AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 1994

BETORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

RICHARD J. DURBIN, Illinois Chairman

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MARCY KAPTUR, Ohio
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ROBERT B. FOSTER, TIMOTHY K. SANDERS, and CAROL MURPHY, Staff Assistants

DIETARY SUPPLEMENTS

Printed for the use of the Committee on Appropriations
HEARINGS
BEFORE A
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HOUSE OF REPRESENTATIVES
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WASHINGTON : 1993
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AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 1994

Monday, October 18, 1993.

DIETARY SUPPLEMENTS

WITNESSES

HON. BILL RICHARDSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW MEXICO
HON. ORRIN G. HATCH, A UNITED STATES SENATOR FROM THE STATE OF UTAH
HON. ELTON GALLEGGY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. Durbin. Today we are convening the Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies for a hearing on dietary supplements. The purpose of this hearing is to discuss balance, striking a balance between ensuring the safety and accurate labeling of dietary supplements while protecting the American consumer's freedom to choose. The vitamin and dietary supplement industry is big business with sales in excess of $4 billion annually. Many of the products sold are on the cutting edge of modern thinking about our health and the quality of our life, but there are also dietary supplements for sale in America which are worthless and dangerous. Innocent people endangered their lives because some unscrupulous companies have sold lethal doses of so-called health foods.

The role of government and the FDA is the central issue of this hearing. There have been excesses by this agency and there have certainly been excesses by the dietary supplement industry as they have lobbied Capitol Hill.

Today we are looking for balance, not a consensus but a balance of viewpoints on this emotional issue. A balance between government and the dietary supplement industry so that Americans can enjoy even better health in the years ahead.

I will now recognize my colleague from New Mexico, Mr. Skeen.

Mr. Skeen. I agree that the key word in this whole discussion is going to be balance. I think we in the United States are probably more interested in safeguarding the public and the things that are being consumed.

The things that we have to consider at these hearings is how much regulation is necessary, what are the problems that have caused us to become concerned about regulation. Also, how much cost is involved in doing an adequate job of regulating the public health and safety. So I agree with you, this is a timely hearing.

(1)
We have had a lot of the discussions prior to our regular hearing process during the appropriations cycle. I want to welcome especially my colleague from New Mexico, Bill Richardson, and Mr. Gallegly. Senator Hatch, glad to have you here.

Let's get on with the business of seeing what we can do about this problem.

Mr. DURBIN. Unless my colleagues have an opening statement, we will start with the first panel. The first panel of witnesses includes our colleague from New Mexico, the Honorable Bill Richardson; the Senator from Utah, Orrin Hatch; Congressman Elton Gallegly from the State of California.

I will start with Mr. Richardson.

Mr. RICHARDSON. Mr. Chairman, thank you very much for holding this hearing, honoring our request to deal with this issue and for your very balanced statement. I also would like to thank my good friend and colleague, Senator Hatch, the pioneer on this issue; and my friend, Elton Gallegly, who has labored very hard on this issue. My colleagues have done a very good job of spreading the importance of ensuring access to dietary supplements for people who want them.

Mr. Chairman, at a time when our President has released a comprehensive plan to reform this Nation's health care system, we should be doing all that we can to secure the freedom of consumers to choose safe dietary supplements and to help them prevent illnesses and disease. This is what this issue is about; the safe use of dietary supplements could save the Nation billions of dollars in health care costs, but people are not as informed as they could be because manufacturers aren't allowed to provide the information consumers need.

The issue is also about the appropriate level of government regulation and the proper use of scarce government resources.

Mr. Chairman, I also want to call note to the tremendous public outpouring of support for the legislation that all of us here have introduced, close to 60 Members of the United States Senate and over 150—hopefully, soon to be 200—Members of the House.

Mr. Chairman, we are also concerned about the FDA's role on this issue. Federal courts have found recently that the FDA's attempt to regulate supplements as food additives, in the words of 1st Circuit Court's opinion is "nonsensical and hence incorrect," and in the words of the 7th District Court's opinion, "defies logic and common sense." The 7th District Court went so far as to say that FDA's efforts represented "an Alice in Wonderland approach to regulation."

As a legislator, I resent FDA's using its and our limited resources to litigate cases by reasoning which is clearly contrary to legislative intent. There are adequate precautions for safety in the legislation that we have introduced. I am by no means saying that we must cast all caution to the wind and not be concerned about potential risks of fraud and injury to consumers of supplements, and I detest any effort to try to portray H.R. 1709, the Dietary Supplement Health and Education Act, as a bill that in unconcerned about fraud and safety.

H.R. 1709 requires that all supplement manufacturers employ good manufacturing practices as well as notify the FDA prior to
any significant changes in their manufacturing. My legislation would also require manufacturers to notify the FDA 30 days prior to marketing products with health claims. These health claims must be truthful, nonmisleading, and based upon the totality of scientific evidence.

H.R. 1709 does not take anything away from the enforcement powers of FDA to prosecute misleading and false claims. If anything, H.R. 1709 strengthens those powers.

Mr. Chairman, the bottom line is that manufacturers of supplements must be allowed to make truthful and nonmisleading health claims when there is known scientific evidence backing those claims. To prohibit such claims is to block the constitutional right to free speech. Any regulatory process that forces health claims for supplements to be preapproved by the FDA without procedural safeguards, such as prompt agency action and judicial review, can easily be construed as prior restraint of constitutionally protected speech. In fact, Mr. Chairman, in a case decided by the Supreme Court last year, Enfield v. Fane, the court held that government regulation cannot inadvertently bar truthful and nonmisleading statements in efforts to bar fraudulent and deceptive speech.

Mr. Chairman, I believe that the regulations of our legislation do not meet this test. This is particularly true when one realizes that the proposed regulations of the FDA extend the materials written by independent third parties such as The New York Times and the New England Journal of Medicine.

The proposed regulations of the Nutrition Labeling and Education amendments cannot be allowed to stand. Such a strict regulatory scheme that promotes prior restraint must be accompanied by safeguards of prompt agency action and a guarantee of judicial review. Our legislation provides for prompt agency action and judicial review for truthful and nonmisleading claims while still giving FDA the latitude to stop false and misleading claims.

Mr. Chairman, I believe that my bill represents the proper balance that you so eloquently stated at the outset of this hearing between the need to protect first amendment rights with a need to prevent fraud and public safety. To stand back and let the proposed regulations from the FDA go into effect would take away not just consumer choice but the first amendment rights.

Mr. Chairman, once again, I think this is a matter of choice, this is a matter of freedom of consumer choice, it is a matter of proper balance. It is also something that, as we look at health care, we should look at the use of vitamins and dietary supplements and America’s and consumers’ requests to be free to pick their own vitamins and dietary supplements as an inherent right.

It is up to government to protect with adequate safeguards but at the same time, Mr. Chairman, I think this is a matter, as evidenced by the tremendous public support that is spread across this country, that the government use its proper role of safeguarding but not overly interfere as we believe it is doing now.

Again, I thank you for allowing me to testify.

Mr. DURBIN. Thank you.

[The information follows:]
October 18, 1993
Congressman Bill Richardson
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

Mr. Chairman, I would like to begin today by commending you for holding this hearing on the Food and Drug Administration and its regulatory powers. I have received thousands of letters on this subject and I know from discussions with you and other members of your subcommittee that you've received the same outpouring of public response. Clearly, American citizens would like to see Congress strike a balance with public safety and access to quality products given equal weight.

Two bills, H.R. 1709, legislation that I introduced in April, and S. 784, introduced by Senator Hatch, have created an immense amount of mail. If you have read those letters closely and if you have talked to people about these bills, I believe that you will soon discover that their concerns reach well beyond what these bills would do if passed.

The public wants government to be as efficient as possible. Not wasteful. Not unnecessarily large. Not intrusive when no action is needed.

Mr. Chairman, in the first week of September, President Clinton and Vice-President Gore introduced a comprehensive plan to reinvent government. Obviously, one of the products of this plan would be the elimination of the unnecessary use of precious federal dollars by self-perpetuating bureaucracies.

The President heard the call for a new direction to government several times during his campaign last year. He told people that if he was elected President, he would act quickly to pare unnecessary federal spending.
With our federal deficit continuing to climb each year, President Clinton is well aware of the need for a new direction for government.

It's time for Congress to be fully aware that we can no longer afford the luxury of over-regulation. We don't have federal dollars to waste.

I believe that message is particularly embarrassing for all of us when it is affirmed by other respected institutions in our society.

Federal courts have repeatedly rebuked the Food and Drug Administration for its ridiculous actions. The FDA has chosen to use its time and resources to file suits alleging that dietary supplements are unapproved drugs or unapproved -- and therefore presumably unsafe -- food additives.

For example, using a provision of FDA regulations that bars food additives unless specifically approved by the agency, FDA seized gelcaps containing black currant seed oil and evening primrose oil, alleging that the caps were "food" and the oil inside an "unapproved food additive."

The First Circuit called FDA's reasoning "non-sensical and hence...incorrect." The Court noted that the FDA was not able to prove its allegations that black currant seed oil might be unhealthful.

Mr. Chairman, it is not only healthful, but is one of the leading treatments currently available for chronic fatigue syndrome.

In fact, the Court concluded, "The proposition that placing a single-ingredient food product into an inert capsule...converts that food into a food additive perverts the statutory text, undermines legislative intent, and defenestrates common sense. We cannot accept [it.]"

With its very definite castigation, the First Circuit does not stand alone.
The Seventh Circuit referred to the application of the food additive regulations to dietary supplements as "defying logic and common sense." The Court stated that the FDA's claims amounted to an "Alice in Wonderland approach," which could only be seen as an attempt to "make an end-run around the statutory scheme and shift...the burden of [proof]...."

Not only have courts rejected FDA's attempts to regulate dietary supplements as food additives, but attempts by FDA to classify supplements as drugs have been equally unsuccessful.

The Court for the Northern District of California rejected this approach as well, stating that the FDA's approach raised "significant issues of overreaching...[and that it was] apparently the FDA's view that if a company makes a claim that milk helps prevent rickets, milk suddenly becomes a drug."

As a legislator, I find what I have just quoted to be embarrassing and infuriating. We cannot afford to have any federal agency using limited resources to litigate spurious claims.

I don't believe this is how the American public wants to see their tax dollars spent.

Don't misunderstand me, I am not saying that we should cast all caution to the wind and be totally unconcerned about potential risks of fraud and injury to consumers. That's not what I am saying.

I am saying that we must strike a balance between ensuring access to desired products for consumers and public safety. I believe my bill, H.R. 1709, the Dietary Supplements Health and Education Act of 1993, strikes such a balance.

H.R. 1709 requires that all supplement manufacturers employ good manufacturing practices.
The bill also requires manufacturers to notify FDA prior to any significant changes in their manufacturing.

My legislation would also require manufacturers to notify the FDA 30 days prior to marketing products with health claims.

These health claims must be truthful, non-misleading and based upon the totality of scientific evidence.

Most importantly, H.R. 1709 does not detract from the enforcement powers of FDA to prosecute false and misleading claims. If anything, H.R. 1709 strengthens those powers.

I cannot emphasize enough that manufacturers of dietary supplements must be allowed to make truthful and non-misleading health claims when there is scientific evidence backing those claims.

To prohibit such claims is to block the constitutional right to free speech, the cornerstone of our Constitution. This is truly contradictory to what the role of government ought to be.

Any regulatory process that forces health claims for dietary supplements to be pre-approved by the FDA without procedural safeguards such as prompt agency action and judicial review can certainly be construed as prior restraint of constitutionally protected speech.

The Supreme Court has repeatedly held that First Amendment protections extend to commercial speech, and if government regulation is needed, it must be narrowly tailored to advance government interests.

As a matter of fact, Mr. Chairman, in a case decided by the Supreme Court this year, the Court held that government regulation cannot inadvertently bar truthful and non-misleading statements in efforts to bar fraudulent and deceptive speech.
I believe that the regulations of the Nutrition Labeling and Education Amendments of 1990 that were published in the June 18th edition of the Federal Register do not meet this test. This is particularly true when one realizes that the proposed regulations from the FDA extend to materials written by independent third parties such as The New York Times and the New England Journal of Medicine.

These proposed regulations cannot be allowed to stand.

Such a strict regulatory scheme that promotes prior restraint of free speech must be accompanied by safeguards of prompt agency action and a guarantee of judicial review.

Thus far, this is not the case.

My legislation provides for prompt agency action and judicial review for truthful and non-misleading claims while still giving the FDA the latitude to stop false and misleading claims.

Mr. Chairman, I pride myself on my pro-consumer record in Congress and my devotion to constituents. I don’t want anyone harmed by dangerous supplements, contaminated products, or misled by false claims. But the FDA has gone far beyond their consumer protection mission in their regulation of supplements.

Given the view laid out by President Clinton and Vice-President Gore for a new direction for government, I believe it is high time for FDA to heed the call.
Mr. Durbin. Senator Hatch.

Senator Hatch. Thank you, Mr. Chairman, Members of the committee. I am honored to be here and I feel deeply honored to be able to say a few words about this because I think it is very, very important.

I would like to echo my friend Bill Richardson's comments and say I couldn't agree with him more. My personal view is that this hearing is one of the most important this subcommittee will undertake. I know that sounds a bit inflated, but the dietary supplement industry is large, some $4 billion throughout the country, in fact $700 million to a billion dollars in my home State. I recognize that it is small compared to our country's $998 health care bill this coming year.

The reason this hearing is so important and the reason we introduced the Richardson-Hatch legislation, the Dietary Supplement Health and Education Act, I might call it Richardson-Hatch-Gallegly because our good friend has done a great deal on this legislation, as well—the fact is that the FDA, in our opinion, has gone overboard in its regulation of dietary supplements. This drives up costs to the government, and it can drive up costs to consumers if FDA gets its way and puts up expensive barriers to the marketing and promotion of supplements at a time when we have high health care costs and we need health promotion and disease prevention approaches.

We are finding more and more dietary supplements can be of great help. FDA will tell you that they spend very few resources on dietary supplements, some 15 to 20 FTE's per year. That is just for enforcement, and it is only the tip of the iceberg. Perhaps you can ask them about all the FTEs it takes to prepare their proposals requiring such a strenuous preclearance process for health claims that even Vitamin E, and an antioxidant taken by eight out of ten physicians to prevent heart disease, can't make it through the regulatory morass.

Perhaps you can ask them about their study of dietary supplements, their media appearances and the other activities that run up the clock on FDA overtime.

The FDA's regulatory doomsday machine is growing ever more powerful, and you see it in all aspects of their operations. The medical device industry, another healthy American industry being overregulated by the FDA, is all but being driven offshore by incredible bureaucratic delays in device approvals. Approvals for the most simple devices, which used to take 90 days, are now running at least nine months by my calculations.

The FDA has never liked dietary supplements to begin with; the agency's animosity towards the product is legendary, going back for decades. That is why Congress had to step in and pass the Rogers-Proxmire amendment back in 1976, and I believe it is time to do it again.

The premise behind our bill is simple. Our country's health care reform debates point out two important national goals: making Americans healthier and restraining health care costs. The 100 million Americans who use dietary supplements know that these products can help to meet both those goals.
Our country should be doing what it can to help citizens live healthy lifestyles. We should not allow the government to put up excessive roadblocks so that consumers cannot get truthful information about the benefits of dietary supplements; and similarly, we should not allow the government to require a stringent preclearance process which keeps dietary supplements off the market.

There is no need to set up a lot of new bureaucratic machinery to deal with products that have been used safely for centuries. There is some need to fine-tune the current system, and that is one of the goals of our legislation.

The recent example of folic acid—which even FDA’s parent agency, the Public Health Service acknowledges can help prevent birth defects—is an excellent example of how the machinery is broken.

Despite the fact that the Centers for Disease Control recommended folic acid two years ago—in fact, we have known about it for 11 years, but two years ago CDC recommended folic acid be taken by pregnant women. And I might add the PHS, a year ago—despite all that, the FDA has embarked on a cumbersome regulatory process that guarantees a folic acid claim for supplements cannot be made well into next year. Meanwhile, 100 babies per month are born with preventable birth defects.

I have been a great fan of the FDA, and I challenge anybody to show they have worked any harder to try and help the FDA than I have over the 17 years I have been in Congress. FDA has been on the front lines doing battle in some very, very important issues. They overview 25 percent of all the consumer products in America. They are overworked, they are in lousy facilities, in various locations all over this city.

There are a lot of things that have been inhibiting for them, and yet they still do a good job; and there is no more capable general, in my opinion, than David Kessler. But in all candor, I say that sometimes, too, the FDA has its regulatory priorities out of whack and that is certainly the case with dietary supplements.

I believe I speak for all when I say that we want to work this out with the administration so we get an acceptable bill enacted before we adjourn. We hope the subcommittee will work with us because this is an important issue with precedent for other areas of FDA regulation. I think it is important for us in Congress to send a message to them that we want them not only to listen to us here, but to do the things that are right in response to what we feel may be right as well

Already this year, under the subcommittee’s capable leadership, you have tackled honey, mohair and tea, I have a feeling—I couldn’t resist. I have a feeling that we can work out dietary supplements as well, and I am counting on your helping, so please help us.

[The information follows:]
Mr. Chairman:

I would just like to echo Bill Richardson's comments and say I couldn't agree with him more.

This hearing is probably one of the most important the Subcommittee will undertake.

I know that may sound inflated.

The dietary supplement industry is large...some $4 billion nationwide and over $700 million in my home state of Utah. But I recognize it is small compared to our country's $800+ billion health care industry.

The reason this hearing is so important, and the reason we introduced the Richardson-Hatch legislation, the Dietary Supplement Health and Education Act, is that the Food and Drug Administration has simply gone overboard in its regulation of dietary supplements -- as Bill mentioned.
This drives up costs to the government and it can drive up costs to consumers if FDA gets its way and puts up expensive barriers to the marketing and promotion of supplements.

Now, FDA will tell you that they spend very few resources on dietary supplements, some 15 to 20 FTEs a year. But that's just for enforcement and it's only the tip of the iceberg.

Perhaps you can ask them about all the FTEs it takes to prepare their proposals requiring such a strenuous pre-clearance process for health claims that even Vitamin E, an anti-oxidant taken by 8 out of 10 physicians to prevent heart disease, can't make it through the regulatory morass.

Perhaps you can ask them about their study of dietary supplements, their media appearances, and the other activities that run up the clock on FDA overtime.

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being over-regulated by the FDA -- is all but being driven offshore by incredible bureaucratic delays in device approvals. Approvals for the most simple devices, which used to take 90 days, are now running at least 9 months by my calculations.

The FDA has never liked dietary supplements to begin with; the agency's animosity toward the product is legendary, going back for decades. That's why Congress had to step in and pass the Rogers/Proxmire amendment back in 1976. IT'S TIME TO DO IT AGAIN.

The premise behind our bill is simple. Our country's health care reform debate points out two important national goals: making Americans healthier and restraining health care costs. The 100 million Americans who use dietary supplements know that these products can help meet both goals.

Our country should be doing what it can to help citizens live healthy lifestyles. We should not allow the government to put up excessive roadblocks so that consumers cannot get truthful
information about the benefits of dietary supplements. And, similarly, we should not allow government to require a stringent pre-clearance process which keeps dietary supplements off the market.

There is no need to set up a lot of new bureaucratic machinery to deal with products that have been used safely for centuries. There is some need to fine-tune the current system. That is the goal of our legislation.

The recent example of folic acid -- which even FDA's parent agency the Public Health Service acknowledges can help prevent birth defects -- is an excellent example of how the machinery is broken.

Despite the fact that the CDC recommended folic acid two years ago, and the PHS a year ago, the FDA has embarked on a cumbersome regulatory process that guarantees a folic acid claim for supplements cannot be made well into next year. Meanwhile, 100 babies per month are born with preventable birth defects.
I have been a great fan of the FDA; it's on the frontlines doing battle on some very important issues, and there is no more capable general than David Kessler.

But in all candor I say that sometimes the FDA has its regulatory priorities out of whack. That is the case with dietary supplements.

I believe I speak for Bill when I say we want to work this out with the Administration so that we can get an acceptable bill enacted before we adjourn. We hope the Subcommittee will work with us, because this is an important, important issue with precedent for other areas of FDA regulation.

Already this year, under the Subcommittee’s capable leadership, we’ve tackled honey, mohair and tea. I am sure we can work out dietary supplements as well!

# # #
Mr. GALLEGLY. He is a tough act to follow.

Thank you very much and I thank the subcommittee for giving us the opportunity to testify before you today. For the sake of brevity, I would ask that my full statement be made part of the record, and I will summarize. I would like to particularly thank Senator Hatch for his tremendous effort on this issue and also Congressman Richardson, who some believe that—we are not philosophical clones on all issues, but certainly on this issue we have worked very diligently together and I want to thank him for all of his hard work.

My legislation, the Health Freedom Act of 1993 more commonly referred to as H.R. 509, is designed to protect the public’s right to purchase dietary supplements so long as the labeling and advertising is truthful, reasonable and not misleading, and there exists a reasonable scientific basis for product claims. It will ensure that consumers will continue to be allowed to make their own decisions while protecting the public from fraud and deception.

It has been clearly established that dietary supplements can promote health and prevent certain diseases. Despite this, the FDA has been working for years to make it difficult for consumers to obtain vitamins, minerals, herbs and other food substances that they wish to use to supplement their regular diet.

I believe we must weigh the need for government to protect the public from misleading claims with the right of consumers to purchase products they want and the ability of companies to make those products. My bill would do just that by prohibiting the FDA from regulating dietary supplements as drugs solely because of their potency. It would also allow manufacturers to inform consumers about the documented beneficial aspects of their products and ensure prompt judicial review if the FDA tries to block a health-related claim under existing law.

Mr. Chairman, the Health Freedom Act of 1993 is a reasonable approach. It ensures that consumers can continue to have access to these supplements and that they can be informed of their benefits. At the same time, the bill does nothing to remove FDA’s power to take action against manufacturers who make false labeling or advertising claims or claims for which there is no reasonable scientific basis. The bottom line is that the FDA has no business regulating dietary supplements, and there is no need for it. My legislation would remove this ongoing threat once and for all.

Mr. Chairman and Members of the subcommittee, I urge you to diligently consider this legislation and thank you very much for the opportunity to testify.

Mr. DURBIN. Thank you for your testimony.

[The information follows:]
Statement of Congressman Elton Gallegly  
Before the Subcommittee on Agriculture, Rural Development,  
FDA and Related Agencies  

October 18, 1993

Mr. Chairman and Members of the Subcommittee, thank you for giving me this opportunity to address you today on the important issue of preserving the right of American consumers to consume the dietary supplements of their choice.

I'm pleased to join my good friends and colleagues, Senator Orrin Hatch of Utah and Congressman Bill Richardson of New Mexico, in testifying today. We all recognize that Senator Hatch has long been a leader in protecting the public's right to consume the dietary supplements of their choice, and Congressman Richardson has done a yeoman's job on this important issue as well. While our approaches may differ somewhat, we all agree that action is needed, and we hope you, Chairman Durbin, and the Members of this panel will help us ensure that the American people retain their access to vitamins and other dietary supplements.

My legislation, H.R. 509, also known as the Health Freedom Act of 1993, is designed to protect the public's right to purchase dietary supplements, so long as the labeling and advertising is truthful and not misleading and there exists a reasonable scientific basis for product claims. I believe it ensures that consumers will continue to be allowed to make their own decisions while protecting the public from outright fraud and deception.

A little background on this issue is in order.

Extensive research has shown that dietary supplements can promote health and prevent certain diseases. Yet, despite these valuable and beneficial properties, officials at the Food and Drug Administration have been working for years to make it difficult for consumers to obtain vitamins, minerals, herbs, fish oil and other food substances that they wish to use to supplement their regular diets.

In my opinion, the legitimate interest of government in protecting the public from fraudulent and misleading claims about products should be weighed against the right of consumers to purchase any dietary supplement products they want and the ability of companies to market such products and to promote the free flow of health- and disease-related information.

Here is what my bill would do:
-- Prohibit the FDA from regulating dietary supplements (as defined in the bill) as a drug solely because of the potency of a substance in the supplement. It extends to all dietary supplements the principle well established in the Proxmire amendments that the FDA cannot classify a food substance as a drug merely because it exceeds the level of potency that the FDA believes is useful.

-- Prohibit the FDA from regulating as a "food additive" a food substance provided by a dietary supplement.

-- Ensure that labeling or advertising about dietary supplements may include claims or other information about the relationship of the supplement or its substances to a disease or health-related condition. All claims must be truthful and not misleading and there must be scientific evidence that provides a reasonable basis for such claims.

-- Stop the FDA from requiring that disease- or health-related claims concerning a dietary supplement be approved by or conform to a regulation issued by the FDA before they can be used in labeling or advertising of that product.

-- Ensure that if the FDA issues a warning letter concerning a dietary supplement, asserting that a health-related claim is false or misleading or lacks scientific justification, the manufacturer may seek prompt judicial review of the merits of the FDA's assertion.

It's also important to note that the Health Freedom Act of 1993 does not require prior FDA approval of health claims before a product can be introduced, nor does it expand FDA authority over these supplements in any way. For that reason, my legislation, which, by the way, is identical to legislation introduced in the last Congress by our good friend Senator Hatch, is strongly supported by a large segment of the nutrition industry and health food advocates.

Simply put, the FDA does not prevent people from eating conventional food products that are high in calories, cholesterol, saturated fat, sodium and caffeine, so it should not attempt to impose unreasonable and unnecessary regulations on dietary supplements that many consumers want and many health professionals recommend.
Mr. Chairman, the Health Freedom Act of 1993 is a reasonable approach. It gives the health foods industry the ability to ensure that consumers can be informed of their products' health-promoting and disease-prevention benefits, along with the flexibility to ensure that the health-conscious public is keep abreast of scientific advances in the field. At the same time, the bill does nothing to remove the FDA's power to take action against manufacturers who make false labeling or advertising claims, or claims for which there is no reasonable scientific basis.

The basic issue remains - the FDA has no business regulating dietary supplements, and there is no need for it. Unlike other proposals pending before this House, my legislation would take care of this problem and remove the ongoing threat of regulation once and for all.

Once again, Mr. Chairman, thank you for this opportunity to address the Subcommittee.

# # #
Mr. Durbin. Let me open with a few questions to see if we can arrive at a consensus. Can a person take too many vitamins?

Senator Hatch. I think you can take too much of anything. There is no question. If you eat a ton of potatoes a day, you will probably get cancer. The FDA—one of the reasons this became such a critical problem in the 1960s and 1970s and resulted in the Rogers-Proxmire bill was because the FDA was setting reasonable daily allowances or recommended daily allowances so low that literally—they wanted to basically make prescription drugs out of anything over 150 percent of the recommended daily allowance.

We found through the years that greater potency can lead to greater health promotion and disease prevention. No question, you can take too much of anything. Frankly, a lot of vitamins would just be—the system would spew them off, but vitamin A and D you can take too much of, and I suspect there may be others.

One thing FDA cannot point to is any real mishaps in this industry over the last 4,000 years. The ones they do point to can be easily explained, in my opinion. So the answer is yes, but unlikely with the current potencies that most vitamin and mineral companies make.

Mr. Durbin. You are saying that dietary supplements, as with other things that we ingest, can be taken at levels that could be toxic?

Senator Hatch. I am saying that it is somewhat unlikely, in light of the current state of knowledge and manufacturing practices of the industry as a whole. I don’t think you can point to many, if any, instances where the current manufacturing practices and the products that are on the market are going to be deleterious to people. You can differ on what the potency should be, of course.

Mr. Durbin. A couple of examples. Iron toxicity from consumption of supplements is one of the most common forms of poisoning of preschool children.

Senator Hatch. That is not a vitamin, that is a mineral.

Mr. Durbin. I am trying to make it fairly generic. When I refer to vitamin, I am referring to all dietary supplements and—

Senator Hatch. Herbal products.

Mr. Durbin. Five children in L.A. County died from an overdose of a prenatal vitamin, mineral supplement in June of this year. Salenium also can be toxic, Vitamin B-6 and other.

The reason I ask that as a starting question is as I understand your legislation, it prohibits the Food and Drug Administration from establishing maximum limits on the potency of any supplement.

Senator Hatch. No, it doesn’t. In the case of the ingesting of too much iron in those children, it was a safety cap problem where people left these out and kids ingested much more than anybody should ever ingest with regard to iron. So that is a different problem from whether or not iron and vitamin and mineral products are safe.

But having said that, the FDA, after our legislation passes, will still have the power to take anything off the market that is toxic, poisonous, deleterious or otherwise unsafe for human consumption; and they would have not only the right, but the obligation to do so.
Mr. Durbin. I want to get to that. As I understand H.R. 1709, Mr. Richardson's bill, it prohibits the Secretary from establishing maximum limits on potency of any supplement or any of its ingredients. Exceptions are made for individuals with specific diseases, children under 12, pregnant or lactating women.

But I think your legislation would basically prohibit establishment of maximum limits on the potency of any supplement.

Senator Hatch. Unless they become toxic or unsanitary or deleterious. If FDA can prove that something is toxic or unsanitary or unfit for human consumption, the FDA would have an obligation to warn us of that. The problem is the FDA coming in and setting recommended daily allowances so low that—and trying to hold to their allowances that fly in the face of real science.

Take vitamin E. I mentioned that eight out of ten doctors take vitamin E at 800 milligrams a day minimum. If you look at the recommended daily allowance, it is like 35 milligrams a day or something like that. It is at least 15 times lower than what or should I say the science recommendation today is 15 times higher than what they call "recommended daily allowances." It is a real problem.

And, you know, FDA still will have plenty of power under our bill, all the powers it currently has and I think will have a little bit more, because if they can show that any ingredient is toxic or unsanitary or whatever, they can take every product off the market that has that ingredient in it.

Mr. Richardson. I think the Chairman has asked some good questions. The point of this legislation is—and a large point of it is—that science should be the obvious determinant to answer these questions, and it has been our view that the FDA has taken too much of a law enforcement attitude as opposed to a scientific attitude.

A main component of this legislation is that a great deal of purview over such issues be done by the National Institutes of Health, where science could make these decisions.

Secondly, in 1709 there is a 30-day prenotification to the FDA of any product, plus there is a requirement for any manufacturing change that the FDA be properly notified. So we are talking is balance.

As we have discussed before, we are in a legislative arena. We hope to deal with some of these issues in the days ahead, but the basic component here is that science should make these decisions. We are trying to bring as much of the scientific process to bear as we move ahead.

Mr. Durbin. The point I would like to move to is what has been raised by Mr. Richardson and by Senator Hatch. One of the more significant elements of your legislation would be a shifting of the burden of proof, as it presently stands. If I owned a pharmaceutical company and came up with what would be a medical breakthrough for an illness, I am responsible to go to the FDA and to prove with scientific evidence that the desired result will occur when a person takes this drug. You have said that you have changed this.

As I understand your bill, a supplement could claim that it cures a disease; it would then be the responsibility of the Food and Drug
Administration to prove that it doesn't, which is quite a turnaround from the current state of the law.

I have read all of the scenarios. I found it interesting that the dietary supplement folks don't want to be treated as either a food or a drug; they want to be in a special category, and they want the government to have the burden of proving they are wrong when they make a health claim. Is that an accurate portrayal of the drift of your legislation?

Senator HATCH. No question, they do not want to be treated as prescription drugs; 30,000 to 60,000 people die a year from prescription drugs. You can't point to many people who have ever died from taking dietary supplements, so it is a completely different thing.

As you know, the safety and efficacy process at FDA for pharmaceuticals is up to 12 years now at a cost of $260 to $360 million. One of the reasons we passed the user fee aspect of the legislation last year, upon which we attached the moratorium for a year, was basically so we could cut down on that time. There aren't the incidences of death or failure that you have with the pharmaceutical industry, where they really do need to be that protected and the costs are a consequence of that.

In this particular case, if we made a safety and efficacy process similar to that of pharmaceuticals, most people in this country could not afford to buy dietary supplements. So I think we have to work out the claims problem. That is why I am calling for the administration and others to sit down and help us to work it out.

Mr. DURBIN. I have not taken a Brain Pep, but I may before the hearing is over.

Mr. GALLEGLY. Is that the industrial strength?

Mr. DURBIN. I hope it is. I have ultra female and ultra male and we have ultra hair for those who need it.

Let me talk about health claims. Here is one called Nature's Response, a complete health enhancer made by Nature Source International in Las Vegas. The circular on this would suggest we ought to buy it because here are the things which this product will do. It will inhibit the reproduction of herpes, measles and the HIV virus in vitro. I suppose that means in the laboratory. It will stimulate the body to produce more immune-protective substances, and some words I can't read. It will inhibit the growth of cancer.

This is an example of a product that I assume, under your bill, could be put on the market and then it would be the FDA's responsibility to prove that they are wrong, that in fact it does not inhibit cancer; is that true?

Senator HATCH. That is probably true, except for one thing. The FDA can seize products that have unapproved disease claims right now under Sections 304 and 502. They, can sue a company or seize products which falsely state on labels quality or quantity of ingredients under Section 403.

They can refer for criminal charges a company that markets a falsely labeled supplement, Section 302; they can use publicity to shut down a industry, for example Chilean Grapes, protein powder, et cetera. They can send warning letters threatening civil or criminal action if the supplement or labeling is not taken off the market, and they can inspect every supplement factory and take samples
of products and labels. In addition, they can sue for an injunction or a temporary restraining order any company selling a product that is toxic or unsanitary and seize the products as well.

If those claims are improper or wrong, it shouldn’t take the scientists at FDA or NIH or anywhere else long to disprove that.

Mr. DURBIN. But while they are disproving it, the product is on the market.

Senator HATCH. And if the product is hurting somebody, that is another matter. I have met over the last six months a number of doctors.

I don’t think anybody—I don’t think I have to take a second seat to anybody with regard to my desire to resolve problems involving HIV. As you know, Senator Kennedy and I have worked hand in glove to pass the first and second major bills in that area, and I have a tremendous interest in seeing that we follow through with that. But I now have run into all kinds of doctors who are being inhibited in using dietary and nutritional therapy to resolve problems with HIV, where they are having better success than some of the pharmaceutical products that are being used.

If that product is not what it says it is, the FDA has plenty of authority to take it off the marketplace. And why should we? In an industry where you cannot point to incidences of harm that you can in the pharmaceutical industry, why should we make these little manufacturers, who do a very good job, and these little health food stores—why should we put the burden of proof on them rather than the FDA, which is supposed to be the scientific agency, and especially with a FDA that takes 11 years to tell women how folic acid will prevent neural tube defects and at least have had two years since CDC has told them and one year since PHS has told them, and they still aren’t getting out the recommendation, when you have 100 kids a month whose neural tube defects or spina bifida could be prevented; and they are dragging their feet.

