically-sound medical products is demonstrated by the Agency's enforcement actions to combat fraudulent, misbranded, and misleading dietary supplements. For example, over the last 15 months, FDA has witnessed the voluntary destruction of approximately \$7.7 million of dietary supplements that were determined to be non-compliant with the FD&C Act and has monitored two voluntary recalls of dietary supplement products.

FDA also sent numerous Warning Letters to marketers of products represented as dietary supplements but whose products did not qualify as such because claims on them caused them to be misbranded and/or unapproved drugs. At least two of these Warning Letters were sent to firms whose products were marketed in lieu of approved drugs that were available to the public. For example, one made claims that its products were alternatives to vaccinations/immunizations against anthrax, measles, smallpox, and encephalitis; the other promoted its product as a natural alternative to Ritalin for ADHD. This calendar year, FDA also issued Warning Letters to 18 firms marketing coral calcium products as effective treatments or cures for a variety of disease conditions. In addition, FDA and the FTC warned website operators, manufacturers, and distributors who were making misleading or deceptive claims on the Internet regarding their products ability to prevent, treat, or cure SARS that they must cease making these impermissible claims. FDA also issued Warning Letters to 8 firms marketing "dietary supplements" as street drug alter-

natives and warned 26 firms to stop making unproven claims that ephedrine-containing dietary supplements could enhance athletic performance.

Lastly, over the course of the last 15 months FDA utilized its judicial and administrative enforcement tools to take one injunction action and 8 seizure actions against marketers of, and/or fraudulent dietary supplements. Six of the seizure actions occurred in FY 2003 alone, including 3 that were undertaken in cooperation with FTC.

Health Fraud

Traditionally, FDA has taken action against violative dietary supplements as part of its health fraud efforts. Generally, FDA defines health fraud as the deceptive promotion, advertising, distribution, or sale of articles that are represented as being effective to diagnose, prevent, cure, treat, or mitigate an illness or condition, or provide a beneficial effect on health where the product has not been scientifically proven safe and effective for such purposes.

The Internet is one avenue by which fraudulent products have been promoted. The use of the Internet by our Nation's citizens, from school age children to seniors, has opened up vast new opportunities for the exchange of information and for enhancing commerce in all types of consumer products. The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy. In the health sector, tele-medicine allows people in remote areas to access the expertise of doctors in the Nation's finest academic health centers. The Internet also permits an increasing number of individuals to obtaining meaningful medical information that helps them understand health issues and treatment options. As beneficial as this technology can be, it also creates a new marketplace for activity that is illegal, such as the sale of unapproved new drugs, prescription drugs dispensed without a prescription, and products marketed with fraudulent claims about health benefits. Also, because the Internet is a worldwide communications system, U.S. citizens are now more directly susceptible to fraud from sources both foreign and domestic.

Consumers respond to these promotions by spending billions of dollars a year on fraudulent health products. They hope to find a cure for their illness or improve their well-being or appearance. Yet, consumers often fall victim to products and devices that do nothing more than cheat them out of their money, steer them away from useful proven treatments, and possibly do more harm than good.

FDA Website Triage Process

In June 1999, FDA established a case assessment or "triage" team with representatives from the Offices of Criminal Investigation within the Office of Regulatory Affairs, the Center for Drug Evaluation and Research, the Office of Chief Counsel, and the Office of Policy. The scope of this group has been expanded to cover all FDA Centers and regulated products including the CFSAN's Office of Nutritional Products, Labeling and Dietary Supplements.

Under the triage process, FDA identifies websites that potentially violate the FD&C Act from the Agency's Internet monitoring activity, other Federal or foreign law enforcement agencies including our joint partnership with the Federal Trade Commission (FTC), and from states and the public. The triage team evaluates each case to determine whether or not it should be pursued through a civil or criminal investigation. Using this information, we give priority to cases involving unapproved new drugs, health fraud, prescription drugs sold without a valid prescription, and products with the potential for causing serious or life-threatening reactions.

This triage process results in improved coordination of criminal and civil enforcement actions within the Agency, reduces overlapping efforts, and helps the Agency appropriately achieve a maximum deterrent effect when taking action to remove harmful products from the market.

Oversight of Dietary Supplements

FDA shares Federal oversight of dietary supplements with the Federal Trade Commission (FTC). FDA regulates the safety, manufacturing, and labeling of dietary supplements, while 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.

As with all of FDA's activities, priorities are established based on benefit/risk to public health. The Agency's enforcement of fraudulent health products is based on a priority system that is often driven by whether a fraudulent product poses a direct or indirect risk to public health. The susceptibility of the population is also an element that we consider when determining risk. For example, cancer patients are considered a highly susceptible population, as many have exhausted conventional or

standard care treatments, and may be desperate to try anything that offers hope of a cure.

Products that present a direct health hazard to consumers are the Agency's highest priority. These are products that have a reasonable potential for causing direct serious adverse effects, or for which there is documentation of injury or death. 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.

Products that are not themselves hazardous can still present an indirect health hazard in that the consumer may delay or forego proven medical treatments or drug therapies, or rely on these products for benefits that simply are never going to materialize. Examples include unproven products promoted for the treatment of cancer, Alzheimer's disease, arthritis, heart disease, and high blood pressure.

In addition to these direct and indirect health risks, we also give priority to products that undermine the integrity of the new drug application (NDA) and Over-the-Counter (OTC) drug review processes. The NDA and OTC drug review procedures provide consumers with assurance that prescription and OTC drugs are both safe and effective. To avoid undermining these procedures, it is essential for FDA to maintain vigorous surveillance, provide prompt industry guidance and outreach, and take enforcement action regarding fraudulent products. Such actions help ensure that manufacturers comply with the requirement to submit an NDA to the Agency for their product and that the playing field is fair and equitable for those who do.

Initiation of Enforcement Activity

When a problem arises with a product, or the Agency receives information that a product may violate the FD&C Act or regulations, FDA can take a number of enforcement actions to protect the public. For example, FDA may initially work with a product's manufacturer or marketer to correct the problem voluntarily. If that fails, the Agency may bring a lawsuit to seize the product and/or enjoin the firm marketing or distributing the product. When warranted, FDA may also seek criminal penalties, including prison sentences, against parties who break the law.

In the appendix attached to my testimony, I describe some of FDA's recent dietary supplement enforcement activities. As you will see, our enforcement actions are wide-ranging and diverse and take full advantage of the entire breadth of enforcement tools that are available to FDA. You will also see that the type of cases that we have brought have evolved over time. We hope that they also illustrate to the public and the industry that we will take action when warranted, and that FDA also remains committed to consumer and industry education about the proper labeling and use of dietary supplements.

Outreach and Education

FDA recognizes that traditional enforcement actions and coordinated efforts with other agencies are necessary, but these steps are not the only components of a thoughtful enforcement strategy. We fully appreciate that the dietary supplement industry has a vested interest in curbing fraudulent operators and practices and that most of FDA's regulated industries are interested in complying with the Act—and do so. For this reason, FDA will continue in its efforts to complement these measures with industry and consumer education and will continue to assist the industry by issuing regulations and guidance documents addressing the manufacture, labeling, and sale of dietary supplements.

Examples of prominent FDA outreach activities in this area include:

- continuing to develop mechanisms, including expanded use of our website, to communicate critical information and useful strategies about dietary supplements to industry and consumers. Coordination with groups like the Better Business Bureau, and with professional groups like the American Medical Association, will help FDA to reach the broadest possible audience;
- continuing to encourage consumers to involve their health care practitioners in their health care decisions. Ultimately, however, consumers must be able to evaluate the accuracy of labeling claims, and with the assistance of health professionals when appropriate, determine which dietary supplements are right for them. Accordingly, through written materials and web-based resources, FDA has provided consumers with the means to make informed choices about dietary supplements. Examples include *FDA Talk Papers*, articles in the *FDA Consumer* magazine, and information on FDA's website to educate consumers about safely purchasing FDA-regulated products. Other examples of these materials include CFSAN's "Overview of Dietary Supplements" and "Tips for the Savvy Supplement User." CFSAN has also published consumer advisories concerning

dangerous products, such as the advisory that the Agency issued about dietary supplements containing kava, a botanical ingredient;

- continuing to communicate with industry regarding those practices that are permissible under DSHEA. We will continue our practice of providing this information through guidance documents and information posted on the Agency's website. For example, FDA's "Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide" discusses compliance with the Agency's regulations implementing DSHEA's labeling provisions; and
- leveraging resources by continuing to coordinate mutually effective relationships with other Federal and state entities involved in combating health fraud. For example, in 1992, FDA began sponsoring a National Health Fraud Working Group. This working group is comprised of representatives from the Association of Food and Drug Officials, State Attorneys General, FTC, Health Canada, and FDA representatives from headquarters and field offices. The group meets on a regular basis to facilitate the coordination of regulatory activities, information exchange, and leveraging the efforts of each member agency.

Partnership with Federal Trade Commission (FTC)

As discussed earlier, FTC and FDA have a long-standing history of working together to combat health fraud. This partnership was formed out a recognition that although protection of the public health may be FDA's primary goal, the other can contribute to achieving this goal. To further their mutual interest in consumer protection, FDA and FTC formed a Dietary Supplement Enforcement Group to closely coordinate their enforcement efforts against health care fraud. A major activity includes Operation Cure-All, which is aimed at halting the Internet promotion of products, including dietary supplements, that make false or misleading disease claims. In addition, FDA and FTC chair an Interagency Health Fraud Steering Committee that meets regularly to coordinate activity on these issues. The workgroup includes Federal agencies in the U.S. and Canada, and Mexico also has been invited to join the group. As part of its effort to curb Internet health fraud, FDA 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. These efforts have led to many successful actions that have protected the public health. Together, we have succeeded in accomplishing goals that neither one of our agencies could accomplish individually.

Dietary Supplements Containing Ephedrine Alkaloids

A number of plant genera, including ephedra, are known to contain ephedrine alkaloids. Ma huang is a common name given to Chinese Ephedra, which is used in traditional Chinese medicine. Ephedra has been shown to contain various chemical stimulants, including the alkaloids ephedrine, pseudoephedrine, phenylpropanolamine and norpseudoephedrine, as well as various tannins and related chemicals. The concentrations of these alkaloids depend upon many factors, such as the species, parts of the plant used, time of harvest, growing location, and production methods. Ephedrine and pseudoephedrine are used in some OTC and prescription drugs, where they have been demonstrated to be safe and effective for the labeled use.

Dietary supplements containing ephedrine alkaloids have known, and potentially serious, side effects. While ephedra has been used in herbal medicine preparations for thousands of years, in recent years ephedra has been sold primarily in dietary supplement products for weight control, as well as in products promoted to boost energy levels or to enhance athletic performance. Some ephedra-containing products have been marketed as herbal alternatives to illicit street drugs. Ephedra-containing products often contain other stimulants, such as caffeine, that may have synergistic effects and increase the potential for adverse effects.

A number of adverse effects associated with ephedrine alkaloid-containing dietary supplements have been reported to FDA. These include elevated blood pressure, rapid heartbeat, nerve damage, muscle injury, psychosis, and memory loss. More serious effects have also been reported, including heart attack, stroke, seizure, and death.

As the tragic deaths of the Baltimore Orioles' pitching prospect Steve Bechler and of Sean Riggins, the sixteen-year-old from Illinois have reminded us that use of ephedra, particularly in sports, raises serious concerns about safety and has long posed difficult issues for health care professionals, regulators, and consumers. These concerns stem from both the mechanism of action of ephedrine alkaloids on the sym-

pathetic nervous system, and accumulating evidence of potentially serious adverse events after use of ephedra-containing products.

While there has been considerable debate about the safety and effectiveness of dietary supplements like ephedra, as well as the most effective approach to regulating them, one thing is clear: although dietary supplements are regulated as foods and not drugs, the consumer should not assume they are always safe to use. “Natural” does not necessarily mean safe. In particular, botanical and herbal products may have active ingredients with pharmacologic properties similar to, or in the case of ephedra identical to, drug products. They have the potential to cause adverse effects, as well as interactions with prescription and OTC drugs and with ingredients in other dietary supplements.

Use of Ephedra by Athletes

Although FDA is reviewing ephedrine alkaloids under DSHEA to assess the safety concerns, FDA has particular concerns about the use of ephedra by persons engaged in strenuous exercise. A recent study by RAND, discussed in more detail below, concluded that ephedra has minimal if any proven benefit for enhancing sports performance. Yet ephedra acts like an adrenaline boost, stressing the heart, raising blood pressure, and increasing metabolism. Moreover, the stimulating effects of ephedra may mask the signs of fatigue, causing even the most well-conditioned athletes to push beyond their physical limits.² Thus, ephedra’s risks are potentially much more serious for competitive athletes than for the general population. As FDA has said before, ephedra should not be used by people who engage in strenuous activity.

Because of the special risks of ephedra use in athletes, sports leagues that have acted to restrict ephedra use are making a prudent decision. Even as the Agency evaluates the safety of ephedra use in the population more generally, including its use for weight loss, we see that ephedra poses special risks in the context of sports performance with little or no identified benefit for athletes.

FDA’s Actions on Ephedrine Alkaloids

The Agency’s professional, scientific and legal staffs are currently working hard to address the extraordinary challenges presented by these products. Earlier this year, the Agency published a *Federal Register* notice reopening the comment period on its 1997 proposed rule on dietary supplements containing ephedrine alkaloids to seek comment on new scientific evidence about the risks of these products and on a proposed warning statement for the labels of these products. Our *Federal Register* announcement also sought comments on whether, in light of current information, FDA should determine that dietary supplements containing ephedrine alkaloids present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or under ordinary conditions of use if the labeling is silent.

We are currently in the process of analyzing the over 30,000 public comments we received earlier this summer as well as adverse event information and the best available scientific evidence of ephedra’s pharmacology and mechanism of action. We are in the final stages of our deliberative review, so I cannot discuss the specifics of that process or the anticipated outcome. However, I want to emphasize that we are committed to moving forward expeditiously to make a determination that is well grounded in all available scientific evidence and that is protective of the public health in accordance with DSHEA.

While we are undertaking these reviews, the Agency has dramatically increased its enforcement actions against ephedrine alkaloids and other dietary supplement products making false or misleading claims. These actions, many of which have been undertaken in collaboration with the FTC, are having an impact on the marketing of dietary supplements in general and ephedra in particular.

Sports Uses of Ephedra

On February 28, 2003, based on the conclusions of the RAND study, FDA warned 26 firms to cease making unproven claims that ephedrine-containing dietary supplements enhance athletic performance.³ The actions were primarily a result of the

² *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*. File Inventory, Evidence Report/Technology Assessment Number 76. AHRQ Publication No. 03–E022, March 2003. Agency for Healthcare Research and Quality, Rockville, Maryland.

³ *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*. File Inventory, Evidence Report/Technology Assessment Number 76. AHRQ Publication No. 03–E022, March 2003. Agency for Healthcare Research and Quality, Rockville, Maryland.

Agency's surveillance of the firms' websites. Fourteen of the firms responded to the warning letters by discontinuing the product or the claim. The remaining twelve firms were inspected by FDA. Of those twelve inspected firms, all but one either discontinued the product or the objectionable claims. Investigation for consideration of regulatory action against the remaining firm is ongoing. Since performance enhancement was one of the two principal ways in which ephedra has been marketed, the impact of these warning letters has been substantial. FDA continues to monitor the compliance of products on the Internet.

Dietary Supplement Current Good Manufacturing Practices

Another important aspect of FDA's regulatory and surveillance programs is to help ensure that dietary supplements are manufactured in a manner that will not result in adulteration. DSHEA gave FDA the authority to promulgate regulations for dietary supplement current good manufacturing practices (CGMPs).

On March 13, 2003, FDA published a proposed rule to establish CGMPs for dietary supplements. FDA's proposed rule, if finalized as proposed, will give consumers greater confidence that the dietary supplements they choose to use will have the identity, strength, purity, quality or composition claimed on the label. The CGMPs will help prevent product quality problems such as superpotency, subpotency, contamination, improper packaging, and mislabeling.

The proposed rule would:

- include requirements on the design and construction of physical plants, to facilitate maintenance, cleaning, and proper manufacturing operations;
- include requirements for production and process controls with the use of a quality control unit in the manufacturing, packaging and label operations;
- include requirements for product testing and handling of consumer complaints; and
- apply to all firms that manufacture, package, or hold dietary ingredients or dietary supplements, including those involved with testing, quality control, packaging, labeling, and distribution. The proposed regulations also would apply to both domestic and foreign firms that manufacture, package, or hold dietary ingredients and dietary supplements for distribution into the U.S.

The public comment period on this proposed rule closed on August 11, 2003. The Agency is carefully reviewing all of the comments.

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

ENFORCEMENT STRATEGIES USED TO ENFORCE DSHEA

Inspections That Resulted in Voluntary Compliance

In October 2003, FDA witnessed the voluntary destruction of Royal Tongan Limu, a liquid dietary supplement distributed by NBTY, Inc., in Murphysboro, Illinois. This destruction concluded a series of Agency actions that started with the issuance of a Cyber Letter to Dynamic Essentials of Lake Mary, Florida for health claims associated with the product that were made on the firm's website. Subsequent follow up revealed that Dynamic Essentials was a subsidiary of NBTY, and that the product was being distributed from NBTY's Illinois location. Even after the issuance of the Cyber Letter, the product remained in distribution channels and, therefore, FDA recommended a seizure action. However, in lieu of seizure, the firm chose to voluntarily destroy its inventory of approximately 90,000 bottles of Royal Tongan Limu, along with the product's related literature and materials. Approximately 188 tons of material was destroyed with an estimated value of \$2.7 million.

On April 30, 2003, Nature's Youth, LLC, of Centerville, Massachusetts, voluntarily destroyed approximately 5,700 boxes of its misbranded product, "Nature's Youth hGH." This destruction occurred at locations in Massachusetts and Florida, and involved approximately \$515,000 worth of the product. The firm's action was the result of an FDA advisory that the products appeared to be misbranded by virtue of unsubstantiated "structure and function" statements that claimed that the product would, among other things, "improve physical performance, speed recovery from training, increase cardiac output, and increase immune functions." The product also claimed to be "your body's best defense against aging."

In January, 2003, FDA and the U.S. Marshals Service served an inspection warrant that would allow FDA to witness the voluntary destruction of \$4 million to \$5 million worth of products known as "Yellow Jackets" and "Black Beauties." The warrant was served at NVE Pharmaceuticals, the manufacturer of the products, located in New Jersey. A distributor in the Netherlands promoted the products on the Inter-

net 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. An attempt by FDA to inspect the manufacturer of the products on October 8, 2002, resulted in an inspection refusal, forcing FDA to obtain an inspection warrant. FDA obtained an additional inspection warrant in January 2003. After NVE stopped marketing Yellow Jackets and Black Beauties, it began marketing “Yellow Swarm” and “Midnight Stallion” as replacement products. Although these products appear to be almost identical in formulation and appearance to the previous products, they no longer bear street drug names or claims.

FDA conducted a May 2002 inspection of Fresh Vitamins, a manufacturer of Noni Fresh Juice. Fresh Vitamins marketed its product to treat conditions ranging from immune system disorders to arthritis, malaria, and alcohol addiction. Following the inspection, the firm’s president stated that he had removed impermissible claims from the firm’s website and that he was educating himself on FDA policy regarding dietary supplement claims.

Following a May 2002 inspection of Health Ventures, a manufacturer of Miracle Bust, a FDA investigator witnessed the destruction of the company’s inventory. The company signed an affidavit stating that it would voluntarily stop the sale and distribution of Miracle Bust, delete references to it on its website, and refrain from placing future orders from its contract manufacturer.

Voluntary Recalls

On May 23, 2003, Best Life International, Mayaguez, Puerto Rico, 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.

On February 11, 2003, Best Life International recalled Ancom Anti-Hypertensive Compound tablets. Although these products claimed to be dietary supplements, they were found to contain several prescription drug ingredients, including reserpine, diazepam, promethazine, and hydrochlorothiazide. The product was sold on the Internet and at retail stores.

Warning Letters

On September 30, 2003, FDA issued a Warning Letter to Dr. Gordon Joseph, Chelationcare Centers U.S.A., Scottsdale, Arizona. Dr. Joseph’s websites, <http://www.anti-thrax.com> and <http://www.homeovax.com> marketed an anthrax vaccine alternative and viral immune alternative immunizations and vaccinations. The anti-anthrax vaccine contained *Bacillus anthracis* and other ingredients that are recognized in the Homeopathic Pharmacopeia of the United States (HPUS). The “Viral Immune” product made claims that it was a defense against smallpox, measles, and encephalitis viruses. These statements, and the therapeutic claims establishing the intended use of the products, caused them to be misbranded drugs.

A Warning Letter was issued to Michael Peng, President of Greenvalley, LLC, located in Farmingdale, New York on September 26, 2003, for offering trans-dermal products intended for the treatment of diabetes and prostate disease-related symptoms via a website, <http://gyconline.com>. Moreover, although the products were represented as dietary supplements, they did not qualify as dietary supplements since they were not intended for ingestion as set forth in the Act. Additionally, FDA had no information to indicate that the products were generally recognized as safe and effective for their intended use; and the products were misbranded because the labeling failed to bear adequate directions for use.

On July 22, 2003, FDA issued a Warning Letter to Ayoula Dublin, New York, New York, for marketing and distributing “Lipostabil,” an injectable product that claimed to break down and dissolve fat “for the person who wants to lose those last 5–10 extra pounds.” Although the product claimed to be a dietary supplement, its route of administration disqualified it as a dietary supplement (since it was not intended for ingestion). Moreover, the product’s structure/function claims and lack of substantiation to show that the product was generally recognized as safe and effective for its intended use made it a new drug without an approved drug application.

On June 9 and 10, 2003, FDA issued Warning Letters to 18 firms that operated 24 websites marketing multiple coral calcium products as effective treatments or cures for a variety of diseases and conditions. Many of these coral calcium products also made unsubstantiated structure/function claims. Coral Calcium Supreme was promoted in nationally televised 30-minute infomercials featuring Kevin Trudeau

and Robert Barefoot on cable channels such as Discovery Channel, Comedy Central, and Bravo.

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. The 8 letters were targeted primarily to manufacturers of products that contained ephedrine or norephedrine hydrochloride and whose products were labeled as dietary supplements for use in weight loss, suppression of appetite, and enhanced libido.

On February 28, 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. These warnings were issued primarily as a result of the Agency’s surveillance of the firms’ websites. Fourteen of the firms responded to the Warning Letters by discontinuing the violative products and/or fraudulent claims. FDA inspected the twelve remaining firms. Since performance enhancement is one of the two principal ways in which ephedra products have been marketed, the impact of these Warning Letters was substantial. FDA continues to monitor the firms/websites/products to ensure their compliance with applicable regulations.

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.

In mid-June 2002, FDA sent seven Warning Letters to manufacturers of products containing synthetic ephedrine.

In 2002, the Agency issued 17 Dietary Supplement Warning Letters, with products containing synthetic ephedrine receiving particular attention. Marketers promoted these products for use in weight loss, energy enhancement, and to increase libido. However, the presence of synthetic ephedrine placed the products outside the definition of a dietary supplement.

Seizures and Injunctions

On September 22, 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. Despite FDA’s warnings, the defendant and his related businesses repeatedly sold dietary supplements that claimed to treat obesity and erectile dysfunction. Earlier in June 2003, FDA had issued a “Public Health Alert” warning consumers not to purchase or consume certain dietary supplements sold by Hi-Tech Pharmaceuticals, Inc., and related businesses because FDA test results had found that the supplements were adulterated with the prescription-strength drug ingredient tadalafil. An interaction between certain prescription drugs containing nitrates (such as nitroglycerin) and tadalafil could cause a drastic lowering of blood pressure. The possibility that patients who did, indeed, take nitrates could have consumed the supplements was very real since erectile dysfunction is often a common problem in people who have diabetes, hypertension, high cholesterol, and heart disease.

On September 18, 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, which caused them to be unapproved drugs. FDA had warned Jean’s Greens in November 2001, to change its labeling for the products, but it did not comply. The seized goods, which included 385 bottles and 78 mix packages, were worth more than \$4,000.