You would give them the authority—I am saying, should we give them the authority to require vitamin and minerals to go off the charts as far as cost, like pharmaceuticals today? I don’t think so.

Mr. DURBIN. Of course that raises a question this committee would have to cope with; if your legislation passes, we would have to cope with how many more people would be needed at FDA.

Senator HATCH. I am willing to work with you on that and do everything in my power to do that.

Mr. DURBIN. Is the industry interested in the user fee?

Senator HATCH. I don’t think anybody is interested in user fees at this point. Let me say this: I am willing to help find the money because I do believe that FDA is treated like a hated stepsister. We give less money to FDA as the Federal Government than Dr. Kessler had to run his hospital in The Bronx. That is a tragedy when you consider 25 percent of all consumer products go through there. So even though I sound like I am harsh against FDA, I still think they have their hands full, and we ought to give them the equipment, the facilities, the scientific instrumentation and the data processing to help them do a better job and we are not doing that as Members of Congress.

Mr. DURBIN. One of the things that kept coming through as I read this was the fact that many of these products are not designed
to take into account the impact on children. I think there was only one of the bottles that I have here that has a child-proof cap, ultra-female. Looks like ultra-male kids can have theirs.

The one that gets me, though, is herbs for kids “Anti-At chew” which is made in Bozeman, Montana, it, just has a P.O. box. It contains a lot of herbs, and I can’t pronounce most of them, but it does contain willow, wild unsprayed willow, which it is my understanding is similar to aspirin.

I have noted that on a common bottle of aspirin there is a basic warning about its impact on children and when it should be taken. There are no warnings on here. Is it your suggestion that the FDA should not require warnings on dietary supplements, even for those that might be used by children?

Mr. Gallegly. I would certainly say, and again, the discussion that we have had here, getting back to the burden of proof, has been the big issue that we have been talking about here. If, in fact, there is a product that provides any potential harm and there is not a warning, then of course that company is certainly open for claim and the FDA role there is, I think, as we have discussed.

I would like to back up because when you are talking about the need for increased personnel at FDA should our legislation pass, I certainly agree with that, and—but when you talk about balance and the effect, what it would cost to hire the new personnel, I would submit to you if we take the other approach we are going to be putting literally thousands and thousands of small-business people out of business. We are going to be putting the small health food stores out of business. We are going to be putting small manufacturers out of business. And I think there would be multiples of people being put out of business versus the needed help that maybe FDA should have in the process.

In addition, we will be depriving tens of thousands access to something that they believe in and that has been proven to be beneficial to them healthwise.

Mr. Durbin. Mr. Skeen.

Mr. Skeen. Thank you, Mr. Chairman.

In my part of the country we have people known as curanderos, and we have substances called yerbas, herbs that are probably some of the greatest medicines in the world as far as our communities are concerned because our people rely on them. I don’t know how much science was involved, but I think it was mostly common practice. That is how we generated a lot of the food additives and pharmaceuticals, et cetera.

Bill, you mentioned science—how much scientific work goes on in this field outside of the manufacturing side of it?

Mr. Richardson. Well, first, let me acknowledge what my colleague said about the long tradition in our State. I got involved in this alternative medicine issue in Santa Fe. It is a hotbed for alternative medicine. We have had native Americans for years and, as you mentioned, the curanderos from the Hispanic communities practicing successfully for years practices that many of my colleagues may not be aware of that don’t necessarily require all those pills and all those bottles.

My point here that I wanted to make is that vitamin, dietary supplements, herbs, should not be treated as food and drugs. That
is the reason for our legislation. What we have talked about, and I know my colleague has some impressive bottles there, is that the majority, the large majority of vitamin and dietary supplements have been successful, and they have made people healthier, and we are talking about preventive health and not just in the historical tradition of my State.

The emphasis has been on science. And there should be more science, more work done by our National Institutes of Health and others to answer the toxicity questions.

By the way, I have been a very strong supporter of continued FDA enforcement action. I was a supporter of the bill that Congressman Waxman and Senator Hatch published over the years to give the FDA more resources and give them more strength.

I personally support user fees. I think that if we are going to fund the FDA adequately this makes sense. I think Dr. Kessler in many areas has a very strong record, but I think when it comes to dietary supplements and advice, I don’t know what the science that they are using is because the decisions have not been right.

The folic acid decision is a terrible one. It took a long time. And what we need to have is judicial review, rightful claims, and what we are trying to do is achieve a balance.

My main point is that I do think that there are a number of very safe, good products that are out there. Nobody is for bad apples, and I am sure that, like every industry, the dietary industry has some. I think what we are talking about here is a balance.

Mr. Skeen. I agree.

I will turn the question around. How many cases of abuse have we found? Is this thing of dire consequence? Is it critical? Are we losing people attributable to misuse of dietary supplements?

Mr. Richardson. I don’t think so. I think the record is a very good one by this industry. We are talking about—the Clinton administration health-care plan has, I think, an assumption of $500 billion that we are going to save from preventive health care. It seems to me if we use proper nutrition and nutrients and vitamins as millions of Americans are using that we would be healthier. I think it is a matter of letting our people make the choices.

Mr. Skeen. Have these companies been sued?

Senator Hatch. Every time they are they basically have won the suit. Generally, the FDA brought suits trying to use the food additive theory to get at vitamins and minerals, herbal products and amino acids. In the few cases brought by the industry it has won. FDA has not been a really good-faith actor in this area, in at least my opinion.

When you look at these bills with regard to unreliable health claims, the opposite is true. This bill would put the onus on every company, to come up with substantiation showing the totality of scientific evidence. FDA would get advance notice and a right to sue before claims were made. Information will get to the public, however, to protect them against long-term disease that they otherwise wouldn’t get.

You know, the FDA—some people thought the FDA might not be able to take quick enforcement action. That is untrue again. It gives the company 60 days to appeal a threat by FDA to close down a product or a company. Until now FDA can threaten jail, and mil-
lion dollar fines can prevent a companies from even challenging these particular actions.

Mr. SKEEN. They have that power?

Senator HATCH. Yes. You cannot—you have a greater chance of being injured falling down the steps at home than you do taking these products.

Mr. GALLEGLY. I would like to add probably the issue that we hear more publicly about and you may hear about in the next panel is the issue of L-tryptophan. The thing that is very important to point out is all the FDA regulation in the world would not have prevented the few tragic cases. It was bad batches. You can have a bad batch of anything and have a problem and still have the labeling right.

Mr. SKEEN. We learned that during prohibition, didn’t we? If you have a bad batch you are in big trouble.

Senator HATCH. There have been some 45 deaths attributed to L-tryptophan, but it clearly was a tainted batch. FDA denied that. They claimed that they have evidence that there still might be something wrong with L-tryptophan, and I don’t think they can make the case, and I don’t think they think they can, deep down.

Mr. SKEEN. What we are talking about here is an eagerness to overregulate, which we in government do a great deal of the time. Now, I am not beating up on FDA, it is a fine agency. We ask them to do far too much and pay them far too little.

On the other hand, you have got folks who come up with cures for something, and they can put on any kind of label they want. Somewhere in the middle we have to reach a happy medium and have some kind of a cause and effect relationship. I think that is what we are trying to approach here and also keep it within a feasible cost relationship as well.

I commend you all for being here. I think these hearings are going to produce a lot of good things, and I am not going to take any of those additives because I wouldn’t want to overdose on the brain.

Mr. DURBIN. We both have a long way to go. I understand Mr. Richardson has to leave.

Thank you for your testimony today.

If the other two panel members would stay—Ms. DeLauro.

Ms. DeLAURO. Thank you, Mr. Chairman.

I want to thank my colleagues for their testimony this morning. I wanted just to agree with the Senator and his comment on L-tryptophan, that whether or not it was just a tainted batch that was responsible for the 45 deaths or thereabouts, but the jury is still out as to whether or not it was a tainted batch or whether L-tryptophan itself was responsible for the deterioration of health and near death of a number of people.

When I sat on the Government Operations Committee in the last session of Congress and listened to the testimony of the witnesses who had taken L-tryptophan, it was a rather incredible experience to sit there and listen to what happened to people. I would hope soon we would have some conclusive evidence in that area.

I wanted to ask the question that we have talked about science, we have talked about ways in which we can look at approving claims for dietary supplements. I want to ask your sense of what
the standards ought to be to approve a claim for dietary supplements. We have heard the totality of information. We have heard of the significant scientific agreement. Can you just talk about what your views are on what that standard ought to be?

Senator HATCH. We call it significant scientific evidence. We believe that the FDA, in using significant scientific agreement, has set the standards so high that nobody can meet them and, frankly, deliberately so because they don't like this industry.

Frankly, what we would do is we would require significant scientific evidence. In other words if you can show scientific evidence that justifies the formulation then it would be all right. It would be a lesser standard. But, nevertheless, this is not the pharmaceutical industry. This does not have the incidence of difficulty or the incidence of death or the incidence of illness that other industries in the true pharmaceutical industry have.

So we do believe—frankly, the burden I don’t think has been shifted. Only in one way—the FDA has tried to bring these cases under a food additive theory, claiming that the burden is on the manufacturer, and the courts have uniformly held that is not so. So we don't believe the burden has ever been on the manufacturer. We do think under our bill they would have to show significant scientific evidence and some prior history of effective use to make a claim.

Ms. DELAUNO. Why shouldn't dietary supplements and foods additives be considered as food or food additives?

Senator HATCH. Because they are not. They are basically food. Herbal products have been around for 4,000 years without much incidence. Where you have evidence of toxicity certainly I think responsible companies ought to either not include that or mention it.

Ms. DELAUNO. If we could assume that you could put a standard health claim in place, one that all science could agree with in some way, would you favor a health claim approval process that required the manufacturer to submit evidence prospectively as the basis of the proposed claim, which also would require the FDA to rule on that claim within a certain time period?

Senator HATCH. No, because this is not an industry where people have been badly hurt or killed or otherwise where they have had serious health conditions, by and large. Frankly, we don't think it should be legislated the same way the pharmaceutical industry should be. I would be the first to say that we need a safety and efficacy process there.

Ms. DELAUNO. NLEA, which has jurisdiction here, was in fact a relaxation of the Food and Drug and Cosmetic Act of 1906, in fact trying to lessen the restrictions in these areas that we are talking about. So it already is a lessening of restrictions than what the prior standard was?

Senator HATCH. Not the way the FDA interprets it. If you look at their regulations in this area they would put many, many companies out of business, and people would be bereft of some of these health-promoting dietary supplements that are very beneficial to them or they couldn't afford them if the FDA got its way.

FDA will say to you, I saw David Kessler sit in the House and say that 80 percent of all this industry is just fine. We think it it is a lot better than 80 percent, and we are constantly encouraging
this industry to make sure that it is as close to perfect as it can be. They will say, we are not going to outlaw a lot of things, but the fact of the matter is if they get their way under those regulations they could put anybody out of business they want to at any time.

We think our bill accentuates the powers they already have, and we grant them additional powers.

Ms. DeLAURO. What if the FDA established an outside panel with experts, medical experts, industry representation that made recommendations on health claims and again dealt with trying to work in some sort of a timely response?

Senator HATCH. We provide in one of the bills that the NIH would be that panel. We wouldn’t mind having pure science. When you have prejudice, which is what FDA exhibited for better than 30 years now, that ought to be stopped, and especially in an industry that is not known for hurting people.

Frankly, it is time to have a reasonable approach here that sets the standards once and for all that is not onerous and burdensome so that it puts a lot of people out of business. I think it is time to quit treating the American consumers like we are a bunch of idiots and can’t decide that hair growth isn’t going to work. We are not a bunch of idiots. We can make consumer choices and we do know what we are doing, and 100 million people buy these products and most are buying them for their better health benefits.

Ms. DeLAURO. Thank you Senator.
Thank you, Mr. Chairman.
Mr. DURBIN. Mr. Myers.
Mr. MYERS. Thank you Mr. Chairman.

I guess I am the oldest person here. I can remember the medicine man. I don’t think they rode horse and buggys in my time, but they came into town and said, “This bottle will cure dandruff, lumbago. You can grow hair if you rub enough on.” I guess that is what we are trying to prevent, medicine men from selling something that doesn’t exist.

We have had Dr. Kessler before the committee a great many times. We asked him, is it true you want to make all vitamins and food supplements subject to having to write a prescription? He assured us that isn’t true, but the American people aren’t convinced of that.

I haven’t read either one of your three bills. I haven’t had time to read them. As I understand, Senator, you do cover vitamins in your bill?

Senator HATCH. We cover vitamins, minerals, herbal products and amino acids.

Mr. MYERS. Elton, in your bill——
Mr. GALLEGLY. Same thing.

Mr. MYERS. Yours and Bill’s are identical?

Mr. GALLEGLY. No. Bill and Senator Hatch—mine has a small difference. In fact, we have been working out the differences.

Senator HATCH. I would love to have his bill. Frankly, Elton and I are—Elton, Bill and I are working very closely. I would call this the Richardson-Hatch-Gallegly approach——

Mr. GALLEGLY. We are merging our thoughts, and I think we will come up with basically the same results.
Mr. Myers. Do you include vitamins in your bills?
Mr. Gallegly. Yes.
Mr. Myers. The Richardson bill has food supplements?
Mr. Gallegly. Different categories.
Mr. Myers. You suggest that you are cautious about putting in the same category vitamins and food additives.
Senator Hatch: They are not food additives. They are basically foods. If you have a food additive then you will have to go through the safety and efficacy process that pharmaceuticals go through. And we don’t want to have to do that because that $260 to $360 million would price the industry out of the ball park, an industry which does a lot of good, not real harm.
Mr. Myers. I think we all recognize that there are food additives and food supplements and vitamins that for certain people give them a lot of help. And possibly it does help reduce our eventual health costs, and we are all searching for that. We have a lot of bills coming up in Congress right now, and the administration is quite concerned about this. We are all concerned about this, but at the same time a happy balance. How do you strike that balance?
Mr. Gallegly. First of all, John, you made the reference to the medicine man coming to town with his violin and his snake oil. Nothing that we are presenting here would preclude the FDA from going after anyone that makes a false claim, a misleading or detrimental claim. So we certainly agree that we are not out there advocating or promoting anything that is misleading or providing for anything other than for the health of this country.
Senator Hatch. The FDA has plenty of power to regulate this industry. We actually—at the consequent added cost, I have to be the first to say that there may have to be some fine tuning. We are meeting with folks here in the House. We are certainly negotiating with other Senators.
We don’t want to the ruin the industry. We want to get the very few who really are wrongful out of the industry and out of the business. We want it to be a self-cleansing industry, which largely it is. Frankly, I think most of us can be very proud of the industry and what they do.
Mr. Myers. Do either of your three bills give more authority to the Food and Drug Administration than they have now?
Senator Hatch. If they can show an ingredient is deleterious, if they can prove that it is deleterious, they can force any product off the market that has that a bad ingredient in it.
We also require substantiation with regard to manufacturing, and there are some other aspects, too. But we keep the industry alive. We keep the costs down so the average consumer can afford these beneficial dietary supplements.
Like Mr. Skeen said, in my home State, too, there have been a lot of these herbal preparations that have been more beneficial, far more so than some pharmaceuticals for years. It works the other way, too.
Mr. Myers. The question about burden of proof came up. I was not certain I understood your response. If I want to cut something up and say it will cure the itch, would there be a burden of proof on me to prove that before it goes to the market or is the burden of proof on FDA to come and say you are misrepresenting?
Senator Hatch. Right now, it is on the FDA and it would remain there. If the FDA can show some of these substances have been beneficial or not beneficial, they ought to have to come in and prove it. They should not be able to force anybody off the marketplace because somebody at FDA doesn't like the product or the claim or whatever. It ought to be based on fact.

Mr. Myers. You provide for due process then?

Senator Hatch. Sure.

Mr. Myers. I guess I should get a copy of the bill and read it.

Senator Hatch. We want you to be a cosponsor.

Mr. Myers. I have a lot of constituents who, next to NAFTA and health care, they are concerned about this. I share their concern. I take vitamins around campaign time. I don't otherwise.

Mr. Durbin. Mr. Peterson.

Mr. Peterson. Thank you, Mr. Chairman. I thank you for holding this hearing. I think this is a good opportunity for us to address a subject that I feel is very important.

The consumer in America today is very interested in diet supplements. There are a lot of folks who are really into, if you want to call it "natural health activities," and I don't think we want to take that away from them. I think they are generally well-informed with regard to what they want and what they need.

I am certain there is some exploitation, too, that has to be reined in. We are not seeking who is oldest here, but I grew up with Hadacol. Hadacol was supposed to do everything. It made you feel real good because it was 75 or 80 percent alcohol. These kinds of exploitations are what we have to avoid. This balance is what we are seeking.

But I would like to know if the associations and the manufacturers are self-policing, and to what extent would you see that enhanced by your bill?

Senator Hatch. Well, I have to say that the industry itself has taken certain minerals off the market from time to time. Germanium was one of them, after a death. There is an increasing desire on the part of those who are in the various trade associations like the NNFA, to see that their people meet good manufacturing standards and that they continually exchange information and continually compete in a fair and decent manner. I think you see a lot more of that than the FDA and some of the critics are indicating.

Frankly, most of these products are pretty safe. In fact, almost all of them are. The question is, what are the parameters. I think you will find if you look at the industry as a whole, it is very responsible.

Mr. Gallegly. I think it is important to note too that the industry has a greater incentive to police than anyone else does.

Mr. Peterson. Are they policing for content or for claims?

Mr. Gallegly. Both.

Senator Hatch. But mainly content.

Mr. Peterson. In your bills you are giving more focus on what the FDA can do above the self-policing policies. Would that prevent misleading claims?

Senator Hatch. Actually, our bill, as it is currently written, will try to work out the claims aspect of it. As currently written, as long as they can show significant and scientific evidence, they can make
the claims, and a history of prior safe use, they can make those claims.

The FDA would have to prove the claim is invalid or falling. We think that is where the burden ought to be in an industry where there is relative safety. Frankly, if you don't do it that way, the FDA will put a lot of these people out of business.

Mr. Peterson. Are we talking content or label? If the FDA found something that was unsafe and they went through the due process, would the manufacturer only be required to change the label or would they have to change the content?

Mr. Gallegly. It depends on whether the problem was with the claim or the content, or both. Of course, the FDA certainly still has full authority to prove either the claim or the content.

Mr. Peterson. Under the rules the FDA is proposing now, would they not have to just remove the label?

Mr. Gallegly. That is basically correct.

Mr. Peterson. So you are strengthening that police power?

Senator Hatch. One of the problems with FDA is that they know they cannot prove these products are unsafe. If you give them that power, they will put people out of business. There is a prejudice at FDA, in my humble opinion, that flies against this industry, in my opinion.

We are saying FDA has the right to take anything that is falsely advertised off the market. They don't need this bill to do it. They have that power. They can take anything off the market that is poisonous or toxic. They have that power.

What they want is more power than that. Frankly, we think if this were an industry where there were a lot of people dying or sickness that came out of the woodwork, that is another matter. That is not that kind of industry.

This industry has been around for 4,000 years or better, and has helped people all along. Frankly, when we are concerned about health care, we ought to encourage people to take dietary supplements.

FDA must have the burden before they can take somebody off the marketplace to meet a due process burden.

Mr. Peterson. I agree with my colleague, Mr. Skeen. FDA has done some remarkable work and has made some incredible advances, I think, in the last few years. I don't know if their prejudices have changed, as you have suggested.

Senator Hatch. I don't think they have.

Mr. Peterson. One of the things in looking for balance, perhaps we can look for categories and fence in various categories and treat them differently. Is that a possibility, to suggest that we can look at vitamins as a specific category and work on that and make rules specific just to that category that might be different from another category?

Senator Hatch. We would argue against that, because we believe that these products are basically safe. We have lifetime experience and science has proven them to be safe. If there is a claim that they are not, then by the gosh the almighty Federal Government, which has the money and the power to prove they are not, then why put the burden on them?
Mr. Gallegly. Not only that, you are going to be putting those and thousands of people who are manufacturing a product out of business because they cannot do it. Even more important is you are going to be depriving a tremendous number of people from a supplement that they depend on in their everyday lives. We are talking about tens of millions of people. Probably the one group that is most affected are our seniors.

It was not until after I drafted the bill that I really started getting the mail. The mail is unbelievable. I have never seen such an outpouring of concerns, particularly from senior citizens. It is not limited to seniors, but I really had no idea when I started on this.

Senator Hatch. I have never seen an issue that has polarized the majority of these people. The reason is that we consumers don't want to be treated like a bunch of nincompoops. When outrageous claims are made, people don't spend the same amount of money on those as they do on regular dietary supplements. Doctors take them.

Vitamin E, they are saying that 800 milligrams will help to prevent cardiovascular disease, cut it way down. Eight out of 10 doctors do this for themselves. Why can't these manufacturers know they would be better off taking that dietary supplement of 800 milligrams of vitamin E a day and have the same benefits that doctors who already know what they are obtaining? If there is wrong with the claim, let the FDA get together with the other systems in our government and say this claim is not accurate. We ought to clean it up and make it right.

Mr. Peterson. I am very interested in this subject and my constituents are very concerned about it as well. It seems to me, before we start to look at what we will do about it, we have to determine what problems exist first. I am not certain we are on that track.

Senator Hatch. We are suggesting there is not a problem, that it is prejudice.

Mr. Peterson. The bills out there are all fix-it bills. I am not so sure we know the level of repair required. I think we need to settle on that before we do a major overhaul.

Senator Hatch. We think we do know the level. We think the only fix-it part of it is to keep the FDA from overregulating and overusing its power to stop the American consumer from getting products that literally are keeping them healthier and happier.

Mr. Peterson. When I say the problem, I acknowledge saying whether or not the industry is injurious to the consumer. That has to be established.

Thank you.

Mr. Durbin. Mr. Walsh.

Mr. Walsh. Thank you, Mr. Chairman.

I agree with all my colleagues. This is a very provocative and hot issue right now. Everybody is interested in it. There is a lot of mail on it.

I compliment the Chairman for calling this hearing. It is a very important hearing. As I understand it, the food labeling law, NLEA 1990 is what is driving your legislation. In other words, is there a way to resolve this without passing more laws?
Senator Hatch. There is a way, but NLEA is not what is driving this. It is the interpretation that the FDA is placing on the NLEA in the proposed legislation that is driving this. When we raised the issue last year, and raised cane about it and put it on a one-year moratorium to give the FDA a chance to change their act and their regulations, they came up with the same regulations. It was insulting to everyone involved. It was an anti-dietary supplementary approach.

Frankly, we think it will take this kind of legislation to end the bias against this industry and its products. That is why so many people are worked up about it.

Mr. Walsh. My understanding was that the burden of proof is currently on the manufacturer. My understanding of both of my colleagues, legislation was that the FDA would have to show that there is a health concern with any product before it can be removed from the market.

Mr. Gallegly. What we are working diligently to safeguard is that the burden of proof would be put on the FDA.

Mr. Walsh. Is it there now?

Mr. Gallegly. I don't think it is there now. That is where the gray area is.

Mr. Walsh. I am not nearly as steeped in this as you two gentlemen are. Is it that there has to be some sort of convergence of scientific proof in order for the manufacturer to claim that the supplement has this effect; is that the case?

Senator Hatch. No. Under our bill the manufacturers and those who sell these products would have to have a credible scientific evidence for any claims that they make and for any potencies that they claim are valid.

The FDA has the burden of proof of coming in and showing that a product is unsafe. What they want, they want the burden of proof to be on the industry, which cannot afford to even meet that burden.

Mr. Walsh. It would put them into that efficacy process?

Senator Hatch. It would. If they got into that, you could count on vitamins and minerals being priced right out of the market.

Mr. Walsh. Can you give us an idea of what the largest manufacturer of these dietary supplements might earn in a year?

Senator Hatch. It is hard to say.

Mr. Walsh. Are any making $260 million?

Senator Hatch. It is about a $4 billion industry across the country. I am sure there are some larger manufacturers. A lot of them are manufactured by a relatively small number of manufacturers, at least that is my understanding, who are high quality manufacturers and who I think meet the standards that really ought to be met.

There might be different labels put on different dietary supplements, but they basically have the standards that they claim.

Mr. Walsh. You would like to have these dietary supplements treated differently than food?

Senator Hatch. We want them treated like dietary supplements and that is that they are valid marketable items, and that FDA should not be making them into prescription drugs or regulating them out of existence.
Mr. Walsh. Do you believe the FDA would treat dietary supplements, given the fact that you don’t have the legislation now and if this legislation were to be defeated in either/or both Houses, do you think the FDA would begin to treat these as prescription drugs?

Senator Hatch. You mean unfairly? There is no question in my mind. They would let one or two brands go without incident. They know there would be a greater buzz saw if they tried to do that.

But history bears up the fact that they have long tried to make it go through a safety and efficacy product acceptance similar to prescription drugs which have much more potential for toxicity and danger.

There would be a lot of businesses put out of business and jobs would be lost and lots of people would not be able to afford to take these dietary supplements that are so beneficial to their health.

Mr. Gallegly. I think your question could best be answered by the fact that that is the purpose of this legislation. If there was not that concern, we would not have that legislation, and you would not have half the Members of the United States Senate supporting that legislation and what will soon be 200 Members of the House.

Mr. Walsh. My concern is based on experience with FDA in the way they are treating medical devices right now. If they were to treat dietary supplements the way they treat medical devices, we are going to have a lot of mad people.

Mr. Gallegly. You are going to see tens of thousands, if not hundreds of thousands of people rely on something, have it taken away from them or have it financially prohibitive.

Senator Hatch. I share your opinion on medical devices. It used to be class 1 and 2. Today it takes months and months to get 1 and 2 and if you have to get to class 3, you are in trouble.

The medical device industry is about to go offshore because of that. I don’t blame FDA for this because frankly they are understaffed, under equipped, they don’t have a central campus with the best scientific instruments. They are harassed.

But there is a bias out there against the dietary supplement industry that is not desirable and does not deserve to exist. I don’t think anybody likes the FDA better than I do.

Mr. Walsh. I am sure you like it better than I do.

Senator Hatch. I like it. I think basically they do a good job. But there is a defense bias against this industry that has to be stopped and that is what these bills will do.

Mr. Durbin. Mr. Pastor.

Mr. Pastor. I think I received more mail on this subject than on NAFTA or anything else. My grandmother, for fever, would take mesquite bark, boil it and allow it to cool, consume it and it would lower the fever. She did not have published articles on it. To her, it was buyer beware. If you wanted to drink it, you knew it is your grandmother giving it to you.

I kind of see this testimony today in that light. There is no problem. But because FDA perceives a potential problem and they have a bias against the industry, which neither wants to be a food additive or a prescription drug.

I conclude from this panel that the labeling and advertising is truthful is not misleading because, as Senator Hatch says, there is
a significant scientific evidence to show there is a basis for their claims.

One of the standards that has been brought up a number of times is the incidence of harm. Senator Hatch has stated a number of times that these dietary supplements have a history of beneficial use.

Yet, Congressman Skeen says there is very little to show cause and effect. Especially, I am concerned about those instances where a product is consumed, regularly, over a number of years. How do we establish what caused a problem? First of all, cause and effect may not be there, there may be other illnesses and the harm may come years down. How do you deal with that problem?

Mr. GALLEGLY. I don’t know that there is any fail-safe method in the world to protect everyone from everything. I want to get back to a comment you made at the beginning Mr. Pastor.

With all due respect to the FDA, the reason we have put so much energy into this legislation and it has been received so well in both the House and Senate, is that it really appears like so many other government agencies, we have folks out with solutions in search of problems.

I think your point was right on. I appreciate it.

Mr. PASTOR. I got that from you guys.

Senator HATCH. Well, we are impressed with your analysis then. There have been significant pharmaceutical discoveries from Native American herbal preparations.

There have been a lot of benefits from some of the alternative medicine approaches. I think there is no way to be absolutely safe on everything, but in this industry it has been in existence for well over 4,000 years and, yes, there have been some instances where people have been hurt but they have been so few and far between compared to anything else, like 1 in 35 million, it is now insanity to say we should turn this industry over to the regulatory clutches of the FDA and make it similar to prescription drugs.

Do you wonder why you are paying $3 a pill for some prescription drugs, three years for safety, how much does it take to get back the three years of research. That is the part never told around here. In this case, we have an industry that is a responsible basic industry.

Of course there are some bad actors, but as opposed to it being a snake oil industry as some in the FDA have done in open testimony it is not only falling, it is offensive.

There is no way you can be sure of anything but by and large, the 4,000 year history of this industry shows that the American consumers are not stupid. They can figure it out for themselves.

Mr. PASTOR. What type of the standards would you ask the FDA to look at since there has not been a history of harm, and there is a history of beneficial use. It seems to me you are saying they should not get involved in the regulation of these products, as I understand.

Senator HATCH. Only to the extent that they have plenty of power to take these actions.

Mr. PASTOR. Until you show a history of incidents of harm and then go in and apply the due process procedures.
Senator Hatch. Or if you could show any toxicity, or deleterious effects or poisonous. They have that power now.

Mr. Pastor. You mentioned vitamin A and its dosage, and Dr. Pauling and vitamin C. So you feel if there are sufficient published histories, maybe the FDA should not intervene.

Senator Hatch. There is enough overwhelming amount of material on dietary supplements that would lead people to believe that they are very beneficial to consumers.

Mr. Pastor. The first thread through this was this is neither a food, a food additive, nor a prescription drug. So therefore, the public is bright enough to know what they are buying and, basically, buyer beware. If you want to take this supplement to make your hair grow or give you brain power, then it is your choice.

Senator Hatch. That is one of the positions I would take. Frankly, a lot of people, even if they don’t benefit think they do, and that makes them feeling better and that is a beneficial result. But in most cases, they benefit from the dietary supplement.

Mr. Skeen. Will you yield?

Mr. Pastor. Yes.

Mr. Skeen. I have known the Senator since he has been up here. If you are taking those vitamins, you are a good advocate.

Senator Hatch. Let me say this: This has been a real privilege to be here. I admire what you are doing here. I know we are all calling you the House of Lords, but this is where the real fights take place. I hope we have been able to explain this from our perspective. We really need your health.

Mr. Durbin. Ms. DeLauro.

Ms. DeLauro. This is a question of labeling, is that correct, and potentially changing the label. It is not changing the content, not taking the product off the market. The product can still be sold but, potentially, the label would have to be changed if it does not meet some collective scientific consensus. It doesn’t even have to meet a consensus of scientific research.

There are no clinical trials. It doesn’t need to have a consensus of scientific research, but that would change the label but the product could still be sold. It could still be on the market.

Senator Hatch. If the FDA gets its way, as I interpret the regulations, they would have the authority to take anything off the market they want to. That is just plain wrong. That is too much power. It is the Federal Government dictating to everybody what they can and cannot do. Frankly, it is an unjustified approach toward an industry that really has to do primarily a very fine job.

Mr. Durbin. Thank you.
WITNESSES

ABBEY S. MEYERS, EXECUTIVE DIRECTOR, NATIONAL ORGANIZATION FOR RARE DISORDERS

DAYNA M. TOLLEY, EOSINOPHILIA MYALGIA SYNDROME (EMS) PATIENT CAMILLA RAWLEIGH, DAUGHTER OF EMS VICTIM

Mr. Durbin. I would like to call the next panel. Abbey S. Meyers, Executive Director, National Organization for Rare Disorders; Dayna M. Tolley, Eosinophilia-Myalgia Syndrome Patient, and Camilla Rawleigh, daughter of an EMS victim.

In the interest of wrapping this up on a timely basis for the cooperation of the witnesses and my colleagues, we are going to hold testimony of these multi-panels to five minutes each. We will be flexible because some of you have come a long way.

My colleagues, let us try to keep our questions brief and to the point so we can move through this as expeditiously as possible.

Ms. Meyers.

Ms. Meyers. Thank you for holding this important hearing. I think it is extremely important that many of these issues are being laid upon the table. I want to say that this is one of the best lobbying campaigns I have ever seen on Capitol Hill by the health food lobbyists. I hope they don’t move into the health care arena and use their powers on the Clinton health reform proposal. They have really done an awesome job of convincing people and panicking people that these products will not be available if the FDA’s labeling laws go into effect.

We hope they do go into effect. We are concerned about valid medical uses of some of these products. There is a group of disorders known as “Inborn errors of metabolism” which are diseases that are treated by vitamins and minerals and natural products.

The problem is that this industry, being so unregulated, doesn’t even put into the pills and capsules the amount of product that is listed on the label. The tablets don’t dissolve in a timely manner in your stomach. We don’t know which of the products is valid and which is not. If you have a medical condition and your life depends upon it and you don’t know whether you are getting the right amount of the active ingredient, it can be very tragic.

We are concerned about the purity, the bioequivalence, the safety and the dissolution of these products. We know that Congress regulates other industries, the automobile industry. You tell them that they have to have bumpers that will withstand a certain crash. You regulate toys so children don’t choke on the pieces. But here are items that people take every day and you are not regulating them. Why?

Now, Senator Hatch says that if a product makes a false medical claim, like “baldness,” it is a buyer beware market. And if you are stupid enough to buy something that you think is going to grow hair on your head well, that’s it. Most of these things, because of
our terrible health insurance system, are bought by elderly because they don't have prescription drug coverage, and the poor because they don't have health insurance.

So it is a huge market out there for people who have been taken advantage of and don't have the education to know what is a decent product and is a false claim.

Just to test this, we were concerned about a product called Carnitine, which is an amino acid derivative which is manufactured both in prescription form and over-the-counter. We sent some samples down to Duke University and had them tested. We found out, of the 12 brands, one had no Carnitine at all. One other had a tiny amount. Seven of them did not dissolve in the stomach. Sixty percent of all the brands have less than the content listed on the label.

This industry is ripping off the public. It is not terribly dangerous. Most of it is placebo, has nothing in it. But for the products that do have something in it, they are causing harm. Vitamin B-6 can cause neuropathy. Niacin does lower cholesterol but it can destroy your liver.

There have been a number of deaths and transplants from liver damage caused by niacin. Children are overdosing because they think it is candy. People are getting heart attacks for too much iron. There are substantial safety questions with this. This is not a civil rights issue. This goes to the very essence of really what—maybe I am naive—but what our American government is all about.

Congress is supposed to be here to protect us. If I go out and buy a car and that is a lemon, most states have a law that says the dealer has to buy it back. Well, we are buying a lot of lemons here and nobody in Congress is doing anything to control it. FDA cannot take care of these problems. It is understaffed. Put the burden of proof right back on the industry where it belongs.

Thank you.

Mr. DURBIN. Thank you. I might say you finished within five minutes. That is a model to follow.

[The information follows:]
Testimony of

Abby S. Meyers
Executive Director
National Organization for Rare Disorders
to
Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies

October 18, 1993
Mr. Chairman, Members of the Committee ... we commend you for holding this hearing concerning dietary supplements and particularly the proposed Hatch-Richardson bill (H.R.1709).

I am Abbey Meyers, Executive Director of the National Organization for Rare Disorders, or "NORD." A rare disorder, as defined under the Orphan Drug Act, is a disease or condition that affects fewer than 200,000 thousand Americans. There are more than 5,000 of these illnesses, and even though they're often ignored, they cumulatively touch the lives of more than 20 million Americans and their families.

*It is on their behalf that I am here today, because for many of these people, your deliberations are not an exercise of legislative oversight, but literally a matter of life and death ... and it is on their behalf that I hope to place the idea of responsibility first and foremost in your thoughts and discussions regarding this matter.*

Much as I have a responsibility to set the record straight on what has evolved into a highly distorted and politicized debate on keeping dietary supplements safe, you have a responsibility as elected officials to respond -- to act on your convictions and what you learn through these hearings.

Unfortunately, the concept of responsibility has been largely absent from the discussion about dietary supplements, thanks to a well-orchestrated and well-financed misinformation campaign mounted by some members of the health food industry. This may come as some surprise to you, but there are those who in the interests of profit would cast aside the fundamental principles of quality and safety. And when others demand accountability from them, they would play the role of the helpless "victim" of an Oliver Stone-level conspiracy to drive them out of business.

Well, it's my responsibility to set the record straight on that point by clarifying the very real dangers this lack of principles poses for a sizeable percentage of American patients.

In doing so, I want to ask you to examine the vital role of government, and the role of Congress, in the protection of the general health and welfare of this nation.

First, the health food lobby. This poor little multi-billion dollar industry has done its utmost to convince the public and many members of Congress that FDA is exercising a "power grab," that the government wants to restrict civil rights by preventing people from buying health foods or requiring prescriptions for vitamins. They have convinced many people that FDA is an "enemy" conspiring with the pharmaceutical industry to keep "natural" cures and treatments out of the public's reach.
Through massive direct mail campaigns, expensive displays on the sales floor of their chain stores, and through fill-in-the-blank letters to your offices, they tell people that Big Brother wants to take away their vitamins. Mr. Chairman, this is not a civil rights issue and it is not a government conspiracy; this is outright industrial-sized fraud.

What's their motivation? I can only guess that an industry that purports to have a solution to everything from arthritis to warts to cholera, as this mail-order catalogue claims, would shrink from government oversight and safety regulation. More than any other segment of the American marketplace, the health food sector is a "buyer beware" market ... nowhere is the consumer given the appropriate information needed to make an informed decision about the safety, purity or bioequivalence of health food products.

These products are packaged to look like they've been approved by the government, they're labeled to look like scientific studies support their claims, and they're often sold by individuals who act as though they have been certified to diagnose and treat a medical problem.

Well, they haven't been examined by the government ... there's no scientific proof behind their health claims ... and selling them requires nothing more than minimum-wage job qualifications.

*If any area of private enterprise needs government regulation, it is the dietary supplement industry, because at its best it markets ineffective products with false medical claims, and at its worst it markets dangerous compounds that can kill or maim people without the slightest hint of danger.*

This industry has shown time and time again that the responsibility to produce safe and true-to-claim products is one that they will avoid at any cost. For many people, this poses an easy opportunity to part fools from their money, but for consumers it poses real danger.

As you may know, Mr. Chairman, some people with rare disorders have a valid medical need for the substances that are commonly sold in health food stores. There are almost 200 illnesses due to what is called "inborn errors of metabolism" -- inherited defects of body chemistry. Sometimes these defects are harmless, but sometimes they destroy a newborn baby's ability to produce a key protein, enzyme or vital chemical necessary to keep his or her little body functioning. Some of these metabolic disorders can be treated by compensating for the missing or malfunctioning protein or enzyme with a dietary supplement.

It is absolutely essential that each time they buy a certain dietary supplement they are guaranteed that each tablet contains the ingredients listed on the label, that the
contents are pure, and that they will dissolve in the patient's stomach or blood stream -- much like you want to be sure that the pills prescribed for your heart condition aren't just "good guesses" at dosage or outright placebos.

Many tests in recent years have indicated that dietary supplements are not bioequivalent, their dissolution rates vary, and they often contain too little or too much of the labeled active ingredient. There is little quality control in the manufacture of these products, there are no warnings on the labels, there are no government requirements or standards that companies must conform to, and there aren't even safety caps to keep children from eating tablets like candy. In effect, each bottle of supplements is another game of Russian roulette.

Carnitine, a natural substance developed into an FDA-approved prescription drug called Carnitor, is indicated for carnitine deficiency, a severe metabolic disorder of infancy that causes profound muscle weakness. A lot of research went into determining that carnitine can in fact be effective for these babies, and the FDA went to a lot of trouble to verify the research. Because the supplement industry doesn't have to prove anything to the public, they decided that these findings could be applied to athletes who want to beef up their muscle tone, and they began marketing their version of the substance, called L-Carnitine, in health food stores all over the country.

It's bad enough that their product is marketed with unsubstantiated claims to unsuspecting customers, but its availability on health food store shelves has given rise to something truly deplorable: some insurers and even state Medicaid agencies are refusing to reimburse for the prescription version, and are advising patients to buy the compound over the counter to avoid their responsibility of paying for the proven version.

Let me say for the record: the supplement version is not the same as the prescription version. Last year we sent health food versions of the substance to Duke University for testing. A copy of that study has been provided to you. You will note that one brand contained no carnitine at all, and one contained only trace amounts of the substance. Seven brands would not dissolve in time for the body to benefit from them. A majority of the brands contained less than 60 percent of the carnitine stated on the label. And with most brands, even pills from the same bottle varied significantly in their content and rate of dissolution.

These weren't isolated results. Other studies have shown that quality control is a unicorn in the supplement industry.

Dr. Ralph Shangraw at the University of Maryland School of Pharmacy, for example, found that dissolution in vitamins he tested occurred too slowly for the body to absorb -- becoming "bullets" that go straight through the digestive system.
Another study conducted by Howard University for WRC-TV, here in Washington, showed that 36 percent of the vitamins tested could not meet the disintegration standards developed by the U.S. Pharmacopeia. These researchers did not even test for dissolution or absorption.

Now another drug company is about to submit a New Drug Application for a special form of zinc to treat Wilson's disease, a rare but deadly disorder of copper metabolism. If their product is successful, it would be a breakthrough; right now, the only way to treat the disease is with prescription drugs that must be taken for life and that have severe side effects.

But there's also a potential down side: once their prescription version is on the market, we fear the supplement industry will scramble to produce an inferior counterfeit that will be therapeutically useless. Once again, we'll see insurers refusing to reimburse for the product manufactured under strict FDA standards, forcing people to purchase products from the mall -- products that contain little or none of the active ingredients, or that won't dissolve in their stomachs.

This is a sham, and it is rip-off that the government has allowed to go on for far too long. The patients who need these products for valid medical reasons should have the government's assurance that they are getting what they pay for.

> What we want, Mr. Chairman, is to put the burden of proof for safety and effectiveness on the supplement industry -- not the FDA, so that dietary supplements are of the same quality as generic drugs.

That is, every pill or tablet or teaspoon of a dietary supplement should be absolutely equivalent to other brands; safety warnings should appear on the labels; child-proof containers should be required, and; every consumer should be guaranteed that the ingredients can be utilized by their body within a reasonable time frame.

We're not suggesting that dietary supplements should be removed from the shelves. We're not asking you to make vitamins available only by prescription. We're not asking you to infringe on the public's right to treat themselves. We are asking you to make the producers of dietary supplements accountable to the American public.

To do this, you've got to authorize FDA to assess not only the quality of these products, but their safety as well. There is no way to determine whether a vitamin or mineral tablet or capsule marketed as a dietary supplement has any value at all, or even whether it's safe to swallow.

In fact, a supplement company's manufacturing process is not monitored by FDA. Consequently, it can produce a bad batch -- or countless bad batches -- and nothing will be done until there's a tragedy. This is apparently what happened with the amino...
acid L-Tryptophan, when a new formulation of the product killed 38 people and left 1,500 others irreversibly impaired. The cause was diagnosed only after autopsies, but subsequent studies showed the problem had been there for a long time.

Right now, people are suffering from liver disease caused by Niacin, a commonly sold supplement that is believed to lower cholesterol, and children are overdosing on large dosages of supplements like Iron sold in bottles that don't even have safety caps. A few years ago, 40 babies died after being given intravenous vitamin E for impaired liver function. Apparently, even the physicians thought FDA regulated vitamins in some way, because they never questioned the safety of the product. Because it was a vitamin, and not a drug, there was nothing to compel the manufacturer to test the vitamin E at all. And recently, even Chinese herbs and herbal teas have led to tragedy -- all because the public believes that any "natural" product sold in health food stores is safe.

Mr. Chairman, if the Hatch-Richardson Act is passed by Congress, it will be a major victory for the lobbyists with alligator shoes and blow-dried hair.

And it will be a major blow for children like James Winegar of Maryland, whose severe metabolic disorder responded miserably to different health food supplements, only to respond miraculously to precise doses of the prescription version...

... Or to men like Lynn Robert Joerger, also of Maryland, who is terrified that the magnesium he must purchase from health food stores to treat the symptoms of EMS will lead to something worse...

... or women like the 57-year-old who began vomiting, experiencing nausea and even losing her hair and fingernails after using selenium supplements. The product contained 183 times the labeled amount of selenium...

... or parents who hear of the fate of the two-month-old baby boy who died from an overdose of potassium given by his mother, who obtained misguided advice on treatment for colic from a book called *Let's Have Healthy Children*.

I could go on and on, but I think the point has been made: you have a responsibility to construct a firewall between these products and your constituents -- and that firewall is the regulatory authority that only the Food & Drug Administration can administer. Right now, it seems that only more dead bodies can untie FDA's hands to act, and if you pass the Hatch-Richardson Act, there will be many, many more dead bodies.

The Hatch-Richardson bill would allow manufacturers to make any health claims they want until the FDA has the resources to build a body of evidence that would remove the product from the market. You know very well how limited FDA's resources are, and you know that it's morally, ethically, and fiscally wrong for you to put the burden of
proof on the agency -- and the consequences on the American public.

Car manufacturers and even toy-makers are required to abide by safety standards imposed by the government, even though a large segment of the population hates seat belts and doesn't want to pay the higher costs for stronger bumpers. You must not pass this bill, no matter how much orchestrated mail you get from people who have been whipped into a frenzy by the propaganda of this unregulated and unrepentant industry.

If they will not take responsibility for their actions, then the Congress of the United States must.

Thank you.
DIETARY SUPPLEMENT L-CARNITINE: ANALYSIS OF DIFFERENT BRANDS TO DETERMINE BIOAVAILABILITY AND CONTENT

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ABSTRACT

Tests were conducted on various products containing L-carnitine available in health-food stores. The rates of disintegration of tablets and capsules under simulated physiological conditions were determined and compared with that of a pharmaceutical product. Solutions from the disintegration tests were analyzed for both L-carnitine and racemic (DL) carnitine and results compared with the amounts of L-carnitine expected according to the product labels. Results generally indicated that rates of disintegration were unacceptably long for seven of the twelve health-food brands tested. The users of most of these products would receive less than sixty percent of the advertised amount of L-carnitine. The study also showed that none of the products contained a measurable quantity of D-carnitine and that the pharmaceutical product met acceptable standards for both disintegration and content. The inconsistent behavior of the non-prescription products in the disintegration test indicates a lack of quality control in the manufacturing process.
INTRODUCTION

Some pathological conditions can be alleviated by dietary supplements of essential vitamins or minerals. In many cases, chronic dietary supplementation is required to avoid potentially harmful sequelae. Consequently, many families are faced with the financial burden of providing a long-term supply of one particular vitamin or mineral for an affected child, and of necessity will often turn to the least expensive source. Usually, that source is one of several manufacturers of multi-vitamin and mineral supplements that sell their products in “health food” stores.

One example is the use of L-carnitine supplementation in children with inherited defects in the metabolism of branched-chain amino acids and fatty acids (1,2). There is biochemical evidence to indicate that L-carnitine can act as a detoxifying agent by combining chemically with abnormal metabolites that accumulate in these disorders and facilitating their excretion as harmless derivatives. Pharmaceutical preparations are available, but numerous less expensive products are also available as food supplements. Although there is widespread concern regarding the efficacy and safety of these products (3,4), few studies have been done to provide scientific evidence to support this concern.

One such study, conducted on calcium supplements, found that about half of the products sold directly to the public in tablet or capsule form failed a standard disintegration test and would therefore not be absorbed effectively by the body (5).

The main objective of this study was to compare the efficacy and safety of twelve products claiming to contain L-carnitine, available in health food stores, with a pharmaceutical product. A standard disintegration test was used to assess the ability of tablets and capsules to release their bioactive contents under normal physiological conditions. In the case of carnitine, there is an added concern that some products might contain the D-form of carnitine, which does not have any
benefit for the recipient and may even cause harmful side-effects. Therefore the carnitine content was assayed by two independent methods, one of which is stereospecific (i.e. assays only the L-form of carnitine) and the other not stereospecific (assays L-carnitine plus D-carnitine, if present). In addition to various tablets and capsules or "capulets", some solutions of L-carnitine were also assayed.

METHODS

Experimental Design

The study was conducted in such a way as to assure that the technicians performing tests were unaware of the sources of the products being tested. One person selected samples of the food supplement and pharmaceutical products, using a code which was not made available to the laboratory technicians. Up to five individual samples were selected from each bottle to assess reproducibility. The amount of carnitine in each tablet according to the product label (e.g. 300 mg) was also noted. Each sample was then investigated according to the protocol described below and the results tabulated. The protocol was designed to estimate the amount of material available for the biological function after ingestion, not the amount present in the formulation.

The methods used for the analysis were developed in this laboratory, which is certified to perform carnitine assays in human subjects for clinical diagnostic purposes by the College of American Pathologists (CAP).

Disintegration Test

The ability of a tablet or capsule to release the biologically active material it contains was assessed by a standard method (6). Each tablet was placed in a beaker containing 0.5 L of 0.01 M hydrochloric acid (pH 2) HCl) at 37 °C. The
beaker was placed on a hotplate/stirrer apparatus and the contents stirred with a magnetic bar for up to 1 hr at 37 ± 2 °C. The extent of disintegration and dissolution of each sample was noted at 15 min intervals. After 1 hr, the experiment was stopped. The tablet was considered to be fully disintegrated when it had completely broken up into small particles, most of which had dissolved leaving a small amount of well-dispersed insoluble particulate matter. After allowing 2-3 min for particulate matter to settle, an aliquot of the solution was removed and centrifuged before analysis.

Spectrophotometric L-Carnitine Assay.

L-carnitine was assayed in the solutions remaining after the dissolution experiments on a Cobas Bio centrifugal analyzer, using a recently published method (7). The solutions were diluted as appropriate in order to provide values within the calibration range of the method. Reference standards were used to calibrate the system. Although this method has been validated for use in human plasma (7), its application to tablets and other formulations has not been investigated systematically for possible chemical interference.

Mass Spectrometric Assay For Carnitine.

Aliquots of the same solutions used for the spectrophotometric assay were also analyzed by an isotope-dilution tandem mass spectrometry method recently developed in this laboratory (8). This method has inherently high accuracy and precision, but it is not stereospecific and therefore cannot distinguish between D- and L-carnitine.

RESULTS

The results are presented in Tables 1 and 2. The data regarding disintegration of the tablets or capsules in 0.01 M HCl at 37 °C are summarized under the
## Table 1. Percentage of Specified Content Dissolved

**A: Spectrophotometric Assay** (n.d. = not detected)

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**B: Mass Spectrometric Assay** (n.d. = not detected)

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Concentrations of carnitine assayed in centrifuged solutions or suspensions of the tablets provided. Up to 5 samples were analyzed from each product. Values are given as a percentage of the content specified by the manufacturer. The extent of disintegration of the samples after 1 hr in solution (pH 2, 37 °C) is recorded in the last column of section (A). See text for details.
TABLE 2.
PERCENTAGE OF SPECIFIED CONTENT DISSOLVED

<table>
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<td>4E</td>
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<td>98</td>
<td>89</td>
<td>86</td>
<td>91</td>
<td>n.a.</td>
</tr>
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</table>

Concentrations of carnitine assayed by tandem mass spectrometry in filtered solutions or suspensions of the tablets and solutions provided. Up to 5 samples were analyzed from each product. Values are given as a percentage of the content specified by the manufacturer.

Heading "Disintegration". For each of the coded samples, up to 5 individual specimens were tested. If all the tablets disintegrated within the 1 hr time period allowed, the result was recorded "+++". If all had apparently remained intact, the result was "--". If there was partial disintegration, (or some tablets were intact, others partly disintegrated), the rating "+-" was given. Finally, if the tablets were mostly disintegrated, (or if some were fully and others partially disintegrated), the rating "++-" was given. In the best cases, which included the pharmaceutical specimens and some of the other products, the disintegration took place within 10-15 min for each individual tablet. In all cases there was a small amount of residual insoluble material.
Tables 1A and 1B summarize the results of individual assays for up to 5 tablets or capsules from various bottles of OTC products, using the spectrophotometric method and the mass spectrometry method respectively. Each result is expressed as a percentage of the expected amount according to the product label. Overall, the results from the two methods compared well enough to state that there was no evidence for the presence of D-carnitine in any of the products. The spectrophotometric assay is more prone to chemical interference than mass spectrometry, and might account for some of the discrepancies in results for the two methods.

One product (code 1A) appeared to contain no carnitine, despite the fact that all of the tablets disintegrated and had mostly dissolved well within the 1 hr time limit. One of the other products (code 6A) also gave undetectable amounts of carnitine, but those tablets were still essentially intact after 1 hr. In general, products that did not disintegrate well also tended to give lower carnitine assays than expected. It was also evident that some products showed considerable variation between samples from different preparations supplied by one manufacturer (2F, 6C and 6D) and in some cases between samples from the same bottle (e.g. sample code 8A).

Table 2 summarizes the results of another set of experiments with different samples from the same suppliers, plus some taken from a pharmaceutical product (sample code 6T). In addition, two samples of L-carnitine solution (from one food supplement manufacturer, sample codes 6E and 4E) were tested and compared with a pharmaceutical solution (sample code STL).

The mass spectrometry method only was used for quantitative analysis, since it was deemed unnecessary to repeat the comparison with the spectrophotometric assay. In general, results of disintegration and carnitine assay paralleled the previous set of results given in Table 1A. The disintegration of all 5 tablets from
the pharmaceutical product was rapid and complete, and the assay showed a high level of consistency (sample code 6T). Some of the alternative products were equally impressive (e.g. sample code 2A). Also noteworthy was the inconsistency of results between the samples from 3 different types of preparation from the same supplier (codes 6D, 6C and 2F). These results could most reasonably be ascribed to differences in disintegration rates, because this particular supplier also provided L-carnitine solutions (coded 6E and 4E) for which the results of analysis were comparable with that of the pharmaceutical product (6T).

The precision of the mass spectrometric assay is within $\pm 3\%$ (coefficient of variation), as judged from repeated analysis of the same sample. The overall precision of the assay, including errors of dilution, sample pipetting and instrumental factors, is best judged from the analysis of the 5 aliquots of each of the solutions (codes 4E, 6E and STL). The coefficients of variation ($\%$ standard deviations) were calculated from these three sets of data to be 6\%, 4\% and 6\% respectively. Values in a group that differ by 2 standard deviations (12 \%) or more from each other or average values that differ by more than 12 \% from an acceptable value (85 \%) are considered significant. Thus, only samples 6D, 2A, 6T, STL, 4E and 6E satisfy acceptable criteria for reproducibility.

**DISCUSSION**

From the results of this study, it is apparent that one of the major general problems with the health-food store products is the significant failure rate of tablets or capsules in the disintegration test. Anything less than a "+++" rating should be considered unacceptable. By this criterion, many of the products containing carnitine were unacceptable. The inconsistency of behavior of different specimens even taken from the same bottle suggests a lack of quality control in the manufacturing process of tablets and capsules.
The quantitative data from assays of the carnitine-containing products indicate that none of the suppliers is apparently using the racemic form of carnitine, which consists of equal amounts of D- and L-carnitine. In fact, there was no evidence for the presence of D-carnitine in any of the products tested. On the other hand, most of the solubilized products contained considerably less L-carnitine than the content stated on the label. This is explained in many cases by the failure of the specimens to fully disintegrate in solution, but even in cases where there was complete disintegration some of the products gave low carnitine assays, and one product gave a completely negative result. A reasonable criterion for acceptability is that solutions of fully disintegrated tablets should contain at least 75% of the amount present in the formulation according to the product label. By this criterion, most of the products containing carnitine were unacceptable. There was only one health food supplement formulated as a carnitine solution, and two different samples assayed the same as the pharmaceutical equivalent (within the experimental error).

The data from this and previous studies indicate a lack of quality control in the manufacturing process of tablets and capsules in products sold as food supplements, resulting in gross inconsistencies in the properties of the tablets to disintegrate under physiological conditions within a reasonable time. Furthermore, there is evidence that many of the products contain significantly less than the stated amount of the active substance, suggesting also a lack of quality control in the formulation of the product. With the increasing trend towards the use of these alternative products for the treatment of metabolic disorders, it is reasonable to expect these manufacturers to provide evidence of quality control, in terms of both the content of the active ingredient(s) and the disintegration characteristics of tablet and capsule formulations, before their products can be offered for sale to the public.
ACKNOWLEDGEMENTS

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REFERENCES


Mr. Durbin. Dayna Tolley.

Ms. Tolley. My name is Dayna Tolley and I reside in Locust Grove, Virginia. I have a rare disease called Eosinophilia-Myalgia Syndrome, EMS, contracted in 1989 when I ingested contaminated L-Tryptophan, an amino acid. The product was sold over the counter in a nationally known health food store under an American label, but I was later to find out that 95 percent of all tryptophan being sold in this country was being produced by one company in Japan. It was not a mom and pop operation. It was its third largest chemical company in the world.

I began taking L-Tryptophan on the advice of the National Arthritis Foundation pamphlet on fibrositis/fibromyalgia. I was taking rather large doses—7 grams a day—but not out of their recommended range. I developed lingering bronchitis which would not go away with antibiotics. Then, late one night, I had a frightful simultaneous asthma/esophageal spasm. That was the beginning of repeated esophageal spasms, two to three a day, lasting four to six hours and mimicking a heart attack and causing an inability to swallow food.

It also gave the unpleasant sensation of a golf ball rolling up the esophagus, and caused an inability to swallow food. Then I developed extremely painful muscles accompanied by severe muscle contractions. These were sometimes so strong that they would draw my hand or foot into a claw and leave me screaming until they subsided.

The surface of my skin became so sensitive that I could not rest comfortably on a bed without pain. Then I developed large, hot, red welts on the upper part of my body. My temperature spiked daily and my white blood cell count was high. To add insult to injury, my hair started falling out, and I looked really, really bad, which is typical of toxicological poison.

Needless to say, my doctor was baffled because none of the symptoms fit into a known syndrome. He began treating me as a dismembered body, referring me to this physician and that one, depending on which part of my body was rebelling that day.

Instinctively I felt that something systemic was going on, since it seemed to be affecting every part of me. At one point, I told my husband, "I have never been poisoned, but if I was, this is what it would feel like." And on certain days, I would tell him I was feeling "toxic."

By September 1989, I had reached a crisis stage, still ignorant of the fact that the tryptophan I was taking was contributing to my overall decline. In fact, the worse I felt, the more I took.

I finally begged my attending doctor for cortisone—again, instinctively since I knew it was an anti-inflammatory, and my body was definitely inflamed. We had tried non-steroidal anti-inflammatories to no avail, so against his better judgment he finally gave in. I was put on high doses for 10 days. Within three days, my symptoms began to disappear. This is the miracle of cortisone in early usage; this effect doesn't last.

This provided valuable information as to the possible causes and he referred me to a rheumatologist, thinking I had another esosinophilic illness. It was not until November when it was announced to the public, that I realized that it was the tryptophan.
I was lucky enough by March of 1990 to find one of the few ad hoc specialists on EMS at Georgetown University Hospital and began all the “stab in the dark” treatments.

These consisted of continuing with the cortisone treatments to control the acute symptoms for lack of any other effective treatment, and many experimental medications, to include: Anti-convulsives, anti-rejection drugs, chemotherapy, pain medications, antidepressants, muscle relaxers, anti-asthma, gastric, and so on.

I am now “cortisone dependent,” because my body is unable to make its own now, and it has many undesirable side-effects. There is bone loss, glaucoma, poor wound healing, weight gain, and gross distortions caused by uneven fat deposition. I also have lung damage, a sleep disorder, and cannot regulate my body temperature.

You may say, well, she is not even in a wheel chair as many of the EMS victims are. But I would not be with you here today if it were not for methadone—I am sure you all know it is a powerful narcotic used as a replacement for those trying to get off of heroin. My doctor likens EMS pain to cancer or AIDS pain.

Of course, I have a whole pharacopia just to keep me going from day to day. I keep a cumulative “symptoms list” to document the illness and it now runs four pages. New symptoms continue to crop up unexpectedly. While I feel I have stabilized somewhat this year, for the past two winters I seriously thought I was dying—again, this is an instinctive thing one can only experience to understand—and even began to “put things in order” for my husband and daughter. But when the two springs came, thankfully, I pulled out of it.

The biggest problem with the illness—besides the obvious, pain—is the total unpredictability of it. To say it has torn my life asunder would be a great understatement. Very few people understand this aspect and so I feel castigated at times for being unable to do things or participate in normal activities.

My husband carries a great deal of the burden, social, emotional, and physical; and my daughter, it saddens me to say, cannot remember me as a well person. And even though I am an optimist, the almost monthly death notices I get concerning very young EMS victims is always a reminder to me that my future is uncertain.

When I became ill in 1989, I had a very successful career with the Defense Department as an Intelligence Officer. My career was peaking and I had just move to a “better,” more prestigious and challenging position. I was responsible for very short deadline political-military background papers for such high level consumers as the President, the Joint Chiefs of Staff, Secretaries of Defense and State, and so on.

Since I was the “expert” for a particular geopolitical area, my absence created a great burden on my office and coworkers. So after working for six months with the illness, I decided it was not fair to everyone to continue. Even though I felt the decision was made for me, quitting was the most difficult thing I have ever had to do. This is primarily because I loved my job and felt I had found my “niche”—how many of us can say that?—and because I had trained for 10 years in college for just this sort of job. The lost salary was significant, but it bothered me less. It did force us to relocate further away from the immediate Washington, D.C. area to cut ex-
penses, but this was a burden borne primarily by my husband who still commutes to Capitol Hill, although the move itself and change of school for my daughter was no picnic.

Lastly, but not less importantly, is the great loss of self-esteem I have suffered as a result of losing a rather exciting career to a life at home. I am a pragmatist, so I have tried to make the best of things there. I do have more time with my daughter, although the time is proscribed by my limitations.

Am I at fault for taking an over-the-counter product in an effort to self-medicate? The product I took gave no clue that it was foreign. It bore an American name. Why should I have believed that I would be poisoned from it? I, like many Americans, trusted our government to oversee our safety in such matters. Since this whole tragedy began, we have learned that the Japanese company who produced the tryptophan knew as early as 1984 that their product was contaminated from time to time, and sold it anyway.

Which brings me to another scary aspect. After the birth of my daughter, I suffered a back injury. In 1985, tryptophan was being touted as a pain reliever. In an effort to get off of a narcotic pain reliever, I took L-tryptophan throughout the summer of 1985. In 1986, I developed “strange” symptoms, which the doctors variously called the dreaded chronic fatigue syndrome, fibrositis, and fibromyalgia.

However, after the 1989 EMS, I went back and looked at my medical records and realized I had the very same symptoms, only to a lesser degree. They evolved in the same order and fashion, though. I believe the 1989 episode merely pushed me over the edge.

I bet every one of you knows at least someone who has chronic fatigue syndrome, fibrositis, or fibromyalgia—all thought to be one and the same now by the scientific and medical communities. At last count, CFS had 12 million sufferers.

My point is this: There are a lot of people walking around with something like EMS. It may even be EMS, which is basically just a toxicological poisoning. It has only been since the 1989 EMS epidemic that niacin and some other supplements have been found to also cause EMS. A recent report contracted by the FDA says that taking any amino acid singularly can be dangerous. There is even one, glutamate, which taken in excessive amounts, can induce ALS, or Lou Gehrig’s disease, which is fatal I have a newspaper article about that.

The Japanese company has also admitted to having genetically engineered its product for the last ten years. Then they made a “little boo-boo” and created a—heretofore unknown to mankind—double tryptophan molecule. And how does the body respond to a substance which is totally new to the planet? It treats it as a poison, creates lots of eosinophils to attack the poison which in turn release their own deadly toxins. And even when the original poison is gone, if ever, it continues to ward off the invisible enemy, creating an incurable autoimmune illness.

This year genetically engineered tomatoes will go on the market. Oh, yes, we have been told how great they are. But what happens when that one “little boo-boo” happens? Tomatoes are so insidious—pizza, ketchup, spaghetti, etc. How will we ever track down the one “suspect” tomato where the genetic engineering went awry?
All of these are examples of toxicological/ecological illnesses. Even the Desert Storm soldiers now have their own form of EMS, which is just another mysterious environmental poisoning, but with similar symptoms. Members of Congress now have before them numerous proposals to accomplish health care reform. Many of these cite the need for "preventive medicine." What needs to be determined is what is "real" preventive medicine. I don't mean preventive against natural illness, I mean preventive against all the man-made, man-controlled, man-preventable illness.

My illness is expensive and it is likely to last a lifetime. With 12 million-plus chronic fatigue sufferers alone, we are talking major health costs. Perhaps some of the emphasis should be put on "accident prevention."

Intensified regulation of the vitamin and supplement industry would be a good place to start. The Hatch/Richardson legislation would sabotage this effort. Our propensity should be toward caution, not "carefree" legislation. It is ironic that it was basically "educated, health conscious" people who took the tryptophan in an attempt to avoid something more dangerous. There were mounds of evidence as to the beneficial effects of tryptophan.

Americans are poisoning themselves with everyone else's permission. They are basically trusting and naive and believe that the government is protecting them in this arena. People are always shocked when I tell them how I got sick, but I can tell they never think it could happen to them—it's always an isolated incident, which is what we heard in the previous panel. We may be in a minority but we are your early warning system.

We are on the brink of "the Big One," and it is just a matter of time. What is more important—our collective health as a Nation—or the marketplace? We must regulate the industry in order to protect us from ourselves.

In regard to Senator Hatch's comment about nincompoops, I belong to Mensa and I was unable to make an informed decision because the facts were hidden.

Finally, I would urge you to convince your Appropriations Committee colleagues to fund research on EMS. Ironically it is being funded almost exclusively by the Japanese. I ask you not for selfish reasons, but as a planning tool, using EMS as a prototype for similar toxicological diseases which are imminent.

Thank you for this opportunity, Mr. Chairman and subcommittee members. I would gladly respond to any questions.

Mr. DURBIN. Thank you.

[The information follows:]
TESTIMONY OF
DAYNA M. TOLLEY

BEFORE THE
SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT AND AGENCIES COMMITTEE ON APPROPRIATIONS

U.S. HOUSE OF REPRESENTATIVES
ON

"DIETARY SUPPLEMENTS"

OCTOBER 18, 1993
Mr. Chairman and Members of the Subcommittee:

My name is Dayna Tolley and I reside in Locust Grove, Virginia. I have a rare disease called eosinophilia myalgia syndrome (EMS) contracted in 1989 when I ingested contaminated L-Tryptophan, an amino acid. The product was sold over the counter in a nationally-known health food store under an American label, but I was later to find out that 95% of all tryptophan being sold in this country was being produced by one company in Japan. I began taking tryptophan in May of 1989 on the advice of the National Arthritis Foundation pamphlet on fibrositis/fibromyalgia. I was taking rather large doses (7 grams per day), but not out of their recommended range. I started to develop a lingering bronchitis which would not go away with repeated antibiotics. Then, late one night I had a frightful simultaneous asthma/esophageal spasm. That was the beginning of repeated esophageal spasms --- 2-3 a day, lasting 4-6 hours and mimicking a heart attack. It also gave the unpleasant sensation of a golfball rolling up the esophagus, and caused an inability to swallow food. Then I developed extremely painful muscles accompanied by severe muscle contractions. These were sometimes so strong that they would draw my hand or foot into a claw and leave me screaming until they subsided. The surface of my skin became so sensitive that I could not rest comfortably on a
bed without pain. Then I developed large, hot, red, welts on the upper part of my body. My temperature spiked daily and my white blood cell count was high. To add insult to injury, my hair started falling out, and I looked really, really bad. Needless to say, my doctor was baffled because none of the symptoms fit into a known syndrome. He began treating me as a dismembered body, referring me to this physician and that one, depending on which part of my body was rebelling that day. Instinctively I felt that something systemic was going on, since it seemed to be affecting every part of me. At one point, I told my husband, "I have never been poisoned, but if I was, this is what it would feel like", and on certain days I would tell him I was feeling "toxic".

By September 1989, I had reached a crisis stage, still ignorant of the fact that the tryptophan I was taking was contributing to my overall decline. In fact, the worse I
felt, the more I took. I finally begged my attending doctor for cortisone (again, instinctively since I knew it was an anti-inflammatory, and my body was definitely inflamed). We had tried non-steroidal anti-inflammatories to no avail, so against his better judgment he finally gave in. I was put on high doses for 10 days. Within 3 days my symptoms began to disappear. (This is the miracle of cortisone in early usage; this effect doesn't last). This provided valuable information as to the possible causes and he referred me to a rheumatologist, thinking I had another eserinophilic illness. It was not until November when it was announced to the public, that I realized that it was the tryptophan. I was lucky enough by March of 1990 to find one of the few (ad hoc) specialists on EMS at Georgetown University Hospital and began all the "stab in the dark" treatments.