On June 18, 2003, the U.S. District Court for the Southern District of Florida entered a Consent Decree of Condemnation and Destruction for 450 bottles and 57,000 bulk capsules of dietary supplement products seized by U.S. Marshals at Global Source Management and Consulting, Inc. (Global Source), located in Sunrise, Florida, on February 13, 2003. The seizure occurred after FDA determined that these products claimed to treat a variety of medical conditions, causing them to be drugs. The seizure included almost 20 different products worth nearly \$19,000 that were sold under the names Vitamin Hut and RX for Health through retail outlets and

by mail order. Under the terms of the Consent Decree, the Claimant, Global Source, had to destroy all of the products. In addition, Global Source agreed to cease manufacturing, processing, packing, labeling, holding, or distributing “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.

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 had been 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.

In the summer of 2002, FDA filed two seizure actions against dietary supplements making unsubstantiated claims about their effect on the structure or function of the body.

United States v. Undetermined Quantities of Cases of an Article of Food and Drug Labeled in Part: Brain Nutrient Capsule, involved a 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.

United States v. 172/100 Capsule Bottles, More or Less, of an Article of Food Labeled in Part: Kirkman Taurine 325 mg Dietary Supplement Capsules, concerned a product offered as a supplementary treatment for autism. Materials promoting the product stated, “Dr. Jeff Bradstreet, a physician in Palm Bay, Florida, who treats autistic patients reports good success using Taurine.” The materials further asserted that “[t]aurine may be beneficial in developmental disorders.” FDA alleged that there is no scientific support for these claims.

In March 2002, FDA seized products marketed as dietary supplements that contained synthetic ephedrine. For example, *United States v. 1009 cases et al.*, involved the seizure of nearly \$3 million worth of Amp II Pro Drops from a company doing business as E’OLA International. Although labeled as a supplement, the product contained synthetic ephedrine. FDA alleged that the product violated the law because synthetic ephedrine is not a dietary ingredient. Accordingly, a product containing synthetic ephedrine is not a dietary supplement. The Agency also alleged that the product, which was marketed to treat obesity, made illegal disease claims. The consent decree required the product’s destruction and prohibited E’OLA from manufacturing or distributing products that violate the FD&C Act.

In 2001, FDA brought a seizure 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 “decline[d] to carve out a statutory loophole for drug manufacturers attempting to profit from the illegal drug epidemic by masquerading potentially dangerous substances as dietary supplements.”

In 2001, FDA’s injunction actions also extended to supplement marketers who violated DSHEA’s proscription of disease claims. Samples include:

U.S. v. Lane Labs USA, Inc. and Andrew Lane constituted an injunction action that involved several of Lane Labs’ products, including its shark cartilage product. Lane Labs marketed this product as a dietary supplement, but made unsubstantiated cancer treatment claims about it. FDA contended that the disease claim caused the product to be an unapproved, and therefore illegal, new drug.

U.S. v. Syntrax Innovations, Inc., et al., involved a drug called Triax Metabolic Accelerator, marketed by Syntrax as a dietary supplement for the treatment of obesity and to promote weight loss. FDA scientists determined that the product

contained tiratricol, a hazardous compound that 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.

Criminal Enforcement

As a result of concurrent Federal search warrants executed by OCI in Georgia and New Jersey, FDA warned consumers on June 20, 2003, not to purchase or consume Sibra, Stamina Rx, and Stamina Rx for Women, Y–Y, Spontane ES, and Uroprin. These products, which were marketed as dietary supplements, contained a prescription drug ingredient, tadalafil, which posed health risks when taken with certain prescription drugs containing nitrates. Tadalafil is the active ingredient in Cialis, an Eli Lilly product approved in Europe to treat male erectile dysfunction. The products were being sold over-the-counter and claimed to increase stamina, confidence, and performance. (A civil, permanent injunction was also filed—see description under Seizures/Injunctions.)

In *U.S. v. Cap-Tab Nutritional Formulating and Manufacturing Inc.*, an officer of a corporation known as Cap-Tab, along with the corporation itself, was convicted in June 2002 of one count of introducing misbranded food into interstate commerce. This case stemmed from an allegation that three individuals who were all officers of Cap-Tab conspired and knowingly substituted low-price ingredients for the ingredients listed on the label of their dietary supplement product (encapsulated vegetable powders). Three of the defendants in the case received sentences of one year's probation and were ordered to pay fines of \$500, \$250, and \$5000, respectively. A fourth defendant received a sentence of 180 days' incarceration followed by five years' incarceration on a related state criminal conviction.

In *U.S. v. Diane Eckert-Kunick*, an individual was convicted in April 2002 of introducing unapproved new drugs into interstate commerce and subsequently received a sentence of four months' incarceration in a community correctional center. The defendant, along with her parents, had formed a company known as New Gaia Products (NGP) in 1996. The company manufactured, distributed, and sold dietary supplements including colloidal gold, colloidal silver, and colloidal titanium. The defendant also distributed promotional literature claiming that NGP products cured cancer, rheumatoid arthritis, and heart disease.

In *U.S. v. Theodore Sosangelis and Thomas Knox*, two individuals pled guilty in October 2001 and February 2002, respectively, to trafficking counterfeit dietary supplements in interstate commerce. From January through July 2000, via their company, East Coast Ingredients, the defendants produced inexpensive versions of legal supplements manufactured by Muscletech. After placing fake Muscletech labels on their products, the defendants sold them to customers who believed that they were purchasing legitimate Muscletech dietary supplements. One of the defendants in the case received a sentence of three years' probation and was ordered to pay restitution of almost \$77,000.

FDA determined that the pre-DSHEA product known as Nature's Nutrition Formula One, which was marketed between 1992 and 1994 as an all natural "nutritional supplement" containing plant ingredients, was actually made with two pharmaceutical-grade chemicals, ephedrine hydrochloride and caffeine anhydrous. FDA received more than 100 reports of injuries and adverse reactions related to the product and at least one death was associated with the use of this product. This case was developed by alerts provided from adverse event reports, ORA's field staff, and the work of OCI together with DOJ. Through these sources, FDA learned that the Chemins Company, Inc., which manufactured the product, went to great lengths to hide its actions from the Agency and concealed the actual ingredients of Formula One. As a result, the government initiated a criminal prosecution against the company and its president. On July 7, 2000, a Federal judge sentenced the president to 21 months in jail and fined him and this corporation \$4.7 million. In his plea agreement, the president admitted that he and his company labeled Formula One as "all-natural" but secretly spiked the product with synthetic ephedrine hydrochloride and caffeine anhydrous. He also admitted that the product's labeling failed to disclose the use of the chemicals on the list of ingredients, and that he and his employees had misled FDA investigators and hindered inspections of Chemins. The sentence marked the culmination of a three-year investigation.

Joint Enforcement Actions

On June 19, 2003, in an action initiated by FDA, 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 such as cancer, multiple sclerosis, lupus, and heart disease. Stipulated preliminary injunctions have been entered against Trudeau, Barefoot, Shop America, LLC, and Deonna Enterprises, Inc. The preliminary injunctions prohibit the challenged claims and restrict defendants' ability to use or dissipate their assets. Legal proceedings are ongoing.

On June 17, 2003, U.S. Marshals seized 132,480 bottles of Seasilver, worth nearly \$5.3 million, from Seasilver USA's San Diego, California headquarters in an action initiated by FDA. The complaint for seizure alleged that, although Seasilver USA marketed Seasilver as a dietary supplement, it promoted it on the Internet and in marketing materials sent with the product as a treatment for serious diseases including cancer, diabetes, hypoglycemia, psoriasis, hepatitis, and arthritis. On June 25, 2003, U.S. Marshals seized an additional \$1.7 million worth of Seasilver from a distribution center in Parma, Ohio. In response to an FTC request, the Federal district court in the Southern District of California issued a temporary restraining order on June 13, 2003, prohibiting Seasilver USA, Americoloe Inc., and principals in the companies from making the challenged claims, and froze their assets. FTC is seeking preliminary and permanent injunctive relief, including restitution to consumers who purchased the product. Legal proceedings are ongoing.

On May 27, 2003, the FTC filed a complaint against an individual and four of his corporations for making false and unsubstantiated claims. The individual claimed that that five of the products marketed by him and his corporations as dietary supplements were "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 included: Lung Support Formula (claimed to cure or ameliorate asthma, emphysema, smoking damage and other respiratory problems); Antibetic Pancreas Tonic (claimed to treat or cure diabetes and to lower blood sugar levels); GH3 and GH3 Romanian Youth Formula (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 Testex (claimed to treat erectile dysfunction).

On May 9, 2003, FDA and FTC warned website operators, manufacturers, and distributors to remove misleading or deceptive claims on the Internet that their products may prevent, treat, or cure Severe Acute Respiratory Syndrome (SARS). A net "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 included dietary supplements containing ingredients such as colloidal silver, ascorbic acid, beta glucan, pycnogenol, and oregano oil.

FDA sent Warning Letters to eight firms promoting dietary supplement products as treatment or preventative remedies for SARS over the Internet. FTC also notified violative firms that they were subject to possible civil or criminal actions under the Federal Trade Commission Act. FDA has conducted appropriate follow-up to ensure that the firms have taken appropriate corrective action.

In *World Without Cancer Inc.*, FDA and DOJ, with the assistance of FTC, sought a temporary restraining order, preliminary injunction, and permanent injunction against the marketing of unapproved new drugs by three corporations and one individual. The products, laetrile, in both injectable and tablet forms, and apricot seeds, were promoted as "dietary supplement" cancer treatments through the firm's websites. The preliminary injunction and the subsequent Consent Decree of Permanent Injunction required the defendants to cease using the websites to promote the sale or offer for sale their laetrile products.

The CHAIRMAN. Thank you very much.
Mr. Beales?

**STATEMENT OF HOWARD BEALES, DIRECTOR, BUREAU OF
CONSUMER PROTECTION, FEDERAL TRADE COMMISSION**

Mr. BEALES. Good morning, Mr. Chairman, and thank you for the opportunity to provide information about our efforts to stop false and misleading marketing of dietary supplements.

Although many dietary supplements can provide benefits to consumers, too many of these products continue to promise miraculous results to sick or infirm consumers. Because of this, attacking deceptive dietary supplement claims is one of our top priorities.

Dietary supplements marketed with deceptive or unsubstantiated claims not only cause economic injury to consumers, but they also cause potential health injury if consumers forego effective treatment. For example, in June we sued a company selling a product called Coral Calcium, which the company claimed could treat or cure all forms of cancer and diseases such as multiple sclerosis, lupus, heart disease, and chronic high blood pressure.

I'd like to show you a brief clip from the Coral Calcium infomercial that highlights these outrageous claims. And then it's—there's the Coral Calcium clip, and then right behind it is a little bit from another infomercial promoting the QRay ionic bracelet.

[Video presentation.]

The CHAIRMAN. That interests me.

Mr. BEALES. These are typical of what we've seen in a variety of dietary supplements and other products.

In both of these cases, by the way, we got temporary restraining orders and asset freezes to stop the infomercials and preserve whatever money was there to pay redress to consumers.

We've also sued manufacturers of ephedra weight-loss products who were making unsubstantiated safety and no-side-effects claims. And as early as 1999, we brought cases against marketers of androgen supplements, who claimed that their products could increase strength and muscle mass safely with minimal or no negative side effects. There we were especially concerned about the health risks to teenagers who might be attracted to such products for bodybuilding.

Last December, we announced a joint enforcement initiative with FDA to attack false and unsubstantiated claims for dietary supplements and other health-related products. Since then, we have enjoined deceptive claims for more than \$1 billion in healthcare products, most of which were dietary supplements.

I would also emphasize that in all of our dietary supplement cases, and particularly in cases raising safety concerns, we work closely with, and receive excellent support from, the staff of the Food and Drug Administration. We could not have achieved the results that we have without their assistance.

Finally, I would note that we've found weight loss to be a particularly stubborn area of deceptive and unsubstantiated marketing claims. As this Committee knows, the high rate of obesity in the United States has become a significant health problem. Many marketers have been tempted to profit from this situation by making outrageous, but highly appealing, weight-loss claims for dietary supplements and other products.

As much as we would like to believe otherwise, there are no weight-loss products that will allow us to lose weight while eating all the food we want.

This is an area where we've found that traditional law enforcement is not enough. The Commission is working on other approaches. In particular, our staff is meeting with members of the media to encourage them to weed out facilely-false weight-loss claims before they're disseminated. We're hopeful that this effort will lead to a reduction in the widespread deception that has come to characterize this area.

In conclusion, I'd like to thank you for focusing attention on this important consumer health issue and for giving the FTC an opportunity to discuss its role. We look forward to working with the Committee on initiatives concerning our dietary supplement program and our activities involving weight-loss product marketing. And we look forward to your questions.

[The prepared statement of Mr. Beales follows:]

PREPARED STATEMENT OF HOWARD BEALES, DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION

Mr. Chairman and Members of the Committee, I am Howard Beales, Director of the Bureau of Consumer Protection (BCP) of the Federal Trade Commission ("FTC" or "Commission").¹ The Commission is pleased to have this opportunity to testify about our efforts to ensure the truthfulness and accuracy of marketing for dietary supplements. I will discuss the Commission's mission and our latest activities in this area, including recent coordinated enforcement with the Food and Drug Administration (FDA) and our efforts to address the problem of deceptive weight loss advertising.

The mission of the FTC is to prevent unfair competition and to protect consumers from unfair or deceptive acts or practices in the marketplace. As part of this mission, the Commission has a longstanding and active program to combat fraudulent and deceptive advertising claims about the benefits or safety of health-related products, including dietary supplements.² The dietary supplement industry encompasses a broad range of products, from vitamins and minerals to herbals and hormones, and represents a substantial segment of the consumer healthcare market. Industry sales for 2001 were estimated to be \$17.7 billion.³

Some dietary supplement products offer the potential for real health benefits to consumers. Scientific research is increasingly showing that better diets and better nutrition, including consumption of specific nutrients, can improve consumers' health. At a time when individual consumers are asked to make more decisions about their health care, access to truthful information about health-related products is more important than ever. Consumers, however, will have greater difficulty making good nutrition choices if the marketplace contains bad information.

Unfortunately, unfounded or exaggerated claims for dietary supplements have proliferated. My testimony today will describe the Commission's efforts to deal with the serious threat to consumer health that such fraud presents. I will focus on some areas of particular concern, including deceptive weight loss advertising and Internet health scams that prey on consumer fears about the latest health scare, whether anthrax or Severe Acute Respiratory Syndrome (SARS). I will also describe our recent efforts to step up coordination with FDA.

The FTC's Law Enforcement Efforts

Challenging deceptive claims in the advertising of health care products, and particularly dietary supplements, has long been a priority of the FTC's consumer protection agenda. The Commission has filed more than one hundred law enforcement actions over the past decade challenging false or unsubstantiated claims about the efficacy or safety of a wide variety of supplements.⁴ In recent years, we have increased our commitment of resources to combat deception and fraud in health-related industries and it is currently one of our top consumer protection priorities. Since last December, the FTC has challenged deceptive advertising for health care products with a total of more than \$1 billion in sales, most of that for dietary supplements.⁵

¹The written statement presents the views of the Federal Trade Commission. Oral testimony and responses to questions reflect my views and do not necessarily reflect the views of the Commission or any individual Commissioner.

²Our authority in this area derives from Section 5 of the Federal Trade Commission Act, which prohibits "unfair or deceptive acts and practices in or affecting commerce," and Section 12, which prohibits the false advertisement of "food, drugs, devices, services or cosmetics." 15 U.S.C. §§ 45, 52.

³*Supplement Business Report 2002*, Nutrition Bus. J., § 2 (2002).

⁴A complete list of the Commission's dietary supplement cases is available at <http://www.ftc.gov/bcp/online/pubs/buspubs/dietadvertisingcases.pdf>.

⁵This represents the total sales for products the Commission challenged in seventeen actions from December 2002 through July 2003.

The Commission focuses its enforcement priorities on products that present significant safety concerns for consumers, on advertising making unfounded claims of treatment for serious diseases, and on large national advertising campaigns for products for which the supporting science is nonexistent or clearly inadequate. Many of our recent actions have focused on specific media where fraudulent claims appear to be more prevalent, such as nationally aired infomercials and the Internet. In the past year, the Commission has filed or settled cases challenging claims for supplements marketed for almost every imaginable health problem: to treat serious diseases like cancer, multiple sclerosis, heart disease, emphysema, diabetes, and Alzheimer's; or to cause effortless, substantial and immediate weight loss; or to stop snoring; or even to increase bust size.⁶ We continue to pursue aggressive enforcement and currently have approximately forty active investigations involving other cases of deceptive supplement marketing.

We recognize that an effective enforcement program requires more than just a volume of cases. It also requires strong remedies. In the past year, we have increased our use of the Federal courts in cases of egregious health fraud. The FTC has filed fourteen of the last seventeen actions against supplement and other health product marketers in Federal court which enables us to obtain, when appropriate, immediate injunctions, asset freezes and, in many cases, large judgements for disgorgement of profits or consumer redress. When necessary and appropriate, we have moved to obtain an *ex parte* temporary restraining order. Two recent examples involve allegedly fraudulent multi-million dollar marketing campaigns using the Internet and heavily-aired national infomercials. In our action against *Seasilver USA* for its sale of a concoction of multiple minerals, herbs and other ingredients to treat 650 diseases, the District Court in Nevada immediately placed the defendants under a restraining order, receivership and asset freeze.⁷ We obtained similar relief in our action against Kevin Trudeau, Robert Barefoot, and related parties for their allegedly fraudulent marketing of "Coral Calcium," a purported cure for cancer, multiple sclerosis, and other diseases or conditions.⁸

Our remedies seek to address not just economic injury to consumers but also potential injury to health. When the marketing of a supplement presents a health risk to consumers through misleading or unsubstantiated safety claims, the Commission has imposed strong warning remedies in labeling and advertising, and sometimes restrictions on specific claims or methods of marketing.⁹

⁶*FTC v. Seasilver USA, Inc.*, No. CV-S-03-0676-RLH-LRL (D. Nev. filed June 12, 2003) (complaint for injunctive and other equitable relief involving Internet and infomercial marketing for multi-ingredient supplement for 650 diseases); *FTC v. Kevin Trudeau*, 03 C 904 (N.D. Ill. filed June 9, 2003) (complaint for permanent injunction and other equitable relief involving infomercial marketing of "Coral Calcium Supreme" supplement for several diseases); *Wellquest Int'l, Inc.*, No. CV-03-5002 PA (RNBx) (C.D. Cal. filed July 10, 2003) (complaint and final stipulated orders including \$3.2 million in consumer redress for marketing of "Bloussant" herbal supplement to increase bust size and other products); *FTC v. Health Lab. of N. Am.*, No. 031457 (D.D.C. July 1, 2003) (stipulated final order involving safety and weight loss claims for a supplement containing ephedra); *FTC v. USA Pharmacal Sales, Inc.*, No. 8:03-CV-1366-T23EAJ (M.D. Fla. July 1, 2003) (stipulated final order involving safety and weight loss claims for a supplement containing ephedra); *U.S. v. Michael S. Levey*, No. CV-02-4670 GAF (AJWx) (C.D. Cal. June 30, 2002) (complaint challenging no side effects and weight loss claims for a supplement containing ephedra).

⁷*FTC v. Seasilver USA, Inc.*, No. CV-S-03-0676-RLH-LRL (D. Nev. filed June 12, 2003).

⁸*FTC v. Kevin Trudeau*, No. 03C904 (N.D. Ill. filed June 9, 2003). The FTC has also obtained significant funds for consumer redress in several cases. *See, e.g., FTC v. Rexall Sundown, Inc.*, No. 00-7016-CIV-Martinez (S.D. Fla. March 11, 2003) (stipulated final order including redress fund of up to \$12 million); *FTC v. Enforma Natural Prods., Inc.*, No. 04376JSL (CWx) (C.D. Cal. Apr. 25, 2000) (stipulated final order including \$10 million in consumer redress); *FTC v. Slim America, Inc.*, No. 97-6072-CIV-Ferguson (S.D. Fla. June 30, 1999) (final judgment for permanent injunction and damages, including \$8.3 million in consumer redress).

⁹*See, e.g., FTC v. Health Lab. of N. Am.*, No. 031457 (D.D.C. July 1, 2003) (stipulated final order requiring warning statement for weight loss product containing ephedra); *AST Nutritional Concepts & Research, Inc.*, No. 99-WY-2197 (D. Colo. May 4, 2000) (stipulated final order requiring warnings about the risks of androstenedione, a steroid hormone, and about the risks of ephedra contained in a body-building supplement); *Mex-RX US, Inc.*, No. SACV99-1407-DOC (ANX) (C.D. Cal. Nov. 24, 1999) (stipulated final order requiring warnings about both androstenedione and ephedra); *Panda Herbal Int'l, Inc.*, FTC Dkt. No. C-4018 (July 30, 2001) (consent order requiring warning about interaction of St. John's wort, a botanical ingredient, with certain HIV/AIDS medications); *Global World Media Corp.*, FTC Dkt. No. C-3772 (Oct. 9, 1997) (consent order requiring warning about "Herbal Ecstasy" [sic], a street drug alternative containing ephedra and prohibiting ads for Herbal Ecstasy and similar products containing ephedra in any media where more than 50 percent of the audience is under twenty-one years of age); *Christopher Enter., Inc., et al.*, 2:01 CV-0505 ST (C.D. Utah Nov. 29, 2001) (stipulated final order prohibiting marketing of comfrey, a botanical ingredient associated with severe liver

Continued

Coordination with FDA

The FTC and FDA have concurrent jurisdiction over dietary supplements and other health and nutrition products and work closely to challenge deceptive and unsubstantiated claims. Under a longstanding liaison agreement,¹⁰ the FTC has primary responsibility for the advertising of foods, cosmetics, devices, and over-the-counter drugs, while FDA has primary responsibility for the labeling of those products and advertising of prescription drugs. In many of our investigations of dietary supplement advertising claims, the FDA staff provided scientific expertise and technical assistance. The staff of the two agencies have always coordinated closely on enforcement matters. In the past year, however, the level of cooperation and the volume of coordinated law enforcement has been unprecedented.

In December 2002, FDA Commissioner Mark McClellan announced a significant initiative to improve consumer access to timely and accurate information about nutrition and health in both the dietary supplement and the food marketplaces. The dual goals of this Consumer Health Information for Better Nutrition Initiative are to provide more flexibility for food marketers to convey information about emerging nutrition science and to improve the accuracy of health information for dietary supplements by stepping up enforcement against deceptive claims.

To implement the enforcement component of the initiative, the FTC and FDA staff formed a joint task force on dietary supplement marketing. Through that joint enforcement task force, the two agencies have been able to identify more efficiently the worst offenders, to share more easily information about the marketers and their products, to assess more thoroughly the safety and efficacy data, and to formulate a more effective plan to stop fraud and deception, using the strongest tools available to each agency.

The FTC and FDA announced the results of the first six months of coordinated enforcement efforts on July 10, 2003. For the FTC's part, this coordination resulted in seventeen actions that were filed or settled against supplement advertisers claiming cures for a wide variety of serious diseases and representing deceptive product sales of more than \$1 billion. These efforts include joint FTC Federal court actions and FDA product seizures in the *Seasilver USA* and *Kevin Trudeau/Robert Barefoot* cases. In addition to these two formal joint actions, the FDA also provided technical assistance to the FTC in its investigation and recent action against Glenn Braswell and his company, Gero Vita.¹¹ Glenn Braswell was the principal behind a massive direct-marketing campaign involving a myriad of supplements sold through glossy, magazine-like publications including the *Journal of Longevity*.¹² The products touted by Gero Vita, under names such as "Lung Support Formula," "Antibiotic Pancreas Tonic," and "Therapeutic GH3 Romanian Youth Formula" purported to treat everything from asthma, emphysema, diabetes, and Alzheimer's, to weight loss and aging.