These consisted of continuing with the cortisone treatments to control the really bad, acute symptoms for lack of any other effective treatment, and, many experimental medications, to include: anti-convulsives, anti-rejection, chemotherapy, pain, anti-depressants, muscle relaxers, anti-asthma, gastric, and many more. To this day, I have a whole pharmacopoeia just to keep me going. I am
"corticosteroid dependent", because my body is unable to make it's own now, and it has many undesirable side effects. There is bone loss, glaucoma, poor wound healing, weight gain, and gross distortions caused by uneven fat deposition. As terrible as this sounds, I am still thankful for what the cortisone has done, such as ward off further lung damage. You may say, "Well, she's not even in a wheelchair" (as many EMS victims are), but I would not be with you here today if it were not for methadone— I'm sure you all know it is a powerful narcotic used as a replacement for those trying to get off of heroin. My doctor likens EMS pain to cancer or AIDS pain.

I keep a cumulative "symptoms list" to document the illness and it now runs 4 pages. Symptoms continue to crop up unexpectedly. While I feel I have stabilized somewhat this year, for the past two winters I seriously thought I was dying (again, this is an instinctive thing one can only experience to understand) and even began to "put things in order" for my husband and daughter, but when Spring came, thankfully I pulled out of it. The biggest problem with the illness (besides the obvious: pain) is the total unpredictability of it. To say it has torn my life asunder would be a great understatement. Very few people understand this aspect and so I feel castigated at times for being unable to do things or participate in normal activities. My husband carries a great deal of the burden, social, emotional, and physical; and my daughter, it saddens me to
say, cannot remember me as a well person. And even though I am an optimist, the almost monthly death notices I get concerning very young EMS victims is always a reminder to me that my future is uncertain.

When I became ill in 1989, I had a very successful career with the Defense Department as an Intelligence Officer. My career was peaking and I had just moved to a "better", more prestigious and challenging position. I was responsible for very short deadline politico-military background papers for such high level consumers as the President, the Joint Chiefs of Staff, Secretaries of Defense and State, and so on. Since I was the "expert" for a particular geo-political area, my absence created a great burden on my office and co-workers. So after working for 6 months with the illness, I decided it was not fair to everyone to continue. Even though I felt the decision was made for me, quitting was the most difficult thing I have ever had to do. This is primarily because I loved my job and felt I had found my "niche" (how many of us can say that?), and because I had trained for 10 years in college for just this sort of job (all of which has been lost). The lost salary was significant, but it bothered me less. It did force us to relocate further away from the immediate Washington, D.C. area to cut expenses, but this was a burden born primarily by my husband who still commutes to Capitol Hill, although the move itself and change of school for my daughter was no picnic.
Lastly, but not less importantly, is the great loss of self-esteem I have suffered as a result of losing a rather "heady", exciting career to a life at home. I am a pragmatist so I have tried to make the best of things there. I do have more time with my daughter, although the time is proscribed by my limitations. Worse is the outside world's first impression of me as "a fat, frumpy, uneducated, housewife" (MY words), which is a hard stereotype to continually overcome.

So, how did I get myself in this predicament?? Am I at fault for taking an over-the-counter product in an effort to self-medicate? The product I took gave no clue that it was foreign. It bore an American name. Why should I have believed that I would be poisoned from it? I, like many Americans, trusted our government to oversee our safety in such matters. Since this whole tragedy began, we have learned that the Japanese Company who produced the tryptophan knew as early as 1984 that their product was contaminated from time to time, and sold it anyway.

Which brings me to another scary aspect. After the birth of my daughter, I suffered a back injury. In 1985, tryptophan was being touted as a pain reliever. In an effort to get off of a narcotic pain reliever, I took tryptophan throughout the summer of 1985. In 1986, I developed "strange" symptoms, which the doctors variously called (the dreaded) chronic fatigue syndrome, fibrositis, and fibromyalgia (all catch words for "I don't know").
However, after the 1909 EMS, I went back and looked at my medical records and realized I had the very same symptoms, only to a lesser degree. They evolved in the same order and fashion, though. I believe the 1989 episode merely pushed me over the edge.

I bet every one of you knows at least someone who has chronic fatigue syndrome, fibrositis, or fibromyalgia (all thought to be one and the same now by the scientific and medical communities). At last count, CFS had 12 million sufferers! My point is this—there are a lot of people walking around with something like EMS—-it may even be EMS, which is basically just a toxicological poisoning. Some doctors have found that niacin and some other supplements have caused EMS, and a recent report contracted by the FDA says that taking any amino acid singularly can be dangerous. There is even one, that taken in excessive amounts, can induce ALS, or Lou Gehrig's disease, which is fatal.

The Japanese company has also admitted to having genetically-engineered its product for the last ten years. Then they made a "little boo-boo" and created a (heretofore unknown to mankind) double tryptophan molecule. And how does the body respond to a substance which is totally new to the planet? It treats it as a poison, creates lots of eosinophils to attack the poison (which in turn release their own deadly toxin), and even when the original poison is gone (if ever) continues to bombard the body with toxins
to ward off the invisible enemy, creating an incurable auto-immune illness. (A correlation can be drawn with the breast implant people and silicone who have a very similar illness).

This year genetically-engineered tomatoes will go on the market. Oh yes, we've been told how safe they are. But what happens when that one "little boo-boo" happens? Tomatoes are so insidious—pizza, ketchup, spaghetti, etc. How will we ever track down the one "suspect" tomato where the genetic engineering went awry??

All of these are examples of toxicological/ecological illnesses. Even the Desert Storm soldiers now have their own form of EMS, which is just another mysterious environmental poisoning, but with similar symptoms. Members of Congress now have before them numerous proposals to accomplish health care reform. Many of these cite the need for "preventive medicine". What needs to be determined is what is "real" preventive medicine. I don't mean preventive against natural illness, I mean preventive against all the man-made, man-controlled, man-preventable illness. My illness costs a fortune, as do other similar ones, and is likely to last a lifetime. With 12 million plus chronic fatigue sufferers alone, we are talking major health costs. Perhaps some of the emphasis should be put on "accident prevention".

Intensified regulation of the vitamin and supplement industry would be a good place to start. The
Hatch/Richardson legislation would sabotage this effort. Our propensity should be towards caution, not "carefree" legislation. It is ironic that it was basically "educated, health conscious" people who took the tryptophan in an attempt to avoid something more dangerous (pharmaceuticals). Americans are poisoning themselves with everyone else's permission. They are basically trusting and naive and believe that the government is protecting them in this arena. People are always shocked when I tell them how I got sick, but I can tell they never think it could happen to them---it's always an isolated incident. Well, it isn't just isolated incidents anymore. We are on the brink of "the Big One", it's just a matter of time. What is more important---our collective health as a nation---or the market place? We must regulate the industry in order to protect us from ourselves.

Finally, I would urge you to convince your Appropriations Committee colleagues to fund research on EMS (currently it is being funded almost exclusively by the Japanese). I ask you not for selfish reasons, but as a planning tool, using EMS as a prototype for similar ecological diseases, which are imminent.

Thank you for this opportunity to present testimony. I would gladly respond to any questions.
Mr. Durbin. Camilla Rawleigh.
Ms. Rawleigh. Thank you, Mr. Chairman.

Good afternoon, Chairman Durbin and members of the subcommittee. My name is Camilla Rawleigh, and I live in Gettysburg, Pennsylvania, with my husband, Mike, and my two young daughters, Francesca and Mia.

I am not a scientist or a lawyer, and I do not really understand how the government regulates dietary supplements, but I have been asked to tell you about my family’s experience with the dietary supplement L-tryptophan and, in particular, about my mother Jean’s slow and painful death in January 1990 from a horrible disease called Eosinophilia-Myalgia Syndrome, which was cause by contaminated L-tryptophan manufactured in Japan.

My mother began using L-tryptophan in 1981 because it was recommended to her by a physician as a “natural” way to treat her chronic insomnia. During the next eight years, she used L-tryptophan regularly, up to 5,000 milligrams per day, but always under a doctor’s supervision. I do not know whether L-tryptophan helped my mother sleep, but I never imagined that it could do any harm.

My mother was an energetic woman who served in the Women’s Army Corps at the Pentagon during World War II, and after she married my father she had 7 children in 11 years, but she had a variety of health problems when she got older.

When she developed diabetes in 1988, we were very scared for her, but my mother conscientiously took the medication prescribed for her, she adhered very carefully to a diet, and she began walking up to two miles every day.

By early 1989, at age 69, my mother was in better health and physical condition than she had been in many years, and she seemed to have a very good life.

Indeed, her life absolutely revolved around her children and grandchildren, and I have never known another person who loved so unconditionally. My daughter Francesca was born in August 1988, and my mother could listen on the telephone for what seemed like hours as I told her about Francesca’s growth and development.

I was very close to my mother, and I thought she was one of the world’s greatest authorities on children. My mother adored Francesca, so, in September 1989, I knew that my mother had to be sick when she called me a couple of days before she and my father were supposed to visit us in Gettysburg to tell me that she did not feel well enough to make the trip.

My mother was not a “complainer,” but when I asked her what was wrong, she told me that she was tired all of the time and that she had sharp pains in her shoulders and upper arms.

A couple of weeks later, in October 1989, my mother fell while getting out of bed one morning, and she had to be taken to the hospital. The next three weeks were both frightening and frustrating because Greenwich has an excellent hospital, but the doctors could not explain the cause of my mothers increasing weakness and constant pain. As I said before, two months earlier, as I said before, my mother was walking two miles every day for exercise; now, she could not even walk to the bathroom by herself.
When my mother was discharged from the hospital at the end of the first week in November 1989, she was too weak to care for herself, so my father had to hire nurse's aides to provide 24-hour-a-day assistance. On November 12, 1989, we read in The New York Times that health officials in New Mexico were investigating the possibility that L-tryptophan was connected to the outbreak of a "rare blood affliction" in six States. My mother stopped taking L-tryptophan immediately but, by then, of course, the damage had been done.

Every time I saw my mother several times during the fall of 1989, the change in her appearance was stunning. Although my mother came from a family of tall, vigorous Vermonter, she was now wasting away. My mother also was having increasing difficulty breathing, and in early December she had to be taken to the hospital in an ambulance. About three days later, she went into respiratory failure and had to be placed on a mechanical ventilator in Greenwich Hospital's Critical Care Unit. For the next six weeks, my mother was a patient in the CCU, and, despite the best efforts of the medical and nursing staffs, it was a horrible experience.

My mother was kept awake nearly 24-hours per day by the pumping sound of the ventilator. In addition, her mouth was raw and dry from the plastic tube down her throat, but she was not allowed to drink anything because the liquid might get into her lungs. I would guess that my mother had lost nearly 50 pounds, at this point.

My mother was a woman of great dignity, but her life had become completely undignified. During this time, a tracheotomy was performed on my mother, so she could not speak. I felt so helpless: I did not understand what she was trying to say, but I could imagine what she was feeling because the look of pain and sadness in her eyes was silently eloquent.

Our family was completely torn apart, exhausted, and angry. The seven children, most of whom no longer lived in Connecticut, disrupted their lives and left their own families to be with my mother. My father, who had always been there for my mother, was paralyzed by a sense of helplessness. The stress showed deeply on him, and I began to wonder whether both of my parents were going to die. I often thought to myself that it might be a blessing if my mother died, but I felt guilty because I knew that she did not want to die. She underwent numerous tests and invasive procedures, some of which were experimental, just so she could spend more time with her family. In mid-January 1990, her physicians were able to wean my mother temporarily from the respirator, but we were warned that her condition was very likely to resume deteriorating within a few days. After much discussion with members of our family, my mother decided that she wanted to go home to die. On a Friday in late January 1990, my mother returned for the last time to the big house on the hill in the Riverside section of Greenwich, Connecticut, where she had lived with my father for nearly 40 years and where they had raised seven children. That night, my mother grabbed my face several times as tears rolled down my cheeks and whispered that she loved me. I could not bear to say, "good by," so I didn't. All I needed to say was, "I love you."
On Saturday afternoon, my mother went into a coma. At about 8:00 p.m. that evening, as I was preparing to put my daughter Francesca to bed, we went to my mother’s bedroom to say, “good night,” but Francesca, who was then about 17 months old, spontaneously said, “by, bye,” to her beloved Grandma.

Later that evening, Francesca, who was in the bedroom directly above my mother’s room, cried out loudly in her sleep for about a minute. My mother, who had been in a coma for nearly eight hours, despite constant conversation between her family and a team of nurses, opened her eyes when she heard the crying. I asked if she heard Francesca, but my mother did not respond.

When her beloved “grandbaby” stopped crying, however, my mother closed her eyes for the last time. Her maternal instinct was powerful until the very last moments of her life.

At 1:00 a.m. on Sunday morning, my mother died, and I still think of those final hours whenever there is a cold, rainy night. And I also think of the frigid and windy morning a few days later at St. Mary’s Cemetery in the back country of Greenwich when my mother was buried because her casket seemed so cold and lonely as we drove away.

The finality of it was overwhelming. That was the saddest moment of my life. I have been told that the death certificate stated that the cause of my mother’s death was respiratory failure secondary to Eosinophilia-Myalgia Syndrome cause by L-tryptophan.

During the last four years, all of us have tried to adjust to life without my mother, but it has not been easy. My father retired last December at age 77, after a long career as a textiles industry executive, and he now spends most of his time by himself. I don’t think that he ever will recover from his loss. For months, I felt sad all the time. That feeling has faded, as grief will, but I still think about my mother every day, and I wish she could see my children, who are now five and nearly two. Francesca and I talk about her Grandma a lot because most of what I am today, including virtually everything I believe about parenting, came from my mother. I miss her very, very much.

As I said at the beginning of my statement, I do not understand the complicated legal and scientific issues in the regulation of dietary supplements, and I really do not care who uses products they can buy in pharmacies and health food stores. But I think every product which is sold to treat a problem like insomnia, should be tested to be certain that it is safe. And I do not think that a product manufactured by a large chemical company should say on its label that it is “natural.”

In closing, I would like to say that the only thing I can think of worse than the awful way in which my mother died would be if the government did not learn anything from her experience.

Thank you.

Mr. DURBIN. Thank you.

I thank all of you. We get a lot of political issues here. Sometimes we miss the human side. This panel gives us the human side of an issue.

I am trying to sort this out. I hear spokesmen say it is not a food, it is not a drug, it is not a food additive. It is something else. There is only one other product in the United States that we treat this
way. It is tobacco. It is true the Food and Drug Administration has no jurisdiction over tobacco, because it is neither a food or a drug. The people in the dietary system issue want to be treated differently.

I don't know what the food additive is here, that is why we are here to discuss it. I want to ask whether or not this is simply a "buyer beware" situation, we are dealing with something that is harmless. Certainly, the other panel suggests it is far more than that.

When I was a kid growing up and I had a grandmother, too, who always used to medicate me with her farm remedies. When I came down with a cold her cure was to stick Vicks Vapor Rub into every available orifice and puts a dirty sock around your neck, and you went to bed and got well or else. That was fairly harmless and that product has been around for a century or close to it.

What we are talking about here is far from harmless or a waste of money. There is a lot of trust, that when the American consumer buys this that somebody has taken a look at it. If they can sell it here, it ought to be a good product.

I listened to your testimony, Ms. Tolley, and this one we have been joking about, "Fuel for Thought," you talked about a glutamate. I am a liberal arts major, so forgive me, but this contains L-glutamine free-form amino acid. It is $12.10 cents. It doesn't tell you what it is supposed to do for you. But it is "fuel for thought, neural nutrition." Here is one, "highest quality Japanese pharmaceutical grade amino acid." What does that mean to anybody who buys this, who is foolish enough to think that some pill will make them smarter or think faster? What does it mean in their ultimate health?

What is the role of government, when the Food and Drug Administration can close down the sale of Ragu Spaghetti Sauce because they are saying it is fresh and in fact the ingredients have been cooked, we clearly have some regulation going on to protect the consumers. What we are talking about here is what is the reasonable level of regulation.

What the Richardson-Hatch bill proposes is a significant change from where we are today. It says put it on the market and leave it up to the government to prove that something is wrong with it. That is a big change. It is one that we should not look at lightly.

I think that is why we are here. We are way beyond grandmother's remedies and way beyond something harmless and into matters literally of life and death. I thank you for your testimony.

Ms. MEYERS. Could I just say something? The American public, because of the push of this industry, has begun to think of the word natural as safe. They need to know that natural doesn't mean safe. Tobacco is natural. Hemlock is natural. Putting a word "natural" on a product which may increase its sales, is somehow duping the American public. Those types of words and marketing tactics need to be addressed in whatever law you pass.

Mr. SKEEN. Thank you Mr. Chairman. I think this is why we are holding these hearings. We take a lot for granted. We are used to everything being safe. These days we take everything for granted.

We take packaged foods. We don't cook or smell them, very seldom do we taste them. That is kind of a tragedy, too. Nevertheless,
I think what we are revolving around is a definition of what substances are and which should not be characterized as additives for food. Essentially we are saying that vitamins and food additives are foods. Tryptophan is not a food.

Ms. Tolley. With the molecule which scientists never knew of before 1989.

Mr. Skeen. It is being bioengineered. We are running into a new facet of science for things you should put down the elementary track. We are trying to come up with a definition of what do we mean by minerals, supplements, et cetera. What is the definition of a natural additive to food or something that is a natural substance that can be taken with some kind of trust and certainty that it is not poisonous. Because this is a dangerous age.

We can do a lot with science we couldn’t do 20 years ago. Maybe we need to come up with new definitions and decide who is responsible for enforcing them. That would go a long ways towards resolving some of the problems we have with people talking about pure food additives versus biologically engineered substances. Thank you, Mr. Chairman.

Mr. Durbin. Ms. DeLauro.

Ms. DeLauro. Thank you, Mr. Chairman. I said at the outset with the last panel that the Government Operations Committee hearing with the victims of L-tryptophan was a very powerful one, very powerful for me. I might say that the testimony here this afternoon has been equally as powerful and it is not easy to come before people and tell your own story. So we thank you for doing that and it is a real tragedy. It has had such a profound effect on me and I go back to that hearing almost 12 years ago that I have received the mail and had people come to talk to me at the office. They come with petitions about this issue asking me to sign on to legislation.

I have stayed off the legislation because, as the Chairman said, I am not a scientist. I am not a medical doctor. I don’t know what works and what doesn’t work. But I have been so torn on this issue that I have begged for time with the people who have written to me.

Some may say I have been evasive, because I don’t know where to come down on it yet. I was grateful to have the opportunity to once again listen, to be able to ask questions. I know that there is a fundamental sense that I have. My view is that people ought to know what they are taking. They ought to know what effect it has on their body, on their minds and that as a public official, as someone who is going to at some point sign on to a piece of legislation or not or vote on this is that I need to be clear that we are, in fact, providing the people of this country with the opportunity to know what is in those pills, what it can or cannot do so that they can make an informed judgment.

Yes, it is buyer beware, but they can make an informed judgment about what can have a profound effect on their health and safety. That is what I am trying to take from these discussions and these hearings today and hope really to God that I make an informed judgment that is in the best interest of the people who have put their faith and trust in me to serve in this capacity on this committee and on other committees where we will make a decision.
I have a couple of questions, but I am going to put them aside because fundamentally that is where I want to try to come out. I look forward to, as we go along this process, to be able to ask some questions and to have a continued dialogue with you as to how we ought to make a best judgment for the people we serve.

Abby, thank you for being here again.

Ms. MEYERS. In my written testimony the question is where the burden of proof should be. If we want to continue to go along and have these things, these labels for things that we know they don't work, this was an unsolicited thing that came in the mail on herbal cures. You look under disease, your diseases whether arthritis or cancer or appendicitis, and they will sell you a product for it.

If this is going to continue, then don't change anything. Then this will continue. We started with dead bodies over L-tryptophan. We are going to go on to something else because there are a lot of things out there that these companies will come up with and say is natural and get it on the market and people will die.

It will go on until somebody realizes that we have to do something to regulate these products. We want people to have warnings about side effects. We want to tell you if you take niacin go to your doctor at least once a month for a blood test so you don't damage your system. What these companies are doing here is outrageous and the fact that they are getting away with something that at the beginning of this century that there were laws that were passed to stop the snake oil salesmen, but we still have it going on at the end of this century. That is the pity of it.

Ms. DELAUNO. You mentioned that people with rare disorders have a valid reason to go to their local health food store and look at some of these substances. What advice do you give people on what they take?

Ms. MEYERS. We wish we could get more manufacturers interested in developing prescription drug versions of some of these things because then we would know if you buy a bottle of 100 millimeter tablets, that is what you would get. We only have two prescription drug versions of these substances, one carnitine and one for dialysis patients for calcium.

It is interesting, Mrs. DeLauro, because I found out a couple of weeks ago that I am about to become a grandmother and my daughter-in-law said it is going to take a month to get to my gynecologist. What should I do in the meantime. I said you better get yourself on some vitamins and make sure it has folic acid. She said what brand? I tell you, I have no way to judge. Every bottle might say 4 milligrams of folic acid, but there are no good manufacturing practices that these companies have to conform to.

It may be nothing in there. So that is really what people deserve, a guarantee that just like generic drugs, if you buy folic acid in one brand, all the other brands are going to be equivalent.

Mr. DURBIN. Mr. Myers.

Mr. MYERS. I regret that I had to go to another meeting next door, but I have read your testimony and I have no questions.

Mr. DURBIN. Mr. Peterson.

Mr. PETERSON. I agree that the testimony we have heard today has been remarkable in bringing a focus to this whole issue and something that I think will go down in the record as something
that we will reread over the next few months. But some of the things that have come out here, it seems to me, particularly with this L-tryptophan, is what I was trying to get to before. Can't we categorize these? Are vitamins and calcium different from some of these things being manufactured in a different way than natural substances? And do we have to have regulations that are so broad that we take all these things and put them under one umbrella?

I think we need to discuss that. I couldn't agree with you more that people should know what they are taking and that what they have on the label as to their contents, that is the gross amount or the minute amounts, that it is accurate. They shouldn't have to guess as to the quantities of the capsule they are taking. They should know whether or not they are going to get an overdose or not.

Those are basic things that the industry, if they haven't looked at that, they should be. If they don't, then we will have government step in and do it for them. Those are the parameters. We are trying to discuss how vast is the problem. How bad are the labeling practices now? How much exploitation is taking place and then who is best to actually create the formulas for repair.

Ms. MEYERS. There are other things, too. For instance the dissolution rates of these products. A lot of times they just don't dissolve in your stomach and you don't benefit from anything even though it might have the ingredients that are listed on the label.

Mr. PETERSON. That is the ultimate placebo.

Ms. MEYERS. There are no standards. We found that, first of all, if you buy something over the counter your insurance is not going to reimburse for it. In cases where we have had products that are available by prescription like carnitine, where it is manufactured under good manufacturing practices and it is distributed in bottles that are air tight so that the product doesn't break down, these are all very, very important factors, but even in those cases insurance companies don't want to reimburse for prescription products as long as there is some version on the market that is non-prescription. That is terrible. That is a terrible thing.

We are not—nobody can control the insurance industry and tell them they have to reimburse, but for the insurance industry to feel that these vitamins with no quality controls have the same quality and purity as prescription versions, something is very wrong.

Mr. PETERSON. I was heartened to hear your statement that you want to keep these products available.

Ms. MEYERS. Yes.

Mr. PETERSON. That is what my constituents and I think Americans in general are concerned about. They want the access. Given that and given that both sides want that, it seems to me there is plenty of room for a balance to be struck to the point where we can make sure they are safe, but still on the shelf and that is ultimately what we have to strive for.

Mr. DURBIN. Mr. Walsh.

Mr. WALSH. Thank you very much for your testimony.

Ms. Rawleigh's testimony about her mom brought very vividly back to my mind, the fact that I lost my mother this past July. She made a similar decision to stay at home. We were with her at the
end and it was amazing how sharply it came back into focus. I empathize with you.

Congressman Peterson summed up my sentiments that a balance needs to be struck. People who partake of dietary supplements want to have those made available to them. They don't want to see their favorite products taken off the shelves because of overburdening government regulations and at the same time we have to be very careful of situations similar to this.

I just have one question, that is, what was the contaminant in this L-tryptophan that caused these deaths and illnesses?

Ms. MEYERS. There is a big question about whether it was just this brand. And there is belief that it is something in the L-tryptophan itself that may affect certain people. It seemed to have happened all at once with this one group of people so that they felt that there was adequate reason to believe it happened because of that one brand, but then when they started looking around they found out that it happened from other companies.

Mr. WALSH. People were getting sick from other products?

Ms. MEYERS. Yes.

Ms. TOLLEY. I believe in the 1970s there were medical studies done in Canada and Europe took tryptophan off the market because medical studies showed that taking the amino acids singularly in certain amounts would make you sick. Also in the 1970s was the first case in this country of something called Eosinophilia Myalgia, a muscle disorder. It appeared at NIH.

Sort of the recent theory is that doctors believe that some individuals may have a predisposition to getting a particular type of illness. They don't metabolize tryptophan properly. It is like a double-edged sword; you either get sick from taking just tryptophan or from the contaminants or from both. We might have had a predisposition to taking the amino acids and then gotten the contaminants. They used a new type of bacteria and after it fermented it bound a double molecule that had never existed before.

Mr. WALSH. That molecular element is the contaminant?

Ms. TOLLEY. Yes. The body doesn't recognize it. The body sees it and goes I don't know what this is, so it is poison to the body.

Ms. MEYERS. It is off the market. If you want to have tryptophan for yourself, warm milk and that is tryptophan. That is the way people should be taking that. It is natural instead of manufactured. That warm milk at night is full of tryptophan. That is what makes you sleep and your grandmother was right.

Mr. DURBIN. Mr. Pastor.

Mr. PASTOR. One of the things we tend to forget is that our bodies are chemical factories and we take different elements and chemicals because we need to continue to have the chemical reactions continue. You commented that in milk you find this particular amino acid. I would assume that the formula is the same whether you take it in milk or it is produced in a lab.

Could it be that it is the dosage rather than the element itself?

Ms. MEYERS. It can be manufactured—every company can manufacture it any way it wants.

Mr. PASTOR. But the fact is that this particular amino acid has one formula, whether it is natural or has been provided in a lab. The structure is the same. That is a scientific fact.
Ms. Meyers. In this case it wasn't. The structure was different.

Mr. Pastor. My argument is I agree it was a double molecule so possibly the double molecule affected the body in a different way. But whether you drink it in milk or it is produced in a lab, the single molecule amino acid is the same formula.

Ms. Tolley. There is a report put out by FASEB, a scientific group that the FDA contracted with and they ran through each amino acid that is on the market and studied what would happen if you took too much of any one of them. They found every one of them, if you took excessive amounts, would create some sort of a physical disorder. In the natural form, in the contaminated form——

Mr. Pastor. I don't want to argue about the contaminated form.

Ms. Tolley. Some people took as few as two capsules in the contaminated form and got the illness.

Mr. Pastor. You tell me you took this at the advice of the National Arthritis Foundation pamphlet. Had they run tests on the particular amino acids, what it did to those two diseases?

Ms. Tolley. I doubt it.

Ms. Meyers. No. It was just general medical practice at the time that a lot of doctors were telling people instead of me prescribing a sleeping pill for you, go to your health food store and get tryptophan. It is a natural chemical that puts people to sleep and it was better than a sleeping pill.

Ms. Tolley. The National Arthritis Foundation recommended it for fiber myositis and chronic fatigue syndrome. They said it would put you to sleep and then you wouldn't have muscle pain any more. They recommended 7 grams, which is what I took.

Mr. Pastor. You followed their advice. I would think they are a responsible organization. They would have had scientific background to recommend it. Aren't these people basing——

Ms. Tolley. That pamphlet came out of the doctor's office so fast, I tried to get a copy and I haven't been able to find one. The Arthritis Foundation wouldn't admit that they ever knew the pamphlet existed. It is a collector's item.

Mr. Pastor. They are parts of the DNA which is our basic chemical structure.

Ms. Tolley. This article was from the Washington Post about the glutamate. You can walk into a health food store now and buy glutamate. If you take too much it produces Lou Gehrig's disease. Any one of us could buy it and create our own fatal illness. This was a study done at Johns Hopkins.

Mr. Pastor. One of the elements is incidence of harm. You heard me ask the question, some harm doesn't occur immediately, but can be in the future like testimony with your mother. I would agree that incidents of harm may not be a standard, because it is something that may occur in the future years after it was consumed.

Ms. Meyers. The point that people forget is when you warm up a glass of milk, you are getting a certain amount of tryptophan, but when you go into a health food store you might be getting 10 times the amount that the human body should be taking. Since we have no warning, we have very little understanding of what safe levels are. Anything that you buy in a health food store in a pill as op-
posed to what would come in a natural food is different from what human beings were made to ingest.

Mr. PASTOR. In the label, they should also give the contents and make sure that the contents is not harmful or toxic to the body. A doctor prescribed the amino acids to your mother?

Ms. RAWLEIGH. He recommended it. It was not by prescription. She had had it recommended since 1981 by several different health care workers.

Mr. PASTOR. Thank you.

Mr. DURBIN. We appreciate your testimony very much.
WITNESSES

DAVID A. KESSLER, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION

MICHAEL TAYLOR, DEPUTY COMMISSIONER, FDA, ELIZABETH YETLEY, M.D., ACTING DIRECTOR, OFFICE OF SPECIAL NUTRITIONALS

LORI LOVE, M.D., DIRECTOR OF CLINICAL RESEARCH AND REVIEW

Mr. Durbin. Our next witness is the Commissioner of the Food and Drug Administration, Dr. David Kessler. I want to welcome Commissioner Dr. David Kessler who is a frequent visitor here. If you would be kind enough to introduce the panel joining you today.

Dr. DAVID KESSLER. Thank you, Mr. Chairman. Sitting next to me is Mr. Michael Taylor, Deputy Commissioner for Policy at the agency; Dr. Beth Yetley, Acting Director of our Office of Special Nutritionals; and Dr. Lori Love, Director of Clinical Research and an expert on L-tryptophan.

Thank you for inviting us here today to discuss the subject of certainly an emotional and what at times is an acrimonious debate. Americans view their government with a mixture of reliance and distrust. We want to be free to choose whatever products we like until something goes wrong. Then we turn to our government and want to know why it happened and what the government is going to do about it.

The debate about dietary supplements and what some have called freedom of choice has generated more than its share of misunderstandings and misstatements. I understand that happens when emotions run so high. I hear people claiming that FDA is trying to deny consumers the right to take vitamins and minerals or force them to go to a doctor to get a prescription for their Vitamin C.

I walk into health food stores and I see the leaflets being handed out that say, don't let FDA take your vitamins away. FDA is once again attempting to take away your family's rights to choose nutritional supplements. But let me say absolutely, unequivocally that those statements are false.

FDA is not out to deny anyone access to vitamins and minerals. Please tell your constituents that. Some say that we are trying to put the health food industry out of business. That is also false. This debate is not about vitamins and minerals. I have no problem with customers, consumers taking supplements to improve their diet. I support access to dietary supplements. You should support access to dietary supplements. Mr. Chairman, I don't have a problem if someone wants to sell those products as long as there is no problem with safety, and as long as they don't make a claim that can't be supported.

If someone wants to put sawdust in a bottle and sell it for $14, it is okay with me as long as they don't put a claim that it is useful
to treat or prevent cancer, heart disease, diabetes, or arthritis. That is where I draw the line. When supplements are really being sold as drugs in disguise promoted to treat serious disease, then I believe we have a problem.

Recognize at the outset that the dietary supplement industry is essentially unregulated. When consumers pick up a dietary supplement today, they assume the product is safe. The fact is, there has never been a systematic evaluation of the safety of dietary supplements. When consumers see a health claim for a dietary supplement, they assume it will provide the benefits it touts. In fact, the marketplace is awash in unsubstantiated claims.

Congress set the standards for health claims for foods in the Nutrition Labeling and Education Act—NLEA, but couldn't reach an agreement on the standard for dietary supplements, so you asked FDA to set that standard in regulations.

In November 1991, we proposed that dietary supplements should be subject to the same standard for health claims that Congress clearly articulated for food; not drugs. The standard that Congress articulated in NLEA for foods specified that claims be supported by significant scientific agreement. We didn't see why a health claim should be allowable on a vitamin C tablet, but not on the vitamin C in broccoli or orange juice. We reaffirmed that position in a proposal we issued last June.

Make no mistake about it, there are many supplements on store shelves today making unsubstantiated health claims. The promotion of these products for serious health problems is a pervasive problem. We issued a report in July that includes a list of 500 dietary supplements out there today that claim to treat, cure, or reduce the risk of a variety of health problems, some as serious as cancer and AIDS. These claims appear in current catalogs, brochures and other advertising materials or, in some cases, on the product label itself, as you have demonstrated.

They are also being made by some salespeople at some health food stores. Ninety-three percent of the health food stores, when asked, recommended specific dietary supplements for the treatment of cancer, to fight infection, and to treat high blood pressure.

I have arranged before us today some of the products specifically recommended for those conditions—cancer, immune disease, hypertension. I should also point out that the list of claims in our report is certainly by no means exhaustive, only an indication of the free-for-all that exists in the dietary supplement marketplace today. In our view, these claims are unsubstantiated. In the absence of a clear standard, the best FDA can do, to try to separate the good from the bad when it comes to dietary supplements, is to go after products one by one.

We have taken action against some dietary supplements, and our report includes a representative list of recent FDA enforcement actions. But for every unsubstantiated claim for a serious condition that we catch, there are many more that we don't have the resources to do anything about.

Increasingly, scientists are uncovering important relationships between diet and health, and it may be that we will be able to establish a clear link between a number of specific nutrients and improved health; but the vast majority of these products referred to
as dietary supplements have nothing to do with supplementing the diet. They have no nutritional value. They are being promoted as drugs.

For every dietary supplement in the marketplace that may have some value, unfortunately there are a hundred or more that are out there that are worthless.

In some ways, we risk slipping back to the turn of the century when snake oil salesmen could hawk their potions with promises that couldn’t be kept. What can we do then to separate the good from the bad? Congress and the American people recognized the need to set a standard for drugs in this country, and because we set the right standard, today we have a medical arsenal unparalleled in the world. Consumers can have confidence that the drugs on the market do what they say they are going to do.

There is an issue of credibility here, and the dietary supplement industry, I believe, ought to be concerned about it. When the marketplace is flooded with products making unsubstantiated claims, the products that do offer legitimate benefits become lost in the morass of those that offer nothing.

Go back to what was happening in the supermarket when Congress passed the Nutrition Labeling and Education Act. We had a proliferation of misleading labels and unfounded health claims on packages that undermined the consumer’s faith in the food label. The food industry recognized that it had a credibility problem. The NLEA was a commitment to restoring credibility to the supermarket shelf.