Since December, the two agencies have also issued a combined total of more than 200 Warning Letters, cyber letters, and e-mail advisories to various companies marketing dangerous or fraudulent health products over the Internet. The cyber letter or e-mail warning has proven to be a very effective tool to address the proliferation of health scams on the Internet.¹²

The Internet can be a convenient medium for unscrupulous marketers who hope to profit from consumer fears about the latest public health scare. Many of the e-mail Warning Letters issued by the Commission in the past year have involved the marketing of dietary supplements and other products to treat or prevent SARS, anthrax infections, and various agents of biological, chemical or nuclear terrorism.¹³ Although it would not be feasible to develop a formal case and file an action against each of the many health scams that pervade the Internet, the Commission has achieved voluntary compliance by most of the web marketers contacted in our recent e-mail sweeps. The dietary supplement industry response to the Commission's efforts contributed to the high compliance rate. All of the principal trade associations representing supplement marketers have twice backed the FTC's efforts with strong

toxicity, for internal consumption or application to open wounds, and requiring warning for other uses).

¹⁰ See Working Agreement Between FTC and FDA, 3 Trade Reg. Rep. (CCH) ¶9,859.01 (1971).

¹¹ *FTC v. A. Glenn Braswell*, No. CV 03-3700 DT (PJWx) (C.D. Cal. filed May 27, 2003) (complaint for permanent injunction and other equitable relief).

¹² The FTC has worked to combat Internet health fraud for many years, initiating the "Operation Cure.All" project begun in 1997, that includes the FDA and many other state, federal, and international authorities. Since 1997, the Commission has issued more than 1000 advisory and Warning Letters as part of this project.

¹³ The texts of sample FTC Warning Letters are posted on the FTC website. See, e.g., <<http://www3.ftc.gov/opa/2002/01/warnair.htm>>.

public pronouncements against unfounded claims—first in the case of anthrax treatments, and more recently in the case of SARS-related promotions.¹⁴

Weight Loss Advertising

In some segments of the health products industry, even the most active enforcement program and toughest remedies cannot completely clean up the deception. The rapidly growing, multi-billion dollar weight loss industry appears to be one area for which the Commission must consider other approaches, and enlist new partners, to augment traditional law enforcement.

The high rate of obesity in the United States has become a significant health problem. More Americans, including children, are overweight or obese than ever before. As a result, diabetes and many other weight-related illnesses are also increasing. Many Federal agencies, scientific organizations, health professionals, and consumer groups are trying to better understand the complex causes of obesity and how it can be reversed. The Commission can address one aspect of the problem by stopping the companies that pitch ineffective products promising quick, easy, and dramatic weight loss. Such products not only are a waste of money, but also lure consumers away from more difficult but successful weight loss strategies.

It is no surprise that many marketers have been tempted to profit from the growing obesity problem with outrageous but highly appealing claims for dietary supplements and other products and programs. The U.S. market for weight loss products reached \$37.1 billion in 2001 and has been growing at a rate of 6–7 percent a year.¹⁵ Few things sell better than a magic bullet for weight loss and it is precisely that quick and easy weight loss pill that we saw dominating the market in our 2001 review of weight loss advertising.

In September 2002, the staff of the Federal Trade Commission released the *Report on Weight-Loss Advertising: An Analysis of Current Trends* (Weight Loss Advertising Report).¹⁶ The Report analyzed claims from 300 advertisements disseminated during 2001 and concluded that the use of false or misleading claims in weight-loss advertising is widespread. More than half (55 percent) of the 300 ads made claims that were almost certainly false or at the very least likely to lack substantiation. A comparison of these ads with a sample from 1992 revealed a much higher frequency of questionable claims and marketing techniques in 2001 compared to a decade ago. For example, ads in the 2001 sample were much more likely to promise substantial, rapid and permanent weight loss, often without any diet or exercise. Furthermore, two-thirds of the products promoted in 2001 were dietary supplements, representing a major shift from 1992 when meal replacement products were the most promoted category.¹⁷

As with any instance of deceptive advertising, the Commission has responded with tough enforcement. The agency has taken action against nearly one hundred deceptively marketed weight loss products, most of them supplements, since 1990. Despite such constant and vigorous law enforcement actions, deceptive weight loss advertising has increased over the same period.

Traditional law enforcement alone is not an adequate solution to weight loss scams. The Commission is working actively on other approaches to augment its traditional enforcement and is reaching out to new partners in this effort. The Commission held a public workshop in November 2002 to identify new approaches to fighting the proliferation of misleading claims.¹⁸ Government officials, scientists, public health groups, marketers of weight loss products, advertising professionals, and representatives of the media participated in the day-long event. A report on the results of the workshop will be released in the next few months.

One encouraging outcome of the FTC's report and workshop has been a renewed interest by responsible members of the weight loss and dietary supplement industries to partner with government and other groups in meaningful self-regulatory efforts. Just two weeks ago, the FTC and the Partnership for Healthy Weight Management, a broad coalition that includes the FTC, public health groups, scientists and industry representatives, hosted a meeting of trade associations representing the dietary supplement industry and private companies engaged in the marketing of weight loss products and services. The purpose of the meeting was to consider the development of self-regulatory guidelines for weight loss advertisers. There are many challenges to developing a successful self-regulatory program, but the indi-

¹⁴ See <<http://www.ftc.gov/opa/2001/11/webwarnltr.htm>> (FTC Warning Letter describing joint industry statement of support).

¹⁵ Marketdata Enterprises, Inc., *The U.S. Weight Loss & Diet Control Market 6* (2002).

¹⁶ Copies of the *Weight Loss Advertising Report* can be found at <<http://www3.ftc.gov/bcp/reports/weightloss.pdf>>.

¹⁷ *Weight Loss Advertising Report* at 21.

¹⁸ Advertising of Weight Loss Products, 67 *Fed. Reg.* 59,289 (2002).

vidual companies and associations that attended this meeting demonstrated a real commitment to the effort.

In addition, subsequent to the weight loss report, the FTC staff met with members of the media and other interested parties to encourage them to weed out facily false weight loss advertising claims before they are disseminated.¹⁹ We believe that the media can play a significant role here in cleaning up the weight loss market and we hope to minimize the burden on those that are willing to take on this responsibility. A significant focus of the Commission's 2002 workshop was on identifying claims that are not scientifically feasible for any weight loss product, such as "eat all you want and still lose weight." Based on the testimony from the workshop, other comments received, and the agency's experience in policing weight loss advertising, the Commission staff has distilled, and will shortly publish, a brief checklist to aid media screening of weight loss ads.

Conclusion

The FTC will work closely with FDA to continue to reach out to marketers, the media, and other interested parties to combat deception in dietary supplement marketing. We will maintain our high level of traditional enforcement activities while exploring other approaches to enhance those efforts. The Commission thanks the Committee for focusing attention on this important consumer issue and for giving the Federal Trade Commission an opportunity to discuss its role. The Commission looks forward to working with the Committee on our initiatives involving the marketing of dietary supplements.

The CHAIRMAN. Thank you very much, Mr. Beales. I want to thank both of you for being here today.

Mr. Taylor, in your statement—I agree with it—you say, "Use of these products has grown dramatically in popularity in the United States." And it seems to me that should heighten our concern, if the use of products has—that supplements containing steroid precursors—and it seems to me that for you to say that, "Scientific evidence about the benefits or adverse consequences of steroid precursors appears to be inconclusive," what does it require for it to be conclusive?

Mr. TAYLOR. Well, sir, what FDA is doing right now is, we're in the process of taking—of reviewing the science that's connected to these steroid precursors. The analysis involving steroid precursors involves complex analysis of the legal and regulatory issues, and one of the factors that's involved in this analysis is safety data, which, quite frankly, is in short supply, because there aren't that many studies conducted, either by industry or the government, regarding these products.

Nonetheless, we are working expeditiously to determine how to classify steroid precursors, specifically whether they should be regulated as a dietary supplement or a drug. And we hope to have a decision, in a matter weeks and not months, as to how to classify these products.

However, I also want to emphasize that there's a tendency to lump all steroid precursors together. And, quite frankly, the analysis is a little more nuanced than that. Based on the chemistry of the products, we really have to look at the products on a case-by-

¹⁹ See, e.g., Remarks of FTC Chairman Timothy J. Muris to the Cable Television Advertising Bureau (Feb. 11, 2003), *Do the Right Thing* (Apologies to Spike Lee), <<http://www.ftc.gov/speeches/muris/030211rightthing.htm>>; Remarks By Commissioner Sheila F. Anthony Before The Food and Drug Law Institute 45th Annual Educational Conference (Apr. 16, 2002), *Combating Deception in Dietary Supplement Advertising*, <<http://www.ftc.gov/speeches/anthony/dssp2.htm>>; Remarks of Commissioner Orson Swindle to the Aggressive Advertising and the Law Conference (Apr. 28, 2003), *Combating Deceptive Advertising—The Role of Advertisers, the Media, and the FTC*, <<http://www.ftc.gov/speeches/swindle/030428aggressive.htm>>.

case basis in order to determine where it rests within our regulatory rubric.

The CHAIRMAN. Well, for you to say that the evidence is inconclusive, at least as far as some steroid precursors are concerned, I think, flies in the face of, not anecdotal evidence, but reported evidence.

Mr. TAYLOR. Well, Mr. Chairman, I didn't mean to suggest that the evidence was conclusive. Obviously, in the context of THG, we have made a conclusion that it falls outside the context of a dietary supplement, and that we will regulate it as an unapproved new drug.

What I'm saying is that we haven't made a final determination, and we're looking at the body of evidence as it relates to each of these steroid precursors, and that we'll be making a decision soon.

So I don't mean to suggest that it's inconclusive, because we haven't finished our review, but that's something we are undertaking expeditiously.

The CHAIRMAN. But the thing that bothers me about this process is that THG comes on the market or as it becomes used by a large number of people, then it comes to your attention, then you analyze it, and then you decide that it should be banned. We're always playing catch up. We're always playing catch up here.

Why don't we ban these things? And then that would prevent it from coming on the market, Mr. Taylor.

Mr. TAYLOR. Because—

The CHAIRMAN. And sure as the sun will come up tomorrow, when THG is banned, some smart lab somewhere in America—and witnesses will testify to this fact—will come up with another and probably even harder to detect than THG was until we invented—so I think the head of the Anti-Doping Agency, our witness, will clearly testify that we're playing catch up rather than prevention.

Mr. TAYLOR. I would agree with that assessment. We were just recently made aware of THG, and you're absolutely correct—

The CHAIRMAN. And you will be made aware of another drug—

Mr. TAYLOR. You've absolutely right. There are—

The CHAIRMAN.—and of another product. How many lives are destroyed before you decide that they should be banned?

Mr. TAYLOR. Well, sir, as I said, as we become aware of each product, it will undergo the analysis, and we will act on it as quickly as we can.

The CHAIRMAN. If you banned all steroid precursors, then you wouldn't have to worry about it when it comes out on the market. Well, let me tell you why I'm a little bit skeptical. Why did it take 9 years, 9 years, to propose a rule pursuant to DSHEA to ensure good manufacturer practices by dietary supplement manufacturers? Why 9 years, Mr. Taylor?

Mr. TAYLOR. Sir, I don't have the answer to that. I've only been involved in the process a short period of time. But I can tell you that in March of 2003, we issued a proposed rule that would give the agency the ability to ensure that all products are pure, potent, that they're manufactured consistently. It would, as proposed, ensure that there were good quality control processes in place. The comment period for that proposed rule ended in the middle of August, and we're currently reviewing those comments, and we hope

to have a final rule as quickly as we can. We do think it's an important step in regulating—

The CHAIRMAN. What is “quickly as we can”? That's a great line, Mr. Taylor. When is “as quickly as we can”? Because 9 years, so far, was, quote, “as quickly as you can.”

Mr. TAYLOR. Sir, I can't give you an exact date, but you—I mean, your point is warranted. This is something that's important and needs to be done quickly, and we are in the process of doing so.

The CHAIRMAN. So maybe since the record is clear that it took 9 years to propose the rule, then maybe it may not be, quote, “as quickly as possible”—“as quickly as possible” may be in the eye of the beholder. And the fact that you weren't—it didn't happen on your watch, Mr. Taylor, is not sufficient statement for me or American consumers, to be honest with you. You're representing an Agency, not yourself, and your Agency took 9 years before you even proposed a rule, which has not been put into effect yet. That's your agency.

Mr. TAYLOR. You're absolutely right, Mr. Chairman. My point was that I cannot explain the delay. I only can walk you through what has happened since I've been involved. That's not to make an excuse.

The CHAIRMAN. Currently DSHEA doesn't mandate that manufacturers provide the FDA all consumer reports of adverse health effects caused by manufacturers' products. Why in the world shouldn't manufacturers be required to report adverse health effects that's caused by any product, no matter what it is?

Mr. TAYLOR. Well, in the context of pharmaceuticals, our manufacturers are required to report adverse events for over-the-counter products that were approved to a new drug application and for prescription pharmaceuticals. Manufacturers are not required to submit mandatory adverse events for those over-the-counter products that were—

The CHAIRMAN. You put out a product, you get complaints from the users, but you don't have to report it to anybody.

Mr. TAYLOR. That's correct. Under the current statute, the submission of the adverse event reports is purely voluntary.

The CHAIRMAN. I won't ask you whether you agree with that or not.

Mr. Beales, what assurances do consumers have that what is included as an ingredient on the label of a dietary supplement is, in fact, contained in the product? How do you test to ensure products do what their manufacturers claim they do?

Mr. BEALES. Well, what we do—our focus is on the marketing claims that are made for the dietary supplements, and what we do is look at what the manufacturer is claiming the product—

The CHAIRMAN. You require a bottle of water to list what is in the bottle of water, right?

Mr. BEALES. Well, that's not our requirement, no. I mean, our focus is what you say the bottle of water will do. And then we ask to see the scientific evidence that substantiates that.

The CHAIRMAN. Well, if you see the Yellow Jacket bottle there that contains a list of certain ingredients, how do you know that those ingredients are, indeed, factual?

Mr. BEALES. Well, we can have the product tested. And in some circumstances, we've done that. But usually what our focus has been is the claims about what the product will do.

The CHAIRMAN. Well, Mr. Taylor, I want to go back to you for a second. The reason why I'm incensed about this issue is because I'm hearing more and more from high school coaches, from parents, from all kinds of people, including a very interesting article in *Sports Illustrated*, that more and more young people are beginning to use these steroid precursors and other products, which are available over the counter. The NCAA and the—oh, let me just—"The NFL, NCAA, World Anti-Doping Agency, which oversees Olympic drug testing, all ban ephedra." But yet a young person now can walk into any drugstore or gas station and buy it. Now, does it sound like there's some—a problem there, Mr. Taylor?

Mr. TAYLOR. There is a problem. I mean, we support the efforts of those organizations. When we asked the RAND Corporation to study the adverse events that we supplied to them, one of their conclusions was that ephedra posed special risk in the context of sports performance, with little or no benefit. And so one of the things that we did do this year is, we issued Warning Letters to approximately 26 manufacturers who were marketing products specifically for sports performance. One of the reasons we're concerned about its use in the context of sports performance is because it can act as an adrenaline boost and masks—and it will sometimes mask conditions of fatigue, which we think might be harmful to an athlete who's unaware of the fact that they're laboring. So it is of concern to us, and we have sent Warning Letters. And in response to those Warning Letters, all but one site removed their claims and stopped engaging in the practice.

The CHAIRMAN. Well, finally, Mr. Beales, I understand that here's the product names that have steroid precursors in them—Sos Extreme, Cyclo Extreme, Megabol-X, Anabol-X, et cetera. They're clearly marketing to young people, right?

Mr. BEALES. Well, some of them clearly are.

The CHAIRMAN. Well, Senator Smith?

**STATEMENT OF HON. GORDON H. SMITH,
U.S. SENATOR FROM OREGON**

Senator SMITH. Thank you, Mr. Chairman, for holding this hearing. I think your questions indicate just how important it is that we keep the focus on this area, because I, like you, am aware of many young people who are utilizing these things, which professional athletes are now banned from using. And we seem to be in a pill-driven society. If you want more or want to feel better, somehow, pop a pill and you can be made better.

And so I guess you know, this is a new area for me, and so I don't want to necessarily repeat what the Chairman has asked, but I am concerned about whether or not the Dietary Supplement Health and Education Act, that Senator Hatch's testimony speaks to, is working.

Is it working, Mr. Taylor? Are we getting the information out to the consuming public that there are some dangerous things out there, or are we just always swinging behind the curve here?

Mr. TAYLOR. Well, let me break down my answer in two parts. In the context of enforcement, over the last 2 years we've increased the number of cases that we've brought, we've increased the number of notifications that we've provided to industry regarding the nature of the product. So we are doing a better job of utilizing the authorities that are contained in DSHEA. And if you look at our enforcement work over the last 5 years, you'll notice a steep increase.

So I do think that we are doing a better job of enforcing DSHEA, and we'll continue to do so. Our main priority is those products that pose a direct risk to the consumer or indirect risk to the consumer. And what I mean by indirect risk is that if you notice, in the appendix to my testimony, that there are fair number of products that are marketed in lieu of approved drugs. For example, we witnessed the voluntary destruction of a product that was marketed as a cure for anthrax, smallpox, and other conditions. Obviously, there are approved drugs that treat or cure that condition. So when a product poses an indirect risk, we also make that a high priority.

So we have done more with those authorities in terms of the enforcement side. But an important part of that enforcement side, enforcement strategy, is also informing the public. And one of the things that we've learned from the FTC is how to hone our message better and how to reach more people regarding the potential danger that these products pose.

We have found that by doing good consumer outreach, good education, and providing good guidance to industry, that more people can be reached in terms of providing the message regarding particular products that we think are potentially dangerous.

Senator SMITH. I'm curious about when you two hand off the baton from the FDA to the FTC. I mean, how does it work? Is it working well and can it be improved?

Mr. TAYLOR. Well, I'll let Mr. Beales speak for himself. It's not so much handing off the baton. Our authority is actually complementary. We regulate the manufacturing, the distribution, and the labeling, while the FTC's responsibility—jurisdictional responsibility is the advertising. And from FDA's perspective, one of the reasons that we think working with the FTC is so beneficial is because there is a point in time where we've tried to bring a case, and a company could try to change their practices in a way to evade FDA, but they might still fall under FTC's rubric. They might still—they might be changing the manufacturing or the distribution of the product, but they might still have advertising issues that FDA could not deal with because of the jurisdictional limitations. By working with FTC in a complementary manner, at the same time on the same cases, we provide better relief to the American public by ensuring that these products, if they are manufactured improperly, are dealt with from that standpoint, if they're improperly labeled, dealing with them from that standpoint, and if their advertising is not permissible, we also are able to deal with those companies from that perspective. It provides greater relief, and it gives strength to the government's overall efforts to deal with these products.

Senator SMITH. Mr. Beales, what do you—

Mr. BEALES. I think we have a very strong working relationship and that has really enabled us to accomplish a great deal of what we have accomplished on the enforcement side. We have a staff-level group that meets regularly, where we talk about the cases that are in the pipeline, who has the best remedies, who's in the best place to proceed, and where we get help from FDA on the scientific issues, that is not particularly our expertise. And sometimes we've done that with joint enforcement actions against a particular company, where we've enjoined the—or sought an injunction to block the sale of the product, FDA has actually seized the product to get what's out there off the market.

Senator SMITH. Well, it's my understanding that over 18,000 side-effect claims have been made against Metabolife, and I'm wondering what role in that case, with that company, the FDA and the FTC are pursuing together.

Mr. BEALES. Well, under our rules, investigations are non-public, and we can't confirm or deny that there are particular investigations. What we've been especially interested in in the ephedra area is claims—express safety claims. The evidence about safe or unsafe is controversial and not our expertise, but it's fairly clear that there is doubt there. And we don't think that the evidence will substantiate an express claim that this product is safe or that there are no side effects. We've challenged claims like that in a number of cases.

Mr. TAYLOR. Sir, I can't comment on ongoing investigations, either, but I can tell you that those adverse events were submitted by the Agency to the RAND Corporation as part of the RAND Corporation's study, and it's that class of data that we're currently reviewing, in terms of our next steps regarding ephedra.

We issued—we reopened the comment period on the 1997 proposed rule, in March. We also proposed new warning labels for ephedra. And Metabolife's adverse events are part of the record that the agency is considering. As it looks at these safety issues and addresses that, we'll deal with ephedra in the future.

Senator SMITH. Thank you very much, Mr. Chairman.

The CHAIRMAN. I thank you both. I thank you very much for appearing today, and I appreciate it. Thanks for your good works.

Our next panel is Mr. Terry Madden, Chief Executive Officer of the United States Anti-Doping Agency, Mr. David Seckman, Executive Director and CEO, National Nutritional Foods Association, Dr. Arthur Grollman, Distinguished Professor of Pharmacological Sciences at the State University of New York, Mr. Charles Bell, Programs Director at the Consumers Union, and Mr. Greg Davis, Student at the University of San Diego School of Law.

I want to thank you all for coming today, and I would like to begin and welcome back Mr. Madden.

**STATEMENT OF TERRY MADDEN, CHIEF EXECUTIVE OFFICER,
UNITED STATES ANTI-DOPING AGENCY**

Mr. MADDEN. Thank you, Mr. Chairman. Thank you, Mr. Smith. Good morning.

My name is Terry Madden. Thank you for the opportunity to testify. Today I come to you as the CEO of the United States Anti-Doping Agency, which has been recognized by Congress as the

independent national anti-doping agency for Olympic and Paralympic sport in the United States. Our mission is to protect and preserve the health of athletes, the integrity of competition, and the well-being of sports through the elimination of doping. Last year, we conducted more than 6,000 tests for steroids and other prohibited substances.

I'm here today to speak to you about the increasing number of products sold over the counter in the United States that contain anabolic steroid precursors. These products, marketed and sold as dietary supplements, contain substances such as androstenedione and norandrostenedione. These substances are one chemical step away from anabolic steroids. Once ingested, these products are converted within the body into anabolic steroids. While this is a problem that affects athletes, it is, in truth, a significant public-health issue that transcends sport and places America's consumers at risk.

The perils of anabolic steroid use are well known. In Olympic sport, the most notable systematic, state-supported program of doping with anabolic steroids was conducted by the East Germans from 1974 until the Berlin Wall fell. The results of this program have since been substantiated through the testimony of many of the athletes themselves, their coaches, and during the East German doping trials.

One of the anabolic substances developed by the East Germans as part of their doping program was androstenedione. In the body, androstenedione metabolizes into the anabolic steroid, testosterone, and other steroids. The documented side effects of steroid and steroid precursors among these East German athletes, particularly women athletes, are severe, and include effects on the liver and reproductive system, susceptibility to cancers, and permanent masculinization of women. Other side effects include growth arrest in adolescents and shrinking of testicles and impotence in men.

Today, American consumers can walk into their corner nutrition store and buy products containing androstenedione. After professional athletes acknowledged that they had used androstenedione, sales of these supplements in the United States dramatically increased. This phenomenal demand, particularly among teenagers, led to the mass-marketing of other steroid precursors, like 19-norandrostenedione, which metabolizes into the body into steroid nandrolone, another controlled substance. Now the nutrition shelves and the Internet are flooded with products containing these steroid precursors.

Further, the manufacturers of these substances attempt to take advantage of DSHEA by touting these substances as natural and implying in their advertising that natural equals safe.

Under the current regulatory scheme, a manufacturer is not required to test its steroid precursor product for either side effects or purity prior to putting it on the shelf. This is of particular concern when women and adolescents are considered. Instead, the burden rests on the government agencies to prove that a particular product is harmful. However, by the time action is taken against a specific product, an unscrupulous manufacturer could simply make a minor chemical change and reintroduce the product.

The marketers of these products glorify the muscle-building qualities of these substances, and do everything possible to rein-

force the association between these products and controlled anabolic steroids. These products are marketed under the names that reinforce their connection to anabolic steroids, including Cycloroid, Masterbolan, Anabol-X, Paradrol, and Animal Stak. These products are advertised as equal or better than real steroids, and promise the user huge gains in muscle mass. The advertising also stresses that these products are legal, in order to raise the implication that they must be safe.

In a society where high school athletes can sign multi-million dollar endorsement contracts, we cannot expect teenagers to ignore advertisements claiming that these products are safe alternatives to steroids and will make them ripped, huge, improve their athletic performance, and give them the body of their dreams.