If we were so concerned about deceptive food labels, shouldn’t we be at least as concerned about false claims for dietary supplements?

Much is at stake for consumers. Believe me, I appreciate the appeal of a simple cure. We would all rather take some miracle pill than undergo more arduous and sometimes uncertain treatments. But unfortunately, cures don’t always come packaged as neatly as we would hope. And patients who would forsake therapies that would offer some real benefit to the siren song of empty promises have a lot to lose.

Let me turn to the issue of safety. Unfortunately there is a widespread perception in this country that because something is called natural it is safe. We have learned that nothing could be further from the truth.

The recent and tragic example that you heard about in the previous panel really emphasizes that point. Many Americans turned to L-tryptophan, an amino acid touted as natural to treat conditions such as depression and insomnia. Physicians sent patients to health food stores for this product, assuming it was harmless. At least 38 people have died and thousands more are suffering permanent disabilities from a disease called EMS after taking L-tryptophan. Initially, it was thought that the illness was caused by an impurity in certain batches, but recent studies suggest that EMS is associated with L-tryptophan either alone or in combination with the impurity or another component in the supplement.

We are concerned about the safety of other amino acids and herbs, as well. There is very little data available on these products. We have listed in our report, and on those charts you see, serious
adverse reactions associated with 16 products that are marketed today as dietary supplements.

Think about it: Nearly half our prescription drugs today are derived from plants, and no one doubts for a moment that drugs can have toxic effects. That is why we insist on such rigorous testing to separate out those with unacceptable toxicity. Why then should we assume that all risks disappear when plants are sold for dietary supplements for therapeutic purposes?

Mr. Chairman, it is time that we do what needs to be done. Congress has a choice and an opportunity. On the labeling side, you can support the standard for dietary supplement health claims, the significant scientific agreement standard, consistent with the standard that you previously established in the Nutrition Labeling and Education Act for food. This will benefit consumers by keeping unsupported claims out of the marketplace. It will give consumers a meaningful choice, one based on science, not on salesmanship.

If you decide to go in another direction, you need to understand the consequences of that choice. Some would have you permit marketers to decide whether a health claim is appropriate without review by the FDA. Remember that the proliferation of health claims on food labels in the 1980s occurred precisely because companies, rather than the FDA, decided what health claims could be made. This approach opened the floodgates to claims that have no scientific basis. It puts the consumer in an impossible situation because there is no way of telling what works from what doesn't work.

Furthermore, if companies are allowed to make claims without sound studies to back them up, there is no incentive to do the studies that will finally determine which products offer real benefits.

We stand ready to work with you, Mr. Chairman. We are justifiably proud of this country's history of consumer protection. We have worked hard to keep adulterated and misbranded food and drugs off the market. Allowing the dietary supplement industry to continue to make unsubstantiated claims flies in the face of all that we have strived so hard to achieve.

[The information follows:]
STATEMENT BY
DAVID A. KESSLER, M. D.
COMMISSIONER

FOOD AND DRUG ADMINISTRATION
PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON AGRICULTURE
COMMITTEE ON APPROPRIATIONS
UNITED STATES HOUSE OF REPRESENTATIVES

OCTOBER 18, 1993

TO BE RELEASED ONLY UPON DELIVERY
Mr. Chairman and Members of the Subcommittee:

I am David Kessler, Commissioner of Food and Drugs. I am accompanied today by Michael Taylor, Deputy Commissioner for Policy; Gary Dykstra, Deputy Associate Commissioner for Regulatory Affairs; Mitchell Zeller from the Office of the Deputy Commissioner for Policy; Dr. Elizabeth Yetley, Acting Director, Office of Special Nutritionals, and Dr. Lori Love, Director, Clinical Research and Review Staff, both in our Center for Food Safety and Applied Nutrition; Dr. Robert Temple, Director, Office of Drug Evaluation I, in our Center for Drug Evaluation and Research; and Margaret Jane Porter, our Chief Counsel.

Today's hearing focuses on one of the oldest public policy debates involving the Food and Drug Administration (FDA)—how should the Federal government regulate the marketing and use of dietary supplements?

FDA welcomes the open exchange of views on dietary supplements. As this debate unfolds, it is important for the congressional community and all other interested parties to understand FDA's perspective on this significant public health issue and to recognize the precise focus of FDA's concerns.

The starting point of the debate is understanding how broadly the term "dietary supplement" is being used by consumers and the industry. The term "dietary supplement" commonly is used to
refer to everything from the traditional vitamin and mineral nutritional supplements to capsules and tablets that contain amino acids, herbs, and other substances that have a history of medicinal use such as yohimbine and white willow bark. The traditional vitamin and mineral products comprise more than 80 percent of the multibillion dollar dietary supplement market and raise no serious concerns as long as they are sold without disease prevention or treatment claims, have potencies that do not raise safety questions, and are manufactured using appropriate quality control standards. These products are not what the current debate is about. Contrary to what Members of Congress may be hearing, FDA has no intention of forcing consumers to get a doctor's prescription to obtain vitamins or minerals. Nor is the Agency intent on forcing health food stores out of business.

The remaining products on the market—amino acids, herbs and other botanicals, and other substances—often raise questions about safety and labeling. Many of these products have no recognized role in nutrition, frequently bear express or implied disease prevention or treatment claims, and have been marketed for specific therapeutic purposes. Some of these products have been associated with serious, even fatal, adverse reactions.

The current debate is about the safety and proper labeling of these products, and any other product that makes a scientifically
unsubstantiated disease prevention or treatment claim. While today's debate is being shaped by some recent regulatory and Congressional concerns, the fundamental issue has been with us for decades. For example, as in the Laetrile controversy and other cases, the present controversy is the conflict between what marketers want to claim about unproven remedies and what is the extent of the government's responsibility to ensure that those claims have a scientific basis.

The challenge to all participants in the dietary supplement debate--Congress, consumers, industry, FDA, and others--is to strike the right balance between ensuring the safety and proper labeling of all of these products while at the same time preserving consumers' freedom of choice. Freedom of choice means little unless consumers have meaningful and accurate information on safety and effectiveness in deciding whether to purchase these products.

BACKGROUND AND HOW FDA SEES THE ISSUES

The nature of the dietary supplement debate has changed over the last 50 years. Immediately following the 1938 passage of the Federal Food, Drug, and Cosmetic Act (FDC Act), FDA's concern was to identify appropriate daily intakes of vitamins and minerals to ensure that minimum nutritional needs were being met.
In 1966, FDA proposed new regulations regarding the labeling and content of special dietary food products and new definitions and standards of identity for vitamin and mineral substances. In addition to rules for food fortification, definitions for low-calorie foods, and a general condemnation of useless (but highly promoted) nutrients, FDA proposed that multi-vitamin and mineral product labels bear the following statement:

Vitamins and minerals are supplied in abundant amounts in the foods we eat. The Food and Nutrition Board of the National Research Council recommends that dietary needs be satisfied by foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements.

This so-called "crepe label," in particular, met with uniform disapproval from not only the health food industry and vitamin manufacturers, but also from nutritionists and even from the Association of Food and Drug Officials of the United States.

FDA stayed its 1966 regulations and conducted public hearings on dietary supplements from 1968 until 1970.
By the early 1970's, FDA's interest—and the public debate—had shifted to high potency vitamin supplements and whether their potencies should be limited to "nutritionally rational" levels if they were to be marketed as "foods" rather than "drugs."

Congress settled that debate in 1976 with the Proxmire Amendment, which permits FDA to limit potency only for safety reasons.

This issue has now come full circle since 1966; and, a new element to the debate has emerged. There are new scientific understandings of the links between diet and health, and there are some exciting possibilities, such as the possibility that higher consumption of foods with certain antioxidant vitamins may lead to lower cancer rates.

As scientific evidence assessing the effects of diet and health accumulates, it is important that FDA carefully weigh the benefits and potential risks in order to protect the health of the American consumer and to allow appropriate claims when they are substantiated by scientific data. Equally important, FDA continues to have concerns about the safety of some products now sold as dietary supplements and about the scientific validity of therapeutic claims associated with many dietary supplement products.

The role of dietary supplements
The emerging knowledge about the potential role of diet, including specific nutrients, as well as behavioral changes, in promoting health and reducing the risk of certain diseases has enormous implications for public health.

FDA is dedicated to assisting health-conscious consumers to make informed choices about the role of nutritional supplements in their diet. The Agency is carefully reviewing scientific data linking diet and disease and is making decisions as quickly as the available science allows. For example, on October 8, 1993, FDA proposed to revise the food labeling regulations to authorize the use of a health claim about the relationship between folate and the risk of neural tube birth defects on labels or in labeling of foods in conventional food form or dietary supplements.

Also, FDA announced two other proposed regulations concerning folic acid. One proposal is to amend the standards of identity for enriched bread, rolls and buns, enriched flour, and other cereal and grain products to require the addition of folic acid to products labeled "enriched." The other proposal is to amend the food additive regulations by setting limits for the use of folic acid on a per serving basis in accord with the Nutrition Labeling and Education Act of 1990; to allow for the addition of folic acid to foods for which standards of identity exist, where such standards permit or require the addition of folic acid; to
make breakfast cereals the only food, for which standards of identity do not exist, to which folic acid may be added; to continue to permit the use of folic acid in infant formulas, dietary supplements, and foods for special dietary use; and to incorporate specifications on folic acid consistent with those in the Food Chemicals Codex.

Also, on October 8, 1993, FDA proposed not to authorize health claims relating to an association between fiber and cancer, fiber and heart disease, antioxidant vitamins and cancer, omega-3 fatty acids and coronary heart disease, and zinc and immune function in the elderly on the label or in the labeling of dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances. The proposal is based on the agency's tentative determination that there is not significant scientific agreement among experts about the relationship between nutrient-disease relationships nor are the claims supported by the totality of publicly available scientific evidence. The proposal provides an opportunity for interested persons to submit new scientific data and comments on the five nutrient-disease relationships mentioned above. The agency will review all comments received and will conduct its own literature review to obtain recent scientific evidence.

In addition, FDA will soon announce that it is cosponsoring with other research and health organizations an open symposium in
early November on antioxidant vitamins and cancer and cardiovascular disease. The purpose of the symposium will be to discuss the available science, to identify any unmet research needs, and to discuss ways of facilitating research to meet these needs. FDA will consider the results of this symposium in making a final decision about whether to authorize a health claim on antioxidant vitamins and cancer and cardiovascular disease.

There is much to be lost if we drift from a scientific base in making our decisions and allow the marketplace to be filled with unsubstantiated claims on products of unproven safety. The public's health could be at risk—both from unrecognized risks and from the potential for diverting patients from proven methods of treatment, including many that are life-saving, and replacing them with unproven products—and scarce health care dollars would be wasted.

SAFETY CONCERNS

Amino acids, herbs, and a host of other supplement products are more likely to raise public health concerns than traditional vitamin and mineral supplements marketed at reasonable potencies.

FDA is concerned about safety even though there has not been a large number of adverse reactions reported for these products. The lack of reported injuries is not particularly surprising
because there is not an adequate system in place to discover them and to link injuries with the ingestion of a particular substance. That is why Congress adopted a premarket approval system in the Food Additives Amendment in 1958. When injuries are not immediate and dramatic, they are often hard to link to their cause. This is true even for injuries from conventional drugs, which are given in the context of excellent physician recordkeeping and used in a conventional health care system that looks for such events; it is far more true of substances given outside a conventional health care system.

FDA efforts in the past to encourage reporting of adverse effects met with industry resistance. Moreover, physicians, in taking medical histories, usually do not inquire about dietary supplement use, and patients often do not volunteer this information. Thus, there is a significant possibility that many adverse reactions to dietary supplements go unrecognized and, as a result, unreported.

Nonetheless, increasing numbers of serious adverse reactions associated with the use of dietary supplements are being reported in the scientific literature and to public health officials worldwide. The first report of these reactions is usually not the first occurrence. The adverse reactions were often there—but not recognized.
During the last year, FDA's Center for Food Safety and Applied Nutrition (CFSAN) was reorganized and a new office was created to place greater emphasis on dietary supplements. The Office of Special Nutritionals (OSN) collects and evaluates information reported to FDA on the adverse effects from dietary supplements. With the help of OSN, FDA has begun to identify dietary supplements for which serious adverse effects have been documented.

As you know, on July 29, 1993, FDA released a four part report concerning the dietary supplement marketplace. I am submitting a copy of that report for the record. One part of the report includes the most current information FDA has gathered on the health hazards associated with some dietary supplements.

Specific examples of safety concerns include:

**Amino acids**

FDA requested a voluntary recall of the amino acid L-tryptophan after published reports associated its ingestion with an epidemic of a connective tissue disease called eosinophilia myalgia syndrome (EMS). More than 1,500 cases, including 38 deaths, were reported to public health agencies, although the incidence of this disorder is thought to be much higher.
Despite recent intense research, the exact cause of EMS and an understanding of how it develops have not been established. Initial epidemiological studies implicated the L-tryptophan produced by a single Japanese manufacturer. Also, the studies noted that certain impurities were identifiable in batches of case-associated L-tryptophan. These findings suggested that some impurity or other component in these batches of L-tryptophan may have been responsible for EMS. However, both initial and subsequent epidemiological studies on the EMS epidemic have identified cases of EMS and of another related disease, eosinophilic fasciitis, that occurred before the 1989 epidemic and cannot be related to L-tryptophan produced by the same Japanese manufacturer. Other data indicate that L-tryptophan, either alone or in combination with some other component in the supplement products, may be responsible for some of the pathological features in EMS. Taken together, these findings support previous suggestions that the L-tryptophan-associated EMS was caused by several factors and is not solely related to an impurity in a single source of L-tryptophan.

In 1990, following the L-tryptophan-associated EMS outbreaks, FDA contracted with the Federation of American Societies of Experimental Biology (FASEB) to review the safety data on amino acids. FASEB reviewed the available scientific literature on the safety of each of the amino acids and gave special emphasis to metabolism, genetic influences on metabolism, and population
groups at potentially higher risk for adverse health effects from use of amino acids in supplements. FASEB concluded that there was insufficient available information to establish a safe upper intake level for any amino acid supplement. FASEB also concluded, based on an evaluation of the limited data on patterns of amino acid use and adverse health effects, that the safety of unrestricted use of particular amino acids in dietary supplements cannot be assumed. FASEB made a number of recommendations including a systematic evaluation of certain effects of these substances. These experts also recommended that potentially vulnerable subgroups—the young, the elderly, women of childbearing age, and people with suppressed immune systems—use amino acids only under responsible medical supervision.

In the Federal Register of June 18, 1993, FDA issued an Advance Notice of Proposed Rulemaking (ANPR) to announce that we are reviewing the manner in which we regulate the safety of dietary supplements, and that we are requesting comment on approaches, consistent with the requirements of the FDC Act, for ensuring the safety of products offered as dietary supplements. The ANPR was published in response to the Dietary Supplement Act of 1992, recent developments and events in the marketplace, and to receive comment on the FASEB report.

FDA also announced in the ANPR the availability of a report by an internal FDA task force that was established in May 1991,
following the EMS outbreak associated with the consumption of L-tryptophan-containing dietary supplements. The FDA Task Force was asked to review the Agency's regulatory program for dietary supplements and to recommend improvements. Known as the Dietary Supplement Task Force, it was composed of Agency staff with experience and expertise in regulatory, nutritional, legal, and medical issues related to supplements. The Task Force was asked to examine a number of issues, including whether safety concerns exist regarding dietary supplements, and, if so, to recommend a regulatory framework to distinguish supplements that raise safety concerns from those that do not. The Task Force completed its work in May 1992 when it submitted a report with recommendations to the Commissioner. It must be emphasized that nothing in the Task Force report represents Agency policy. FDA has made the recommendations of the Task Force available for public comment. The Agency will review the comments it receives and then decide what actions appear to be appropriate.

Also, the ANPR contained FDA's announcement that we intend to bring amino acid-containing products into compliance with the law and requested that manufacturers of these products submit any additional information that may be available on the safety and use of individual amino acids or combinations of amino acids as ingredients in dietary supplements.

Herbals
Many herbal and other botanical products are derived from familiar food-use herbs, but many others are derived from plants that have no traditional food use and no known nutritional value. Although many of these plant products are marketed as being "natural," "natural" is no guarantee of safety.

Some of our most potent drugs (morphine, certain cancer drugs, and many antibiotics) are derived from natural plant sources, as are certain historic poisons (hemlock, strychnine, and belladonna). "Natural" products from plants come with the same full range of potential benefits and risks as synthesized materials. Furthermore, the dose of an active ingredient, whether from a "natural" or synthetic product, determines its usefulness and safety or its toxicity. Manufacturing controls are important for both types of products. Adverse effects vary greatly depending on the particular species and strain of plant, when and how it is harvested, what plant parts are used, how the plant materials are processed.

Most herbal products, including many of those used traditionally, have not been subjected to routine safety testing, particularly for the effects of prolonged use. Indeed, given the variability in marketed products, and lack of standardized preparations, safety testing would be difficult. Serious adverse health effects have been recognized with the use of several of these products in animals and humans.
Examples of risky herbals include:

1. **Germander.** Germander is the common name for a group of plants that are contained in medicinal teas, elixirs, capsules, or tablets, either singly or in combination with other herbs, and marketed for the treatment of obesity and to facilitate weight loss.

Since 1986, at least twenty-seven cases of acute nonviral hepatitis (liver disease), including one death, have been associated with the use of commercially available germander products in France. These cases show a clear temporal relationship between ingestion of germander and onset of hepatitis, as well as resolution of symptoms when the use of germander was stopped. In 12 cases, re-administration of germander was followed by prompt recurrence of hepatitis. Recovery occurred gradually, in most cases approximately 2 to 6 months after withdrawal of germander. Analyses of these cases do not indicate a strong relationship between the dosage or duration of ingestion and the occurrence of hepatitis. On the basis of these cases, the French Ministry of Health has forbidden the use of germander in drugs.

2. **Comfrey.** Various species of comfrey, including common comfrey and Russian comfrey, are used in herbal preparations. Comfrey is widely sold in the United States in teas, tablets,
capsules, tinctures, medicinal poultices and lotions. Since
1985, at least seven cases of hepatic veno-occlusive disease
(obstruction of blood flow from the liver with potential scarring
(cirrhosis)), including one death, have been associated with the
use of commercially available oral comfrey products.

Comfrey, like a number of other plants, e.g., Senecio species,
contains pyrrolizidine alkaloids. The toxicity of these
pyrrolizidine alkaloids to humans is well-documented. Hepatic
veno-occlusive disease, following ingestion of pyrrolizidine
alkaloid-containing herbal products, has been documented
repeatedly throughout the world. Hepatic veno-occlusive disease
is usually acute and may result in fatal liver failure.

The United Kingdom, Australia, Canada, and Germany have recently
restricted the availability of products containing comfrey, and
other countries permit use of comfrey only under a physician's
prescription.

3. Chaparral. Chaparral, commonly called the creosote bush, is
a desert shrub with a long history of use as a traditional
medicine by Native Americans. Chaparral is marketed as a tea, as
well as in tablet, capsule and concentrated extract form, and has
been promoted as a natural antioxidant "blood purifier," cancer
cure and acne treatment. The most abundant component of
chaparral is nordihydroguaiaretic acid (NDGA), which was removed
from FDA's list of substances considered safe when it was determined to be nephrotoxic (harmful to the kidneys) in animal studies.

At least six cases (five in the U.S. and one in Canada) of acute non-viral hepatitis (rapidly developing liver damage) have been associated with the consumption of chaparral as a dietary supplement. Additional cases have been reported and are under investigation. In the majority of the cases reported thus far, the injury to the liver resolves over time, after discontinuation of the product. In at least two patients, however, there is evidence that chaparral consumption caused irreversible liver damage. One patient suffered terminal liver failure requiring liver transplant.

The first cases linking chaparral to liver damage in the U.S. surfaced in August and September 1992. By October, the Centers for Disease Control and Prevention (CDC) had discussed the reported cases and the potential link between acute, non-viral hepatitis and chaparral in an article published in CDC's Morbidity and Mortality Weekly Report. And by December 1992, FDA had issued a health warning against using this product.

4. Yohimbe. Yohimbe is a tree bark containing a variety of pharmacologically active alkaloids. It is marketed in a number of products for body building and "enhanced male performance."
Serious adverse effects, including renal failure, seizures and death, have been reported to FDA with products containing yohimbe and are currently under investigation.

The major active alkaloid in yohimbe is yohimbine, a chemical that causes vasodilation, thereby lowering blood pressure. Yohimbine is also a prescription drug in the United States. Side effects are well recognized and may include central nervous stimulation that causes anxiety attacks. Symptoms of overdosage include weakness and nervous stimulation followed by paralysis, fatigue, stomach disorders, and ultimately death.

5. Lobelia. Lobelia, also known as Indian tobacco, contains pyridine-derived alkaloids, primarily lobeline. These alkaloids have pharmacological actions similar to, although less potent than, nicotine. There have been several reported cases of adverse reactions associated with consumption of supplements containing lobelia. Depending on the dose, lobeline can cause either autonomic nervous system stimulation or depression. At low doses, it produces bronchial dilation and increased respiratory rate. Higher doses result in respiratory depression, as well as sweating, rapid heart rate, hypotension, and even coma and death. As little as 50 milligrams of dried herb or a single milliliter of lobelia tincture has caused these reactions.
Because of its similarity to nicotine, lobelia may be dangerous to susceptible populations, including children, pregnant women and individuals with cardiac disease. Lobelia is nevertheless found in dietary supplement products that are marketed for use by children and infants, pregnant women, and smokers.

6. Jin Bu Huan. Jin Bu Huan is a Chinese herbal product claimed to be good for "insomnia due to pain," ulcer, stomach neuralgia, pain in shrunken womb after childbirth, nervous insomnia, and spasmodic cough. Jin Bu Huan has been recently reported to be responsible for the poisoning of at least three young children (ages 13 months to 2 1/2 years), who accidently ingested this product. The children were hospitalized with rapid-onset, life-threatening bradycardia (very low heart rate), and central nervous system and respiratory depression. One child required intubation (assisted breathing). All three ultimately recovered, following intensive medical care. Although the product label identified the plant source for Jin Bu Huan as Polygala chinensis, this appears to be incorrect since preliminary analyses indicate the presence of tetrahydropalmatine (THP), a chemical not found in Polygala. THP is found, however, in high concentrations in plants of certain Stephania species. In animals, exposure to THP results in sedation, analgesia, and neuromuscular blockade (paralysis). The symptoms of the three children are consistent with these effects. An additional case
of THP toxicity, reported in the Netherlands, appears to be associated with the same product, and is being investigated.

7. Herbal Products containing Stephania and Magnolia species. A Chinese herbal preparation containing Stephania and Magnolia species that was sold as weight-loss treatment in Belgium has been implicated recently as a cause of severe kidney injury in at least 48 women. These cases were only discovered by diligent investigations by physicians treating two young women who presented with similar cases of rapidly progressing kidney disease that required renal dialysis. Once it was determined that both these women had used the herbal diet treatment, further investigation of kidney dialysis center in Belgium found a total of 48 individuals with kidney injury who had used the herbal product. At the time that a report of these adverse effects was published in February 1993, 18 of the 48 women had terminal kidney failure that will require either kidney transplantation or life-long renal dialysis.

8. Ma huang. Ma huang is one of several names for herbal products containing members of genus Ephedra. Serious adverse effects, including hypertension (elevated blood pressure), palpitations (rapid heart rate), neuropathy (nerve damage), myopathy (muscle injury), psychosis, stroke, and memory loss, have been reported to FDA with products containing Ma huang as ingredients and are currently under investigation. The Ephedras
have been shown to contain various chemical stimulants, including the alkaloids ephedrine, pseudoephedrine and norpseudoephedrine, as well as various tannins and related chemicals.

The concentrations of these alkaloids depend upon the particular species of Ephedra used. Ephedrine and pseudoephedrine are amphetamine-like chemicals used in over-the-counter (OTC) and prescription drugs. Many of these stimulants have known serious side effects. Ma huang is sold in products for weight control, as well as in products that boost energy levels. These products often contain other stimulants, such as caffeine, which may have synergistic effects and increase the potential for adverse effects.

9. Willow bark. White willow bark is often marketed in products for use by children, and is often promoted as "aspirin-free." White willow contains a natural component, salicin, that is converted in the body to the same active ingredient (salicylic acid) that is a component of aspirin. However, unlike aspirin, willow bark's label has no warning—as FDA requires on aspirin labeling—that children should not take aspirin for chickenpox or influenza symptoms, because of an association with the serious illness Reye syndrome. Because willow bark shares many of the same chemical properties and the same side effects as aspirin, willow bark should also be avoided by aspirin-sensitive adults.
Vitamins and Minerals

Even the more traditional vitamins and minerals, when marketed at potencies far higher than needed to prevent deficiencies, can pose safety problems. The margin of safety between the RDA and the toxic level varies greatly depending on the nutrient and is unknown for several nutrients. Also, ingredients that are naturally occurring in conventional foods often are concentrated in supplements, making it easy to greatly exceed the normal intakes from conventional foods. The bulk and calorie content of traditional foods somewhat limits the amount of these foods that can be consumed and, thus, the intake of any one ingredient is limited. A single ingredient in excess may cause imbalances in other nutrients. Excess zinc, for instance, interferes with absorption of copper, an essential nutrient. It is common knowledge that most substances cause adverse effects at some level.

Some risks of nutrients taken at excessive potencies include:

1. Niacin. Niacin taken in high doses is known to cause a wide range of adverse effects. The RDA for niacin is 20 mg. Niacin is marketed in dietary supplements at potencies of 250 mg, 400 mg, and 500 mg, in both immediate and slow-release formulations. Daily doses of 500 mg from slow-release formulations, and 750 mg of immediate release niacin, have been associated with severe
adverse reactions, including gastrointestinal distress (burning pain, nausea, vomiting, bloating, cramping, and diarrhea) and mild to severe liver damage. Less common, but more serious (in some cases life-threatening), reactions include liver injury, myopathy (muscle disease), maculopathy of the eyes (injury to the eyes resulting in decreased vision), coagulopathy (increased bleeding problems), cytopenia (decreases in cell types in the blood), hypotensive myocardial ischemia (heart injury caused by too low a blood pressure), and metabolic acidosis (increases in the acidity of the blood and urine).

2. **Vitamin A.** Vitamin A is found in several forms in dietary supplements. Preformed vitamin A (vitamin A acetate and vitamin A palmitate) has well-recognized toxicity when consumed at levels of 25,000 International Units (IU) per day, or higher.

The adverse effects associated with consumption of vitamin A at 25,000 IU or higher doses include severe liver injury (including cirrhosis), bone and cartilage pathologies, elevated intracranial pressure, and birth defects in infants whose mothers consumed vitamin A during pregnancy. Groups especially vulnerable to vitamin A toxicity are children, pregnant women, and those with liver disease caused by a variety of factors, including alcohol, viral hepatitis, and severe protein-energy malnutrition. There are some studies that suggest vitamin A toxicity has occurred at levels of ingestion below 25,000 IU.
3. **Vitamin B6.** Neurologic toxicity, including ataxia (alteration in balance) and sensory neuropathy (changes in sensations due to nerve injury), is associated with intake of vitamin B6 supplements at levels above 100 mg per day. As little as 50 mg per day has caused resumption of symptoms in an individual previously injured by higher intakes.

4. **Selenium.** Selenium is a mineral found in dietary supplement products. At high doses (approximately 800 to 1,000 micrograms per day), selenium can cause tissue damage, especially in tissues or organs that concentrate the element. The toxicity of selenium depends upon the chemical form of selenium in the ingested supplement and upon the selenium levels in the foods consumed. Human injuries have occurred following ingestion of high doses over a few weeks.

**Other products**

**Germanium.** Germanium is a non-essential element. Germanium has been marketed in the form of inorganic salts and novel organogermanium compounds as a dietary supplement. These products are promoted for their claimed immunomodulatory effects or as "health-promoting" elixirs. Germanium supplements, when used chronically, have caused nephrotoxicity (kidney injury) and death.
Since 1982, there have been 20 reported cases of acute renal failure, including two deaths, attributed to oral intakes of germanium elixirs. In surviving patients, kidney function improved after discontinuation of germanium, but none of the patients has recovered normal kidney function.

Germanium products have been the subject of an FDA Import Alert since June 1988.

LABELING ISSUES

Congress enacted the Nutrition Labeling and Education Act of 1990 (NLEA) in response to two developments. First, major scientific advances linking diet and disease prevention have taken place over the last 30 years. Second, throughout the 1980's food marketers tried to capitalize on the diet/disease connection and the supermarket shelves were filled with false and misleading health claims on food labels.

The NLEA expressly authorized FDA to permit explicit disease-related claims for nutrients on the labels of foods and dietary supplements.

In the NLEA, Congress said that health claims for conventional foods were appropriate if, based on the publicly available evidence, FDA determined there was significant agreement among
experts regarding the scientific validity of the claim. However, Congress asked FDA to determine the appropriate standard to be applied to health claims for dietary supplements.

In 1991, FDA issued a proposed rule to apply the NLEA standard of "significant scientific agreement" to health claims for dietary supplements. The agency's experts simply could not discern a public health reason to subject a claim for the health benefits of vitamin C in dietary supplements to a different standard from the one Congress mandated in the NLEA for vitamin C in broccoli or orange juice or for vitamin C added as a fortificant to foods.

FDA's 1991 proposal generated an intense response from dietary supplement manufacturers and consumers. This reaction was based in part on misrepresentations about what the Agency had proposed. FDA and many congressional offices received angry letters and phone calls from consumers who had been told that FDA was trying to make vitamin and mineral products available only by prescription. The FDA has no such plans.

Another message communicated to congressional offices was that FDA was trying to restrict the rights of consumers. In fact, FDA fully supports the right of dietary supplement consumers to exercise their "freedom of choice." However, critical questions exist about how real or free that choice actually is when some of the health-related claims on product labels are not
scientifically valid or are incomplete and misleading, and when some of the products themselves may be unsafe.

It is critically important to remember that the proliferation of false and unsubstantiated claims (such as "fat free," "cholesterol free," ) on conventional food labels in the 1980's occurred precisely because companies, rather than FDA, determined on their own what each claim meant. The promotion of unsubstantiated health claims associated with dietary supplement labeling has mushroomed. If FDA is not permitted to review health claims before they appear in labeling, this promotion of unsubstantiated claims will expand even more.

To illustrate the vastness of this problem, the four part report that I mentioned earlier provides examples of the pervasiveness of unsubstantiated claims currently being made for dietary supplements in the U.S. marketplace and, as I indicated earlier, reviews safety hazards associated with dietary supplements. We believe that the report illustrates a marketplace with a large number of products with unsubstantiated claims.

The four parts of the report are as follows:

--a list, with more than 500 examples, of products and the unsubstantiated claims currently being made for those products;
--a representative list of recent FDA enforcement actions;

--a list of oral representations of specific products for hypertension, immune system problems, and cancer by employees of stores selling dietary supplements; and

--a narrative report describing serious adverse reactions associated with 16 ingredients marketed as components of dietary supplements.

Because of the vast number of products on the market with unsubstantiated claims or unproven safety, FDA has not been able to and can not take regulatory action against every product. Even with our cooperative efforts with the states and other Federal agencies, the level of enforcement resources devoted to dietary supplements is relatively small given the size of the industry nationally. The program is administered under a Compliance Policy Guide (CPG) that was issued in June 1987.

The CPG describes FDA's two priorities for enforcement activities, in order of importance, as follows:

(1) products that are potentially harmful when used as directed or in a customary manner (a direct health hazard posing a risk of serious or life-threatening health effects);
(2) products bearing misleading or deceptive claims posing a significant risk of adverse health effects (an indirect health hazard resulting from the delay or discontinuance of appropriate medical treatment).

Using the above criteria and on a case-by-case basis, FDA has successfully regulated many products as evidenced by the report I have released here today. It is easy to see, however, in a comparison with our report on products with unsubstantiated health claims, that FDA is unable to keep up. FDA just does not have the resources to investigate every product on the market with unsubstantiated claims. It is equally important to understand that there are many competing public health priorities facing FDA, and that the Agency must divide its scarce resources among all of the important issues that demand our attention.

H.R. 1709

A final issue transcends label claims and the safety of dietary supplements. The dietary supplement legislation recently introduced in Congress, H.R. 1709, would significantly alter the safety and labeling standards in the FDC Act. For the last 35 years, Congress has placed the burden of establishing safety on manufacturers. Current law requires that there be a reasonable
certainty of no harm from food ingredients. This standard has enabled FDA to act swiftly in cases of real harm.

Under the proposed legislation, the burden of proof, in most cases, would switch from the manufacturer to FDA. Ingredient safety would be presumed, and products would be sold, until evidence of harm is identified. At that point, however, it might be too late for consumers who had unknowingly been exposed to long-term health risks such as cancer or other serious irreversible diseases.

The proposed legislation also would eliminate the need of manufacturers to demonstrate to FDA the scientific validity of a nutrient-disease relationship before making a health claim for an ingredient of a dietary supplement. By contrast, the principal feature of the existing statutory framework is that FDA conducts a review of the scientific literature before authorizing claims about a particular nutrient-disease relationship.

For instance, under current law, if the substance qualifies as a food (because it is used for its taste, aroma, or nutritional value) this review is conducted under the NLEA health claims requirements. If the product does not qualify as a food, Congress requires that the review be conducted under the drug approval provisions of the law.
All of this would change under H.R. 1709. This bill would require FDA to abandon its traditional role of gatekeeper, a function that is designed to protect consumers and enhance freedom of choice by keeping unsubstantiated health claims out of the marketplace.

Instead, the proposed legislation would permit companies to make the initial judgment, without any real guidance as to the standards to use to determine whether a health claim is appropriate. A claim could be made as long as it accurately described the supporting evidence. Thus, a claim could be based on one small preliminary study that in no way establishes the nutrient-disease relationship, as long as the label statements accurately portray the results of that study.

If this legislation is enacted, FDA would only be able to take action after a claim was already on the product label and in stores. Other provisions in the bill could tie FDA up in lengthy administrative proceedings and litigation before final action could be taken to protect consumers from false and deceptive claims.

CONCLUSION

FDA welcomes the dietary supplement debate. We understand and respect the consumer's right to choose dietary supplements that
are safe and bear claims that are scientifically valid. Under these circumstances their ability to choose is well informed and thus truly free.