For Olympic athletes who know to avoid these products, there remains another concern. In increasing numbers, athletes are failing doping tests after taking mislabeled dietary supplements. Studies have shown that an alarmingly high percentage of dietary supplements contain doping substances that are not disclosed on the label.

For example, a recent study of 624 dietary supplements by the International Olympic Committee found that 41 percent of the products from American companies contained a steroid precursor or banned substance not disclosed on the label.

The CHAIRMAN. Did you find that remarkable?

Mr. MADDEN. I find that extremely high, Senator. It's very worrisome to our athletes. Remembering that the athletes—these could be tainted supplements, and the athletes are taking them, believing them to be clean products and it will assist them just as vitamins would. Their fear is that—

The CHAIRMAN. And who's supposed to monitor that?

Mr. MADDEN. Senator, I think that's a Washington question, but I would suggest the FDA.

The CHAIRMAN. Thank you, sir.

Mr. MADDEN. USADA believes that the current, effectively unregulated, availability of products containing steroid precursors in the United States is a health crisis that affects not just Olympic athletes, but every American teenager who dreams of becoming a professional or Olympic athlete and every consumer who takes one of these products without being informed of the risks. Additionally, because of the risk of contamination, American consumers may be unknowingly ingesting steroid precursors.

There is simply no credible argument supporting the over-the-counter availability of products containing steroid precursors. I am sure that Congress would take immediate action to prevent a pill that, once swallowed, would metabolize into cocaine, from being sold over the counter, yet that is what is happening every day with steroid precursors in America. It is illegal to sell a steroid without a prescription, but currently it is perfectly legal to sell a pill that creates the steroid in the body. Every day that these products remain on the shelves is another day that American consumers are placed at risk. The time has come to put a stop to the proliferation of these dangerous products.

On behalf of USADA, I would like to thank Senators Biden, Hatch, Grassley, and Harkin for their attention to this matter, and

commend their introduction of the Anabolic Steroid Control Act of 2003. This important bill amends the Controlled Substance Act by scheduling the substances I have discussed here today, and making it easier to schedule any anabolic steroid precursors introduced by manufacturers in the future. USADA believes that this bill is an appropriate solution to the steroid precursors problem.

Similarly, I would like to thank Congressman Sweeney and Congressman Osborne for their support on this issue and the introduction of the Anabolic Steroid Precursor Control and Health Education Act, which also effectively addresses this issue by amending the Controlled Substances Act to make it easier to schedule the precursors of previously scheduled anabolic steroids.

Finally, I would like to thank this Committee for its time and its interest in this important public health issue.

Thank you.

[The prepared statement of Mr. Madden follows:]

PREPARED STATEMENT OF TERRY MADDEN, CHIEF EXECUTIVE OFFICER,
UNITED STATES ANTI-DOPING AGENCY

Mr. Chairman, Members of the Committee, good morning, my name is Terry Madden. Thank you for the opportunity to testify. Today I come to you as the CEO of the United States Anti-Doping Agency, which has been recognized by Congress as the independent, national anti-doping agency for Olympic and Paralympic sport in the United States. Our mission is to protect and preserve the health of athletes, the integrity of competition, and the well-being of sport through the elimination of doping. Last year we conducted more than 6,000 tests for steroids and other prohibited doping substances.

I am here today to speak to you about the increasing number of products sold over-the-counter in the United States that contain anabolic steroid precursors. These products, marketed and sold as dietary supplements, contain substances, such as androstenedione and norandrostenedione. These substances are one chemical step away from anabolic steroids. Once ingested these products are converted within the body into anabolic steroids. While this is a problem that affects athletes, it is, in truth, a significant public health issue that transcends sport and places American consumers at risk.

The perils of anabolic steroid use are well known. In Olympic sport, the most notable, systematic state-supported program of doping with anabolic steroids was conducted by the East Germans from 1974 until the Berlin Wall fell. The results of this program have since been substantiated through the testimony of many of the athletes themselves, their coaches and doctors during the East German doping trials. One of the anabolic substances developed by the East Germans as part of their doping program was androstenedione. In the body, androstenedione metabolizes into the anabolic steroid, testosterone, and other steroids.

The documented side effects of steroids and steroid precursors among these East German athletes, particularly women athletes, are severe and include effects on the liver and reproductive system, susceptibility to cancers, and permanent masculinization of women. Other side effects include growth arrest in adolescents, and shrinking of testicles and impotence in men.

Today, American consumers can walk into their corner nutrition store and buy products containing androstenedione. After professional athletes acknowledged that they used androstenedione, sales of these supplements in the United States dramatically increased. This phenomenal demand, particularly among teenagers, led to the mass marketing of other steroid precursors like 19-norandrostenedione, which metabolizes in the body into the steroid nandrolone, another controlled substance. Now the nutrition store shelves, and the Internet, are flooded with products containing these steroid precursors. Further, the manufacturers of these substances attempt to take advantage of DSHEA by touting these substances as "natural," and implying in their advertising that "natural" equals safe.

Under the current regulatory scheme, a manufacturer is not required to test its steroid precursor product for either side effects or purity prior to putting it on the shelf. This is of particular concern when women and adolescents are considered. Instead, the burden rests on the government agencies to prove that a particular product is harmful. However, by the time action is taken against a specific product, an

unscrupulous manufacturer could simply make a minor chemical change and re-introduce the product.

The marketers of these products glorify the muscle-building qualities of these substances and do everything possible to reinforce the association between these products and controlled anabolic steroids. These products are marketed under names that reinforce their connection to anabolic steroids, including "Cycloroid," "Masterbolan," "Anabol-X," "Paradrol," and "Animal Stak." These products are advertised as equal to or better than the "real steroids" and promise the user huge gains in muscle mass. The advertising also stresses that these products are "legal" in order to raise the implication that they must be safe.

In a society where high school athletes can sign multi-million dollar endorsement contracts, we cannot expect teenagers to ignore advertisements claiming that these products are "safe alternatives" to steroids and will make them "ripped," "huge," improve their athletic performance and give them the body of their dreams.

For Olympic athletes, who know to avoid these products, there remains another concern. In increasing numbers, athletes are failing doping tests after taking mis-labeled dietary supplements. Studies have shown that an alarmingly high percentage of dietary supplements contain doping substances that are not disclosed on the label. For example, a recent study of 624 dietary supplements by the International Olympic Committee found that 41 percent of the products from American companies contained a steroid precursor or banned substance not disclosed on the label.

USADA believes that the current effectively unregulated availability of products containing steroid precursors in the United States is a health crisis that affects not just Olympic athletes, but every American teenager who dreams of becoming a professional or Olympic athlete, and every consumer who takes one of these products without being informed of the risks. Additionally, because of the risk of contamination, American consumers may unknowingly be ingesting steroid precursors.

There is simply no credible argument supporting the over-the-counter availability of products containing steroid precursors. I am sure that Congress would take immediate action to prevent a pill, that once swallowed would metabolize into cocaine, from being sold over-the-counter. Yet that is what is happening every day with steroid precursors in America. It is illegal to sell a steroid without a prescription, but, currently it is perfectly legal to sell a pill that creates the steroid in the body. Every day that these products remain on the shelves is another day that American consumers are placed at risk. The time has come to put a stop to the proliferation of these dangerous products.

On behalf of USADA, I would like to thank Senator Biden, Senator Hatch, Senator Grassley and Senator Harkin for their attention to this matter and commend their introduction of The Anabolic Steroid Control Act of 2003. This important bill amends the Controlled Substances Act by scheduling the substances I have discussed here today and making it easier to schedule any anabolic steroid precursors introduced by manufacturers in the future. USADA believes that this bill is an appropriate solution to the steroid precursors problem. Similarly, I would like to thank Congressman Sweeney and Congressman Osborne for their support on this issue and the introduction of The Anabolic Steroid Precursor Control and Health Education Act (H.R. 207), which also effectively addresses this issue by amending the Controlled Substances Act, to make it easier to schedule the precursors of previously scheduled anabolic steroids. Finally, I would like to thank this Committee for its time and its interest in this important public health issue. Thank you.

The CHAIRMAN. Thank you, Mr. Madden. And I would like to thank your agency for all that it does, particularly as regards the United States Olympic and USOC. Thank you.

Mr. Seckman?

**STATEMENT OF DAVID R. SECKMAN, EXECUTIVE DIRECTOR/
CEO, NATIONAL NUTRITIONAL FOODS ASSOCIATION (NNFA)**

Mr. SECKMAN. Chairman McCain and honorable Members of the Committee, thank you for the opportunity to be here this morning as a representative of the dietary supplement industry.

I am David Seckman, Executive Director and CEO of the National Nutritional Foods Association. Founded in 1936, we're the oldest and largest trade association in the natural products industry. We represent the interest of more than 5,000 retailers, manu-

facturers, suppliers, and distributors of health foods, dietary supplements, and related items.

The Committee has asked me to address a number of issues regarding dietary supplements. Let me start with the law, the Dietary Supplement Health and Education Act of 1994, as it underlies all that we will address here today.

DSHEA is often wrongly characterized as taking away the Food and Drug Administration's ability to regulate supplements. In fact, DSHEA increased FDA's enforcement powers. These powers included, 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, and keeping a new dietary ingredient from being marketed if not enough safety data is received.

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

Before I discuss the lack of implementation and enforcement of DSHEA, I would like to commend the FDA Commissioner McClellan for the progress he's made in these areas. But there is still much more to be done. Let me give you a few examples.

A regulation for good manufacturing practice for dietary supplements, as provided by DSHEA, was just introduced this year, more than 9 years after the law was enacted. Under the rule, manufacturers would be required to evaluate the identity, purity, strength, composition of their dietary supplement ingredients and dietary supplements. The industry supported the introduction of the regulation, and we encourage its swift finalization, implementation, and enforcement.

There has been much concern voiced recently about the use of performance-enhancing products in sports, particularly by high school athletes. Specifically targeted have been pro-hormone products such as androstenedione, or andro. The industry and lawmakers have repeatedly asked the FDA to determine whether these products are actually dietary supplements, as defined by DSHEA.

In the absence of a response from the FDA, Senate bill 1780, which the industry supports, has been introduced. While this legislation, if enacted, will put to rest the argument about whether or not andro is a dietary supplement, it is, indeed, unfortunate that lawmakers felt the need to resort to a time-consuming legislative solution, when a regulatory one would have been much quicker and more appropriate.

More than any other product, ephedra is pointed to as evidence of DSHEA's lack of effectiveness. But what ephedra illustrates is not DSHEA's shortcomings, but the tentativeness and reluctance of the FDA in enforcing the law. Whatever your opinion on the safety or effectiveness of ephedra, there should be no question that DSHEA provides the FDA with the power to take unsafe products off the market. And whether that action is the validation of ephedra as a safe and useful dietary supplement or its removal

from the marketplace, we fully support the FDA's empowerment to act.

The FDA is not alone in regulating dietary supplements. 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 advertisers who disobey the law. The industry applauds and supports these efforts, and hope that they will continue.

Enhanced media coverage of the relatively rare case of dietary supplements causing an injury has resulted in misconceptions about their safety. The truth is that dietary supplements are far safer than most common foods and drugs. For instance, a common OTC pain reliever is responsible for more than 17,000 deaths annually. Prescription drugs, for all their testing and lengthy usage directions, are estimated to be one of the top five leading causes of death in the U.S., at more than 106,000 annually. And more than 5,000 Americans die each year from food-borne illnesses.

You may hear statistics this morning from other sources regarding dietary supplements. Well, let me tell you what the FDA says. According to the agency, it's received 1,212 reports of adverse events regarding dietary supplements in 2001. There are those who claim that this number would be much higher were a different reporting system in place. This summer, FDA implemented an extensively revamped reporting system for dietary supplements. This should yield more accurate data about potential problems with these products and others. This new system should be given a chance to work.

Although it's not the focus of this hearing, we should also not lose sight of the important benefit dietary supplements have on human health. For example, the American Medical Association recently recommended that every adult take a multivitamin daily. Not only has research demonstrated the health benefits of dietary supplements, it has also shown that they can reduce healthcare costs by billions of dollars. For instance, a study recently published earlier this month reported that a daily multivitamin could reduce healthcare costs for seniors by \$1.6 billion annually. Another study in a major medical journal reported that increased intake of Vitamin E, folic acid, and zinc could save \$20 billion annually in hospital costs by reducing heart disease, birth defects, and premature deaths. These are not isolated examples.

In summary, DSHEA provided more label information, increased FDA enforcement authority to preserve consumer safety, and mandated higher product standards. 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 safety, efficacy, or quality, 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 the law. The new bill, Senate bill 1538, the DSHEA Full Implementation and Enforcement Act, will give the FDA the funding it needs to ensure that the law is carried out as Congress intended.

The second is for the FDA to quickly finalize and begin enforcement of the good manufacturing practices for dietary supplements. Although most dietary supplement manufacturers adhere to product standards that meet or exceed what is currently required, a Federal GMP regulation would bring all others into line, as well.

And, finally, my recommendation is stop seeking legislative solutions to regulatory problems when it comes to DSHEA. Changing DSHEA to give the FDA increased authority, when it has not fully applied its current powers, will simply perpetuate the current situation.

Thank you.

[The prepared statement of Mr. Seckman follows:]

PREPARED STATEMENT OF DAVID R. SECKMAN, EXECUTIVE DIRECTOR/CEO,
NATIONAL NUTRITIONAL FOODS ASSOCIATION (NNFA)

Chairman McCain and Honorable Members of the Committee on Commerce, Science, and Transportation, thank you for the opportunity to address the Committee with respect to the dietary supplement industry. I am David Seckman, Executive Director and CEO of the National Nutritional Foods Association (NNFA). NNFA was founded in 1936 and is the oldest and largest trade association in the natural products industry. We represent the interests of more than 5,000 retailers, manufacturers, suppliers and distributors of health foods, dietary supplements and related items.

The Committee has asked that I address a number of issues regarding dietary supplements, including how these products are sold and the effectiveness of the law that governs them. Let me start with the law, as it underlies all that we will discuss here today.

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.

Before I discuss lack of implementation and enforcement of DSHEA, let me say that the FDA, under the leadership of Commissioner McClellan, has made progress in implementation of the law and has become more active in its enforcement. But there is still much more to be done. Let me give you a few examples.

Good Manufacturing Practices

A regulation for good manufacturing practices for dietary supplements, which was provided for by DSHEA, was only introduced this year, more than nine years after the law was enacted. Under the rule, manufacturers would be required to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. The industry was not an impediment to the introduction of this regulation. In fact, the leading trade associations and their members encouraged and welcomed its release. 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. Now that FDA has proposed a regulation, we encourage its swift finalization, implementation and enforcement.

Performance Enhancing Products

There has been much concern voiced recently about the use of performance-enhancing products in sports, particularly by high school athletes. Specifically targeted have been pro-hormone products such as androstenedione, or “andro.” Although the FDA has been asked for several years by both industry and lawmakers to determine whether these products are actually dietary supplements as defined by DSHEA, the agency has not responded. While I believe that the FDA has the authority under DSHEA to effectively deal with this issue, the controversy continues. With that in mind, the industry last week voiced its support for a new bill, S. 1780, the “Anabolic Steroid Control Act of 2003,” that will place andro and products like it under the Controlled Substances Act. Although this legislation, if enacted, will put to rest the argument about whether or not andro is a dietary supplement, it is unfortunate that we needed to resort to a complex and protracted legislative solution when a regulatory one would have been much swifter and more appropriate.

Ephedra

More than any other, ephedra is the product that has been pointed to as evidence of DSHEA’s lack of effectiveness. But what ephedra is really emblematic of is not DSHEA’s shortcomings, but the tentativeness and reluctance of the FDA in enforcing the law. No matter your opinion on the safety or effectiveness of ephedra, what should be indisputable is that DSHEA clearly provides the FDA with the power to take unsafe products off the market. And whether that action is validation of ephedra as a safe and useful dietary supplement or its removal from the marketplace, we fully support the FDA’s empowerment to act.

Truth in Advertising

The FDA is not alone in regulating dietary supplements. 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.

Safety

If there were not a presupposition that dietary supplements are inherently unsafe, we would not be here this morning. Therefore, I believe we need to put supplement safety in perspective. Intense media coverage of the relatively rare cases of certain dietary supplements causing injury has resulted in misconception about their safety. The truth is that dietary supplements are far safer than most common foods and drugs that consumers use without a second thought. For instance, a common OTC pain reliever 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

¹ Wolfe M.M., Lichtenstein D.R., Singh G., “Medical Progress: Gastrointestinal Toxicity of Non-steroidal Anti-inflammatory Drugs,” *New England Journal of Medicine* 340:1888–1899 (1999).

in the U.S. at more than 106,000 annually.² And, more than 5,000 Americans die each year from food borne illnesses.³

You may hear statistics this morning from other sources regarding dietary supplements, but let me tell you what the FDA says. According to the agency, it received 1,214 reports of adverse events regarding dietary supplements in 2001.⁴ (An adverse event is described as being an undesirable experience associated with the use of a product, but not necessarily caused by using the product). There are those who claim this number 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 efforts that will provide a constructive and impartial representation of dietary supplement safety.

I believe, however, that reports of adverse reactions to dietary supplements will continue to remain relatively low. In support of this assertion, I would refer to another well regarded source, the American Association of Poison Control Centers. In this group's most recent report of poison control centers throughout the United States, adverse reactions to drugs are more than 800 percent higher than those for dietary supplements.⁵ If consumers are expected to make informed decisions about the safety of dietary supplements—or anything else—they deserve to know all the facts. And the facts are that, in addition to providing undisputed health benefits to millions of Americans, dietary supplements are far safer to consume than drugs and most foods.

Although it is not the focus of this hearing, we should also not lose sight of the important benefits dietary supplements have on human health. When Congress passed DSHEA it acknowledged that there may be a connection between dietary supplement use, reduced expenses, and disease prevention. In fact, current research is bearing out this very supposition. As examples, the American Medical Association recently reversed its position on the value of taking a daily multivitamin, suggesting that every adult would benefit from a daily multivitamin.⁶ Not only has research demonstrated the health benefits of dietary supplements, it has also shown that they can reduce health-care costs by billions of dollars. For example, a study published earlier this month reported that if seniors took a multivitamin daily it could reduce health care costs by \$1.6 billion annually.⁷ 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.⁸ These are not isolated examples.

In summary, DSHEA provided more label information, increased FDA enforcement authority to preserve consumer safety and mandated higher product standards. 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 safety, efficacy or quality, 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. Passage of a new bill introduced in the Senate by Senators Tom Harkin and Orrin Hatch, S. 1538, would do just that. This bill, "The DSHEA Full

²Lazarou, Jason, Pomeranz, Bruce H., Corey, Paul N., "Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies," *Journal of the American Medical Association* 279:1200–1205 (1998).

³Paul S. Mead, et al., "Food-Related Illness and Death in the United States," *Morbidity and Mortality Weekly Report* (Sept.–Oct. 1999). Electronic version available at <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm#Figure%201>.

⁴U.S. Food and Drug Administration, "FDA Proposes Manufacturing and Labeling Standards for all Dietary Supplements," *backgrounder*, March 7, 2003. Electronic version available at <http://www.fda.gov/bbs/topics/NEWS/dietarysup/background.htm>.

⁵Toby L. Litovitz, et al., "2001 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System," *American Journal of Emergency Medicine*, 20, No. 5 (2002). Electronic version available at www.aapcc.org/Annual%20Reports/01report/2001%20TESS%20Full%20Report.pdf.

⁶"Vitamins for Chronic Disease Prevention in Adults." Kathleen M. Fairfield, M.D., Dr.PH.; Robert H. Fletcher, M.D., M.Sc.; *Journal of the American Medical Association* (June 19, 2002, Vol. 287 No. 3: 3116–3126)

⁷"A Study of the Cost Effects of Daily Multivitamins for Older Adults." DaVanzo J.E., Dobson A., Consumji M., Gilani J., McMahon J.P., Preston B., Sen N., presented by The Lewin Group October 2, 2003.

⁸"Potential Health Economic Benefits of Vitamin Supplementation." A. Bendich; R. Mallick; S. Leader. *Western Journal of Medicine* (1997, Vol. 166: 306–312).

Implementation and Enforcement Act,” 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, which was created by DSHEA to expand research and provide consumer information on dietary supplements.

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. Changing DSHEA to give the FDA increased authority when it has not fully applied its current powers will simply perpetuate the current situation.

The CHAIRMAN. Was it a lack of funding that caused a 9-year delay to propose a rule pursuant to DSHEA, Mr. Seckman?

Mr. SECKMAN. Mr. Chairman, I think that very well could have been the case. I know that—

The CHAIRMAN. Really? That’s remarkable.
Dr. Grollman?

STATEMENT OF ARTHUR P. GROLLMAN, M.D., DISTINGUISHED PROFESSOR, PHARMACOLOGICAL SCIENCES; EVELYN GLICK PROFESSOR, EXPERIMENTAL MEDICINE, STATE UNIVERSITY OF NEW YORK AT STONY BROOK

Dr. GROLLMAN. Senator McCain, Senator Smith, Members of the Committee, thank you for inviting me to speak on this important subject.

I testify here as an academic clinical pharmacologist, meaning that I’m a physician trained in internal medicine who conducts research on the pharmacology of drugs, including botanicals. I’m also a Professor of Medicine and Pharmacological Scientist at the State University of New York at Stony Brook.

Professors are like politicians, they have difficulty condensing their thoughts into 5 minutes, so I’ll make sure, at the onset, that I leave you with three key points, which I expand on in my written testimony and document in the supplementary material.

First, a vast family of botanical substances, incorrectly designated dietary supplements, include highly toxic and even some carcinogenic herbs creating a serious public-health hazard.

Second, the problems that DSHEA has created are very difficult to remedy by banning or restricting individual substances or even groups of substances, since designations are readily circumvented.

Finally, I will offer some specific recommendations as to how DSHEA could be usefully amended.

Let me begin by reminding you that DSHEA allows herbs and so-called natural products, including steroid hormone precursors, to be marketed as dietary supplements. Under this classification, herbs used in traditional folk medicine need not be tested for safety. As a result, physicians, pharmacists, researchers, and even some leaders in the botanical industry see DSHEA as an accident waiting to happen.

Historically, accidents involving drugs safety have led to congressional regulatory actions. But where public health is concerned, Senator, it’s preferable to prevent such disasters.

I will cite three examples where the loss of regulatory power by FDA resulted in the injury to tens of thousands of Americans, a number that increases every day. Aristolochia has been used throughout the world as an herbal remedy for 2,000 years. Nevertheless, a decade ago, about a hundred otherwise healthy young women given this herb at a weight loss clinic developed irreversible kidney failure, requiring dialysis or transplantation. Half of these women subsequently developed kidney cancer. This syndrome, known as Chinese herb nephropathy, has now been reported in all countries. Yet dozens of Aristolochia products are still marketed in the U.S. as dietary supplements readily available under a bewildering variety of names for purchase through a hundred Internet sites. The FDA and this Committee was formally notified of this imminent hazard last March.

What can we learn from this unfortunate situation? First, that herbs used for centuries in folk medicine are not necessarily safe, but rather may exert serious toxic effects, including causing cancer. But Aristolochia is not unique. Comfrey tea and kava are both highly toxic to the liver. Sassafras also contains a known carcinogen. Many other examples are referenced in my written testimony.

It's important to recognize that under DSHEA, dangerous botanical products can be advertised and marketed with impunity as dietary supplements. The renal toxicity and carcinogenic properties of Aristolochic acid were established decades ago. Results of the clinical studies were published in major medical journals prohibiting this herb from being introduced as a prescription or over-the-counter drug, but not as a dietary supplement. This is an incredible and, I hope you'll agree, intolerable situation.

In considering ephedra, we deal with another of the so-called natural products used in folk medicine, in this case one that has also been studied as a drug. But serious toxicity is associated with herbal ephedra—stroke, heart attack, psychosis—account for more adverse effects than all other dietary supplements combined, and led to hearings in several congressional committees and the introduction of several bills.

These statistics are even more frightening in view of the fact that less than 1 percent of adverse reactions to dietary supplements are reported to FDA. Importantly, research shows that ephedra does not enhance athletic performance, and its effects on weight reduction are short-term and minimal. Thus, the risk-benefit ratio for medically unsupervised use of ephedra is unacceptable.

A third example of drug-induced toxicity may prove to be the Achilles heel of DSHEA, namely the risk created by herb/prescription drug interactions. Remember that every chemical we take into our bodies undergoes metabolism by specific enzymes. To cite just one example, St. John's wort, widely used for self-treatment for depression, is handled by the same enzymes that metabolize a vast variety of prescription drugs, including those used by millions of Americans for hypertension, heart failure, asthma, AIDS, and other chronic diseases. Thus, although relative innocuous when taken alone, the use of St. John's wort can lead to a deactivation of life-saving drugs on which many Americans with chronic diseases depend. The extent of this problem could be significantly reduced by

requiring manufacturers to perform relatively low-cost safety testing.

So given the seriousness of the situation, I would like to make some specific recommendations for amending DSHEA, mindful that 15 percent of all Americans currently take herbal remedies, also that vitamins and minerals do not present a serious safety problem for consumers.

But first let me make an important point. It is difficult to craft legislation directed against a single agent, such as ephedra or androstenedione, or even classes of agents like stimulants or anabolic steroids. When baseball player Steve Bechler's premature death called public attention to the danger of ephedra, the manufacturer of that supplement simply replaced it immediately by synephrine, a chemical cousin with similar pharmacological properties and toxicity to ephedra, then brazenly marketed this product as ephedra-free.

Thus, the goal to protecting the health of the American public can be better achieved by specifically amending DSHEA as described in my written testimony. The three cardinal recommendations may be summarized as follows.

First, as recommended by the Office of the Inspector General, manufacturers should report all adverse-effect drug reactions to FDA.

Second, the burden of proof for demonstrating that a dietary supplement does not present a significant or unreasonable risk should be placed where it belongs, on the manufacturer, rather than FDA.

Third, labels of dietary supplements should clearly indicate what and how much is in the package, and provide explicit warnings of possible adverse effects, including herb/prescription drug interactions.

I thank you, Senator McCain and Members of this Committee, for considering this important matter that threatens consumer health and, therefore, must take precedence over the interests of the botanical industry.

[The prepared statement of Dr. Grollman follows:]

PREPARED STATEMENT OF ARTHUR P. GROLLMAN M.D., DISTINGUISHED PROFESSOR, PHARMACOLOGICAL SCIENCES; EVELYN GLICK PROFESSOR, EXPERIMENTAL MEDICINE, STATE UNIVERSITY OF NEW YORK AT STONY BROOK

HERBAL REMEDIES—NEW REGULATIONS NEEDED TO PROTECT PUBLIC HEALTH *

In 2001, Americans spent \$17.76 billion on dietary supplements, \$4.18 billion of which were spent on herbs and other botanical remedies.¹ These herbal products have greatly increased in popularity over the past decade, most likely stimulated by the high prices of prescription drugs, restricted access to physicians resulting from managed care procedures, media reports of adverse effects of prescription drugs and, most importantly, enactment in 1994 of the Dietary Supplement and Health Education Act (DSHEA). By broadly defining herbs and other botanicals as "dietary supplements," which they most assuredly are not, DSHEA significantly changed the rules for evaluating and enforcing claims for effectiveness and safety of these products.² This inappropriate product classification has resulted in a serious and growing public health problem.

The perception that herbal remedies are inherently safe is based primarily on tradition rather than on systematic studies designed to detect adverse effects. Nevertheless, evidence of their toxicity is accumulating.^{3–10} This is not surprising because

* Adapted from Marcus, DM and Grollman, AP. *N Engl J Med* 2002; 347: 2073–2076.

it is well-established that botanicals are, in fact, "crude drugs of vegetable origin"¹¹ and contain complex mixtures of chemicals, many of which are potentially toxic. In the past year alone, the FDA was compelled to issue warnings of nephrotoxicity (kidney damage), hepatotoxicity (liver damage) and carcinogenicity (cancer development) associated with herbal products containing kava, comfrey and aristolochic acid, all herbal remedies used widely in the U.S. and Europe.⁵ In addition to their own toxicities,^{9,10} botanical products are associated with other factors that affect their safety; several of these are discussed below.

Lack of Standardization

The safe and effective use of any medicinal compound requires that each product sold has the same composition and biological activity. Unfortunately, botanical preparations rarely meet these criteria because of problems in identifying the plants, the variability in genetic make-up of the plants, variations in growing conditions, harvesting, and processing of extracts and, above all, the inability to identify active pharmacologic agents within the large number of chemicals present in plants. A few companies have developed methods to standardize herbal preparations, but these techniques do not assure pharmacologic activity or stability. Moreover, chemical analyses of supposedly standardized herbal preparations reveal that many such products do not contain the amount of compound stated on the label.^{12,13} "Their potency may vary and their purity is suspect," warns the Medical Letter.³

Adulteration of Botanical Preparations

Many herbal products have been found to contain prescription or over-the-counter drugs and dangerous heavy metals.¹⁴⁻¹⁷ In 1998, the California Department of Health reported that 32 percent of Asian herbal medicines sold in that state contained undeclared pharmaceuticals or heavy metals.¹⁵ The drugs most frequently found were ephedrine, chlorpheniramine, methyltestosterone and phenacetin; 10-15 percent contained lead, mercury and arsenic. Subsequently, more than 500 Chinese herbal medicines were screened for the presence of heavy metals and/or any of 134 selected drugs.¹⁶ Approximately 10 percent were found to contain undeclared drugs and/or toxic levels of metals. The FDA and other investigators¹⁷ have also reported the presence of prescription drugs, including glyburide, sildenafil, colchicine, adrenal steroids, alprazolam, phenylbutazone and fenfluramine in products claimed to contain only natural ingredients.

One "supplement," PC-SPES, is a patented herbal preparation marketed to enhance "prostate health," but commonly used to treat prostate cancer. Reports of its effectiveness have appeared in major medical journals.^{18,19} After chemical analysis of PC-SPES revealed the presence of diethylstilbesterol (an estrogen), indomethacin (an extremely potent nonsteroidal anti-inflammatory drug), and/or warfarin (an anti-clotting drug),¹⁸ this product was removed from the market.

Recently, the Japanese Ministry of Health, Labour and Welfare reported that the use of certain imported Chinese dietary supplements was associated with liver failure and/or extremely high thyroid function.²⁰ These products proved to be adulterated with drugs and 622 patients became ill, with 148 requiring hospitalization; three deaths occurred.²¹ The offending products were recalled and the Ministry will henceforth require manufacturers to chemically analyze all imported dietary supplements.

All of these cases should be considered as warnings to us about the state of purity of products on our store shelves. It is DSHEA that allows them to be placed there and to stay there.

Herb-Drug Interactions

Interactions between herbal products and prescription or over-the-counter (OTC) drugs constitutes one of the greatest risks posed by the use of botanical remedies.

Botanical medicines can act through a variety of mechanisms to alter the actions and metabolism of prescription and OTC drugs.²² St. John's wort, for example, increases the level of specific enzymes (i.e., the cytochrome P-450 isozyme CYP3A4 and intestinal P-glycoprotein), which leads to a decrease in the blood level of many drugs, including cyclosporine (needed to prevent transplanted organ rejection), antiretroviral agents (needed to keep HIV in check), digoxin (to protect the heart) and warfarin (to prevent blood clotting in patients with certain dangerous clotting conditions).²³ In fact, serious adverse effects have been reported in patients taking cyclosporine or antiretroviral agents when they added St. John's wort, which caused blood levels of their life-saving drug to fall to amounts that were no longer therapeutic.

The extent of herb-drug interactions is unclear, but its potential magnitude can be judged by a recent survey of medication use in the U.S.²⁴ Among individuals over the age of 18 years, 50 percent took at least one prescription drug during the pre-

ceding week. Among women 65 years or older, 23 percent took at least five prescription drugs. Importantly, *16 percent of people taking prescription drugs also took a herbal/supplement*. Thus, many Americans unknowingly risk therapeutic failures or adverse effects due to herb-drug interactions, especially older individuals who take multiple medications for chronic diseases.

Lack of Adverse Event Reporting

The FDA maintains surveillance of prescription drugs by requiring manufacturers to report promptly to the agency all adverse effects brought to their attention. Even with these requirements, it is estimated that only 10 percent of serious adverse effects associated with the use of prescription drugs are ultimately reported to the FDA.²⁵ It is fortunate, however, that the manufacturers must demonstrate safety of the prescription drugs in clearly defined clinical trials before the FDA permits the product to be marketed.

Unfortunately, such premarket safety testing is *not* required for dietary supplements and there is no mandatory requirement for manufacturers of supplements to record, investigate or forward to FDA reports of adverse effects they might receive. In addition, although some adverse reactions to botanical medicines are immediate and produce symptoms, others, such as kidney failure and development of cancers, have a delayed and gradual onset and their relationship to earlier consumption of an herbal remedy may not be apparent.

This lack of adverse event reporting to the FDA has generated concern at the level of the HHS Office of the Inspector General.²⁵ In 2001, the FDA received approximately 500 reports of adverse events related to dietary supplements, while Poison Control Centers in the United States received 19,468 such reports,²⁶ up from 6,914 in 1998. In addition, the FDA often is unable to investigate reports they do receive because the consumer's identity and address cannot be obtained or the ingredients of the supplement and the identity and address of the manufacturer are unknown. *The Inspector General's report estimates that less than 1 percent of adverse events caused by dietary supplements, including herbs, are reported to FDA and only a fraction of these are adequately investigated.*

Current Regulation of Botanical Medicines

Regulation of food and drugs has always been strongly resisted by industry, and Congress has acted only in response to strong pressure from the public. *The Food and Drug acts passed in the 20th century to provide important protection to the public, were largely circumvented for dietary supplements by passage of DSHEA*. This single piece of legislation negated work conducted over decades to ensure that *all* medications were studied and evaluated for safety and efficacy before they reached the American public. Importantly, DSHEA freed the dietary supplement industry from effective oversight by the FDA by transferring the burden of proof for establishing herbal medicine safety away from the manufacturer and to the FDA. It is shocking to realize that dietary supplements are now subject to lower safety standards than are food additives and that consumers are provided with more information about the composition and nutritional value of a loaf of bread than about the ingredients and potential hazards of botanical medicines.

The way in which restrictions imposed by DSHEA hinder the FDA from promptly removing dangerous products from the market may be appreciated by considering two examples. One clear problem is that posed by the herbal supplement ephedra. Ephedrine alkaloids are present in many supplements marketed for weight loss and to boost energy. Like their chemical relative methamphetamine, or "speed," they have powerful stimulatory effects on the cardiovascular and central nervous systems, and their use has been associated with strokes, heart rhythm abnormalities, seizures, acute psychoses, heart attacks and death.^{27,28} More than 18,000 adverse events related to ephedra have been reported to FDA, including 117 deaths and the actual number of these events undoubtedly is far greater.²⁹ In addition, 33 deaths of military personnel led the U.S. Army to ban the sale of ephedra products from its commissaries worldwide.²⁹ Metabolife 346, a product containing ephedra, caffeine and several herbs, is taken by an estimated 12 million Americans. It was revealed recently that 14,480 complaints of adverse reactions had been registered with the company, including 2,000 significant adverse events;²⁹ several hundred of these required hospitalization and there were 80 incidents of serious injury or death. Incredibly, under current regulations there is no penalty for withholding reports of adverse effects; nevertheless, the Justice Department, at the FDA's request, has initiated a criminal investigation of Metabolife because of false statements claiming the absence of adverse effects. Canadian—but not American—health authorities have requested voluntary recall of health products containing ephedra, noting its enhanced toxicity when combined with caffeine.³⁰ Ephedra accounts for 64 percent of all ad-

verse reactions to herbs in the United States, yet ephedra products represent only 0.82 percent of herbal product sales.³¹

A particularly dramatic example of the toxicity of herbal products is the kidney failure and subsequent kidney cancer caused by *Aristolochia fangchi*, used for centuries in Europe and China as an herbal remedy. The clinical toxicity of *A. fangchi* was recognized in 1991 when this herb was substituted for another in a weight loss preparation used in a Belgian health spa.^{6,32} Of 105 patients affected by this herb who developed kidney disease (and treated in one medical center), 39 with end-stage kidney failure decided to have their kidney removed completely because of concerns about developing kidney cancer. Indeed, actual carcinomas were found in 18 of these patients and a precancerous condition (urothelial dysplasia) in 19 others.³³ This syndrome, aristolochic acid nephropathy, was also found in patients in other countries, including the United States.⁶ As a result of warnings issued by the FDA, a number of herbal products containing aristolochic acid were withdrawn from the market in 2001. Importantly, the names of these products, such as Joint Ease, and Balance and Harmony, contained no information suggesting the presence of aristolochic acid, which had, nevertheless, been documented to be toxic to the kidney and carcinogenic in rats.³⁴ Even today, 19 products containing aristolochic acid and 95 products suspected to contain aristolochic acid can be purchased over the Internet.³⁵

New Regulations Are Needed

Public awareness of the hazards of dietary supplements has increased in recent years and a majority of Americans now support legislation (a) requiring the FDA to review the safety of new dietary supplements prior to their sale; (b) providing increased authority for the FDA to remove unsafe products from the market; and (c) regulating advertising claims about the health benefits of dietary supplements.³⁶ However, for the FDA to effectively carry out its mandate to protect public health, new legislation and resources are required. The legislative proposals outlined below could accomplish this goal without denying consumers access to this popular class of products.

(1) *The address and telephone numbers of all companies, as well as the names of the responsible persons, involved in manufacturing dietary supplements for sale in the U.S. should be directly registered with FDA.* Currently, the FDA is severely limited in its efforts to investigate adverse effects of dietary supplements because of the lack of information about manufacturers and distributors.

(2) *Manufacturers of dietary supplements must provide evidence of good manufacturing practices (GMP) and the FDA should be given the authority to inspect manufacturers' records.* In 1999, the FDA held public meetings and published an advance notice of proposed regulations that address this issue. Implementation of even this proposal has been blocked by the botanical industry. Such an extension of GMP to herbal manufacturers could go far toward preventing adulteration and ensuring standardization of marketed botanical products.

(3) *Congress should require manufacturers of dietary supplements to report all adverse effects to the FDA to ensure identification of potential public health problems as quickly as possible.* Postmarketing surveillance is an essential element of this proposed legislative reform. Serious adverse effects should be reported to FDA promptly; others should be reported on a quarterly basis. CFSAN's Adverse Event Reporting System (CAERS) provides a mechanism for consumers and health care providers to report adverse events or illness thought to be related to the use of a dietary supplement. Congressional appropriations should continue to fund this system, which facilitates tracking and analysis of adverse events associated with dietary supplements. However, complete reporting information from all sources, including manufacturers, is required to ensure prompt and accurate identification of potential public health problems. Once FDA identifies a potential problem, it should notify the manufacturer who would then be required to respond to FDA within 30 days and to conduct discussions with FDA regarding appropriate corrective action.

(4) *The burden of proof for demonstrating that a dietary supplement does not present a "significant or unreasonable risk of illness or injury under conditions of recommended use, as suggested on the label", should be placed on the manufacturer.* Under DSHEA, the FDA must carry the burden of proving "significant or unreasonable risk" before it can remove a dangerous product, such as aristolochic acid or ephedra, from store shelves. Manufacturers should be required to provide evidence of safety either when a new product is introduced or when serious adverse effects are uncovered from the sale of an existing product during postmarketing surveillance. As the manufacturers benefit from product sales, they should also pay the costs of conducting appropriate safety test-

ing, as required for prescription and over-the-counter drugs. FDA does not have the resources nor the infrastructure to conduct safety testing for the multitude of marketed dietary supplements, and testing can be conducted more efficiently using the manufacturer's extensive knowledge of its own product.

(5) *Dietary supplements should carry labels containing a list of constituents that clearly and unambiguously identifies herbs by their botanical and common names. If pharmacologically active principle(s) are known, the concentration of such substances should appear on the label. Information regarding possible adverse effects, including the potential for herb-drug interactions, should be included in the information provided to the consumer.*

(6) *The Department of Health and Human Services should organize expert panels to review the safety of all dietary supplements, except for essential nutrients and single and multivitamin preparations.* This process should be modeled after the National Academy of Sciences Drug Efficacy Study, which completed the complex task of evaluating the safety and efficacy of 4,000 drugs in just three years.

Conclusions

The medical community has been slow to respond to the public health issues and educational problems resulting from the weakened regulation of dietary supplements.³⁷ However, the numerous reports of adverse effects and deaths associated with botanical health products, the easy distribution and widespread sale of adulterated products, and a marked increase in misleading promotional claims via the Internet demand prompt action to protect the public health. The European Parliament currently is considering measures to ensure that all traditional herbal medicinal products used in member countries demonstrate efficacy and an acceptable level of safety.³⁸ The legislative reforms that I am proposing here will be opposed by powerful political and economic forces^{2,39} and by many proponents of complementary and alternative medicine. Nevertheless, Congress should stand up for the public health, recognize the critical need for new regulatory safeguards, and ensure additional government funding to carry them out. It is time that the public health interest superseded that of the botanical industry.

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[The following Attachments have been retained in Committee files:

Gold, LS, Aristolochic Acid, an Herbal Carcinogen, Sold on the Web after FDA Alert. *N Engl J Med* 2003; 349:1576–1577.

<http://potency.berkeley.edu/pdfs/NEJM.pdf>

March 4, 2003 letter from LS Gold, Ph.D. to Dr. Christine L. Taylor.

[http://potency.berkeley.edu/pdfs/
FDAAristolochicAcidLetter.pdf](http://potency.berkeley.edu/pdfs/FDAAristolochicAcidLetter.pdf)

June 24, 2003 letter from LS Gold, Ph.D. to Dr. Christine L. Taylor and Dr. Robert Moore.

<http://potency.berkeley.edu/pdfs/FDAAAJuneLetter.pdf>

April 4, 2003 letter from Hon. Henry A. Waxman, Hon. Edward M. Kennedy, and Hon. Richard Durbin to Dockets Management Branch, Food and Drug Administration, Rockville, MD.]

The CHAIRMAN. I thank you, Dr. Grollman.

We will have to take a 10 to 15 minute break here while we go to the floor and vote and return, and then we'll recommence the hearing and hear from our remaining two witnesses.

[Recess.]

The CHAIRMAN. We will reconvene the hearing. I want to thank the witnesses for their patience. We will hear from Charles Bell, Programs Director at the Consumers Union. And, Mr. Bell, thank you, and I apologize to all the witnesses for the delay, as required by voting.

**STATEMENT OF CHARLES W.F. BELL, PROGRAMS DIRECTOR,
CONSUMERS UNION OF U.S., INC.**

Mr. BELL. Good morning, Chairman McCain and Members of the Committee. Thank you very much for providing me the opportunity to testify before you today.

I'm Charles Bell, Programs Director for Consumers Union, the nonprofit publisher of *Consumer Reports* magazine. Our mission at Consumers Union is to test products, inform the public, and protect consumers.

Today I offer this testimony on dietary supplements as part of our consumer protection function. *Consumer Reports* and *Consumer Reports on Health* newsletter have published several major articles on dietary supplements, which I have attached for your reference, and we continue to investigate these issues.

While many dietary supplements are generally safe, and many have important health benefits for consumers, there is a significant number and a growing number of highly questionable supplement products that would probably not be allowed on the market if they were subject to pre-market safety testing and evaluation.

In 1995, *Consumer Reports* magazine published a list of five supplements that, according to the FDA, can cause serious harm to consumers: chaparral, ephedra, comfrey, lobelia, and yohimbe. These are all herbal supplements.

Eight years later, all five of these supplements are still being marketed and sold in the United States. Thus, unsafe dietary supplement products in the aftermath of DSHEA can remain on the market for many years in the same stream of commerce as products approved by the FDA as safe and effective for their intended use.

Also, new products can be introduced overnight that contain novel, untested ingredients and/or novel combinations of new and/or existing supplement ingredients.

Health providers and public-health authorities typically receive little pre-market or post-market information about how such products may affect human health and interact with medicines that patients are already taking. And even where serious problems are documented, it is difficult for the FDA to take prompt action to protect consumers.

We believe that dietary supplements containing ephedra poses significant, unreasonable risk of illness and injury under conditions of use that are indicated on product labels. Under that standard, the FDA should be able to remove these products from the market. We've written twice to the FDA asking them to remove ephedra.

Because the Federal Government has failed to act, over the last 3 years we have successfully worked for local bans on the sale of supplements containing ephedra for minors and adults in Suffolk County, New York; Westchester County, New York; and the states of Illinois, New York, and California. We urge other states and local governments to pass similar local bans. We recognize that a state-by-state ban, and even a substance-by-substance ban, as Dr. Grollman indicated, is not the best way to go. We need to change the system that allowed ephedra to get through.

In Suffolk County in New York State, the ephedra bans were strongly supported by Karen and Tom Schlendorf, of Northport, Long Island, whose son, Peter, died in 1998 while taking supplements containing ephedra while on spring break in Florida, and also by Doug Hanson, of Huntington, Long Island, whose wife, Ann Marie Capatie, suffered a fatal stroke while working out in a gym after taking ephedra supplements in 1998.

Now, despite all the calls by health organization and sporting organizations, ephedra stimulants are still widely available in the marketplace today. Several major national retail chains, including CVS, GNC, Walgreen's, Eckerd, and 7-Eleven, have announced that they will no longer stock dietary supplement products containing ephedra, and several major manufacturers have also withdrawn their products.

But despite these high-profile changes in the market, our ongoing research suggests that herbal supplements containing ephedra are still widely available at lower-profile retail sites, such as independent pharmacies, gas stations, and truck stops, and convenience and health-food stores. We also see that ephedra is present not just in weight-loss supplements, the best-known use, but also in supplements marketed as energy boosters and alternatives to street drugs, such as ecstasy and speed.

Ephedra alkaloids are also turning up in supplements under names that consumers may not recognize: *epitonin*, *Ma Huang*, *sida cordifolia*, and *sinica*. Labels listing ingredients are often in small print and hard to decipher, and those labels do not necessarily provide appropriate warning of potential hazards or indicate how many milligrams of each substance are present. Many supplements with ephedra also contain caffeine or other herbal compounds, such as guarana, kola nut, *paulina cupana*, and mate, as well as green and black tea. Some products appear to far exceed the recommended daily intake for caffeine of 300 milligrams. And consumers cannot necessarily rely on pharmacy or retail employees

for accurate information about whether products contain ephedra or not.

On the issue of steroid precursors, there are dangerous loopholes in DSHEA and the Controlled Substances Act that permit manufacturers to aggressively market and sell untested, unregulated steroid equivalents to the public, including persons under 18. As we noted in the *Consumer Reports* article, sports medicine researchers have only tested products like andro and creatine in adults. There has been no systematic testing of these drugs in minors. And, for ethical reasons, such tests will probably not be conducted. Because of serious safety concerns, numerous sporting and medical associations, including the AMA and the American Academy of Pediatrics, believe steroid precursors should be classified as controlled substances.

In terms of recommendations, we would support provisions in the Dietary Supplement Safety Act of 2003, S. 722, introduced by Senator Richard Durbin, that would require stimulants to be approved as new drugs and would declare foods containing unapproved stimulants to be adulterated and prohibit the introduction into interstate commerce of a supplement containing a stimulant, unless it's approved by the Secretary of Health and Human Services.

These provisions would be extremely helpful for addressing the hazards posed by herbal, hard stimulants, such as ephedra and steroid precursors.

We also think that pre-market safety testing should be required in targeted areas, particularly for supplements that are deemed to be of special concern by the FDA and other health authorities. While stimulants and steroid precursors are important classes of substances we need to be concerned about, we also agree with Dr. Grollman that there are many herbs that are highly toxic and carcinogenic and have serious interactions with other medications that patients are likely to take. We need to have an effective way of using medical criteria to identify supplements of concern that should be investigated, and shift the burden of proof for showing supplements are safe to the manufacturer, where it belongs. The current situation that we have, we have externalized costs of these products onto the public sector, and we've externalized the risks onto consumers.