The explosion of knowledge over the last 30 years represents a public health opportunity of enormous potential value. FDA's responsibility, as always, is to ensure that Americans have access to products that are safe and that actually do what they claim to do.

Mr. Chairman, that concludes our testimony. We would be happy to answer any questions.
Mr. Durbin. Thank you very much, Doctor.
Let me ask you a few questions. I want to try to sort out where we stand and where we may be heading in terms of health claims.
If we can accept as my premise—most of us understand that a diet high in fiber is good for you, and that it can help to avoid certain health problems related to cancer or heart disease. So far, am I all right?
Dr. David Kessler. Yes, sir.
Mr. Durbin. Where the question arises is when you are not talking about a diet high in fiber, but fiber itself in an isolated form, whether or not it still has that same benefit for the individual. As I understand it now, there are several ways to ingest fiber, a fibrous diet—a baked potato might have a certain amount of fiber in it that is good for you, without butter or sour cream.
What kind of representation can be made next to the potato bin in our supermarket once we have gone through this labeling act? What could we find there?
Dr. David Kessler. Foods that are high in fiber are allowed, under our regulations, to make health claims that the risk of cancer may be reduced from foods that are high in fiber; and that is also true for cardiovascular disease. That is what the evidence shows. It is the foods that are high in fiber.
Why is that the case? That is because foods that are high in fiber also are low in fat; there may be another ingredient, but the evidence is there for foods.
The same evidence has not been presented for simply taking a capsule. If you have the sour cream and the baked potato and the butter, and you also take the capsule with fiber, that is not the same. There is no evidence that the supplement itself reduces the risk of cancer or heart disease.
Mr. Durbin. What about food additives? This is not a good example, because I imagine this is loaded with fiber. Cereals, you can’t walk down a cereal line without seeing all of the beta carotene, all the vitamins, high in fiber. They are just short of saying why they are good for you. Is that going to change?
Dr. David Kessler. By May 4, 1994 new food labels will appear and, in fact, the regulations allow health claims specifically for foods that are high in fiber. We also have foods that are low in fat, helping to prevent heart disease. Dr. Yetley can tell you which claims we have permitted. We will permit a health claim statement about the role of fruits and vegetables that are high in antioxidants in reducing the risk of cancer and heart disease. That is where the science is.
On November 1st we will hold a symposium on the antioxidant question in dietary supplements. There is emerging evidence in that field, and we need to look at that.
Beginning May 4, 1994, as you walk down the supermarket aisle you can rest assured that there is a sound scientific base for health claims on food labels.
Mr. Durbin. When it comes to fiber tablets, isolated fiber, what you are saying is you don’t believe the scientific evidence is there to prove that it has the same positive impact in terms of health benefit?
Dr. David Kessler. That is correct. We don't see the science there on that. I could let Dr. Yetley go through the science if you would like.

Mr. Durbin. I am trying to take this through with a shorthand version. I assume that if I had a company that sold a tablet that had fiber in it that I would have to go through, under current law, a different procedure to be able to not just sell this tablet in the future but be able to represent that my high-fiber tablet is going to have the same benefit as this cereal or that baked potato in terms of reducing cancer risk or heart disease?

Dr. David Kessler. Yes, there would have to be scientific evidence that showed that taking fiber alone outside of a diet would have affect. There needs to be some science to that.

Mr. Durbin. Senator Hatch and Mr. Richardson argue that that is an expensive undertaking. They used $360 million, 12 years in the evaluation process, et cetera. Is that what you are faced with if you are the manufacturer of a fiber tablet under existing law if you want to make a health claim?

Dr. David Kessler. No. Congress specifically set a different standard for foods in the Nutrition Labeling and Education Act. You did not use the drug standard. Prior to the Nutrition Labeling and Education Act in 1990 if you wanted to say fiber reduces the risk of cancer or heart disease it automatically became a drug, and then you had to do adequate and well-controlled trials. The level of proof was a very high one and still is for a drug.

What Congress did in 1990 was to recognize that food can contribute to health, and you lowered that standard. You changed that standard from well-controlled trials to one of significant scientific agreement that allows claims to be approved based on a lot of different types of studies.

For example, we are not relying on the manufacturers of folic acid, but on a Hungarian study and a study done in the U.K. The manufacturer didn't undertake a study. Foods have a different standard from drugs, where we can establish that scientific basis more readily.

Mr. Durbin. For example, a brand of product like Metamucil which I understand is a fiber supplement which would not fall in the two categories, a food additive or—am I right? It would be a dietary supplement—heads are nodding in every direction here.

Dr. David Kessler. I would be happy to submit information for the record, but my understanding is that Metamucil has been regulated for years as an over-the-counter drug. Basically, it is a nonprescription drug.

Mr. Durbin. Would it fall in the category of dietary supplement?

Mr. Taylor. A claim for any product for use as a laxative or other drug kind of effect under the existing law would be regulated as a drug. If you took a fiber material and put it into a solution and sold it as a dietary supplement and simply said fiber, dietary supplement, it would be classified as a dietary supplement. Without a claim for a drug benefit, it would have access to the market without that process.

Mr. Durbin. But the claim is what I am getting to. Can I make a claim as the maker of Metamucil that it is going to reduce the
incidence of heart disease or cancer and if I make that claim do I have to go through the regular drug process?

Dr. David Kessler. You may not.

Congress specifically intended that foods be subject to a lesser standard. Establishing the relationship between diet and health doesn't require the drug standard. They don't necessarily require controlled trials, or the same level of proof. Wherein you had 90 percent of the National Academy of Sciences essentially agreeing that with that kind of proof on certain risk reduction claims like reducing the risk of cancer or heart disease, the agency could rely on different scientific evidence in making those decisions for foods.

Now the question becomes what should the standard be for dietary supplements, and Congress couldn't agree on what that standard was in 1990. Some said it should be higher than the standard for foods because it is a concentrated form. Some said it should be the same as for foods, and others said it should be less than foods.

Congress couldn't reach an agreement on that so you asked the agency to make the decision. We proposed that the standard for claims should be the same for dietary supplements as for foods. That decision has prompted all the mail you have gotten, and we are seen as the bad guys in this.

What is striking to me is that this current campaign is being waged with FDA being portrayed as the bad guy. It is always easy to make a target out of a government agency. But what is really at stake here, I believe, is the standard that Congress set out in the Nutrition Labeling and Education Act. It is the standard for foods. It is not the standard for drugs as some would have you believe.

Mr. Durbin. Two more issues.

I asked the question of Senator Hatch and Mr. Richardson if a person can take too many vitamins. What is your opinion?

Dr. David Kessler. Certainly. Certain vitamins, vitamins A, B-6, and D, have toxic levels and you can see cases of nerve damage associated with high-potency vitamin B-6, liver deformities associated with high-potency vitamin A."

Mr. Durbin. I understand legislation prohibits your agency from establishing maximum limits on the potency of any supplement except for categories of elderly, children—

Dr. David Kessler. That is correct. Their legislation would do that, yes.

Mr. Durbin. What is the impact on the Food and Drug Administration if it is your burden to prove that a health claim is wrong? In other words, the industry could put a product on the market, give you 30 days notice it is going on the market, and then you have to prove that that health claim is wrong?

Dr. David Kessler. My personal opinion is you couldn't appropriate enough money for us to be able to go and make the case against each and every company. It is an enormous burden. You are talking about enormous investigation and litigation costs, and that burden would be placed on the taxpayer.

Mr. Durbin. Let me move to an item which I am sure you don't want to talk about, what happened in King County in 1992. You have gotten a lot of publicity about it, your agency has.
There have been a lot of articles written and references made to a raid on Dr. Jonathan Wright's alternative medicine clinic there and whether guns were drawn and whether the agency was heavy-handed.

Mr. TAYLOR. We get asked this question at every hearing.

What has been portrayed as some kind of heavy-handed government raid was something different. That clinic had been under investigation out of concern about an ongoing practice of importing illegal drugs and injecting drugs without observing normal controls that would assure that it is safe. On some occasions Dr. Wright denied entry to legally authorized government inspectors to investigate.

Based on evidence gathered, however, the government did go to a Federal magistrate, obtained a Federal search warrant that was executed in the company of local law enforcement officers, who do carry weapons, and that search warrant was properly executed in accordance with local law enforcement procedures. There was a weapon drawn.

The picture that has been painted, however, of weapons drawn and heavy-handed entry to the facility are not the facts. Entrance was granted, and the matter is pending before a grand jury.

Dr. DAVID KESSLER. I am not privy to the information.

Mr. DURBIN. Mr. Skeen.

Mr. SKEEN. Thank you, Mr. Chairman.

I want to give you a ridiculous proposal. Given the approach that you have seen, what recommendations would you make either to make it work or just to kill it?

Dr. DAVID KESSLER. Mr. Chairman—

Mr. SKEEN. This is your chance.

Dr. DAVID KESSLER. The administration wants very much to work with you and the Chairman, and Congressman Richardson on coming up with something that makes sense. We oppose the Richardson–Hatch bill. I think that, if you are asking me personally—

Mr. SKEEN. Yes sir, I am.

Dr. DAVID KESSLER [continuing]. I think we need to provide access to products. Just clean up the labels. That is what I ask.

We are not going to put anyone out of business. If you want to sell those products, that is fine. As long as there are no problems with safety, as long as you clean up the labels—there is no reason why you have to make claims for Nature's Response, the product the Chairman held up—just get the HIV claim off the label.

That is what really bothers me as a physician. That is where I draw the line. Provide access, just clean up the labels. That is all I am asking for.

Mr. SKEEN. We have gone through the process of legislating nutritional labels in very specific terms. No one has any regulatory authority over the labeling on these—no one?

Dr. DAVID KESSLER. It gets even worse. There are a couple of other areas that I think we need to think about.

The one that Abbey Meyers raised is the issue of how these products are made. Do you really know what is in there just because it is on the label? What do you know about how it was made or
what is actually in there? I think we need to think about good manufacturing practices.

Another thing there may be value in doing, and it will be expensive, but it may be worth doing, is a systematic safety review. In 1972, the agency proposed to remove L-tryptophan from the list of Generally Recognized As Safe (GRAS substances). The Canadians took action against amino acids in the 1980's. I wish we had done that back then.

Every time we try to go after a product there is an outcry. I think we need to talk about how we can do a safety review, how we can assure good manufacturing practices, and how we can make sure that products are not falsely touted for cancer, AIDS, or diabetes.

Mr. SKEEN. Safety review, good labeling and some assurance of what is in that thing?

Dr. DAVID KESSLER. Basic stuff. Provide access, but don't allow vulnerable people to be led to believe that something is going to do something which it is not.

Mr. SKEEN. Thank you very much.

Ms. DELAUNO. Thank you very much.

Do you believe that the dietary supplements ought to be regarded as food or food additives? Do you think that when Congress said they lowered the standard or looked at relaxing the standard on food, and I asked this of Senator Hatch, and he said, no, they should not, they should not be included with food, they are a separate category.

Dr. DAVID KESSLER. What some would have you do is lower the standard even further than the standard of food. Personally I don't agree with that. I see no reason why there should be a different standard. If you are a food manufacturer and you want to make a claim for vitamin C, why should there be one standard for orange juice and another standard for a capsule that is lower?

Certainly if I were a food manufacturer, I would object to that kind of dual standard.

Ms. DELAUNO. So your sense is that the dietary supplement is food like the orange juice. It is all the same category?

Mr. TAYLOR. The concept in the Nutrition Labeling and Education Act is that nutrients should be subject to this more flexible standard applicable to food, the nutrients in food and the nutrients in dietary supplements. That is what NLEA was about. We are very comfortable that the significant scientific agreement standard is the appropriate standard for nutrients.

Ms. DELAUNO. Talk to me about significant scientific agreement because, again, Senator Hatch talked about it and I wanted to ask again. I think he said significant scientific evidence.

I want to differentiate what you are talking about, about significant scientific agreement versus what is in the legislation and get your standard and what goes into that.

What would be the criteria for looking at these products?

Dr. DAVID KESSLER. Let me give you an example, one that hits home to me. Shark cartilage is being widely sold now in health food stores. It is being sold as a dietary supplement. What the nutritional value of shark cartilage is remains to be seen. There are a lot of cancer patients and brain tumor patients taking it.
I was up in Children's Hospital, and our laboratory did the initial work on shark cartilage. Originally we did calf cartilage and Bob Langer and his crew at MIT moved on to shark cartilage. Dr. Langer published a paper in Science that showed under certain conditions there may be something in the shark cartilage he was looking at, that if you extract it in a certain way might have a certain anti-tumor activity.

Somebody saw that paper. They thought from a marketing perspective, I am going to go out and I am going to market shark cartilage. I talked to the scientists involved. There is no evidence that what is being sold has any anti-tumor effect.

In fact, even preliminary studies have shown that the stuff that is being sold has an inflammatory effect. You have brain tumor patients who are flocking to this. That is not, in my estimation, significant scientific agreement. You need to have evidence.

You don't have to have full agreement. It is not a consensus, but you can have epidemiological studies. You can rely on less evidence. How many members of the National Academy would need to concur to be significant? You did not spell that out, is it five, six out of ten?

There is far from conclusive evidence on folic acid and neural tube defects. There is enough evidence to make the health claim. There are still plenty of scientists who object to the fact that one nutrient is going to be the magic ingredient that is going to reduce neural tube defects. They don't buy it. Yet we believe there is enough scientific evidence.

It is a lower level of evidence, but it gives me enough confidence that when consumers take something now that their risks really may be reduced.

Ms. DeLAURO. And the Richardson/Hatch legislation, their standard would be what?

Dr. DAVID KESSLER. If there is a published paper out there in any non-peer-reviewed journal, just anywhere out there saying anything, you could tout that claim made in a paper.

Ms. DeLAURO. In terms of FDA accomplishing what you want to accomplish, not the burden of proof being on FDA where you responded that we didn't have enough money to be able to appropriate to do that, what is the process FDA would go through to deal with the current products on the market and their claims, and what would that take in terms of resources and timing for FDA to be able to accomplish what you would like to accomplish?

Dr. DAVID KESSLER. Congresswoman, Congress set out in the Nutrition Labeling and Education Act 10 specific associations, fiber and heart disease, fiber and cancer, fish oil and heart disease, a whole number of claims. Let me get Dr. Yetley to describe where we are in that process. I think it has worked.

Dr. YETLEY. We reviewed the scientific evidence for the 10 claims that had been laid out. We approved four nutrient disease claims: one on calcium and osteoporosis, one on low fat diets and cancer, another on diets low in saturated fat and cholesterol and reduced risk of heart disease, and another on low sodium diets and reduced risk of hypertension.

Then we approved three related food type claims, diets high in fiber and diets rich in beta carotene, vitamin C, and vitamin E as-
associated with reduced cancer risk. We are now continuing to look at the issue of the anti-oxidant vitamins and cancer and heart disease by having the open science symposium on November 1 to 3. We will follow that with a science symposium on fiber and chronic disease risk. We are continuing to look at this as the science evolves.

Ms. DeLauro. How long did that take to do?

Dr. Yetley. We had Congressionally mandated guidelines. From the time NLEA was passed until the time we proposed regulations was one year. We had one year to finalize.

Ms. DeLauro. Let me just be clear and make sure I understand. What you have done so far and the connections you have made, and the assurances that whatever products are out there now, you can have a standard of judgment as to whether or not they can continue to do the labeling. The product can stay on the market. You want the label.

Dr. David Kessler. Absolutely. That needs to be emphasized. We are not talking about taking any product or denying access. If people want to sell the product, it is fine, but take off the claim if it cannot be substantiated. That is all we are asking.

Ms. DeLauro. Those associations you have already made, that could happen with the products on them.

Dr. David Kessler. Absolutely.

Ms. DeLauro. How much is remaining and how much time will that take?

Mr. Taylor. Of the 10 claims identified in the statute, we evaluated and made decisions on all of them within a two-year period, and we have now approved a total of eight of those claims. The future process involves the submission of petitions.

The companies are able to submit petitions and we have six months to evaluate the petitions. To date, only one petition has been submitted. The agency stands ready to evaluate petitions that are submitted.

Dr. David Kessler. There is a disconnect, Congresswoman, and I think you put your finger on it. The reason you are getting all this mail, and emotions are running very high, is that people think we are going to deny them access to what they want.

I have no problems personally, I cannot speak for the administration. If you want to codify that access, I support that. I don't believe that what consumers are saying is that they want manufacturers to be making claims that are unsubstantiated. That is not what your mail is saying.

I think that what the person out there wants is access. We are not talking about taking products away. But what is being used here and what got everybody ginned up is what the manufacturers really want, which is to be able to make claims with a lower level of proof. That is what manufacturers want.

So they have said to everybody, FDA is going to take away your vitamins. That is not true.

Ms. DeLauro. Do you have enough resources now to conclude the testing that you have to do to meet the demands of those 10 areas in terms of person power and financial help sources, and then let me ask the other question: The criticism I hear about FDA is the timeliness with which you make these decisions also.
Is that timeliness directed to the resource question?

Dr. DAVID KESSLER. Congresswoman, this committee has worked very closely with FDA to make sure we can do our job and we appreciate that enormously.

I need to point out that there was not one extra dollar appropriated to do NLEA. We have done NLEA without one additional penny. People literally have worked nonstop for two years.

One of the reasons why some of these products are out there is because we have not necessarily invested as much in individual resources and cases as getting the regulations out. We rob Peter to pay Paul.

I think the record on those 10 claims is good. To issue a proposal in a year and be final in two years, to do the science and do it thoroughly in that time, makes me think we have gotten it right. I think there are some areas where we have timeliness issues, and I have no problem stipulating to those, but I don’t think that is the case here.

Ms. DELAURO. Would FDA be amenable to an outside panel that was set up to make recommendations to the FDA and in terms of a time certain on deliberation?

Dr. DAVID KESSLER. I have a little problem. I mean if you stand to gain when you serve on a panel. So I have a little problem with industry. As far as outside experts, that is in fact what we did last week. Thursday and Friday of last week, we asked a panel of outside experts, distinguished scientists, to look at the folic acid question and look very hard. They were not of one mind. But we did seek outside expertise and generally we followed that outside expertise.

So the answer is, yes, I personally favor the outside expertise. I don’t think in the end we can abrogate the responsibility. In the end the decision-making needs to reside within the Department, but I welcome that outside expertise.

Mr. DURBIN. Mr. Myers.

Mr. MYERS. I have been on this committee for more than 20 years, and I am not sure what your responsibility or authority is in this area. Going to the question several others asked about the burden of proof, in response to the Chairman a moment ago, you said if the legislation proposed by some of our previous witnesses should pass, you would not have the resources nor could we appropriate enough money for you to make all the investigations required.

You have five categories here and 200 to 250 products there. Have you examined each of those products?

Dr. DAVID KESSLER. We have taken enforcement actions against some. Again, it is a resource issue. Take shark cartilage for example. As I understand it the strategy on shark cartilage has been that people saw a loophole here, and claimed that shark cartilage could be useful in cancer. That was the claim and the decision was to sell this in health food stores, and to get away from FDA requirements.

There is not a framework for dietary supplements that has ever been spelled out in the Act. If you want to say that shark cartilage is a useful treatment for cancer, the burden should be on the manufacturer to prove that.
If you want to determine whether there is a safety problem involving a single ingredient dietary supplement, under at least two circuits, the burden is on the FDA to establish that a product may be harmful. If it is a multi-ingredient capsule the agency can invoke the food additive provisions where the burden shifts to the manufacturer.

I hope that is 100 percent clear, Mr. Myers. It is very complicated stuff. We have never addressed it. We welcome this opportunity.

Mr. Myers. You have not improved it a whole lot.
Dr. David Kessler. I apologize. I was being facetious.
Mr. Myers. We understand the pharmaceutical company decides they want to market a particular drug. They have to go through a procedure?
Dr. David Kessler. Right.
Mr. Myers. How did you acquire the tests on these items you have here, was there a complaint file?
Dr. David Kessler. You can walk into any health food store and buy these.
Mr. Myers. You have the hazard, hypertension immune system.
Dr. David Kessler. We went in. We visited 129 health food stores throughout this country. We just did a survey. We walked in and said, do you have anything to treat cancer. Those products were sold to us.
We asked do you have anything to fight infection and anything to bolster the immune system and those products were sold to us. We asked for any products to treat hypertension, and these products were sold to us. We have become aware of unsubstantiated health claims for products through brochures and catalogs.
These are just some of the 500 we listed in our report. Those products over there are ones that correlate with those charts where there are specific health hazards.
Mr. Myers. These two you tested in your labs?
Dr. David Kessler. We don’t do a lot of testing ourselves. There is some testing in our laboratory if it documents the health hazards that you see on those charts.
There is no evidence one way or the other. These are just unsubstantiated claims. I am not saying there is nothing pharmacologically active in there, but it is anyone’s guess. I don’t know what is in these bottles.
Mr. Myers. The cancer one is an example. I just spoke at noon for a breast cancer group. If they worked, I don’t know why they are selling them under those labels. They could make millions of dollars.
Dr. David Kessler. If you take 40 cents worth of an ingredient and put on a label that it is useful in cancer, you can sell it for a lot of money. The question is, if you are going to make $1 million selling it, all we are asking is that you have the scientific evidence. We work with NIH to get that evidence.
I understand getting that evidence is hard. You cannot just do it overnight. Knowing whether something really works often involves enormous costs. But what is the choice? You go abroad and look at the drugs available for Alzheimer’s disease that you can buy. There are a number of drugs sold in a number of European
countries. You know the debate on health care costs and on drug prices. At least we know the drugs on the market in this country work. There is no evidence that any of these products displayed here work.

Mr. MYERS. Or did not work, is that right?

Dr. DAVID KESSLER. Absolutely. I have no evidence. All I know is that they have been making claims. There are treatments out there to lower blood pressure. We have come a long way in the last couple of decades to treat hypertension.

But selling products that don't work for high blood pressure when there are effective products out there, I have a problem with that. I just see that as coming very close, unfortunately, to fraud.

Mr. MYERS. Is it possible that it might work for one patient and not another?

Dr. DAVID KESSLER. What we have said in this country is that we are going to require some scientific evidence, by saying that we have products that work and we know what works. Here it is a free-for-all.

Mr. MYERS. Well, it is a very complicated problem and one we hear about in our mail and at home in discussion with our constituents. I am an older American. I am a senior citizen. I hear this all the time from them. They don't want to be denied. I quite agree with them.

I am going to tell you what your remark was, that you do not intend to take anything off the market, just make sure they know what they are buying.

Dr. DAVID KESSLER. The only caveat on that is we have to be sure of any safety problems. That is the only caveat.

Mr. MYERS. The three ladies we had earlier, the three earlier, I read their testimony. There would be a malpractice suit here. It was not what they took, it was a problem in manufacturing.

Now, that has nothing to do with what you are addressing here, does it? Aren't we talking about two different issues here?

Dr. DAVID KESSLER. No, we are not. We are talking about whether there is responsibility and whose responsibility it is. Is it our responsibility after the horse is out of the barn, after 38 people die or thousands and thousands are injured? Is that when you want us to be acting, or do you want some kind of evaluation?

Mr. MYERS. You mean L-tryptophan is not a good drug in any case then. It had nothing to do with manufacturing.

Dr. DAVID KESSLER. I am sitting here amazed, to be honest with you. If you look at the L-tryptophan example, that is complex and the science behind that, and the interaction of the component in the L-tryptophan itself, the science is still emerging. It is certainly not simple.

What I just can't figure out is that there were 38 deaths and between five and 10,000 people injured. That was enough to enact the 1938 Food and Drug Act under the elixir of sulfanilamide. That situation had basically the same numbers. I am sitting up here and people want to lower the standards even further? There is a disconnect for me.

Mr. DURBIN. It was.

Mr. MYERS. It was not a bad batch then?
Dr. LOVE. I would like to correct one misperception that was stated previously and that is that L-tryptophan is not a bio-engineered food. It is made with a fermentation process. Probably most of the acids on the market are made using a fermentation process.

It is true that epidemiologic data relates a change in a particular bacterial strain to the occurrence in the fall and winter of 1989 of the epidemic EMS, but clearly there are cases that go back much farther in time than when this strain came up.

But there are other data that make this even more complex. We know that a similar compound which is 5-hydroxy L-tryptophan, again a tryptophan molecule, but not made with the fermentation process, is associated with a number of cases of EMS in the literature.

There have been at least five animal studies now which have compared the different impurities in the non-case associated L-tryptophan as well as the case-associated L-tryptophan and pure L-tryptophan. These studies are all indicating a role for pure L-tryptophan itself in scarring illnesses and inflammation. Taken together, it is a complex phenomenon that we are seeing that indicates that with the L-tryptophan itself, plus some other impurity, plus a susceptible person, you can get this illness of EMS.

We are now getting other EMS problems with other dietary supplements.

Mr. SKEEN. You mentioned that there was a misstatement made about the bio-engineering. I think I misunderstood when the lady was talking about splicing another molecule or something of that kind. Those are done by fermentation, but there is a way to do it.

Dr. LOVE. The scientist was using the fermentation process and genetically engineered the bacteria so that it made more tryptophan than normal, and it was that change, as well as certain changes in the manufacturing process which included having less filtering time, et cetera that was associated with EMS.

As I mentioned, very clearly, there are cases of EMS that are much older than this change with this genetically engineered bacteria.

Mr. MYERS. If I make the assumption that was not the L-tryptophan itself that was the problem. It was a batch or procedure?

Dr. LOVE. No.

Mr. MYERS. Why didn't you stop it if it was so bad? You had the authority to do it. Why did you let it go through so long?

Dr. DAVID KESSLER. In 1972 Congressman—

Mr. MYERS. I know you were not there then.

Dr. DAVID KESSLER. In 1972 the agency proposed to take action. We never did it. I was not there. I can't tell you. All I know is there are people arguing it should be allowed back on the market today.

Mr. MYERS. If a physician prescribes something or if he makes a mistake in prescribing the wrong drug, he is subject to a suit and a tort claim for malpractice.

Are you aware of any health care or food supplement store or dietary store that has ever been sued for malpractice?

Dr. DAVID KESSLER. Counsel tells me that there are suits.

Mr. MYERS. You might enter them into the record. They are subject to the same type of liability that a physician would be for malpractice?
Dr. David Kessler. We will be happy to provide that.
[The information follows:]
The Agency is aware of recent liability suits involving the dietary supplement L-tryptophan. The number of cases filed is approximately 800.

Mr. Peterson. I will be very short. We have kept you obviously too long. However, I have some concerns that I have on this. The test for the categories that these things set into as a food supplement, as we talked about in nutrients, clearly there are not any in some. That takes us into another category. I am a little concerned that you are going to end up getting into drugs very quickly because I think that is what they are going to be.

So I see that there is a problem in differentiation as to what is a nutrient and what is a drug. There needs to be scientific agreement. The question is how do we ever get to that point when I know that there is not good scientific agreement on aspirin and a whole host of other things.

So scientific agreement is going to be an incredibly difficult problem for everything.

Dr. David Kessler. Congressman, let me take the latter and I think Mr. Taylor can answer the former. Scientific agreement was the decision that Congress felt should apply to food. We have used that under 10 health claims that Dr. Yetley went through.

I think it is a standard that works.

Mr. Taylor. With respect to the definition of what a dietary supplement is, that is one of the most critical issues Congress will have to decide. In NLEA, it was standards for food and nutrients.

The legislation to be introduced would include in the dietary supplement any material whose purpose was to increase dietary intake, whether it is a nutrient or not.

So Congress has to consider what category of substance should be given dietary supplement status and be more flexible than its drug standard.

Dr. David Kessler. We certainly would support those compounds that have nutrient value, vitamins and minerals that have nutrient value being subjected to the same standard, not of drugs, but of foods.

We don’t see any reason why it should be even lower than foods where the burden is on the manufacturer.

Mr. Peterson. I appreciate your testimony. I think we are off to a good start in this debate. You expressed strong open-mindedness in trying to get us where we want to go.

Dr. David Kessler. Thank you.

Mr. Durbin. Mr. Walsh.

Mr. Walsh. This issue is before us as a result of the nutrition labeling laws you passed in 1990. So if a product does not make a health claim, you are not interested.

Dr. David Kessler. As long as there is no problem about safety.

Mr. Walsh. What claim does the shark cartilage have on it?

Dr. David Kessler. There is nothing on it.

Mr. Walsh. They don’t say they cure tumors and other cancers?

Dr. David Kessler. There is nothing on this.

Mr. Walsh. Do all of these make scientific claims?
Dr. David Kessler. If I can use this as an example, what has evolved in the industry is you don't put it on the label. You put on a brochure next to the product.

Mr. Walsh. Is it the case with the shark cartilage, that there is a brochure that goes with it?

Dr. David Kessler. There is a lot of material that has been written about it in books and magazines.

Mr. Walsh. The genus of this shark cartilage business was a medical document, is that not true?

Dr. David Kessler. It was an article in Science that my colleagues published back in the early 80s which has nothing to do with what is in here.

Mr. Walsh. It was about shark cartilage?

Dr. David Kessler. That is correct. You hire a PR firm to attach a copy of that article, and you get it on national television, and you write books about it and promote it.

Mr. Walsh. So even with a change in the law, you could not do anything about that?

Dr. David Kessler. That is not entirely correct. The definition of "labeling" in the act is broader than the definition, and I apologize for being technical, of "label." Labeling is something that can accompany the product. If you sell this product and you have the brochures near it, or sell it in interstate commerce with the brochures, we have jurisdiction.

Mr. Walsh. If none of these products made a claim or put out a brochure about their effect on a certain disease, you wouldn't have a problem?

Dr. David Kessler. That is correct.

Mr. Walsh. Even if they are toxic?

Dr. David Kessler. That is the caveat I raised earlier. If there is a known safety problem, I do have a problem with that.

Mr. Walsh. L-tryptophan, does that have a claim that it had an effect on a certain disease when it was sold?

Dr. David Kessler. In catalogs and brochures that accompanied the product, there were specific disease claims, I am told.

Mr. Walsh. If L-tryptophan does not say it can solve narcolepsy, or whatever, and there is no brochure that goes with it, until it kills someone—

Dr. David Kessler. I am not sure I would use the standard that you would have to wait for somebody to die from that to know that there is a problem.

Mr. Walsh. If one of these brochures made no health claims and had no advertisement with it that said it cures HIV or cancer, or other ailments, then how would you get involved with it until someone got sick or died?

Dr. David Kessler. We would not be. I think when one looks at how we should deal with this wide universe that people want access to, I think that is probably the sensible middle ground; provide access to it, just don't allow claims that are not substantiated. Then I think we have to think about how we are going to do some kind of safety evaluation that is not burdensome, that we can do over time and not have a repeat of things like L-tryptophan. It will be a lot of work for the agency and something that initially I had some questions on, but I think we probably would have to take ac-
tion. I do not think it is unreasonable for the agency to bear some of the burden for a safety evaluation that can be done over time.

Mr. WALSH. The question of timing, I think, then becomes one of the key issues here. The FDA has gotten some bad publicity of late, especially regarding some medical devices. The timing problem is that there is a burden put on the manufacturer of having to jump over the hoops established by FDA.

In the words of one of the witnesses here, the medical device business is going to move offshore because they cannot get over those hoops in America whereas they can in other countries.

You mentioned there would be an enormous financial burden on the FDA, if the burden of proof was put on the FDA, an enormous financial burden in terms of time and money to prove that these products were not safe. You would shift that burden back to the manufacturer. Then wouldn’t they have not only the burden of expense but also the burden of time?

Dr. DAVID KESSLER. Congressman, I don’t disagree with you. I think the issue is what is the alternative. The alternative is really to go back to the turn of the century where you have claims that don’t have the substantiation. Either you want the substantiation that products will work, and that will take effort, or you don’t want it.

I am not denying that it takes resources and time to do the science. Everybody wants access to something today and they also want it to work. And they also want it to be safe.

If you want to determine whether something works and it is safe, it will take some time. I don’t disagree with you.

I wish I had a crystal ball so I could look and see whether a product works and if it is safe. Unfortunately, it takes hard science and somebody has to do it.

The issue is do you want the taxpayer funding it or do you want the person who is selling the product to undertake that burden. I look forward to working with the medical device industry. I think there is an opportunity now. The Chairman and I have spoken. We can make sure, perhaps, that the agency has the resources to fulfill its mandates—to get the science. In the end it is the credibility of the industry. What good does this do the dietary supplement industry?

There is some very exciting evidence that is emerging on certain nutrients that can benefit us all. We need to get the answers. All this other stuff clouds the issue. By lowering the standard and allowing anybody to make whatever claims they want and putting the burden on us, you will have to take one of everything here, every morning, and maybe you would luck out. That is why you have to make a decision whether you want the evidence or not.

Mr. WALSH. My concern is that we can go through a whole new process and expand the FDA and give them new responsibilities, and yet we will still not have solved the problem. We can still have another L-tryptophan. This is not resolved by anything we are doing here right now.

I yield back.

Mr. DURBIN. Mr. Pastor.

Mr. PASTOR. I have had about 10 questions. No, Mr. Chairman, I only have one question.
I want to try to frame it this way. Under the Hatch–Richardson bill, taking that shark cartilage bottle that you have there, you said if I had a label on that that claimed to cure an illness, you would not be happy with that. But, if I show the product’s content and use good manufacturing practices in the manufacturing process, showing that the contents are the same in each tablet, and then conduct a safety review, according to the bill, I do have one scientific article published in Science Magazine, that at least has some link to shark cartilage and what it may do to reduce tumors.

Dr. DAVID KESSLER. The scientist who wrote that study says the stuff in there had nothing to do with the stuff in here.

Mr. PASTOR. Did the study show that shark cartilage did—

Dr. DAVID KESSLER. That is not what it showed. The scientists who did the original study, which the manufacturers are out there touting, say the stuff they did bears no resemblance to what is being sold. Preliminary results show that this does more harm than it does good.

Mr. PASTOR. So the scientist actually took that particular dietary supplement and tested it?

Dr. DAVID KESSLER. There have been initial studies on this in the same animal model. It shows, as opposed to stopping inflammation and blood vessel growth, it increases blood vessel growth.

Mr. PASTOR. So there is no article anywhere that would tell me that shark cartilage would reduce tumor growth?

Dr. DAVID KESSLER. There is an article that talks on the anti-angiogenesis properties of certain particular extracts done in this particular way in a certain animal species. There may be suggestive evidence that in the rabbit eye that you could stop some blood vessels. That is what the Science article shows back in 1982.

The evidence to go from that to this being sold for treatment of cancer in humans just is not there by any standards.