We support the provisions in S. 722 that would authorize the Secretary of the Department of Health and Human Services to require the manufacturers of dietary supplements, or any ingredient in a supplement, to submit data demonstrating that that supplement is safe. The Secretary would then be authorized to review the data and issue a determination that either the ingredient is safe and that continued marketing is approved, or that continued marketing is disapproved because it is either unsafe or it's not shown to be safe.

Dietary supplement manufacturers should also be required to report adverse events to the FDA. The current voluntary reporting system provides insufficient information for public-health authorities to take prompt action regarding harmful products that put consumers at serious risk.

And, finally, we believe that post-marketing surveillance for dietary supplements should be greatly improved. We believe that the

FDA must be given additional resources and a resounding mandate from the Congress to strengthen post-marketing surveillance of dietary supplements.

Once again, I thank you, Chairman McCain and Members of the Committee, for the opportunity to testify, and I look forward to your questions.

[The prepared statement of Mr. Bell follows:]

PREPARED STATEMENT OF CHARLES W.F. BELL, PROGRAMS DIRECTOR,
CONSUMERS UNION OF U.S., INC.

Good morning, Chairman McCain, Ranking Member Hollings, and other members of the Committee. Thank you for providing me the opportunity to come before you today. I am Charles Bell, Programs Director for Consumers Union.¹ Consumers Union is the nonprofit publisher of *Consumer Reports* magazine. Our mission at Consumers Union is to test products, inform the public, and protect consumers. Today I offer this testimony on dietary supplements as part of our consumer protection function.

The 1994 Dietary Supplement Health and Education Act of 1994 (DSHEA) opened the floodgates to thousands of untested herbal products and handcuffed the Food and Drug Administration from performing any meaningful oversight over what has since developed into a multibillion-dollar industry. The law allows anyone to launch a product with a health claim without clearance from any government agency. There's no assurance of either safety or efficacy. And what's on the label is sometimes not in the pill.

The contrast with regulatory standards for pharmaceutical drugs is striking. A proposed new drug can only be approved if it is deemed to be safe in multiple human studies, and companies are required to notify the FDA if consumers suffer serious side effects.

While many dietary supplements are generally safe, and many have important health benefits for consumers, there is a significant and growing number of highly questionable products that would probably not be allowed on the market if they were subject to pre-market safety testing.

In 1995, *Consumer Reports* magazine published a list of five supplements that according to the FDA can cause serious harm to consumers—chaparral, ephedra, comfrey, lobelia, and yohimbe. Eight years later, all five of these supplements are still being marketed and sold.

In the aftermath of DSHEA, unsafe dietary supplement products can remain on the market for many years, in the same stream of commerce as products approved by the FDA as safe and effective for their intended use. Further, new dietary supplement products can be introduced overnight that contain novel, untested ingredients and/or novel combinations of new and/or existing supplement ingredients. Health providers and public health authorities typically receive little pre-market or post-market information about how such products may affect human health, and interact with medicines that patients are already taking. Even where serious problems are documented, such as in the case of supplements like ephedra, which is discussed in detail below, it is difficult for the FDA to take prompt action to protect consumers.

Ephedra: a Case Study of an Uncontrolled Hazard to Public Health

Over the last several years, increasing public attention has focused in particular on the sale and marketing of herbal supplements containing ephedra or ma huang. The ephedra controversy is an important case study, in part because it has been responsible for the largest number of reported adverse events.

The U.S. Food and Drug Administration (FDA) has compelling data showing that ephedra poses serious and unreasonable health risks to consumers. Other studies, including our own analysis of the literature to date, reveal that risks from the use

¹ Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* with approximately 4 million paid circulation, regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

of ephedra far outweigh any benefits. For example, a comprehensive report appearing in the March 26, 2003 issue of *The Journal of the American Medical Association*, linked the use of ephedra with risks of heart, psychiatric, and gastrointestinal problems, while finding insufficient evidence to support its use to enhance athletic performance, or to promote long-term weight loss.

We believe that an outright ban of this particularly hazardous herbal supplement for both children and adults is badly needed to protect consumers from serious potential adverse health effects, including heart attacks, seizures and strokes.

The FDA and Other Health Authorities Have Received Many Reports of the Harmful Effects of Ephedra

Dietary supplement products containing ephedra provide dubious health benefits while posing serious health risks to consumers. From January 1993 through October 2000, the FDA received 1,398 reports of adverse events linked to herbal supplements containing ephedra, including 81 deaths, 32 heart attacks, 62 reports of cardiac arrhythmia, 91 reports of hypertension, 69 strokes and 70 seizures.² Complaints about herbal supplements containing ephedra constituted 42 percent of all dietary supplement complaints, and 59 percent of all reported deaths.³

Those complaints likely represent only the tip of the iceberg, because the vast majority of adverse reactions to dietary supplements or medications are never reported to the FDA, or indeed, to any health professional or agency.

The American Association of Poison Control Centers has reported a steadily increasing number of serious adverse events related to supplements containing ephedra over the last five years. Recent data released by the AAPCC indicates that in the year 2001 alone there were:

- 812 reported events relating to exposure to dietary supplements containing ephedra as a sole ingredient, including 3 deaths, 103 adverse reactions, 10 “major effects” (defined as exhibiting signs or symptoms that were life-threatening or resulted in significant residual disability) and 139 “moderate effects” (defined as exhibiting symptoms or signs that were more pronounced, more prolonged or more systemic in nature than minor symptoms—and where usually some form of treatment is indicated). Of the 812 exposures, 440 persons (54 percent) were treated in a healthcare facility. Forty-eight percent of reported exposures occurred in individuals over 19 years of age.
- 7,115 reported events linked to exposures to multi-botanical supplements containing ephedra as an ingredient, including 3 deaths, 1,075 adverse reactions, 87 “major effects” and 1,325 “moderate effects.” Of the 7,115 exposures, 3,849 persons (54 percent) were treated in a healthcare facility. Forty-three percent of reported exposures occurred in individuals over 19 years of age.⁴

In addition to the above, according to information released by Public Citizen Health Research Group, from 1997 through part of 2001, as many as 33 members of the U.S. military died in ephedra-related deaths. Those who died were between their early 20s and early 40s and were reportedly in good health. As a result, the Army and Air Force military exchanges have removed such products from military commissary shelves worldwide.⁵

There Is Compelling Evidence That Ephedra Poses Serious Risks to Consumers

Two recent independent studies from well-respected academic centers, reported in peer-reviewed journals, scrutinized adverse events reports filed with the FDA between 1995 and 1999. In the reports, researchers found dozens of cases of abnormal heartbeats, strokes and heart attacks that were likely related to ephedra use.

Samenuk and others at the New England Medical Center in Boston analyzed almost 1,000 cases of possible ephedra toxicity submitted to the FDA. They reported in a recent issue of *Mayo Clinic Proceedings* that untoward events were clearly re-

²FDA Special Nutritional Adverse Event Monitoring System (SN/AEMS), FDA Analysis of FDA Data 1/93-2/01, Attachment 1 to 9/5/01 Petition by Public Citizen Health Research Group, available at <http://www.fda.gov/ohrms/dockets/dailys/01/Sep01/091001/cp00001.pdf> (no period).

³*Ibid.*

⁴American Association of Poison Control Centers, 2001 Annual Report of AAPCC Toxic Exposure Surveillance System, also reported in *American Journal of Emergency Medicine*, Vol. 20, No. 5, September 2002, p. 439. Available at: <http://www.aapcc.org/Annual%20Reports/01report/2001%20TESS%20tables%2022ab.pdf>.

⁵Testimony of Sidney M. Wolfe, MD, Director, Public Citizen Health Research Group, Before Senate Governmental Affairs Committee, Subcommittee on Oversight of Government Management Hearing on Dangers of Ephedra, October 8, 2002.

lated to immediate prior use of the drug in 37 people, and that 36 of these 37 victims had taken the product according to the manufacturer's directions. Sixteen suffered a stroke; 10 had a heart attack; and 11 died. The study concluded that "ma Huang use is temporally related to stroke, myocardial infarction, and sudden death; (2) underlying heart or vascular disease is not a prerequisite for ma Huang-related adverse events; and (3) the cardiovascular toxic effects associated with ma Huang were not limited to massive doses."⁶

In the December 21, 2000 issue of *The New England Journal of Medicine*, Haller and Benowitz from the University of California in San Francisco analyzed 140 cases of alleged ephedra toxicity that were reported to the FDA from 1997 to 1999. Abnormal heart rhythms, increases in blood pressure, stroke, sudden death, and heart attack led the list. Of those reactions, 62 percent were thought to be "definitely or probably" or "possibly" due to ephedra. Eight of the 10 deaths were attributed to ephedra, including that of a 15-year-old girl.

The few clinical studies that have been done to date are short-term and have used small numbers of subjects. Adverse reactions included elevated blood pressure, palpitations, chest pain, and extreme irritability. Dropout rates were high in the ephedra—using volunteers.

In the March 26, 2003 issue of *The Journal of the American Medical Association*, Shekelle and colleagues published an evidence-based review of the efficacy and safety of ephedra and ephedrine. (This review was carried out under the auspices of the RAND Institute at the request of the FDA.) According to a summary of Shekelle's analysis of safety data from 50 clinical trials:

Evidence from controlled trials was sufficient to conclude that the use of ephedrine and/or the use of ephedra-containing dietary supplements or ephedrine plus caffeine is associated with two to three times the risk of nausea, vomiting, psychiatric symptoms such as anxiety and change in mood, autonomic hyperactivity, and palpitations.⁷

An additional evaluation of adverse event reports by Shekelle et al. revealed 5 deaths, 4 myocardial infarctions, 11 cerebrovascular accidents, 4 seizures and 8 psychiatric cases as "sentinel events" associated with prior consumption of ephedra or ephedrine.⁸

According to an editorial article that appeared in the same issue of *The Journal of the American Medical Association* (JAMA):

The results of this analysis cast doubt on any claims that use of dietary supplements containing ephedra or ephedrine can help achieve long-term weight loss or weight maintenance or enhance athletic performance. The findings also strongly suggest increased risk of serious adverse effects associated with these products. Moreover, reviewing the accumulated reports of toxicity linked to these compounds, it is hard not to be impressed by the number of serious cardiovascular complications in young adults.⁹

Adverse Reactions with Other Medications Is a Major Safety Concern

Dietary supplements containing ephedra may interact in hard to predict ways with other prescription and over-the-counter medications that consumers are taking. For this reason, Consumers Union recommends that all consumers should consult their physicians before taking dietary supplements.

For example, combinations of ephedra products and over-the-counter cold remedies are a major issue, according to Dr. Richard Cytryn of the New Jersey Chapter of the American College of Cardiology:

Perhaps someone who has a cold does not want to interrupt a personal weight loss plan or a vigorous exercise program. He or she uses the herbal supplement and buys a sympathomimetic medication to alleviate cold symptoms. These people are actually unaware that they are taking a double dose of the drug, thereby compounding their vulnerability to its side effects. This can have potentially deadly results . . . Used indiscriminately, or in combination with contra-

⁶Samuensk, D. et al. Adverse cardiovascular events temporally associated with Ma Huang, an herbal source of ephedrine. *Mayo Clin Proc.* 2002; 77:12–16.

⁷Shekelle, P.G., Hardy, M.L. Morton, S.C. et al. Efficacy and safety of ephedra and ephedrine for weight loss and athletic performance: a meta-analysis. *JAMA* 2003; 289:1537–1545. March 23, 2003.

⁸*Ibid.*

⁹Fontanarosa, P., Rennie, D., DeAngelis, C.D. The Need for Regulation of Dietary Supplements—Lessons from Ephedra, *JAMA* 2003; 289:1568–1570 March 23, 2003

indicated OTC medications, certain other herbs and even with caffeine, ephedra supplements can lead to severe physiological responses.¹⁰

Adult Consumers Are at Risk, in Addition to Children

While much of the discussion of the ephedra problem focuses on persons under 18, the hazards of ephedra are by no means limited to minors. Consumers Union's Chief Medical Adviser Dr. Marvin Lipman, a physician and emeritus professor of medicine at New York Medical College, is particularly concerned about the potential risks to adults who may have known or unknown conditions such as cardiovascular disease, diabetes and hypertension, or who may combine their intake of ephedra with caffeine, other herbal supplements and/or other medications. Further, adult consumers may turn to herbal supplements containing ephedra after many years of physical inactivity, without consulting physicians. As noted above, the AAPCC data indicates that roughly half of all adverse event reports received by poison control centers involve adult consumers.

Manufacturers Have Suppressed Information Regarding Ephedra-related Adverse Events

Strong evidence has now emerged that manufacturers of dietary supplements containing ephedra have been concealing substantial numbers of consumer complaints regarding their products:

On August 15, 2002, the Justice Department disclosed that it was investigating whether Metabolife (a major manufacturer and distributor of ephedra products), had made false statements to the FDA regarding the existence of consumer complaints about its products. On the same day, Metabolife announced that it would turn over 13,000 consumer health complaints or "adverse event reports" to the FDA.¹¹ After analyzing the Metabolife adverse events reports, the special investigations division of the House Committee on Government Reform concluded that 2,000 of the 13,000 reports were "significant" effects, including three deaths, 20 heart attacks, 24 strokes, 40 seizures, 465 episodes of chest pains and 966 reports of heart rhythm disturbances.¹²

Two years ago, depositions in a lawsuit in San Francisco against E'ola (a Utah-based multilevel-marketing firm) regarding a death allegedly linked to ephedra revealed that the company had received 3,500 customer complaints about one of its ephedra weight-loss products. According to the *San Francisco Chronicle*, none of the complaints were ever disclosed to the FDA.¹³

While it isn't clear how many other manufacturers and sellers of ephedra products may be suppressing information regarding potential health effects, those examples do not inspire confidence that serious health impacts arising from the use of herbal supplements will be promptly reported to responsible health authorities under a voluntary reporting system. This also underscores the dangers of allowing herbal medicines in the marketplace without premarket safety testing and a rigorous post-marketing surveillance system.

Health Organizations, Sports Organizations, and State Governments Are Calling for Action to Address the Hazards of Ephedra

Despite the large number of deaths and serious adverse events linked to ephedra use, and repeated requests from consumer and public health organizations, the FDA has failed to ban dietary supplements containing ephedra. We believe this is because the FDA has been hampered in its regulatory efforts by the restrictions placed on the Agency's regulatory authority under DSHEA.

A broad range of health and sporting organizations have spoken out regarding ephedra's hazards:

- The American Medical Association has called for the FDA to remove products containing ephedra from the marketplace.
- The American Heart Association issued a statement in early April stating that supplements containing ephedra "do more harm than good and should be removed from the market."

¹⁰ Cytryn, R. "Weight Loss Aids, Energy Boosters Potentially Hazardous," PR Newswire, January 24, 2002.

¹¹ Neergaard, L. Feds investigate top ephedra seller, Associated Press, August 15, 2002.

¹² Crabtree, P. Metabolife understated danger: firm glossed over complaints about herb ephedra, panel told. *San Diego Union Tribune*, October 9, 2002.

¹³ Howe, K. FDA Stops Tracking Herbal Remedies: Agency says it doesn't have the funding to assess adverse reactions, *San Francisco Chronicle*, February 14, 2000, p. A1.

- The 2003 spring training death of 23 year-old Baltimore Orioles pitcher Steve Bechler prompted Major League Baseball to ban ephedra use by minor league baseball, and open talks with the MLB Players Association regarding these issues.
- The National Football League, the National Collegiate Athletic Association and the International Olympic Committee have also banned ephedra supplements. The deaths of three other prominent athletes, all football players—Korey Stringer of the Minnesota Vikings, Rashidi Wheeler of Northwestern University, and DeV Vaughn Williams of Florida State University—have also been linked to herbal supplements containing ephedra. The NFL has joined with the Blue Cross/Blue Shield Association and other sporting organizations to press for stronger Federal regulation of anabolic steroids and ephedra products.¹⁴
- The American Council on Exercise, America’s Authority on Fitness and “work-out watchdog” issued a statement in April 2003 urging Americans to avoid use of supplements containing ephedra and to consult their physicians before taking any dietary supplement.

Concerned about the delay in Federal action to ban ephedra, state and local governments are enacting legislation to address the ephedra problem directly. However, most government officials we have talked to have clearly stated that they do not have sufficient resources to address public health problems caused by ephedra, and that they would prefer for the FDA to address the hazards posed by ephedra and other supplements.

- At least ten U.S. states, and several local governments have imposed various restrictions on ephedra sales, such as requiring a prescription, outlawing sales to minors, or limiting the maximum dose.
- In 2002, California passed legislation prohibiting the sale of products containing ephedra to minors. The bill also required clear and conspicuous labels that warn consumers of specific potential health risks such as heart attack, stroke and death; indicate that sales to persons under 18 are prohibited; and provide the toll-free number for FDA Medwatch to report adverse events.
- In March 2003, Suffolk County, New York became the first county in the Nation to ban the sale of herbal supplements containing ephedra to adults and kids. The Suffolk County bill was strongly supported by Karen and Tom Schlendorf of Northport, Long Island, whose son Peter died in 1998 after taking supplements containing ephedra while on spring break in Florida; and Doug Hanson, of Huntington, Long Island, whose wife passed away while working out in a gym after taking ephedra supplements in 1998.
- In May 2003, the state of Illinois banned the sale of dietary supplements containing ephedra. Persons who sell supplements containing ephedra in Illinois can now be charged with a Class A misdemeanor, punishable by imprisonment for less than one year and/or a fine of not more than \$5,000 for a first offense.
- In July 2003, Westchester County, New York banned the sale of ephedra to adults, amending a recently passed law that prohibited sales to persons under 18.
- In August 2003, New York state banned the sale of dietary supplements containing ephedra.
- This month, California enacted legislation banning the sale, manufacture, and distribution of ephedra, which takes effect on January 1, 2004.

Ephedra Stimulants Are Still Widely Available

Over the last two years, several major national retail chains, including CVS, GNC, Eckerd and 7-Eleven have announced that they will no longer stock dietary supplement products containing ephedra. Several major manufacturers, including TwinLab, Nature’s Bounty, and Cytodyne, have also announced that they will no longer make and distribute supplements containing ephedra.

Consumer Reports and *Consumer Reports on Health* have published various articles regarding ephedra and other herbal supplements, and we continue to investigate these issues. Our ongoing research suggests that:

- Herbal supplements containing ephedra are still widely available at lower-profile retail sites such as independent pharmacies, gas stations and truck stops, and convenience and health food stores.

¹⁴ Associated Press, “NFL supports supplement regulation laws,” May 2, 2003.

- Ephedra is present not just in weight-loss supplements, the best known use, but also in supplements marketed as energy boosters or alternatives to street drugs such as ecstasy and speed.
- Ephedra alkaloids are turning up in supplements under names that consumers may not recognize: epitonin, Ma Huang, *sida cordifolia* and *sinica*.
- Labels listing ingredients are often in small print, and hard to decipher. Labels do not necessarily provide appropriate warning of potential hazards, or indicate how many milligrams of each substance are present.
- Many ephedra supplements contain caffeine and/or other herbal compounds that contain caffeine, such as guarana, kola nut, *Paulownia*, and mate, as well as green and black tea. Some products appear to far exceed the recommended daily intake for caffeine of 300 milligrams.
- Consumers can't necessarily rely on pharmacy or retail employees for accurate information about whether products contain ephedra or not.

"Ephedra-free" Products Are Not Necessarily Safe

It is important to realize that if and when ephedra is banned at the national level, we may see a variety of other dangerous, untested, unregulated herbal medicines drive right through the huge DSHEA loophole. There are certainly other herbal medicines that cause dangerous interactions that are also on the market today. While they have achieved less visibility, they are nevertheless of great concern to many medical professionals, researchers and patients. We have a serious concern that a variety of serious adverse events involving supplements that are less frequently taken will be overlooked, unless FDA and FTC are given adequate resources to investigate and take prompt enforcement actions.

To take just one example, herbal supplement companies are rushing to market with a variety of compounds to create "ephedra-free" herbal supplements. But as Dr. Paul Coates of the National Institutes of Health's Office of Dietary Supplements has warned, "The fact that a dietary supplement is ephedra-free is not an indication of its safety."¹⁵

DSHEA Loopholes Permit Sale and Marketing of Untested Steroid Equivalents

Dangerous loopholes in DSHEA and the Controlled Substances Act that permit manufacturers to aggressively market and sell untested, unregulated steroid equivalents to the public, including persons under 18. A national survey conducted for the Blue Cross/Blue Shield Association in 1999 found that 6 percent of youths ages 15 to 16 and 8 percent of 17- and 18-year-olds had taken a sports supplement. Yet as we noted in *Consumer Reports* magazine in June 2001, sports-medicine researchers have only tested products like androstenedione and creatine in adults.¹⁶ There has been no systematic testing of these drugs in minors, and for ethical reasons, such tests probably will not be conducted. Because of serious safety concerns, numerous sporting and medical organizations, including the AMA and the American Academy of Pediatrics, believe that steroid precursors should be classified as Controlled Substances.

Post-marketing Surveillance of Dietary Supplements Is "An Inadequate Safety Valve"

In April 2001, the Office of Inspector General at the Department of Health and Human Services concluded that FDA's adverse event reporting system was "an inadequate safety valve" because of inadequate authority and organizational capacity to collect and take action on adverse event reports.¹⁷ The report noted that in contrast to requirements for monograph drugs and new drug application (NDA) drugs, manufacturers of dietary supplements are not required to register their companies or their products with the FDA. As a result, the FDA does not have a list of supplement products and ingredients when it receives an adverse event report. The Inspector General found that FDA was unable to determine the ingredients for 32 percent of products mentioned in adverse event reports (AERs). It also lacked product labels for 77 percent of the products mentioned in the AERs, and product samples for 69 percent of products that it requested. For products referenced in the AERs,

¹⁵Jill Burcum, "Your Health: Ephedra-free products loaded with new herbs of concern," *Minneapolis Star Tribune*, April 29, 2003.

¹⁶"Sports Supplement Dangers," *Consumer Reports*, June 2001, p. 40.

¹⁷Office of Inspector General, Department of Health and Human Services, "Adverse Event Reporting For Dietary Supplements: An Inadequate Safety Valve," April 2001, OEI-01-00-00180.

FDA was unable to determine the manufacturer for 32 percent of the products, and the city and state for 71 percent of manufacturers.¹⁸

Recommendations

(1) The FDA should ban the sale of ephedra and untested steroid equivalents for both minors and adults. If the FDA believes additional legal authority is needed to act on these matters, we strongly urge the Congress to provide that authority.

At a minimum, we would support the provisions in the “Dietary Supplement Safety Act of 2003” (S. 722) that would require stimulants to be approved as new drugs, would declare foods containing unapproved stimulants to be adulterated, and prohibits the introduction into interstate commerce of a supplement containing a stimulant unless it is approved by the Secretary. These provisions would also be extremely helpful for addressing the hazards posed by herbal heart stimulants such as ephedra and steroid precursors.

(2) Pre-market safety testing should be required for dietary supplements, particularly for stimulants deemed to be of special concern by FDA and other health authorities.

Many consumers are surprised to learn the government does not currently evaluate the safety of dietary supplements before they are sold.¹⁹ This situation poses a serious risk to public health, and amounts to a vast, uncontrolled clinical trial on an unsuspecting public. Even Joseph Levitt, Esq., Director of the FDA’s Center for Food Safety and Applied Nutrition, testified in Congress in March 2001 that the current “regulation of dietary supplements is, for the most part, a post-marketing program.”²⁰

We support the provisions in S. 722 that would authorize the Secretary of the Department of Health and Human Services (DHHS) to require the manufacturers of dietary supplements, or any ingredient in a dietary supplement to submit data demonstrating that the dietary supplement is safe. The Secretary would then be authorized to review the data and issue a determination that either the ingredient is safe and that continued marketing is approved, or that continued marketing is disapproved because either it is unsafe, or it has not been shown to be safe.

(3) Dietary supplement manufacturers should be required to report adverse events to the FDA.