Mr. PASTOR. But there is an article?

Dr. DAVID KESSLER. That is my point, Congressman. You can find an article for anything and make any claims. That is my concern about the legislation. I don’t think just because you can wave an article means that there is any credible scientific evidence. Here we have the scientists themselves saying there is no evidence to the stuff in this product and people are waving their article.

Mr. PASTOR. Under H.R. 1709, I could take that article and say it has been shown by—whether it was published in Science or whatever magazine, that if you take a particular shark—take a particular substance from the cartilage, that you will find that either the artery or veins will not increase so, therefore, it might reduce the size of the tumor.

Dr. DAVID KESSLER. You can twist it. You can make 100 jumps to what has been said today.

Mr. PASTOR. So 1709 would say it is okay to say the shark cartilage might reduce—

Dr. DAVID KESSLER. When brain tumor patients are on this they lose their appetite. They have adverse reactions.

Mr. PASTOR. When you say a tablet contains X milligrams of cartilage taken from a particular shark and it may reduce growth, so I am meeting the content requirement. Would that be a good manufacturing process?
Dr. DAVID KESSLER. I have a basic first question. Why is this a dietary supplement?

Mr. PASTOR. It is neither a food or prescription drug, so it has to fall under dietary supplement.

Dr. DAVID KESSLER. It is a marketing scheme, marketed as a dietary supplement to avoid FDA regulation of it.

Mr. PASTOR. If I was to say, based on that Science publication, that X number of milligrams were in one tablet, would I meet the content requirement?

Dr. DAVID KESSLER. Good manufacturing goes a little beyond that. It is how it is manufactured. You want to know the process. If there are X milligrams, that is fine.

Mr. PASTOR. The safety review according to some of the testimony presented before referred to incidence of harm. If there is no incidence of harm, why should you get involved?

Dr. DAVID KESSLER. Absolutely. But it is the fact that it is being touted for that. I came from that laboratory that published that article. That is why it is of such concern to me.

Mr. PASTOR. All I want to point out is that I could take your labeling requirements and take 1709, and if I did not have incidence of harm, then I could sell this product as a dietary supplement.

Dr. DAVID KESSLER. Without the claim.

Mr. PASTOR. I can, I have the article. It is under 1709.

Dr. DAVID KESSLER. That is right. That the article would allow you to put the claim on the bottle and you would walk into a store and see the shark cartilage for the treatment of cancer.

Mr. PASTOR. I yield back my time.

Mr. DURBIN. Are the products in the health hazard group here out of circulation?

Dr. DAVID KESSLER. Dr. Love?

Dr. LOVE. Very few of them are out of circulation.

Dr. DAVID KESSLER. You could sit here and rightfully say FDA is not doing enough.

Mr. DURBIN. You have established those products are dangerous and they are still being sold.

Dr. LOVE. We have tried to make people aware of the risk with these. We are doing limited actions with these. The industry has taken certain limited actions such as with germanium. They made a voluntary recall of many of the chaparral products in December. It is very hard to target all of them. It has to do with how much proof you need before you take some action.

Dr. DAVID KESSLER. The burden is on us for safety for the vast majority of those kind of compounds.

Mr. DURBIN. Under current law, before you get the new responsibility under 1709, if that happens, you cannot keep up with taking hazardous dietary supplements off the market.

Mr. TAYLOR. That is the harsh reality we are dealing with. We have to prove it is a hazard. It takes an enormous amount of resources to do that. We have some investigations under way regarding some of these products, but the universe of products is very large. That is the harsh reality.

Dr. DAVID KESSLER. It is essentially an unregulated industry the way it stands. There are those who want to open the door to even further claims.
Ms. DeLAURO. But the burden of proof is now on the manufacturers?

Dr. DAVID KESSLER. For safety.

Mr. TAYLOR. The problem is that it depends. This was the answer the commissioner gave to Mr. Myers. Under the current state of the law if the materials are in combination with other materials, then we can shift the burden to the company.

The companies have resisted that theory in cases where you are putting the nutrient or the supplement in a capsule. The courts have said, if it is just a single supplement or nutrient in a capsule, then the burden is on FDA to prove the harm. Many of these products are being sold as solutions or liquids and we could not shift the burden.

Dr. DAVID KESSLER. In the case in Washington that the chairman referred to, we had evidence that certain substances, injectables, were not being manufactured using good manufacturing standards. That one action generated an enormous amount of heat.

We have taken certain actions, but tomorrow if FDA takes all of that stuff away, your mail is going to go even further. That is the reality. In 1972, the agency wanted to remove the GRAS status for L-tryptophan and that was not done. The transaction costs in energy and resources, not just dollars, to do each one of these when you are fought tooth and nail, are very high.

Mr. PASTOR. Mr. Chairman, I was just handed this report. It has in here two articles, one by George Comstock that deals with shark cartilage and the other is by James Matthew, Journal of the National Cancer Institute, 1992, which both claim that shark cartilage will diminish tumor growth.

Dr. DAVID KESSLER. I will be glad to go to our colleagues at the National Cancer Institutes. There is no evidence that shark cartilage has effect on human cancer.

Mr. DURBIN. We are going to take a five-minute break and resume. The next panel is Mr. Cordaro, Mr. Kessler, Ms. Whittekin, and Mr. McNamara.

[Recess.]
THE COMMITTEE ON THE LEGISLATIVE Scheduler of the Senate

WITNESSES

J. B. CORDARO, PRESIDENT, COUNCIL FOR RESPONSIBLE NUTRITION; GERRY KESSLER, EXECUTIVE DIRECTOR, NUTRITION HEALTH ALLIANCE;
MARTIE WHITTEKIN, IMMEDIATE PAST PRESIDENT, NATIONAL NUTRITIONAL FOOD ASSOCIATION;
STEPHEN McNAMARA, ON BEHALF OF THE UTAH NATURAL PRODUCT ALLIANCE

Mr. Durbin. If we could ask everyone to please take a seat, we will resume the testimony.

We met Mr. Cardaro, Ms. Whittekin is here. Mr. Kessler will be back in a moment. Mr. McNamara is here.

Mr. Cardaro, would you like to start?

We are going to give you five minutes with a little flexibility and then give the members five minute and hold that very tight.

Mr. CORDARO. Mr. Chairman, in the interest of moving along, although I have a rather detailed statement I submitted for the record and I tried to summarize that to five or so minutes, I would like to shorten it more and go to the heart of what I consider the most critical elements.

As you can see, the Council for Responsible Nutrition, as an association of 66 of the major manufacturers of dietary supplements, has identified several problem areas that we believe find the rationale in the legislation. They are that FDA has demonstrated bias against supplements over the years. Secondly, that FDA has abused its enforcement authority.

Thirdly, FDA has subverted the 1976 amendment to the Food, Drug, and Cosmetic, Act, namely the Rogers-Proxmire Amendment.

Four, that FDA has misinterpreted the health claims standard under the Nutrition Labeling and Education Act.

Five, that the FDA procedures used to implement the NLEA are cumbersome and inhibit implementation.

Sixth, that FDA has a warped definition of what a dietary supplement is, and finally is that the label format that FDA treatment has proposed is inappropriate.

In the statement I have provided to you I have given several examples of what we believe underscores those problem areas. What I would like to do is, I would like to focus on what we consider to be the solution, if you will.

The reason I believe that it is important to talk about the solution—we will speak about that without any reference to my notes—is because I have heard a lot of misinformation about the dietary supplement industry today.

I believe it is important that the members understand we are trying to solve the problem. The problem we are trying to solve is that there are 100 million individuals who use these products and another 160 million people who could be improving the quality of

(135)
their life and health status if they also used dietary supplements. What we should be about is trying to fix a problem that exits.

I refer to an old adage, "If it ain't broke, don't fix it." We are saying it is broken and it might be broken and we ought to try to fix the problem. The Council for Responsible Nutrition believes that the bills that have been introduced by Senator Hatch and Congressman Richardson provided framework for fixing the problem that exists.

Without going through all of the specifics of the bills, I believe that they could be narrowed to three key components. The first is safety, the second is quality standards, and the third is information.

I heard Commissioner Kessler say that these products are virtually unregulated. As much as I respect the Office of the Commissioner and as much as I respect the individual who sits in that office, I have to say that that is nonsense. If that were true, that these products that 100 million consumers use were unregulated, then the FDA and the Commissioner would be negligent in not coming to you years ago saying, we have a problem, these products are not regulated, we have to do something about it.

The problem we have identifies one of the key problems, that FDA misuses their enforcement tools. I have identified two key tools—the food additive mechanism, they have tried to say these products are food additives. The court has told them they are not; two circuit courts have said these are not food additives. They refer to FDA as living in an Alice-in-Wonderland situation.

Second is use of a warning letter. FDA tries to jawbone a manufacturer into doing something by sending a warning letter and not giving the manufacturer judicial due process.

One of the corrections that the Richardson and Hatch bill makes is to give a manufacturer the same right that every American should have, and that is the ability to go to court and to address the concerns that the government has raised.

Those are just two examples of where we believe that the regulatory mechanisms are misused.

As far as safety of products, a statement has been made that there is no evidence that these products are safe. Two comments about that: First, most of the vitamins and mineral products are generally recognized as safe not because of what the industry has done, the industry has not done the grass status reviews. This has been done by independent scientific bodies outside of the industry and has been supported by the government.

The second part that troubles me, especially with the chart that FDA had, in listing all of the concerns about dietary supplements, they fail to recognize the fact that the industry is extremely responsible by taking appropriate safety and regulatory action. The Council for Responsible Nutrition and our sister agency, if I can use that sexist term, the National Nutrition Foods Association, and the herbal groups have taken action such as putting dosage limits on vitamin A, putting dosage limits on B–6.

Niacin came up several times today, but no one mentioned that the industry has been extremely responsible and has put dosage limits on niacin products as well as an informative statement on the products that suggests, if a consumer is using the products to
help lower cholesterol levels, that they should be working in consultation with their physician.

We have done the same thing with quality standards. I am sick and tired of hearing that there are no quality standards for this industry. These products are foods. These products are foods for special dietary use. That is what the Congress has said, and that is what the Food, Drug and Cosmetic Act says.

I am not a lawyer but Steve McNamara, one of the most knowledgeable food and drug lawyers in this area, I believe will sustain the point that I have made. That is the first point, that dietary supplements as foods meet the same GNP standards that all food products meet.

We have gone beyond that. We are working with the U.S. pharmacopoeia, we are working together to develop quality standards that address questions like disintegrating. So if anyone says that there are no quality standards for this industry, they do not know what they are talking about.

On the question of information, the reason that consumers buy these products is because they believe that the individual product will have a health or a nutritional value. What you just heard Commissioner Kessler say is that it is okay with FDA if you market a product but you don't tell the consumer what the value is. I think that is backwards, that the manufacturer ought to be allowed to tell the consumer what the value of the product is; and they need to be held accountable for being able to substantiate what is on the label.

One of the reasons we have problems in the marketplace today is the reason the Commissioner indicated when he held up that product and said, there is nothing on the labeling but the consumer is getting information elsewhere. We can't hold the manufacturer accountable for information that is from secondary or tertiary sources. We believe that the value of the product should be on the label. For that to happen, Congress is going to have to direct the FDA to interpret either the existing NLEA standard or the standard that Senator Hatch and Congressman Richardson proposed in such a way that they no longer choke off the flow of information to the consumer.

The Council has just completed an analysis showing that in the narrow area of hospitalization with five diseases—cancer, heart disease, breast cancer, cataracts—that the hospitalization costs could be reduced by $8.7 billion per year if consumers used optimal amounts of antioxidants. This is a study that was done on a very conservative basis.

I would be happy to provide not only the study but the study leaders to the subcommittee, so that you would have an opportunity to review the data.

Thank you very much.

Mr. DURBIN. Thank you.

[The information follows:]
STATEMENT OF J.B. CORDARO

PRESIDENT

COUNCIL FOR RESPONSIBLE NUTRITION

to

U.S. HOUSE OF REPRESENTATIVES

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FDA AND RELATED AGENCIES

APPROPRIATION COMMITTEE

HEARING ON

DIETARY SUPPLEMENT ISSUES INVOLVING FDA

FULL TESTIMONY

October 18, 1993

An Association of the Nutritional Supplements, Ingredients, and other Nutritional Products Industry
CRN

The Council for Responsible Nutrition (CRN) is a trade association of manufacturers of nutritional supplements, ingredients, and other nutritional products. CRN is dedicated to helping improve the environment for consumers to appreciate the need, benefits, safety, and economy of its members' products.

Specifically, CRN's missions are:

• to increase the awareness of the appropriate dietary role for nutritional supplements, ingredients, and other nutritional products by utilizing authoritative and sound scientific, social, and economic information;

• to enhance the credibility of the nutrition industry's message through a proactive communications strategy;

• to protect and promote the interest of the nutritional supplements, ingredients, and other nutritional products industry in the legislative and regulatory arenas; and

• to promote CRN members' interests through services, activities, and events.

J. B. Cordaro

J. B. Cordaro has been president of the Council for Responsible Nutrition since 1982. Cordaro has 28 years experience in domestic and international food, nutrition, and agricultural activities, including senior positions with the Food Safety Council; the congressional Office of Technology Assessment; and the U.S. State Department's Agency for International Development. He also served as the OTA Board staff representative for Senator Hubert Humphrey (D-MN). He is a graduate of Loyola New Orleans with a B.S. degree in government, economics, and philosophy and attended the Georgetown University Graduate School of Foreign Service. He received his advanced degree in agricultural economics, with a special emphasis on nutrition policy planning, from Cornell University.
Mr. Chairman and Members of the Subcommittee, I thank you for the opportunity to participate in this hearing. Congressman Richardson and Senator Hatch have introduced dietary supplement legislation that CRN strongly supports. Both are owed a deep debt of gratitude for their leadership on this issue.

Mr. Chairman, I have a prepared statement, which I can summarize and, of course, I would be pleased to answer your questions.

Significant confusion surrounds the regulation of dietary supplements. This confusion has created bewilderment for the over 100 million consumers of dietary supplements and for those additional millions who should be supplement users to enhance their health. Today's Tower of Babel results in a cacophony of sounds. The air must be cleared and a new regulatory framework established that benefits consumers.

We need to step back to better appreciate the nature of the problem and the appropriate solutions.

There is an old adage "if it ain't broke, don't fix it."

The reverse of this is just as valid, namely "if it's broke, then fix it." Nowhere is "something broken" more evident than with the regulation of dietary supplements. There is an urgent need for Congressional action on this critical public policy.

FDA's inconsistent and haphazard enforcement of regulations governing dietary supplements harms the industry's ability to serve consumers. Responsible manufacturers shy away from providing consumers with accurate and timely information regarding the health benefits of dietary supplements because they fear unwarranted regulatory action by FDA. A very small number of less scrupulous companies, on the other hand, capitalize on FDA's failure to consistently enforce the existing dietary supplement laws and make inappropriate claims with impunity. Unfortunately, FDA uses the actions of these few to tarnish the whole industry.

This unsatisfactory state of affairs led Congress to pass the Dietary Supplement Act of 1992, which imposed a one-year moratorium on the application of the Nutrition Labeling and Education Act (NLEA) to dietary supplements. The moratorium was designed to permit Congress to study the most effective means of regulating dietary supplements.

Without new legislation now, FDA can be expected to continue its misguided policy of restricting access to products and information that consumers want and need to make healthy dietary choices. Congress must help create a new regulatory framework for supplements based on advances in sound science, safe high-quality products, and accurate, truthful, and nonmisleading consumer information.
Seven problem areas define the rationale for legislation. They are:

- FDA demonstrates supplement bias
- FDA abuses enforcement authority
- FDA subverts 1976 amendments
- FDA misinterprets health claims standard
- FDA procedures cumbersome - inhibit implementation
- FDA warps definition of dietary supplement
- FDA label format proposal inappropriate

**FDA Demonstrates Supplement Bias**

FDA continuously demonstrates a negative bias and longstanding hostility against dietary supplement products. This perspective exists even with widespread consumer acceptance and use of vitamins and the emerging science documenting their value in disease prevention and health promotion. FDA refuses to recognize and support the role of dietary supplements to help people obtain nutrients they need. At various times over the years, FDA has sought to require a label on supplements saying they were unnecessary, has tried to severely restrict the quantity of vitamins and minerals permitted in supplements, has attempted to classify most supplements as drugs, has tried to ban many supplements as "unapproved food additives," and has failed to approve health claims for dietary supplements.

FDA approved a health claim for fruits, vegetables, and grain products containing trivial amounts of antioxidant vitamins to prevent cancer, while refusing to approve a claim for these same nutrients when added as fortificants or when provided in dietary supplements. This is clear evidence of the agency's bias and uneven application of regulations against supplements. Another example is the agency's delay in approving a health claim for folic acid, long after both the Centers for Disease Control and Prevention and the American Academy of Pediatrics acknowledged this was vital public health information which should be communicated to women.

These and other examples confirm FDA's determination to ignore the important role of increased intake of beneficial nutrients to help consumers achieve optimal nutritional status. This mindset which permeates FDA's actions is not in the public interest.

The courts have repeatedly overturned FDA on these issues. Congress acted in 1976 to prevent FDA from unreasonably restricting supplement formulations or classifying them as drugs, through passage of the Rogers-Proxmire vitamin and mineral amendments to the Food, Drug, and Cosmetic Act. Without additional and precise legislation now, FDA is unlikely to change its basic negative attitude toward
supplements and will continue to attempt to restrict consumer access to products and information consumers want and need to make healthy dietary choices. Without legislation, supplement regulation will remain at the whim of FDA and its anti-supplement bias that drives its regulatory decisions.

FDA Abuses Enforcement Authority

FDA currently has adequate enforcement power to assure the safety of dietary supplements and to force products making false claims off the market. This authority is spelled out in the Food, Drug, and Cosmetic Act, which defines dietary supplements as "foods for special dietary use." The enforcement authority includes the ability to issue warning letters, execute product seizures, and to obtain a court injunction against manufacturers and sellers with both civil and criminal penalties for violators. But FDA continually abuses this authority.

In 1973, FDA tried to limit vitamin and mineral supplements to no more than 150 percent of the RDA of any nutrient and to classify all higher levels as drugs. The courts over-ruled this effort on two separate occasions and also over-turned separate FDA attempts to classify vitamins A and D as prescription drugs.

FDA has repeatedly attempted to classify several nutrients as food additives, and thus to ban them from the market on the grounds that they have not been precleared by FDA.

The courts have ruled that "special dietary foods" are required to be safe and wholesome, but do not have to be formally precleared by FDA. The food additive provisions, which were enacted in the 1950's to deal with the increasing number of new chemical additives, were not designed to regulate essential nutrients or other dietary ingredients and consequently they are ill-suited for that use. FDA's attempts to apply these provisions to dietary ingredients are misguided. Two courts of appeals have held within the last year that the food additive provisions are not applicable to single entity dietary supplements. The 7th Circuit Court of Appeals criticized FDA's use of this provision calling it an "Alice-in-Wonderland approach."

In regulations proposed in 1990 and again in 1991, FDA asserted that the trace minerals selenium and chromium, which are recognized to be essential to human health are food additives and are not approved for use in food or supplements. This is a radical departure from past regulatory practice, since FDA has for many years recognized these nutrients as "suitable" ingredients for supplements at levels within the safe and adequate range. This inconsistent and haphazard enforcement of regulations governing dietary supplements must be eliminated.
Another area of inappropriate enforcement involves the issuance of warning letters from FDA that assert a product is in "serious violation" of the law, either because the product allegedly contains false or misleading labeling or because it allegedly contains an "unapproved food additive". These letters are promptly put on public display at FDA headquarters and are frequently the subject of reports in the media. However FDA does not allow the company who manufacturers the product to obtain judicial review of the merits of the assertion. This is fundamentally unfair. FDA should not be allowed to issue threatening and disparaging warning letters without the warning letter being subject to judicial review. On the other hand, FDA points to unsubstantiated claims and refuses to use its existing, ample authority to move against the few such "bad actors."

FDA Subverts 1976 Amendments

In the late 60's and early 70's, FDA began efforts to restrict vitamin and mineral supplements to an arbitrary fraction of the U. S. Recommended Daily Allowances (U.S. RDA). When Congress passed the Rogers Proxmire amendment to the Food, Drug, and Cosmetic Act in 1976, FDA was precluded from taking this approach.

Today, 17 years later, FDA has subverted this Congressional mandate by issuing an Advance Notice of Rule-Making (ANPR) raising the same concepts in a "back door" manner, ignoring past judicial and Congressional directives. Even more troubling, FDA ignores the expert scientists who tell them that there are significant health benefits associated with increased intake of nutrients at levels well above the antiquated RDA levels for deficiency.

FDA has stated publicly that they recognize most vitamins are safe within a very broad range of intakes and that it is not the agency's intention to impose severe limitations on these products. However, the only impression one can draw from reading FDA's ANPR is that the intention of the agency is to do just that. According to the ANPR, all dietary supplements are "food additives" and it furthermore suggests that a "dietary supplement limit" (DSL) should be established for all vitamins, minerals, amino acids, herbs, or other ingredients of supplements. In discussing the establishment of upper limits for vitamins and minerals, the ANPR suggests that one alternative would be to set the upper limits equal to the RDA for each nutrient, or some small multiple of the RDA. Since the RDA is only designed to prevent nutritional deficiencies and not to optimize health and prevent disease, this approach is seriously flawed.

The ANPR contains provisions that make it evident that FDA is returning to the failed policies of 20 years ago, when the agency attempted to severely restrict vitamin and mineral supplements. The ANPR is further indication of the need for new, clear-cut legislation in view of FDA's refusal to be guided by the courts or by previous Acts
of Congress. This legislation should acknowledge what millions of consumers can attest to after decades of prior use, that supplements are safe at recommended levels of intake. FDA should stress, or at least acknowledge, the importance of industry self-regulation, which CRN has pioneered, in those few cases where limits are appropriate.

If there are products that do indeed present some demonstrated safety concerns, those can be addressed on a case-by-case basis, as CRN has done. This way consumers would continue to have access to safe dietary supplements without unreasonable restrictions based on the RDA or some arbitrary multiple of the RDA. But FDA must set forth the basis for any safety concerns they have and legislation must assure that they not use such an approach arbitrarily or capriciously.

**FDA Misinterprets Health Claims Standard**

The narrow interpretation FDA has applied toward health claims restricts the flow of scientifically accurate information to consumers and reduces their opportunity to make more informed dietary choices. By depriving consumers of valuable information, FDA's regulations may have unintended and negative consequences for the long term health status of all Americans.

When Congress passed the NLEA, it adopted a "significant scientific agreement" standard as an alternative to either the FTC's "substantial evidence" standard or a "scientific consensus" standard. The legislative history makes it clear that Congress intended this standard to require a degree of scientific substantiation for health claims falling somewhere between the preexisting two standards.

Even in his testimony before the House Subcommittee on Health and the Environment on July 29, FDA Commissioner David Kessler said "significant scientific agreement" would represent 50-60% accord but still allows some room for dissent.

However, in applying the statutory standard to the 10 claim areas identified in the NLEA by Congress, it appears FDA has misinterpreted Congress' intent and has required an excessive degree of scientific certainty. FDA has operationally defined "significant scientific agreement" to mean almost the same as consensus. Ultimately, this limits consumer access to important information on diet and the potential for reducing the risk of disease and related health care costs.

An illustration of FDA's too-stringent application of the scientific standard is the omega-3 fatty acid and heart disease claim. Many experts wrote to FDA urging that a health claim be permitted in this area. The experts argued that the support of this claim is at least as strong as the evidence for other health claims approved by FDA. Yet FDA continues to deny the claim. If the leading experts doing research in the
field agree that the link between omega-3 fatty acid and heart disease exists and that consumers should be informed, doesn't that constitute "significant scientific agreement?" We certainly believe it meets Commissioner Kessler's standards. And if it isn't, what does, or what will?

How can NLEA be used to facilitate the flow of truthful, scientific information, if FDA adopts unnecessarily restrictive rules governing health claims? Because of FDA's narrow interpretation of "significant scientific agreement," Congress needs to clarify the standard and direct FDA to a more precise application of evaluating health claims. It's time to impose public health considerations into this process to provide consumers access to information that helps reduce the risk of disease.

No license should be given to irresponsible claims. If a claim is made that is false or misleading, FDA will continue to have ample authority to take action against the product as a "misbranded" food. FDA should take action and not just talk about problems in the marketplace.

**FDA Procedures Cumbersome - Inhibit Implementation**

New legislation must better define the systems and procedures for regulating supplements, streamline the decision making process, and facilitate a more cooperative effort between FDA and the supplement industry. CRN has expressed frustration with the procedures used to reach decisions at FDA and has likened it to a "black box." Too little emphasis is placed on the importance of seeking outside, relevant scientific expertise and often when outside opinions are sought, they are not used effectively. An example is the Folic Acid Advisory Committee FDA assembled to evaluate the folic acid health claim issue. The committee was not composed of the specific folic acid researchers most familiar with the data being evaluated.

It is also critical for FDA to streamline its procedures for approving health claims for supplements when recommendations have been issued by another government public health agency. For example, in 1992, FDA joined the Centers for Disease Control and Prevention and other members of the Public Health Service in recommending that all women of child-bearing age get 0.4 mg per day of folic acid to reduce the risk of neural tube birth defects. Unbelievably, it took FDA **13 months** to propose to authorize the inclusion of this information on supplement labeling. Unfortunately, even after FDA's tortuous effort, even now the barriers to making that claim make it almost impossible for industry to implement and for consumers to understand.
FDA Warps Definition of Dietary Supplements

The Food, Drug, and Cosmetic Act does not expressly recognize dietary supplements as a distinct regulatory category. Dietary supplements are encompassed within the category of "foods for special dietary use." Over the years, FDA has regulated dietary supplements sometimes as foods, sometimes as food additives, or sometimes as drugs.

Legislation is needed that would define dietary supplements to include vitamins, minerals, amino acids, herbs, and other "dietary ingredients," i.e., substances that are intended to supplement the diet by increasing the total dietary intake. This broad definition is consistent with the definition that Congress included in the NLEA.

It would include not only dietary supplements sold in tablets, capsules, or similar discrete units, but also acknowledge the reality that supplements are sold in forms characteristic of conventional foods, as long as the product clearly indicated that it was intended to supplement the diet. Consumers would therefore have a choice from various delivery systems to increase their intake of dietary ingredients, and thereby make supplements easier to use and more appealing to consumers.

FDA Label Format Proposal Inappropriate

CRN supports legislation requiring dietary supplement labels to:

- list the name and quantity of each dietary ingredient;
- identify the product as a dietary supplement;
- provide the expiration date.

FDA has taken the untenable position that manufacturers of vitamin and mineral supplements can provide label information only relating to vitamins and minerals. FDA insists this result is mandated by Section 411 of the Food, Drug, and Cosmetic Act. To the extent that FDA's interpretation of Section 411 is accurate, legislation is urgently needed to clarify that manufacturers can provide information about beneficial nutrients, essential or non-essential.

One of the main objectives of the NLEA was to reduce confusion when consumers are confronted with reading a nutrition label. The label format should be user-friendly, readable, and easy to understand. Under the proposal issued by FDA, supplement manufacturers cannot comply with labeling requirements on small package sizes due to space restraints. This does not facilitate an understandable label or implement the intent of Congress.
It is also imperative that any nutrition label format proposed be applicable across the board for all dietary supplements to create consistency and avoid consumer confusion.

Legislation Imperative Now

The cumulative effects of the problems I have just outlined underscore the need for legislation. One provision the legislation must include is to remove the responsibility of establishing regulatory policy for supplements from FDA while keeping FDA's enforcement authority intact. This could be accomplished by establishing an Office for Dietary Supplements within the National Institutes of Health. The Office should be given a mandate to eliminate the long-standing bias and to establish a fair and equitable regulatory policy toward supplements. The Office should be directed to make extensive use of advisory committees composed of industry and consumer representatives, as well as experts in nutrition, who will work with the new Office to ensure the even-handed implementation of a new regulatory framework.

Other principles that should be addressed in the legislation include safety, quality standards and GMP's and health claims.

SAFETY

The Hatch/Richardson bills maintain FDA authority to take action against poisonous or deleterious substances. In addition to current authority, the bills enable FDA to take action against a dietary supplement if:

a) it contains an ingredient that FDA has determined "presents a substantial and unreasonable risk of illness or injury;" or

b) if the manufacturer has not adequately substantiated its safety through a history of safe use or through scientific studies or by other means.

QUALITY STANDARDS AND GMPs

CRN believes that manufacturers should adhere to well-defined quality standards and good manufacturing practices that are properly tailored to dietary supplements. CRN has already developed guidelines for Good Manufacturing Practices (GMPs) for its member companies. The U.S. Pharmacopeia (USP) has adopted these GMPs for use by the dietary supplement industry generally, and has established quality standards for vitamin and mineral supplements.
CRN opposes any suggestion that would have FDA prescribe GMPs and quality standards. The process is already underway by qualified experts at USP. It would not be productive for FDA to engage in needless duplication of effort and waste its own agreeably extremely scarce resources.

**HEALTH CLAIMS**

CRN supports legislation that would overcome FDA's narrow interpretation by which claims are permitted and improve the efficiency of the procedure of getting information to the consumer. H.R.1709 and S.784 accomplish these goals and should be enthusiastically supported.

FDA's failure to approve a workable health claim for folic acid, during the year that has passed since the Public health Service recommendation, is inexcusable. The agency has been reluctant to accept the evidence on folic acid supplements since the NLEA health claims proposals were first issued, and that reluctance has led to continuing delay. The "expert committee" convened by FDA to help with this decision is not expert in this area. It contains only two folic acid researchers and three other nutrition professionals. The majority of the membership is composed of other scientists recruited from various existing FDA drug advisory committees. From the discussion at the first subcommittee meeting, it was evident that most of these other scientists were not previously familiar with folic acid data and were also entirely uninformed or not supportive of the general issues involved in health claims for food.

FDA's failure to approve a health claim for omega-3 fatty acids, in the face of overwhelming agreement among experts that fish oils can help keep hearts and arteries healthy, appears to arise from lack of expertise within the agency and its narrow cadre of advisors. Review of this health claim by experts doing research in the area of omega-3 fatty acids would undoubtedly result in a different decision. Indeed, data submitted in response to the public comment request support a claim.

FDA's approval of a health claim for fruits, vegetables and grain products that are natural sources of vitamin C, beta-carotene, dietary fiber, and soluble fiber--while refusing approval of a health claim for these same nutrients when added as fortificants or when provided in dietary supplements--is evidence of the agency's bias against supplements. It confirms the FDA's determination to ignore the important role of fortification and supplementation in assuring adequate intake of beneficial nutrients.

FDA has misconstrued the NLEA. The agency proposes not only to prohibit manufacturers from making well-substantiated health claims, but also to prohibit manufacturers from disseminating any information regarding the current state of
nutritional science. The absurdity of FDA's position is illustrated by the statement of an FDA official that a supplement manufacturer who provided its customers with a reprint of the New England Journal of Medicine studies documenting the link between vitamin E and heart disease prevention would violate the NLEA.

In other forums, FDA has stated that it would be illegal for a manufacturer to distribute a copy of the agency's own regulations evaluating the evidence on a health claim which was not approved. An example would be FDA's evaluation of the evidence regarding omega-3 fatty acids. Not only does this rigid interpretation of the NLEA make foolish health policy, but it probably violates the First Amendment rights of both manufacturers and consumers.

CRN encourages Congress to provide further guidance and direction to FDA to increase the flow of information to consumers about nutrient/disease relationships. CRN also believes there should be no discrimination between nutrients in food and the same nutrients in supplements.

CRN congratulates Congressman Richardson and his 150 plus co-sponsors in the House of Representatives for the introduction of H.R. 1709, the Dietary Supplement Health and Education Act of 1993. We believe this legislation is a reasonable, rational, and fair approach for Congress to provide direction to the FDA. Coupled with the companion bill of Senator Hatch and his 58 cosponsors, momentum is building for these bills.

The current health care reform initiatives that emphasize the importance of prevention provide added impetus for new dietary supplement legislation. A study just released by a prestigious economic analysis firm demonstrates that the U.S. health care system could save $8.7 billion yearly from reduced hospitalizations resulting from five major diseases if Americans consumed optimal levels of the antioxidant vitamins C, E, and beta-carotene. Over a period of five years, this savings would amount to $43.5 billion. And these figures represent only a portion of the potential savings because hospitalizations represent only one piece of the total medical costs of the diseases studied.

The cost of waiting for FDA to integrate this kind of important information into its regulatory agenda is too great. Congress must show the way by establishing a regulatory framework that acknowledges the important role supplements play to optimize health and prevent disease.
Mr. Durbin. Mr. Gerry Kessler, Executive Director of the Nutrition Health Alliance.

Mr. Gerry Kessler. Thank you. I want to thank the subcommittee for the opportunity of appearing. I understand that the subcommittee is interested in assuring that the FDA is using its resources wisely. I commend you for conducting such an inquiry.

I want to emphasize two points. First, the public has a right to access to dietary supplements. The FDA has repeatedly tried to get supplements off the market by trying to categorize them as food additives or drugs. The Federal courts, Congress and supplement consumers have rejected these efforts to misapply the law. The 1st District Court called FDA's enforcements nonsensical; the 7th Circuit called it an Alice-in-Wonderland approach; and just last week, a Federal court said the government's position is overreaching. The courts said it is apparently the FDA's view that if the company claims milk helps prevent rickets, milk suddenly becomes a drug.

FDA should not be using any of its resources to persist in an enforcement that has been repeatedly criticized by the Federal courts, Congress and the American people.

Second, truthful claims about dietary supplements must be allowed. The current drug-like approval process ensures that consumers will be denied the right to receive this important information. The Richardson bill would allow truthful nonmisleading health information about dietary supplements. Claims would have to be backed by solid science, and the consumer would not have to wait for this critical information until it is perhaps too late for them or their loved ones.

Without getting into a detailed debate on L-tryptophan, I would like to point out that Congress can prevent tragedy like this one by passing the Richardson bill, which would require raw material manufacturers to notify the FDA in advance of any significant changes in the manufacturing process.

It is important to note that the contaminant that was introduced in L-tryptophan was the result of a pharmaceutical company's production process, a process overseen by the Food and Drug Administration. If the Richardson bill had been enacted before this tragedy, the pharmaceutical company which made L-tryptophan would have notified the FDA of significant changes in its manufacturing process, and under the Richardson bill, this contaminant and resulting tragedy would have been prevented.