The current voluntary reporting system provides insufficient information for public health authorities to take prompt action regarding harmful products that put consumers at serious risk. We strongly support provisions in S. 722 that would require manufacturers, packers and distributors of dietary supplement products to collect, review, and report serious adverse events suffered by consumers using their products to the Secretary of the Department of Health and Human Services (DHHS), within 15 days of receiving notice of the event. In addition, the bill would require dietary supplement manufacturers to report on *all* adverse events to DHHS annually.

(4) Post-marketing surveillance for dietary supplements should be improved.

We believe that the FDA must be given additional resources and a resounding mandate from the Congress to strengthen post-marketing surveillance of dietary supplements. As a first step, we support the provisions in S. 722 that would authorize the Secretary of DHHS to require manufacturers of dietary supplements to conduct post-market surveillance if the Secretary determines that consumer use of a manufactured dietary supplement may result in serious adverse events.

Once again, I thank Chairman McCain, and Ranking Member Hollings and the Committee for the opportunity to testify, and I look forward your questions.

¹⁸ *Ibid.*, p. ii.

¹⁹ For example, see “Widespread Ignorance of Regulation and Labeling of Vitamins, Minerals and Food Supplements,” *Health Care News*, Harris Interactive, December, 2002; and Blendon, R. et al., “Americans’ Views on the Use and Regulation of Dietary Supplements,” *Arch. Intern. Med.*, Vol 161, March 26, 2001, p. 805–810.

²⁰ Statement by Joseph Levitt, Esq., Director, CFSAN/FDA, before the Committee on Government Reform, March 20, 2001, available on the Web at <http://www.fda.gov/ola/2001/dietary.html>.

February 10, 2000

Re: Int. 583 In relation to restrictions on sale of ephedrine and the posting of warnings relating to dietary supplements.

Res. 912 Calling upon Congress to restore the authority of the Food and Drug Administration to test and regulate dietary supplements prior to their marketing.

I wish to thank the Committee on Consumer Affairs and the Council of the City of New York for inviting me to speak at this hearing. I believe that I have a unique perspective on the issues of dietary supplements and ephedrine in particular. I am speaking to you today for so many others who can no longer speak for themselves. Young people like my youngest son, Peter Schlendorf but also for Kristopher Michal and Rosanna Porras to mention but a few who suffered from the fatal effect of an herbal supplement containing ephedrine. But now let me tell you about Pete Schlendorf.

As a mother it is very difficult to try to put into words the depth of my feelings for my youngest son. Pete was the joy of my life. From the day he was born, Pete was someone very special. He made me smile every day and I thanked God that I had been blessed with such a wonderful gift. My three children meant the world to me and as a full-time mother I enjoyed every minute that I spent with all of them. On the day that I began my job as a high school guidance counselor, Pete, who was ten, picked a bouquet of flowers from our garden for me. I had always given the children a small gift on the first day of school and told them how proud I was of them. Pete was doing the same thing for me. He was always a kind and thoughtful person who made people feel glad that they knew him. He brightened a room every time he entered it. He was always the center of attention; not because he asked for it, but because it seemed to come to him naturally. Pete was bright, funny, athletic, talented, a leader among his peers. I was proud of his accomplishments and prouder still of the man he was becoming.

Then one day the unimaginable happened—he died.

Pete had gone to Florida on Spring Break with some of his friends. On a cold and overcast day they decided to explore some of the shops along the beach. All week they had seen ads and banners prompting herbal supplements of all kinds. They went into one of the shops and decided to try one. It was all-natural, safe, harmless, the store clerk said that she and her friends take 10 or 12 pills at a time and feel great, it gave them lots of energy! The boys tried it. Pete took somewhere between 4 and 8 pills and almost immediately began to feel strange. His heart rate was faster, he felt tingly, hot all over, had a pounding headache. He took a shower but it didn't help. He told the other boys to go out, that he would lie down for awhile until he felt better and would join them later. The last time his friends saw him alive he was sitting on the edge of the bed reading the label on the box. What had he taken? What was wrong? What should he do? There was no help on that box.

It took weeks, months for us to understand what happened to our beautiful, wonderful, healthy son. We still really don't understand. Perhaps we never will. But at least now we do know the facts. Pete died because a company cared much more about profits than about lives. Pete died because he had an unfortunate chance encounter with Ultimate Xphoria. The manufacturers of this product have admitted that they are not sure how many or which additional herbs were in each batch. They claim not to know where the Ma huang came from, which part of the plant was used, the time of year it was harvested, how strong the concentration was. They didn't know or perhaps didn't care but my son died because Ultimate Xphoria was improperly manufactured and marketed towards young people. A number of ingredients in this product posed a risk to Pete or any other healthy individual. Combined they caused an insurmountable risk of harm. I know that there is a great deal of information in publications or on the Internet that dispute these truths. I have read them myself. But, I have a copy of Pete's autopsy, something no mother should ever have to see, and it shows beyond a shadow of a doubt that there was nothing in Pete's system besides the ingredients in this product. He had been on spring break with his friends but there was no evidence of any drugs or alcohol, nothing but the lethal herbal supplement that he bought over the counter in a little shop on the beach.

Ephedrine is a drug. It has been a drug for over 5,000 years. No amount of legislation will make it a food. Proponents of ephedrine containing supplements like to say that the Chinese have used it for centuries. They have, through practitioners who prescribe it as a part of their traditional medicine, not for weight loss or as an energy boost.

Scientists have agreed on what ephedrine does; dilates bronchial muscles, contracts nasal mucosa, raises blood pressure, and acts as a cardiac stimulator. Al-

though there may be some disagreement as to a safe limit of ephedrine, I do not dispute that in proper hands ephedrine can be appropriate and safe. However, the Dietary Supplement Health and Education Act of 1994 has allowed irresponsible persons to contaminate the marketplace with false claims and dangerous marketing. I doubt it was the intention of Congress to allow people like those who caused my son's death to get rich at the expense of America's youth. I fully understand that there are many people and certainly many manufacturers making millions of dollars from these products who don't want to hear any of this. But I am so glad that this governmental body does have the courage to seek the truth.

I believe that it is our duty, our responsibility to guard and protect each other. Ephedrine should not be sold to minors. Information about herbal supplements should be readily available to all. The risks associated with herbal supplements, the truth about what these products do and what they do not do is vital information. Why would anyone want to deny information, deny the truth to the consumers? The FDA has been limited in their ability to protect the consumer against dangerous herbal supplements by the Dietary Supplement Health and Education Act of 1994. The time is long overdue to examine the results of this Act of Congress. Was this in the best interest of the American public? I can state emphatically that it was not in the best interest of my son, Peter Charles Schlendorf.

Sincerely,

KAREN SCHLENDORF

[The following articles from *Consumer Reports* have been retained in Committee files:

June 2001—Sports-supplement Dangers
 March 1999—Herbal Rx, The promises and pitfalls
 April 1998—Vitamins and minerals and herbs, Oh my!
 October 1998—Uprooting herbal myths]
 The CHAIRMAN. Thank you very much.
 Mr. Davis, welcome. Thank you for your patience.

STATEMENT OF GREG DAVIS, STUDENT, UNIVERSITY OF SAN DIEGO SCHOOL OF LAW

Mr. DAVIS. Thank you. Thank you for having me.

I have a story to share with you today that's kind of eerily similar to the story shared by Senator Durbin earlier this morning.

Four and a half years ago, at the age of 16, I started using the performance-enhancing supplement ephedra. At the time, I was an honor student at my school, a member of the student council, and also the co-captain of my varsity football team.

The CHAIRMAN. At what school?

Mr. DAVIS. San Ramone Valley High School in Danville, California.

Like many athletes, and a lot of high school athletes, I wanted to go pro. You know, I had the dreams of playing college football, but I knew that was going to be very difficult. Performance-enhancing supplements had become a staple of high school athletics. Whenever you see marked improvement in a player's performance, the question isn't asked, "What is this player doing? Are they doing more wind sprints, more bench presses?" It's always asked, "What are they using? What are they taking?" You know, "What extra help are they getting?"

At the time, I was worried that I would be at a competitive disadvantage if I wasn't using performance-enhancing supplements to improve my play. That's when I started researching ephedra. I had heard about it in the weight room, and I went on the Internet and just typed in a quick little search on Yahoo! on performance-enhancing supplements and ephedra. I was amazed by the number of

responses I got, and I looked up the websites, and I looked at the manufacturers' statements, and I was actually really reassured about the safety of the products. The manufacturers pointed to independent laboratory testing that had been done. They noted that it was all herbal or that there was significant regulatory control. I was—like I said, I was very happy with this, and I went ahead and purchased the ephedra product.

That was in February 1999. Again, I want to stress that I was 16 years old. In April 1999, a couple of months later, I suffered my first seizure. I was getting ready for my junior prom. Needless to say, I didn't make it. I was rushed to the hospital. Tests were done, and there was no conclusive result made by the—

The CHAIRMAN. What kind of a seizure?

Mr. DAVIS. Pardon me? A grand mal seizure.

The doctors didn't—weren't able to give me any reason why it happened, and they just kind of patted me on the back and said, "You know, sometimes these things happen with adolescents when they're going through puberty and whatnot, and, you know, just keep your head up and hopefully it won't happen again."

One year later, actually in April of 2000, I suffered a second seizure. Unfortunately, this time I wasn't just preparing for my junior prom, and I wasn't at home in my bathroom. I was actually behind the wheel of my car driving to my friend's house. I got in a pretty bad accident. My car veered off the right side of the road, ran through a guardrail and came to rest against a tree, fortunately. And I say "fortunately," because that tree was right next to a 20-foot fall into a dry creek bed in my hometown.

I was rushed to the hospital again. And luckily, the paramedic on the scene to that car accident was actually the same paramedic that was at my house when I had my first seizure a year before that, so he knew what happened, and rushed me to the hospital. They did some testing again. Again, all the tests showed that everything was fine with me, except this time they ran one extra test, and that was just a normal blood test, which they had to do. It's standard operating procedure when someone loses consciousness behind the wheel of a car.

When they did the blood test, my blood came up positive for amphetamines, a—you know, it's a street drug, speed. At that time, I started putting two and two together and realized that the ephedra, the so-called safe performance-enhancing supplement that I easily got off the Internet, caused me to have these seizures and almost killed me.

I want to close by confirming a suspicion that you mentioned earlier this morning, and that's that most people—and I can assure you most people, if not all young people have the expectation that when they go on the Internet or go to a store, and they're able to purchase something that—without a prescription, over the counter, they expect that it's going to be safe if used as directed. And I would just urge that any change that can be made to protect the American people, and especially protect children, I would definitely encourage those.

Thank you.

The CHAIRMAN. Tell me, Mr. Davis, how widespread was the use of these substances on your athletic teams?

Mr. DAVIS. I wouldn't want to venture a percentage guess, but definitely widespread enough that I felt that I would be at a competitive disadvantage if I wasn't using the product.

The CHAIRMAN. But it was common knowledge that it was used with great frequency by your teammates?

Mr. DAVIS. Definitely. It was a topic of conversation all the time, whenever practice would get boring or someone would make a great play. We'd start talking about the new products out on the market. They had been advertised extensively, and, you know, we mentioned it all the time and talked about it a lot.

The CHAIRMAN. Well, what you do, Mr. Davis, is you attenuate the issue here, because I said at the—and will probably say again, that it's one thing for a professional athlete, a grown individual, to make a decision, even one that's a wrong decision. But, when it encourages young people, such as yourself, and many view it is the only way to be able to compete effectively and reach the professional ranks, then we have a serious national problem. And I thank you for sharing your experience with us. I apologize and I'm very sorry that it happened to you. I hope you regain your health and are able to continue whatever—and pursue whatever career you desire. And I thank you for appearing before the Committee.

Mr. DAVIS. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Seckman, do you agree that steroid precursors should be classified as a controlled substance?

Mr. SECKMAN. Yes. That's why we support Senate bill 1780.

The CHAIRMAN. How is it, then, that you—that the FDA still says it's, quote, "scientifically inconclusive"?

Mr. SECKMAN. I think that's because of the studies, as I think you asked that question before to the FDA. We feel that, in fact, they have the authority to take those types of products off the market under the present authority under DSHEA. But, unfortunately, we've got to go through a process of having it specifically listed in a bill, 1780, to go ahead and take that product off the market.

The CHAIRMAN. But it also seems to me we have reversed the procedure here. Usually, a drug or a substance has to go through an approval process. Now it's on the market, and we have to go through a disapproval process.

Mr. Bell, do you have any comment on that?

Mr. BELL. I think that's exactly right. And as I mentioned, this is a situation where we have shifted the burden to the government to prove that these products are unsafe, rather than requiring the manufacturers and promoters of these products to show that they're safe before they're allowed on the markets.

And I would refer you to the great report that was done by the HHS Office of Inspector General on adverse event reporting for dietary supplements, because they strongly made this point, and they basically are saying adverse event reporting, as we have it now, only captures about less than 1 percent of all the complaints that consumers are experiencing. But even if we had that data, the FDA does not necessarily have adequate product registration data, manufacturer registration data, or clinical data demonstrating that these products are actually safe.

So we think we need to get much more into the prevention mode and have a presumption that a manufacturer of products of certain

types, certain classes, have to be demonstrated to be safe before it would even be allowed to be sold in the marketplace.

The CHAIRMAN. And, Mr. Seckman, since you were in the hot seat here, if you want to respond to any of the other comments, please just raise your hand, because I believe in providing people with equal opportunity here to respond.

Mr. SECKMAN. Well, thank you, Senator.

Just specific on andro, just as a little bit of a way of a background here. In fact, Senator Harkin and Senator Hatch, in the summer of 2001, sent a letter to the FDA asking, in fact, two questions. One was androstenedione, a product that was grandfathered in DSHEA in 1994, and if not, was a new dietary ingredient application filed? We're still waiting for an answer to that. We support them in their quest to get from the FDA whether this is a product or not. But, again, there is a provision under DSHEA that any new dietary ingredient would have to be submitted to, and the FDA has the authority to review that for safety and reject that product. And, in fact, they do reject products.

The CHAIRMAN. Mr. Madden, when you are telling athletes that they cannot use a certain product, and they can walk into a drugstore or a gas station, or anyplace else that sells these kinds of things and get it over the counter, doesn't that make your job harder?

Mr. MADDEN. Senator, it's almost impossible. Actually, the USADA stance is you can't put anything into your body beyond your natural food. We can't promise them that the supplement will not be tainted and they would test positive for—based on a steroid precursor metabolizing in their body—to a steroid. So, we're hamstrung. Yet the athletes—I wish I could say you can take your vitamins. I wish I could say you could take your minerals. I mean, I take vitamins. I take minerals. I'm on the anti- or the pro-heart healthy-heart diet. I take the omega-3 fatty acid. But we can't tell our athletes or allow them to think they can take those.

The CHAIRMAN. Well, you and I know that there's an ongoing investigation that you don't want to get into about the latest designer drug or whatever you want to call it, but doesn't this raise the larger issue—and I'm setting aside the present investigation—that it's a game that you design a way to detect the use of a certain steroid, then some smart people in a laboratory design something that evades your present testing process. Then you have to, either through information or other means, find out that that has to be tested for. In other words, you're continuously behind the curve, is that right? As long as these substances are allowed to be put on the market without an approval process.

Mr. MADDEN. Yes, Senator. It's difficult. But the good news is, the vast majority of America's athletes are clean. They want to compete ethically, they want to do it through hard work.

The CHAIRMAN. But isn't the bad news that there are a whole lot of young people, like Mr. Davis, that are out there saying, "If I want to make it, I've got to take this stuff"?

Mr. MADDEN. Absolutely. That's the bad news. As far as the THG story, it's—very simply, it's an anabolic steroid, designer steroid, created by one or two people in some laboratory. We believe there are only a few of these that are operating in the country. We're not

naive enough to think that they're not creating other steroids in a few labs. But we believe the number is small.

I have to tell you, now that a coach and athletes have come forward to report this story, it shows they have confidence in us, and I believe we're catching up. I believe we may even get ahead of them, and I believe we might know where they're going in the future in a few cases.

The CHAIRMAN. I appreciate your confidence.

Go ahead, Dr. Grollman.

Dr. GROLLMAN. You asked Mr. Madden earlier, was he surprised that 30, 40 percent of the supplements were contaminated. He shouldn't have been, because we have a number of reports looking now broadly at contamination. That's what they run, 30 to 40 percent, not just with steroids, but with prescription drugs, adulterated, heavy metals. These are reported in the major medical journals, and just taking them off the shelf. So that's the standard background of contamination. Some of it deliberate.

The CHAIRMAN. Mr. Seckman, Mr. Madden testifies in his testimony, "A recent study of 624 dietary supplements by the International Olympic Committee found 41 percent of the products from American companies contained a steroid precursor or banned substance not disclosed on the label." What's your response to that?

Mr. SECKMAN. Well, that's clearly illegal if they have those substances in there. It is a requirement of—

The CHAIRMAN. You're representing their industry, and 41 percent of their products are mislabeled and don't contain information that can be harmful to somebody's health. Don't you feel some sense of responsibility?

Mr. SECKMAN. We do. And we, as an industry, have long supported, in fact, not waiting for the good manufacturing practices regulation to come out. After 9 years, we went ahead, as an association, developed our own good manufacturing practices, which we put into place. But, you're right—

The CHAIRMAN. But this was a recent study.

Mr. SECKMAN. Clearly, all products have to list all the ingredients on the label.

The CHAIRMAN. So what is your industry doing to clean this up?

Mr. SECKMAN. Well, we are. We're working hard with the FDA to try to get the regulation, the final regulation out, but not waiting for the—

The CHAIRMAN. You're working with the organization that took 9 years to come up with the regulations? Good luck.

Mr. SECKMAN. That's correct, Senator. That's why we came up with our own good manufacturing practices in 1999, to try to help the industry move in that direction.

The CHAIRMAN. That might be one of the most disturbing facts brought out in this hearing today, because not only do we not have an approval process, but we've got labeling in 41 percent, two out of every—or four out of every ten that has substances that are not disclosed that should be banned. Well, that is very disturbing.

Let me see. Mr. Madden, do you believe that DSHEA should be repealed?

Mr. MADDEN. No, sir. In our opinion, Senator, we've got some unscrupulous supplement manufacturers out there that have found a

way around the Act. They know how to dodge the Act. Actually, Senator Biden's and Hatch's bill that they brought out this year, you should know it has three important factors in it. The first is, it removes the process that the FDA has to prove it promotes muscle growth. That will allow substances to be listed in a quicker manner. Those studies can take 12 to 24 months. And referring back to your last question, yes, we would be behind the eight ball then. We'd always be behind the curve. But their new bill, we're quite pleased with removing the muscle-growth factor.

Also, the criminal sanctions, in the new bill, allows—should put on notice the unscrupulous manufacturers to stay away from this stuff, that they're going to come after them criminally.

And, third, all the known substances USADA is familiar with, they've agreed to list in this new bill, and that's a major step forward. The number of items added is around 24 to 25.

The CHAIRMAN. Dr. Grollman, what's your response to the FDA's claim that the scientific evidence in the steroid precursors is inconclusive?

Dr. GROLLMAN. Well, just take it from ephedra. There can't be more known about pharmacological properties than about ephedra, yet they say there's not enough scientific inclusions—you've heard it here this morning—to be able to come down. If you move that to the steroid precursors, there's far, far less evidence. So if they were under the same thing, they'll never get there on that. You're making it dramatic, and you make it a controlled substance. But, they want the scientific evidence that is somehow there, but nothing compared to what they have put together for ephedra and toxicity. So, that's what's—they were burnt on ephedra, and that's why they're moving slowly or will move slowly if you don't build a fire under them, on these steroid precursors.

Also, I should add, and this hasn't been brought up in the hearing, that under DSHEA, not just herbs are mischaracterized as dietary supplements. They've got a word called metabolite. Well, that's what androstenedione is. That's what DHEA, cholesterol, it is metabolized to those substances, metabolized to testosterone. So one could make a legal case that it's a metabolite, even if it is a controlled substance.

The CHAIRMAN. We have—

Dr. GROLLMAN. And that worries them, too, because they really haven't defined metabolite, or they can't work with that incomplete definition.

The CHAIRMAN. We have an interesting interpretation of facts here. Mr. Seckman, in your statement, you say, "I would refer to another well-regarded source, the American Association of Poison Control Centers. In this group's most recent report of poison control centers throughout the United States, adverse reactions to drugs are more than 800 percent higher than those for dietary supplements." Then Dr. Grollman refers to the same organization, and he says, "In 2001, the FDA received approximately 500 reports of adverse events related to dietary supplements, while poison control centers in the United States received 19,468 such reports."

Are you both right? Go ahead, Mr. Seckman.

Dr. GROLLMAN. Well, that's the report of the pediatrics journals and the poison control centers put that data together. It's in the

journals. Every year they report it, and we just take it from there. It's a public record.

Mr. SECKMAN. And so is ours. It's a cited source there, Senator, so we stand by that, that number.

The CHAIRMAN. Well, I don't—I'll pursue it, but you're saying adverse reactions to drugs are more than 800 percent higher, and they're saying that in the report it was nearly 20,000. So you would have had eight times 20,000—but I—anyway. I guess it's an example of what everybody can do with facts, but—

Go ahead, Mr. Bell.

Mr. BELL. Yes, in my written testimony, I think one thing you could look at is that in—well, for supplements containing ephedra, of the 812 exposures reported by the Association of Poison Control Centers in 2001, 440 persons, 54 percent, were treated in a health care facility. And then for multi-botanical supplements containing ephedra, 3,849 people, 54 percent were treated in a health care facility. So we think this is a huge influx of people seeking treatment who have taken dietary supplements containing ephedra. It was an increase of something like 20 times over the numbers reported in 1999. So, to us, it's very significant. And it's a major burden on the health care system to respond to these problems of unsafe and untested supplements.

The CHAIRMAN. Thank you.

Mr. Seckman, I would like from you, in writing, what your organization intends to do and is doing about the mislabeling issue, what your position is on precursor, steroid precursors, and what legislative remedies you support and do not support. I'd like—I know that's in your statement, but I would like it in writing from your organization.

The CHAIRMAN. We want to work with you, not against you. But, I'd also like to point out to you, I think you've got a PR problem right now, and it's in your interest and in the interest of your industry to be part of the solution and not remain part of the problem. I know that means that you may have to make some difficult decisions. But I think this issue has risen to a level of visibility and will continue to go higher, if any indications are—from what I'm hearing and reading, that it's in your interest, as well as the Nation's interest, to be with us and move forward in trying to resolve—to devise remedies for what is a terrible problem for young Americans like Mr. Davis. OK?

Mr. SECKMAN. Well, we'll certainly comply with that, and we look forward to working with you, too, Senator.

The CHAIRMAN. Thank you.

I'd like to ask if there's any closing comments.

Mr. Davis?

Mr. DAVIS. No.

The CHAIRMAN. Thank you for coming here today.

Mr. DAVIS. Thank you.

The CHAIRMAN. Mr. Bell?

Mr. BELL. Well, just that we believe that safety and advocacy should be the driving concerns when new medicines are introduced into the marketplace, and that they are—they're the dog; they should not be the tail of the dog.

The CHAIRMAN. Dr. Grollman?

Dr. GROLLMAN. Yes. With all the focus on ephedra, I want to really underscore the breadth of the problem. Now, I've given you this example of Aristolochia, and you've probably been on the FDA for taking 9 years. Aristolochia couldn't be more of an imminent hazard. That's the words in the legislation. It causes cancer in people. The World Health Organization has defined it, and it's being sold in health stores and on the Internet. FDA had that on their desk, detailed back in the spring. Here at this fall, they have taken no action whatsoever. If they don't take action on the imminent hazards, then it's clear that the barrier that DSHEA has put up is just too high for them.

The CHAIRMAN. Mr. Seckman?

Mr. SECKMAN. Yes, I think when we're looking at DSHEA 10 years, almost, later, we look at what authorities they were given, as Dr. Grollman said. They were given the authority—in a minute—authority to go ahead and take any of those products off the market, and they haven't done so. And that's our concern, and I think that's what I heard from Senator Durbin and Senator Hatch earlier today, as well. We support their decisions. We await, as I think everyone in this room does, their decision on whether they think that ephedra is a dietary supplement or not. And if it is not—they determine it is not a dietary supplement and should not be sold, it is unsafe, we'll support that decision. We think the authorities given to them under DSHEA, if they would actually implement the law and enforce it, is a workable solution.

The CHAIRMAN. Mr. Madden?

Mr. MADDEN. Senator, when we first began to address the steroid precursor problem 3 years ago, it was an athlete issue for us. But I can assure you, the more we looked at it and the more we investigated it, it's become a health issue for our children, our teenagers, especially women, in our country, and it needs to be addressed as a health issue, not an athlete issue.

I thank you for your time.

The CHAIRMAN. That's a good point.

I thank all the witnesses. This hearing is adjourned.

[Whereupon, at 11:50 a.m., the hearing was adjourned.]

A P P E N D I X

PREPARED STATEMENT OF HON. JOHN B. BREAU, U.S. SENATOR FROM LOUISIANA

Mr. Chairman and Members of the Committee. Thank you for holding this important hearing on the safety and marketing of dietary and specialty supplements.

On September 10, 2001, the Special Committee on Aging held a hearing that focused on companies that mislead consumers with regard to dietary and specialty supplements. While I am certain the vast majority of manufacturers and marketers of supplements are reputable and law abiding. There are often bad actors in any industry.

Supplements are becoming increasingly popular. Our hearing of the Special Committee on Aging estimated that \$27 billion or more is spent on supplements and that 60 percent of these consumers are older Americans. Individuals who are both healthy and ill take supplements for a variety of reasons. Some take supplements to increase energy, build muscles or lose weight. While others have begun taking them as alternatives to traditional medicine and escalating prescription drug costs. More and more our Nation's seniors are turning to these supplements.

As you know, the dietary supplement industry is largely self-regulated. Unlike new prescription and over-the-counter drugs, the law does not require supplements to undergo pre-market approval for safety and efficacy. The current U.S. regulatory system provides little assurance that commercial supplements have predictable pharmacological effects or that product labels provide accurate information. Furthermore, manufacturers of supplements are not required to register with any government agency. This is of great concern.

Surveys have shown that the use of complementary and alternative medicine in the U.S. increased an amazing 380 percent between 1990 and 1997. This trend will almost certainly continue as the baby boomers draw closer to retirement age and seek out new and different ways to maintain and improve their health. We need to know that the products our seniors, and all Americans, are taking are safe and effective.

These products are marketed to our seniors in a variety of ways. One impetus for my investigation into supplements was a magazine my wife received in the mail entitled the *Journal of Longevity*. At first glance it appeared to me to be a scientific journal extolling the virtues of supplements, focusing on those that have alleged "anti-aging" effects. I was drawn in and amazed by the startling new discoveries purported to slow the aging process, give you more energy, a better sex life and a healthier heart, until I realized that the mailer was simply a fancy advertisement for one company's products. The *Journal of Longevity* appears to simply be a series of articles that discuss health issues that seniors face and then provides a simple solution—the solution being a dietary supplement developed and distributed by the same parent company that publishes the magazine.

My investigative hearing focused on Glenn Braswell, one of the largest dealers of dietary supplements and the publisher of the *Journal of Longevity*, who asserted his Fifth Amendment rights at our hearing. What is noteworthy about Mr. Braswell is the following:

- he was convicted in 1983 on Federal charges of mail fraud, perjury and tax evasion, serving seven months for false hair growth.
- in 2003, he was indicted by the IRS on criminal tax evasion charges and the case is ongoing.
- in 2003, the FTC charged him with false advertising of dietary supplements and I understand that case is moving into the discovery phase.
- finally, Mr. Braswell is reported to own at least ten entities, some of which operate from mail outlets in Canada.

We learned some disturbing things through our hearing about Glenn Braswell and supplement sales. We need to continue to weed out the unscrupulous companies

and give law enforcement the necessary resources to do that. Once again thank you for the opportunity to provide this statement and for calling this hearing.

PREPARED STATEMENT OF HON. FRANK R. LAUTENBERG,
U.S. SENATOR FROM NEW JERSEY

Mr. Chairman:

Thank you for holding this hearing on a very important subject. Increasingly, Americans are consuming more and more dietary supplements—\$18 billion per year.

It seems to me that there are *two* basic issues we need to focus on: (1) the *safety* and *efficacy* of the supplements themselves; and (2) how they are marketed.

When it comes to supplements like Vitamin C or folic acid, there is overwhelming scientific consensus about the benefits they offer, proper doses, and so on.

There is much less consensus about supplements like Echinacea, ginkgo biloba, and St. John's Wort.

Because *all* supplements the *good*, the *bad*, and the *ineffective* fall under the DSHEA Act, the Food and Drug Administration has little authority to regulate them. Manufacturers are responsible for ensuring the *safety* of the supplements they sell and do not need prior approval from the FDA.

Supplements may be naturally-occurring. But what happens when they are *combined* with other substances, *condensed into extracts*, or taken in large doses? In many instances, we *just don't know*. What quality control and purity standards exist in the manufacturing process? In many instances, we *just don't know*.

I'm also concerned about the marketing practices of some supplement manufacturers and distributors. It is clear that many of these products are deliberately marketed to younger and younger consumers. What are the health consequences of such a trend? Again, in many instances, we just don't know.

Frankly, some supplement peddlers sound like "snake oil salesmen." There's an old adage, "If it sounds too good to be true, it probably is." Sadly, there's no shortage of people who want to feel younger or look younger or lose weight or build muscle mass and they are susceptible to the barrage of advertising the industry puts forth.

The potential danger of dietary supplements was underscored this past spring when Baltimore Orioles pitcher Steve Bechler reported to camp a little overweight and out of shape. He took ephedra to lose the weight and became one of the 118 people whose deaths have been linked to the use of that particular supplement—so far.

I want to reiterate that many supplements are *safe* and *beneficial* and are *manufactured* and *marketed responsibly*. The issue this Committee needs to resolve is whether the current regulatory regime—which basically amounts to *self-regulation* by the industry—is *adequate* to protect human health and safety.

I look forward to hearing from our witnesses on this important subject.

Thank you, Mr. Chairman.

PREPARED STATEMENT OF JOHN E. SWEENEY, U.S. REPRESENTATIVE FROM NEW YORK

Chairman McCain, thank you for holding this hearing highlighting the dangers of dietary supplements and their distressingly easy availability to consumers of all ages. I laud your willingness to help us fight the good fight and protect future athletes and families from the devastation caused by unsafe additives and false advertising.

I would also like to welcome Terry Madden, Chief Executive Officer of United States Anti-Doping Agency (USADA). As you are aware, USADA, the independent group that conducts drug testing for Olympic-related sports, recently uncovered what appears to be the largest illegal doping scheme in sports history. A previously undetected designer steroid, tetrahydrogestrinone (THG), has been identified and testing indicates as many as a half-dozen athletes in track and field have recently used the performance-enhancing drug. While THG is currently not sold in health stores—the substance has the potential to become available over the counter once it becomes better known. This situation highlights the lengths athletes are willing to go for an unnatural edge over the competition, whether it be enhancing muscle strength with THG or enhancing energy and promoting weight loss with ephedra.

The battle against the reckless availability of performance-enhancing substances became personal for me after Baltimore Orioles pitching prospect Steve Bechler's death last winter and my 16-year-old son, an avid baseball player like his old man, asked me about the supplements he had seen in the locker rooms at his school. I

was horrified to think our young athletes are so desperate to get an edge they would unknowingly damage their developing bodies.

Ephedra manufacturers and distributors promote aggressive marketing schemes targeted at young athletes and prey on the insecurities of many Americans. Often times these campaigns make false promises and do not fully explore the dangers of taking supplements containing ephedra. Until the Food and Drug Administration (FDA) has the means to enforce current regulations and is given the tools to combat this unethical behavior, I believe Congress must act in the best interest of the public.

Under the provisions of the Dietary Supplement Health and Education Act of 1994, the FDA must show that a supplement is unsafe and causes harm before it can be removed from the market. My concerns begin with the fact that there is no provision under any law or regulation that requires a firm to disclose to FDA or consumers the information they have about the safety or purported benefits of their dietary supplement products. Consumers assume dietary supplements are approved by the government before being sold to the public, unfortunately this is simply not true. Until the sequence of allowing these supplements to come to market is revised, sales of this dangerous and harmful ingredient must be restricted.

Let's work together and recognize this battle needs to be fought from many different directions if we are going to be successful in protecting athletes. I have introduced legislation (H.R. 1075) requiring pre-market approval for supplements containing ephedra, it boggles my mind that we may wait until tragedy strikes before Congress acts.

I would also like to take a moment to speak about substances that are labeled as "supplements" by steroid precursor manufacturers. I teamed up with Congressman Osborne to introduce H.R. 207, and am pleased to also collaborate with Senator Biden and Senator Hatch, to combat this public health concern. As more teenagers look for ways to gain a competitive advantage in athletics or obtain the elusive "perfect" body, they are increasingly turning to steroid precursors that are sold over-the-counter and marketed as harmless dietary supplements.

In the United States, a plethora of steroid precursors are being aggressively marketed as over-the-counter steroid equivalents by dietary supplement manufacturers. The most popular of these steroid precursors include the andros (androstenedione and androstenediol) and the 19-nors (19-norandrostenedione and 19-norandrostenediol). Additionally, a number of variations of these basic steroid precursors have flooded the U.S. market in recent years. Supplement manufacturers are rushing to cash in on the appetite of American consumers for any pill with claims that it will magically build muscle.

These dangerous steroid precursors metabolize in the body into anabolic steroids. Anabolic steroids are illegal substances that are regulated by the Controlled Substances Act. Despite the fact that once ingested steroid precursors become anabolic steroids, steroid precursors remain unregulated. Because steroid precursors are legally sold over-the-counter, many young people mistakenly think that these substances are healthy and safe, when in reality they have the same effects and dangers as illegal anabolic steroids. The side effects of steroid precursors pose far greater risks for young people than they do for adults.

Thank you for holding this hearing and working with me to stop the proliferation of these types of dangerous substances.

PREPARED STATEMENT OF HON. JOSEPH R. BIDEN, JR.,
U.S. SENATOR FROM DELAWARE

Chairman McCain and Senator Hollings, thank you for holding this hearing today and for inviting me here to discuss the Anabolic Steroid Control Act of 2003, legislation which Senator Hatch and I introduced last week.

Over the last several weeks, we have all read front-page articles on the dangerous mix of sports and steroids, including a new "designer" steroid known as "THG." Several premier athletes have allegedly tested positive for THG, and there is a Federal grand jury investigation into the alleged manufacture and distribution of this new substance. Our bill would make THG, and several other similar substances, subject to the Controlled Substances Act. Thus, these products would no longer be available over the counter.

Let me begin with a bit of background on how we got here. Thirteen years ago, I held a number of hearings in the Judiciary Committee on the dangers associated with steroid use and introduced legislation to make steroids Schedule III substances.

After my bill became law, a number of steroid users continued to buy and use steroids—only now they were buying them through a developing illicit market. Others relied on new products being developed by scientists, products which may not violate the *letter* of the law, but certainly violate the *spirit* of the law.

These substances, called steroid precursors or pro-steroids, are one step removed from the substances scheduled in the law: when ingested, they metabolize into testosterone. These are products which the United States Anti-Doping Agency, who the Committee will hear from today, has called “the functional equivalent of steroids.”

The most well known of the steroid precursors is androstenedione—often called “andro.” It became a household word when professional baseball player Mark McGuire admitted that he used it when he broke the single season record for home runs. After McGuire revealed that he had taken andro, sales of the product *quadrupled*.

According to a study published in the *Journal of the American Medical Association*, andro increases both testosterone and estrogen levels in the body and it can be especially hazardous in women and children. Andro has also been associated with a decrease in the “good” cholesterol and increased risk of breast cancer.

In addition to the grave *health* effects associated with using andro and other steroid precursors, the *physical* effects can also be quite serious: women can develop masculine sex characteristics including changing of the sexual organs; men can develop feminine sex characteristics including breast development; and adolescent users can permanently stunt their growth.

The International Olympic Committee, the NFL and the NCAA have banned andro and other steroid supplements. Other sports, particularly baseball, have been criticized for refusing to agree to test players for steroid precursors. I should note, however, that Major League Baseball has endorsed my legislation.

And at a hearing in this Committee last year, the Executive Director of the Major League Baseball Players Association said that “it may well be time for the Federal Government to revisit whether [steroid precursors] should also be covered by Schedule III.” I agree with him. Interestingly enough, so do the 79 percent of major league baseball players who, according to a *USA Today* survey, support testing for performance-enhancing drugs.

In my view, it is time for Congress to act so that we can put an end to the charade that andro and similar products are any different from the anabolic steroids that are controlled under current law.

The *USA Today* survey also revealed that 80 percent of fans believe that steroid use is behind some of the records that have been broken recently. It is understandable, therefore, that some players may support testing to preserve the integrity of their records. As Yankee’s shortstop Derek Jeter has been quoted as saying:

“I don’t have a problem with getting tested because I have nothing to hide. Steroids are a big issue. If anything like a home run or any injury happens, people say it’s steroids. That’s not fair.”

To be honest I would be less concerned about what professional athletes are doing to their bodies if their actions did not have such a profound effect on kids. A study by the Kaiser Family Foundation revealed that nearly three-quarters of kids say that they look up to and want to emulate professional athletes.

Sadly, more than half of those kids believe that their sports heroes use steroids and other performance-enhancing drugs to win. That may be why adolescent anabolic steroid use is at its highest level in the past decade, with 1 million teens having used them.

Let me quickly go over what our legislation does. Most importantly, it adds THG, andro and their chemical cousins to the list of anabolic steroids controlled under the Controlled Substances Act and makes it easier for the DEA to add similar substances to that list in the future. It also directs the U.S. Sentencing Commission to review the Federal sentencing guidelines for crimes involving anabolic steroids and consider increasing them. And finally, it authorizes \$15 million for school-based programs highlighting the harmful effects of anabolic steroids.

I’m proud to say that the bill has been endorsed by a wide range of medical, athletic, drug policy and dietary supplement organizations including the United States Anti-Doping Agency, the National Football League, Major League Baseball, the American Medical Association, American Academy of Pediatrics, Community Anti-Drug Coalitions of America, and the Little League. I thank you for your support on this issue as well, Mr. Chairman, and hope that we can continue to work together on this important matter.

NATIONAL NUTRITIONAL FOODS ASSOCIATION
Washington, DC, November 25, 2003

Hon. JOHN MCCAIN,
Chairman,
Senate Committee on Commerce, Science, and Transportation,
Washington, DC.

Dear Chairman McCain:

During the hearing on dietary supplements conducted by the Committee on Commerce, Science, and Transportation last month, you asked me to comment in writing on three topics:

- What my organization intends to do and is doing about mislabeled products.
- What our position is on steroid precursors.
- What legislative remedies we do and do not support in regard to these issues.

Following are my responses to each.

Product Labeling

First let me point out that the Dietary Supplement Health and Education Act, and extensive ensuing regulations, clearly require that what is in the bottle be stated on the label.^{1,2} If this is not the case, then a product is misbranded and the Food and Drug Administration has the ability to remove these products from the market.

I agree that the findings cited by Mr. Madden during his testimony are indeed alarming. I believe Mr. Madden was referring to a study conducted by the International Olympic Committee (IOC) last year.³ In reviewing the findings, it should be noted that there were 634 products (not 624 as reported by Mr. Madden). Of those 634 products, which were obtained from 13 countries, 240 were from the United States. And, of those 240 products, 45—or 18.8 percent—reportedly contained a “positive” substance that was not listed on the label. Although the 18.8 percent is a good deal lower than the 41 percent reported by Mr. Madden, it is still unacceptable.

That is why NNFA, along with two other leading dietary supplement trade associations, the American Herbal Products Association and the Utah Natural Products Alliance, wrote to the chairman of the International Olympic Committee’s Medical Commission when those figures were released in 2002.⁴ In that letter we speculated that there could only be two rational explanations for unlabeled ingredients appearing in supplements: insufficient manufacturing controls or deliberate adulteration.

Regarding the former, my industry has urged the FDA for several years to issue a good manufacturing practices regulation specific to dietary supplements, as provided for in DSHEA, that would eliminate or greatly reduce the chance for inadvertent adulteration.⁵ As you know, after nine years, the FDA just this year proposed a regulation for dietary supplement good manufacturing practices and is currently in the process of reviewing comments in order to issue a final regulation. We have publicly stated on several occasions that we hope this happens soon. In the meantime, NNFA and other industry groups have established their own good manufacturing practices programs to help ensure product quality remains high.⁶

Additionally, NNFA has had a random testing and label registration program in place called TruLabel since 1992. As part of this program, our members’ products are purchased from health food stores and retail outlets and tested to determine that what’s on the label is in the product. Although TruLabel was originally conceived as an internal check on product quality, in response to public interest we recently began publishing test results on our website.⁷

Participation in our TruLabel program is mandatory for supplier members of NNFA, who represent the majority of mainstream dietary supplement manufacturers and distributors. Those whose products fail to meet label claim are given an opportunity to quickly remedy the problem (confirmed through re-testing) or leave the association. To date, we have not had a member unwilling to make any necessary changes to bring their product into compliance. Let me emphasize that cases of products we have tested not meeting label claim are rare and often can be resolved upon retesting of the product.

Over the many years that the TruLabel program has been in place, we have not found the large discrepancies reported by the IOC and others between ingredients listed on the label and those actually in the product. One of the reasons we asked the IOC to let us know which companies failed their tests, was to determine whether these companies were among our members or if these products were sold in health food stores. Without this information, it is impossible to effectively take ac-

tion, as the IOC has urged us to do. To date, we have received no reply from the IOC despite repeated requests for cooperation.

Regarding products that are deliberately adulterated, our position is simple: the FDA should seize these products, halt their sale, and prosecute their manufacturers to the fullest extent of the law. Under both the Federal Food, Drug and Cosmetic Act (FDCA) and DSHEA, such products are unambiguously illegal and the FDA has ample authority to act.⁸

In summary, to eliminate discrepancies between what is on a dietary supplement label and what is in the product, the FDA needs to aggressively go after those companies that either deliberately or accidentally mislabel products. This will send a message that the law cannot be flouted with impunity. The industry will continue to do its part and seek improved cooperation with groups such as the IOC and U.S. Anti-Doping Agency (USADA) to ensure our efforts are the most effective.

Steroid Hormone Precursors

My organization, along with several other dietary supplement trade associations and non-industry groups, including USADA, have publicly voiced our support for S. 1780, the "Anabolic Steroid Control Act of 2003" introduced by Senators Joseph Biden and Orrin Hatch. As a cosponsor of this bill I am certain you know the details of what it provides, but let me briefly explain one of the main reasons why we support it.

For several years, the industry and Senators Hatch and Tom Harkin have called on the FDA to determine whether androstenedione, arguably the best known and most frequently used steroid hormone precursor, could be legally marketed as a dietary supplement. Under DSHEA, if an ingredient meets the definition of a supplement, it can be marketed as such if it was already in commerce prior to the law taking effect. If this was not the case, then a manufacturer must inform the FDA of its decision to market a new dietary ingredient and provide the agency with safety information, prior to its being sold. The FDA can decide not to allow the sale of such products, which I believe it has done in about 40 percent of these cases. At issue with andro, and potentially other ingredients like it, is whether it was being sold prior to DSHEA and if not, whether the FDA received and accepted its application as a new dietary ingredient under DSHEA. Although we believe a regulatory solution to this issue would have been the most appropriate and expedient course of action, this bill will end the controversy over this topic, which is damaging to the industry, the agency, and the athletes who could be banned from competition for using such products.

In supporting this bill, the industry is taking another step toward resolving issues affecting consumer confidence in the dietary supplement category. We are eager to refocus visibility on the safety and benefits of our industry's core products including vitamins, minerals, botanicals, amino acids, and specialty ingredients such as omega-3 fatty acids, SAM-e, glucosamine and chondroitin sulfate.

Solutions

As you know, my contention is that there is no issue with dietary supplements, be it safety, efficacy or quality, which cannot be addressed under the current regulatory and legal framework. Changing DSHEA to give the FDA increased authority when it has not fully applied its current powers will simply perpetuate the current situation. The fact that the FDA has not utilized DSHEA to its full extent is unfortunate, but not uncorrectable. The first step, which is already being made, is to give the FDA the resources it needs to fully implement the law. Amendments to the agriculture appropriations bill and legislation introduced by Senators Harkin and Hatch, S. 1538, will greatly assist the FDA with its mandate.

In addition, the FDA needs to be pressed to quickly come to closure on two important issues that have been pending for far too long: the agency's stance on ephedra and the implementation and enforcement of good manufacturing practices for dietary supplements. More than any other, ephedra is the product that has been pointed to as evidence of DSHEA's lack of effectiveness. But what ephedra is really emblematic of is not DSHEA's shortcomings, but the tentativeness and reluctance of the FDA in enforcing the law. No matter your opinion on the safety or effectiveness of ephedra, what should be indisputable is that DSHEA clearly provides the FDA with the power to take unsafe products off the market. And whether that action is validation of ephedra as a safe and useful dietary supplement or its removal from the marketplace, we fully support the FDA's empowerment to act.

In regard to GMPs, it took the FDA more than nine years to propose a regulation. A drawn-out finalization of that regulation would be intolerable. Although I believe the vast majority of dietary supplement manufacturers have implemented produc-

tion procedures that meet or exceed what is currently required by law, a Federal GMP regulation would bring all others into line, as well.

Finally, Mr. Chairman, I would like to thank you for soliciting the input of my organization as a representative of the legitimate dietary supplement industry. I believe we share the desire to protect the American public from harmful or misrepresented products and I can assure you we are committed to being part of the solution.

Sincerely,

DAVID R. SECKMAN,
Executive Director/CEO.

P.S. Although you did not ask me for an explanation of the statistics I provided regarding data from the American Association of Poison Control Centers, I felt it important to clarify this point and have attached a memorandum from my Chief Science Officer.⁹

MEMORANDUM

DATE: 11/15/2003
TO: David Seckman
FROM: Phil Harvey, Ph.D., R.D.

SUBJECT: POISON CONTROL STATISTICS FOR DIETARY SUPPLEMENTS

Regarding the above, let me explain how I arrived at the statistics that were quoted in the safety article. Each year the American Association of Poison Control Centers (AAPCC) compiles the Toxic Exposure Surveillance System (TESS) data. The 2001 report, which is referenced in the article, contains 2,267,979 cases of toxic exposure reported from 64 participating control centers nationwide. The report breaks the data down in a number of ways, including categorizing the substances and reasons associated with toxic exposure as well as the characteristics of the persons exposed, including age, gender, severity of outcome, etc.

Because the FDA data mentioned in the article are in regard to adverse events, we also looked at adverse reactions in the AAPCC data. The FDA and AAPCC both defined adverse events in a similar way, which is an unanticipated negative reaction to using a product used as recommended as opposed to overdose, misuse or abuse. As you know, much of the criticism of dietary supplements is that they are for some reason inherently unsafe, even used as directed.

In 2001, according to AAPCC data, there were a total of 45,950 reported adverse reactions to drugs (OTC and prescription) and dietary supplements (vitamins, minerals, herbs, amino acids and steroid hormone precursors). To arrive at a total for drugs, we subtracted the totals for the dietary supplements (herbs, amino acids, steroid hormone precursors), vitamins and minerals. Because homeopathic remedies, which were included under the dietary supplement heading, are not regulated as such, we subtracted the 144 adverse reactions from the dietary supplement total and left them in the drug total. This left us with a total of 4,519 adverse reactions for dietary supplements and 41,431 for drugs. Thus, drug adverse reactions as reported in 2001 AAPCC data, were 817 percent higher than those for dietary supplements.

I think this is pretty straightforward, but please let me know if you need further explanation. If you would like to look at the report yourself, you can find it on the Internet at the following Internet address: www.aapcc.org/Annual%20Reports/01report/2001%20TESS%20Full%20Report.pdf.

[The attachments to this letter have been retained in Committee files.]