As for L-tryptophan being dangerous by itself, without the contaminant it is an essential amino acid. It is one of the essential building blocks of life. The manufacturers who produce L-tryptophan or who sold it in the dietary supplement industry recommended 500 milligrams a day.

We take into our diet 12,000 milligrams a day of L-tryptophan from natural sources. If the FDA really believed that L-tryptophan itself was dangerous, why is Canada still selling by prescription millions of dollars of L-tryptophan? If the L-tryptophan is dangerous itself, then they are endangering their public.

Here is a product sold by Mead Johnson called Nutramigen. It is a product for infants. This product is sold in the United States. It is approved by the FDA. It contains added tryptophan and is
sold for our infants. If FDA truly believed that tryptophan was dangerous, why would they allow such a product to be sold with pure tryptophan in it?

This is not naturally occurring. This is synthetically manufactured tryptophan.

There were many companies in this industry, in this country, that were leading sellers of L-tryptophan at the time this occurrence took place. My company did not buy L-tryptophan from Showa Denko and didn't have a single lawsuit on L-tryptophan.

The problem is the result of a contaminant. The FDA knew—knows that that came from a pharmaceutical company and not a dietary supplement company, and what we really would like to see is an investigation into Showa Denko, into what took place in this area in an effort to stop this from happening in the future. I believe that the Richardson bill would be our best effort to do that, since it would require any changes that were significant, that could affect the health of the public, to be reported immediately to FDA so they could oversee that company and take action.

Thank you.

Mr. DURBIN. Thank you, Mr. Kessler.

[The information follows:]
Dietary Supplement Regulation

Statement before the Committee submitted by
Gerald Kessler
President

for
House Appropriations Subcommittee on Agriculture, FDA, and Rural Development
Honorable Richard Durbin, Chairman
October 18, 1993
Mr. Chairman and members of this distinguished committee:

My name is Gerald Kessler. I serve as the President of the Nutritional Health Alliance, a 501-c-4 non-profit educational and advocacy organization. It was founded in 1992 as an alliance among the consumers of natural products—dietary supplements-organic and whole foods, health professionals, retailers, and manufacturers, united to respond to the Food and Drug Administration's regulations issued in accordance with the Nutrition and Labeling Education Act of 1990 or NLEA. Unlike other self-appointed "consumer groups", we actually are supported by consumers who use dietary supplements. We exist to protect the public's right to access and availability of safe and beneficial dietary supplements and to allow truthful, nonmisleading health information on their use. We support and endorse the passage of the Dietary Supplement Health and Education Act, HR 1709 & S. 784. We very much want legislation that will protect consumers, assure quality and safety, and allow responsible, truthful, nonmisleading claims.

The issue of dietary supplement regulation has become controversial and it requires action from this Congress. I want to emphasize two points: First, the public has a right to access to all dietary supplements; vitamins, minerals, herbs, amino acids, and other dietary supplements. The Food and Drug Administration has repeatedly tried to get dietary supplements off the market by trying to categorize them as food additives or drugs. The Federal courts, Congress, and supplement consumers and manufacturers have rejected these efforts to misapply the law. Despite the FDA's protestations that they will not remove supplements from the market, we urge Congress not to listen these words, but to investigate the facts themselves; read the fine print of the FDA's proposals, and to read the judicial opinions of several federal courts on FDA's misapplication of the law. One Federal court called the FDA's use of the food additive provision of the law to remove a dietary supplement, "nonsensical". Another Federal court called it "an Alice in Wonderland approach to commit an end run around the statutory scheme." Just last week, a federal district court in California called the FDA's position on alleged unapproved drug claims for dietary supplements to be, "overreaching". The Court said "it is apparently the FDA's view that if a company claims milk helps prevent rickets, milk suddenly becomes a drug." This overreaching by the Food and Drug Administration must come to an end.

This agency suffers from a long-standing bias against dietary supplements. Historically, Congress has had to address this issue before. In 1976, it passed
the Rogers-Proxmire Amendment, barring the FDA from classifying vitamin and minerals as drugs due to potency. Under the guise of the well intended Nutritional Labeling and Education Act, the FDA once again is seeking to expand its authority to enact regulations that will result in the restriction or removal of dietary supplements from the market. We attach as part of our testimony a brief review and analysis of the FDA's proposed regulations issued June 18, 1993 in the Federal Register and the Dietary Supplement Task Force Report.

The second point which must be addressed by the Congress is that truthful, non-misleading claims must be allowed. Currently, the Food and Drug Administration is using a drug-like approval process under NLEA to allow health claims. The FDA only approved one out of seven affirmative health claims; calcium to prevent osteoporosis. The FDA recently announced it was going to allow a health claim for folic acid and the prevention of neural tube birth defects, a condition which affects 2500 babies a year. This claim was approved despite the fact that the FDA had known for several years that this condition was preventable with folic acid and that the Center for Disease Control and Prevention issued a public health advisory to all women of child bearing age that these defects could be prevented with adequate intake of folic acid. In the interim, women kept ignorant of this claim were at risk and even some unfortunately, gave birth to children with these irreversible defects. If this is how the FDA is going to approve a health claim that Congress authorized it to, we fear for the public health in general for the many other health claims which can be supported by good science.

The solution to this problem lies in HR 1709 and S. 784. This bill will allow truthful, non-misleading health information about dietary supplements. Claims would have to be backed by solid science, and consumers would not have to wait for this critical information until it is perhaps too late for them or their loved ones. We emphasize that the FDA's ability to prosecute for fraudulent or misleading claims and remove any such or unsafe products would be unaltered by the enactment of HR. 1709 & S. 784.
This ANPR represents FDA's official position of how they intend to regulate dietary supplements. This document frequently defers to the recommendations of the Dietary Supplement Task Force Report for these regulatory guidelines.

Pg. 33697-"FDA will consider whether the drug uses of particular amino acids are so well established and widespread as to justify rulemaking to establish as a matter of law that these products are drugs."

Pg. 33698-"Many of these substances ("herbs without a history of documented traditional food use, and plant extracts") have no recognized nutritive value or technical effects."

Pg. 33690-"For many of these ingredients, there are no GRAS (Generally Recognized As Safe) or food additive regulations in effect, and FDA has no basis on which to determine if the ingredient is GRAS."

Pg. 33708-"When herbs are consumed primarily for their taste, aroma, or nutritive value, they are foods. If the herbs are intended (emphasis added) to be consumed for their medicinal effects, however, they are drugs."

Pg. 33709-"A product whose intended use is as a drug will continue to be subject to regulation as a drug."

Pg. 33710- states that "the fact that some herbs have been used for thousands of years does not necessarily justify a conclusion by FDA that their use is safe."

Commentary:

FDA is using the guise of consumer safety to justify their classifying of non-GRAS substances (herbs) as unapproved "food additives". In the proposed regulations (pg. 33699, 33707 & 33709), FDA is attempting to contend that only herbs with a documented "food use", or that are defined as "conventional"
foods are eligible for consideration as being GRAS. Likewise, only substances which fit FDA's definition of a conventional food will be eligible for consideration of a health claim making it impossible for the American public to learn about the health promoting benefits of herbal products in the marketplace.

Restricting Nutrient Potencies

Despite assertions in the media and to Congress to the contrary, the Agency is proposing to restrict potencies by establishing "Dietary Supplement Limits" for herbal products and food supplements as stated on page three of their copy of the Advanced Notice of Proposed Rulemaking of June 18, 1993.

"... to insure the safety of products containing vitamins and minerals, the agency should adopt a Dietary Supplement Limit (DSL) for each vitamin and essential mineral."

They assert that nutrient potencies that exceed the level normally found in foods are in reality drugs. A current New England Journal of Medicine article reported that Vitamin E supplementation can reduce the risk of heart disease in women by 41% and 37% in men. FDA contends that this is justification to classify Vitamin E as a drug because its "intended use" could be to prevent heart disease. To regulate Vitamin E or Garlic in the same way as toxic pharmaceutical drugs and medical devices are, appears to be counter-productive (Vitamin E costs 12 cents per dose and has no side-effects). Such a provision was attempted by FDA in the early 1970's and was the cause of the first round of the Dietary Supplement debate in Congress. This led to the enactment of the Proxmire Amendment which prevents FDA from imposing such arbitrary limits. FDA is seeking to overturn this provision.

Amino Acids Restricted

The FDA refers to the Task Force Report in affirming their stance to limit the availability of protein supplements stating: "there is insufficient evidence to establish 'safe upper levels' of consumption for amino acid supplements." Because of this finding, they justify such a restriction. However, page 14 of the
FASEB report states: "Amino acids as constituents of proteins consumed as foods, are 'safe because foods are inherently safe" and further states "...Amino acids used as dietary supplements, per se, are by definition deemed safe." FDA has either intentionally, or unintentionally misinterpreted the findings of FASEB. The document actually demonstrates there is a large measure of safety with regards to supplementation of individual amino acids.

Furthermore, testimony was presented at a congressional hearing on July 29, 1993 which showed that there are over 400 human studies which demonstrate the safety of single ingredient amino acids for human consumption.

The "Intended Use" Provision-Regulating Supplements as Drugs

FDA is taking a new developed position regarding the regulation of products under their jurisdiction. In the past, regulatory action would be taken if a product was marketed with an unapproved health or disease relationship claim. Now, FDA is contesting that the 'intended use' of the product can constitute regulatory action regardless of whether or not the product itself complies with all regulatory provisions. FDA specifically cites the use of the simple B-Vitamin, niacin, as a nutrient that would be regulated as a drug simply because it has been established that it can lower cholesterol. This establishes a highly dangerous precedent. The majority of people consume dietary supplements for their health-promoting or disease-preventing properties. The FDA classifies any substance used in the treatment, cure, mitigation or even prevention of disease as being a drug. Therefore, the overwhelming majority of herbal products and food supplements are in jeopardy under this new provision.

Herb Safety

In 1992, the World Health Organization released a document entitled Guidelines for The Assessment of Herbal Medicines. This document was designed to provide developing and developed nations with guidelines for how traditional herbal medicines could be integrated into the health care delivery systems of the respective nations. Safety was the overriding
criterion by which the availability of herbal products on the market would be determined.

The WHO Guidelines state: "A guiding principle should be that if the product has been traditionally used without demonstrated harm no specific restrictive regulatory action should be undertaken unless new evidence demands a revised risk-benefit assessment... Prolonged and apparently uneventful use of a substance usually offers testimony of its safety."

J.M. Kingsbury in his book The Problem of Poisonous Plants, points out that not only must the inherent safety/toxicity of the substance be examined, but also the ability of the substance to negate the inherent defenses that every organism has evolved to deal with such potential toxins. He notes, "In order for a plant to be functionally poisonous, it must not only contain a toxic secondary compound, but also possess effective means of presenting that compound to an animal in sufficient concentration, and the compound must be capable of overcoming whatever physiological or biochemical defenses the animal may possess against it. Thus, the presence of a known poisonous principle, even in toxicologically significant amounts, in a plant does not automatically mean that either man or a given species of animal will ever be effectively poisoned by the plant."

A review of the scientific data reveals that the incidence of toxicity from herbal medicines worldwide are extremely rare. In the United States, an exhaustive search of the National Library of Medicine, Centers for Disease Control and the American Association of Poison Control Centers statistics was conducted. Each source documents that toxicity due to ingestion of herbal products is non-existent. Ironically, three of the top four causes of lethal poisonings in the U.S. are due to FDA-approved drugs, and the majority of complaints registered with FDA are attributed to adverse effects of artificial sweeteners. At a recent World Health Organization symposium on the Utilization of Medicinal Plants, Dr. Norman Farnsworth, Ph.D., one of the world's leading pharmacognosists, stated:
"Herbal medicines do not present a major problem with regard to toxicity based on a survey of the scientific literature. In fact, of all classes of substances reported to cause toxicity of sufficient magnitude to be reported in the United States, plants are the least problematic."

The relative safety of herbal products has been assessed both via their extensive historical use, and in many cases, by scientific methods. In addition, the herbalist's and herbal products communities have acted swiftly and effectively to restrict the commerce of potentially toxic herbs, most often pre-empting the FDA in this regard. For the FDA to continue to misrepresent the existing data in an attempt to mislead the public, is not acting in the public's best interest, and shows that FDA has lost is ability to objectively assess public need.
Excerpts From FDA's Dietary Supplement Task Force Report
Released June 15, 1993

The FDA convened an internal Dietary Supplement Task Force in 1991 designed to provide the agency with recommendations of how dietary supplements of vitamins, minerals and herbs should be regulated. This report was published in May, 1992, but not released until thirteen months later, despite the fact that this was at a time when the dietary supplement debate was raging more than ever before. Many of the proposals of the Task Force report are reflected in the Advanced Notice of Proposed Rulemaking published by FDA in the June 18, 1993 Federal Register pursuant to the Nutrition Labeling and Education. The FDA is requesting that comments on the Task Force report and the proposed rulings be submitted by an extended deadline of December 15, 1993.

Pages 2-3
"The task force considered various issues in its deliberations, including how to insure the safety of dietary supplements; how to limit the potential for fraud, i.e., disease claims made on labels or through other means, e.g., magazine articles, newsletters and advertisements; and what steps are necessary to ensure the presence of dietary supplements on the market does not act as a disincentive for drug development. Balanced against these concerns is the strong desire of American consumers for access to dietary supplements. This desire was voiced at the public meeting, and it is one that FDA has tended to ignore in the past."

Pages 3-5
1) Vitamins and Minerals
   The primary recommendation of the task force with regards to vitamins and minerals is to establish a safe daily intake level for each nutrient. Though the Proxmire amendment specifically prevents FDA from establishing limits on nutrient potencies, FDA is seeking to overturn this ruling in a stated attempt to insure public safety.

2) Amino Acids
The Task Force is recommending that amino acids be regulated as drugs when they are sold in capsule or tablet form. If a manufacturer attempts to include a health or disease-related claim on an amino, the product would be classified as a "drug". However, the report also states: "it would require development of a substantial factual record, however, to classify specific amino as drugs per se." This statement may be a preamble to an approval process that is equally prohibitive as that applied to synthetically-derived pharmaceuticals.

The basis for FDA's Amino Acid recommendations is from a report the FDA contracted with the Federation of the American Society of Experimental Biology (FASEB). The purpose of the report was to determine the safety of individual amino acids. The Task Force report quotes FASEB stating that "there is insufficient evidence to establish safe upper levels of consumption for amino acid supplements." However, page 14 of the FASEB report states: "Amino acids as constituents of proteins consumed as foods, are 'safe' because foods are inherently safe ... Amino acids used as dietary supplements, per se, are by definition deemed safe." Also, recent testimony submitted to the House Subcommittee on Health and Environment at hearing on July 29, 1993, provided evidence that over 440 human safety studies have done on human consumption of single ingredient amino acids showing no harmful effects. Of these 440 studies, 200 were on the safety of L-Tryptophan in human beings. Again, no harmful effects were shown.

Page 17- FDA's Proposed "Intended Use" Theory Of Dietary Supplements Will Brand Supplements As Drugs

The Task Force has also studied the concept of "intended use" as it relates to dietary supplements that are used and covertly promoted for use as drugs and has offered recommendations for the regulation of such products." FDA specifically makes an example of the simple B Vitamin Niacin, that is sold "under the guise of a nutrient, but is being used for "lowering blood cholesterol", as an example of a misbranded drug.
FDA is also contending on pg. 17 that a "substance used in dietary supplements must be prior-sanctioned, GRAS or listed under a food additive regulation."

Page 19-20 Herbs

"Herbal products marketed as supplements in tablets, capsules or other form, present a unique problem to the agency. These products are not taken for their taste, aroma, flavor or nutritional value..."

Page 20-Protein Products

"The Task Force has considered the agency's regulation of protein products containing added vitamins and minerals that are currently marketed and represented for a number of uses, including weight loss, weight gain, body building, and general protein and nutrient supplementation. The Task Force believes that protein products containing added vitamins, minerals and amino acids are subject, to the extent applicable, to the recommendations of this report."

NOTE: This section reaffirms FDA's intention of regulating a wide variety of protein and amino products as drugs. This includes protein products for general protein supplementation in blender drinks as well as individual amino acid tablets.

Page 21-Fatty Acids

The report states: "the safety of these fatty acids (including linoleic, arachidonic, and linolenic acids, as well as Omega 3's from Fish Oil,) for use as dietary supplements has not been demonstrated."

NOTE: Supplements such as Cod Liver, other Fish, Wheat Germ and Evening Primrose Oils have been used by millions of consumers for decades yet FDA is recommending their availability be restricted for alleged safety concerns.

Page 22 -Carnitine

FDA is recommending that Carnitine not be available over the counter as a dietary supplement based in the fact that it is beneficial for a number of diseased conditions, that, in their mind, requires medical supervision. This is in spite of the fact that the
report acknowledges that carnitine in newborn infants is not synthesized in the necessary amounts to maintain sufficient blood levels. While this is corrected with normal development, some infants suffer from a metabolic disorder which requires supplementation for life. Carnitine is available by prescription (Carnitor) or as a dietary supplement. The FDA contends that healthy people should be denied the ability to use Carnitine simply because some use it for medical conditions. This is similar to saying that healthy people should be denied the use of calcium simply because others use calcium to prevent osteoporosis.

Other Dietary Supplement Products

This "all other" category of supplements includes non-essential nutrients, herbs without a history of documented traditional food use, plant and animal extracts, and certain other substances. For this category of dietary supplement products, the task force recommended continued use of the "food additive" provisions of the statute unless drug claims are made. Under present food additive provisions, a food additive must be prior approved by FDA before it is marketed. In order for FDA to remove a safe herbal product from the market, it must show that the herb is a "unapproved food additive" on a case by case basis. FDA has used this provision in an attempt to remove safe products from the market in what has been described by the courts as a "Alice in Wonderland approach". Allowing FDA to establish, as a matter of law, that herbs and other such supplements are automatically defined as "food additives", will result in FDA removing the majority of these products from the market with broad sweeping action.

Page 24-Nutrient Well-being is Obtained From the Diet

The report states that the predominant view of those within the nutrition research and health practitioner communities is that the majority of Americans receive adequate nutrition as reflected in the levels indicated by the Recommended Daily Allowances (RDA's). A large percentage of the nation's leading nutritional researchers and research institutes acknowledge that the RDA's were established as a means to prevent gross clinical manifestations of nutritional deficiency. They further acknowledge that nutrient levels for optimal health are in many
cases much higher than RDA levels, and in some cases, even higher than what is obtainable from foods. Two primary examples are supplemental Beta Carotene and the stimulation of CD4 cells in AIDS patients, Vitamin E supplementation in reducing the risk of heart disease and Zinc supplementation in reducing the incidence of macular degeneration. (See Tufts, Harvard, JON, Blumberg, Block, Howe et.al.)

Page 27-28 Defining A Vitamin

"Vitamin- An organic substance that is essential for health but cannot be synthesized by humans, and therefore, must be provided by the diet. If a substance is not essential in the diet it is not a vitamin." FDA recognizes only 13 of the hundreds of nutritional components of foods to be "essential". We would point out that this is a myopic view of nutrition. Science continues to show how hundreds of components of foods can affect the structure and function of the body. Also, who is the FDA to say what is and what is not of nutritive value. A classic example of the FDA's narrow mindset is Vitamin E. Discovered in the 1900's, Vitamin E was claimed to be an invaluable nutrient to the human body. Researchers reported potential benefits of Vitamin E in protecting against cardiovascular disease in the 1940's. Yet, the FDA did not recognize Vitamin E as an essential nutrient until the late 1960's!
Quotes From the Federal Food and Drug Administration Regarding Dietary Supplements

"... Pay careful attention to what is happening [with dietary supplements] in the legislative arena ... if these efforts are successful, there could be created a class of products to compete with approved drugs that are subject to less regulation than approved drugs ... the establishment of a separate regulatory category for supplements could undercut exclusivity rights enjoyed by the holders of approved drug applications."

David Adams, FDA Deputy Commissioner for Policy before the Drug Information Association Annual Meeting, July 12, 1993

"...the task force considered many issues in its deliberations including: to ensure the existence of dietary supplements on the market does not act as a disincentive for drug development..."

Dietary Supplement Task Force Report released June 15, 1993

"It has become fashionable in some quarters to argue that women ought to be able to make such [breast implant] decisions on their own. If members of our society were empowered to make their own decisions about the entire range of products for which the FDA has responsibility, however, the whole rationale for the agency would cease to exist.

Dr. David Kessler, Reported from the New England Journal of Medicine-Wall Street Journal 6/24/92
Mr. DURBIN. Martie Whittekin is the immediate past President of the National Nutritional Food Association.

Ms. WHITTEKIN. NNFA would like to thank the subcommittee for its continuing leadership in this area and having the opportunity to set the record straight. We appreciate your stamina.

I would like to ditto what Mr. Cordaro said about this not being an unregulated industry. We are regulated as foods and as drugs. As soon as we say anything that sounds like it might have some kind of therapeutic benefit, then we become drugs, so we get it from both directions.

I would like to address the subject of safety because it has come up today. Even the FDA admits that most dietary supplements are safe. This chart, which is in my written testimony—as you can see, statistically, supplements are safe. The relative safety of supplements is really not an issue if you keep it in perspective.

I wish I had asked the FDA to please leave their two charts so we could address some of the individual items on the list that have already been resolved or where the risk was misrepresented. In one case, it was a formula, that some Chinese company put a pharmaceutical drug in and that caused a problem. There were specific items listed. The L-tryptophan incident was a tragedy, and the stories we heard today were moving, but they are not more representative of what the industry is about than the Jack-In-the-Box incident is about the food industry as a whole in the country.

The industry was a victim of that contamination. Besides loss of credibility and sales, one of my stores is being sued.

We are ultimately responsible for these things. The industry is making very strong strides in improving our self-regulation, so that we can protect ourselves from the pharmaceutical companies that we ultimately have to buy some of our raw ingredients from. The product was produced to prescription standards.

1709 would be a step in the right direction. We could be here all night rebutting that testimony.

In brief, let me say that FDA appears to be stretching, if not mischaracterizing the science here. The animal studies cited used as much as 140 times the dosage level that a human would have consumed, and in some cases, it was injected. The experts at the Mayo Clinic disagree, and I think their results are very credible.

One of the results of the absence of L-tryptophan has been increased use of Prozac, which is a drug that has addressed some of the same problems that these doctors sent people to buy L-tryptophan for. That drug has been responsible for over 1,300 deaths; so there are always trade-offs, and I think it is important that you keep this in perspective.

It has been brought up that it would be better if we had warning labels. We agree. When we try to put on the label what we would really like to say about the proper use and safe use and dosage labels that—the FDA makes us take them off or stop selling the product because we have implied that this must have a benefit and, therefore, it is a drug. It is a Catch-22. I think the rules need updating; it would probably make their life easier in the long run.

The core issue is not safety, but how to adequately substantiate health claims. We believe that the process we have now is unfair for food products as well as supplements.
The Kellogg Company invested several million dollars in producing four studies on the isolated fiber which we were talking about earlier, apart from the foods, the benefits in lowering cholesterol—several studies. For years, they have been sitting at the FDA in a drawer. They told me, we aren't going to do more research of this kind because there is no benefit. We can't get the claim through the process. There is no incentive for our company.

So I think there are basic issues beyond what is happening to supplements. Supplements, FDA so far approved one claim. You have heard there are thousands of products—one health claim. It is not conceivable that there is only one nutrient that has a benefit.

Dr. Kessler said we know what drugs do. That is not true. Over 51 percent of all the drugs that are released as having been proven efficacious have some serious post-approval risk or are not effective. The real test is what happens in the public, and we have met that test.

Dr. Kessler was correct about one thing; he said that food claims do not have to meet a drug standard. We have to meet one that is much, much tougher. Getting scientists to agree is harder than running some controlled studies which these companies do on their own and control them the way they want them controlled; they can follow a procedure, come out with an end product and show it to FDA and get approval. They are asking us to get most of the scientists in the country to agree on something.

Economists, congressmen, people with ideas don't necessarily agree. We are asking for a standard of evidence that would hold up in court.

Our company should be accountable, that when they make a claim they can actually support it in a court of law, not that they can make up anything they want to.

One of the key things is the difference between an unsubstantiated claim and an unapproved claim. True, you have an implied unapproved claim there. I was confused by what the FDA had here this afternoon because products didn't have claims on them. If the company printed literature, the FDA would have gone after them. They were here because somebody told somebody there was a benefit.

This is a gray area of the law. Are we not allowed to talk about things, publish books or get on TV? It is getting murky. There are people making extreme claims.

One product, the liquid one, sounds pretty far out, and the FDA has plenty of authority to have the company take the product off the market and sort it out later. You may be surprised to know that most of those things, while they are surprising claims, are not unsubstantiated claims. They have not been approved, and that is one reason they are such big secrets from the public.

I have a big stack of textbooks—it is full of citations from peer review journals taking each topic and showing the substantiation. That is one year's worth of studies.

Here is one for every claim that was in the FDA alleged 500-year report. This is a government document. It has documentation in there for sugar control, for example. It has for nutrients to build healthy hair. It has nutrients for diabetes, arthritis, calcium for osteoporosis, vitamin A, et cetera. This was published 22 years ago.
This isn't what somebody's brother-in-law came up with. This is documented.

This stack here, that is just garlic, studies on the benefits of garlic. We can't talk about any of them. They fall into two or three main categories. There is no level of proof today that will meet the FDA standard. That is why the whole process needs to be changed.

[The statement of Ms. Whittlekin follows:]
TESTIMONY OF

MARTIE WHITTEKIN

IMMEDIATE PAST PRESIDENT

NATIONAL NUTRITIONAL FOOD ASSOCIATION

ON THE

REGULATION OF DIETARY SUPPLEMENTS

BEFORE THE

HOUSE APPROPRIATIONS COMMITTEE

SUBCOMMITTEE ON AGRICULTURE

OCTOBER 18, 1993
Chairman Durbin, Ranking Minority Member Skeen and members of the subcommittee, thank you for inviting the National Nutritional Food Association (NNFA) to testify before you today on the issue of the Food and Drug Administration’s (FDA) regulation of dietary supplements. I am Martie Whittekin, the immediate past president of the association.

The NNFA is the trade association representing manufacturers, distributors and retailers in the health food/dietary supplement industry. The approximately 13,000 businesses in the industry serve 10.5 million customers per week, staff 340,000 employees, pay 1.8 billion dollars in wages and sell 3 billion dollars of dietary supplements annually.

Our association testified before your subcommittee on April 1 of this year, specifically to request that the subcommittee consider legislation that would preclude the Secretary of Health and Human Services from using fiscal year 1994 appropriated funds to finalize or implement the NLEA regulations as they apply to dietary supplements. Mr. Chairman, you will recall that you were so concerned with the matter at that time, that you requested a meeting between the NNFA and FDA Commissioner Dr. David Kessler. We thank you for the audience and would like to point to several developments since that May meeting.

Mr. Chairman, you may recall that in our April testimony, we noted that in proposing labeling regulations for dietary supplements, the FDA had rejected the allowance of the nutrient/disease prevention link - or "health claim" - between folic acid and neural tube defects in the fetuses of pregnant women. We cited the rejection of that claim as typical of FDA policy that is driven not by science, but by politics. Now, just last week, after tremendous media coverage of the supplement labeling issue, after overwhelming comment from the public, and after expressed concern from many members of Congress, the FDA has proposed that folic acid supplements be able to carry the health claim of birth defect reduction.

Mr. Chairman, there is one other very important development that has transpired since our last meeting. H.R. 1709 and S. 784, the Dietary Supplement Health and Education Act, introduced by Congressman Bill Richardson and Senator Orrin Hatch respectively, now enjoy substantial bipartisan support. H.R. 1709 has 144 cosponsors, while S. 784 has 59 cosponsors.

The issue of supplement regulation is of critical importance to all of the consumers of the natural products industry and to our members who are well aware that the FDA’s Nutrition Labeling and Education Act (NLEA) regulations will be implemented on December 31, 1993. Those regulations will severely impact the natural products industry and, more importantly, will negatively impact the health of consumers.

While we understand that the subcommittee has already approved the Labor HHS Appropriations bill, the public outcry that has ensued since our last meeting, and the heightened awareness of the controversy by members of Congress, warrants legislation
that will correct the unnecessary burdensome FDA supplement regulations that will become law on December 31, 1993.

Last year Congress passed a one-year moratorium on the implementation of the NLEA regulations with respect to supplements for the purpose of examining the agency’s intentions and to better understand the health ramifications of such action. This year the FDA has re-proposed even more stringent regulations. For this reason, passage of H.R. 1709 this year is vital. Should Congress not address this matter and allow the FDA’s rules to go into effect, millions of Americans will be denied access to many supplements as well as to the dietary information they need to improve their health and to help prevent deadly afflictions such as heart disease and cancer.

On June 15 of this year, the FDA issued an Advance Notice of Proposed Rulemaking (ANPR) that would enable the FDA to arbitrarily remove most supplements - specifically herbs and multiple-component products - from the market by classifying them as “food activities.” FDA has lost several recent court cases that have reaffirmed the illegality of such action with respect to single ingredient supplements. However, the agency has openly stated its intention to remove many safe and efficacious multiple ingredient supplements from stores’ shelves by classifying these products as food additives, or even drugs. Many supplements, including antioxidant formulas, amino acids, and herbal products could be either regulated as drugs or removed from stores’ shelves under the guise of “food additives,” should the agency choose to enforce in such a manner. H.R. 1709 would not permit such arbitrary and unnecessary enforcement by legislating that dietary supplements are neither drugs nor food additives. However, under the legislation, FDA would still have the power to seize unsafe products, enforce against false or misleading claims or regulate products that do not comply with certain Good Manufacturing Practices (GMPs). What the FDA could not do under the legislation would be to misapply the food additive provision of current law against dietary supplements.

I would like to address the matter of safety. Please know that FDA has never enforced against a dietary supplement by declaring a product to be "unsafe." Should a product be proven unsafe, or in any way be associated with an unsafe condition, the NNFA has consistently recommended removal of such product from store’s shelves - and in all such cases the industry has readily complied. The NNFA’s first priority is the safety of dietary supplements for the consumer. We support reasonable regulation by the FDA that ensures the safety of products and that does not infringe on the consumer’s ability to choose products that benefit their health. H.R. 1709 and S. 784 would protect the consumer by mandating that manufacturers of supplements have on file adequate substantiation of the safety of a dietary supplement. Attached to my testimony are two charts. The first compares the relative "toxicity" of various products or incidents and the second summarizes three studies of how many dollars can be saved through disease prevention. These charts illustrate that dietary supplements are quite safe and that they and help reduce health care costs.
On June 15th of this year, FDA also re-issued proposed regulations on the labeling of supplements. To no one's surprise, the agency again rejected the key nutrient/disease links that Congress had directed the agency to address, including the well-established link between antioxidant vitamins and cancer.

The FDA's regulations will not enable the consumer to learn of the health benefits of supplements through any literature produced by the product's manufacturer, including the products' label. This ban also prevents health food stores from providing consumers with third-party scientific literature through newsletters or by placing scientific articles next to products on store shelves. This is one reason why legislative relief is necessary. The only health benefit claim currently permitted by the FDA is that for a calcium supplement and the prevention of osteoporosis. Consumers will not be able to learn that scientific consensus exists on the correlation between antioxidant vitamins and the reduced risk of cancer or heart disease. Curiously, the FDA did approve several health claims, including the link between fiber-containing grains, fruits and vegetable and cancer for foods.

The FDA has not taken full advantage of the body of scientific evidence that correlates nutrient consumption with decreasing risks for certain diseases. The FDA regulations would not permit herbal products - even those with a history of scientifically documented safe and effective use - to make benefit claims on their labels. This imperils the freedom of the consumer to choose dietary supplements based on available knowledge. What made the rejection by the agency of these health claims - of this vital knowledge - so illogical, is the preponderance of science in the area. I would like to insert into the hearing record an annotated bibliography of some scientific articles that demonstrate the variety of evidence that supports supplements in a total health care plan.

Mr. Chairman, since our last meeting, there has been another development that our association finds very disconcerting. On June 15th, the FDA released the final report of the "Dietary Supplements Task Force," which recommends policy to regulate dietary supplements. In the executive summary of that report, it is noted that the task force "considered various issues in its deliberations, including ... what steps are necessary to ensure that the existence of dietary supplements on the market does not act as a disincentive for drug development." This statement offers some insight into the institutional bias by the agency toward our industry.

A history of over-regulation of dietary supplements by FDA has been chronicled and is evidenced in particular by the agency's June 15 proposal to place maximum limits on the amount of consumption of certain vitamins and minerals, which is not allowed under current law. H.R. 1709 would reinforce existing law in that respect. Under the ANPR, the U.S. RDA (Recommended Daily Allowances) would be replaced with a new standard, the RDI (Reference Daily Intake). The RDI's are significantly lower than the U.S. RDA's. These proposed rules run contrary to the consensus within the scientific community that the U.S. RDA is the appropriate measure of acceptable nutritional intake.
In the last year and a half, articles describing the positive effects of vitamins in *The New York Times, Times, Newsweek, and U.S. New & World Report* have created a new appreciation among the general population of the importance of vitamins and other dietary supplements. Television shows, such as last week's Larry King Live, Dateline NBC earlier this year as well as national and local media coverage have educated the public to the problem with FDA's policies. A recent national survey found that confidence in the safety of dietary supplements is high and that most people believe that supplements have beneficial effects.

It is incumbent upon the Congress to pass legislation that will help the health care of all Americans, while enabling them to continue to have the freedom to choose dietary supplements based on all available knowledge.

Thank you, Mr. Chairman. I would be happy to respond to any questions that the committee may have on this matter.
CHART 1  
ESTIMATED SAVINGS IN DISEASE CARE COSTS  
From Improved Nutrition/Prevention Information Dissemination

Kellog Report Estimates:

<table>
<thead>
<tr>
<th>Disease</th>
<th>Savings</th>
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<tbody>
<tr>
<td>Respiratory</td>
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<tr>
<td>Arthritis</td>
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<tr>
<td>Mental illness</td>
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<tr>
<td>Alcoholism</td>
<td>14.5</td>
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<tr>
<td>Digestive Disease</td>
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</tr>
<tr>
<td>Kidney &amp; Urinary</td>
<td>1.3</td>
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</table>

$20.5 Billion

Health Studies Collegium:

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<tr>
<td>Cancer</td>
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<td>Stroke</td>
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<tr>
<td>Cardiovascular</td>
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<td>Adult Diabetes</td>
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<tr>
<td>Gingival &amp; Dental</td>
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<tr>
<td>Neural Tube Defects</td>
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</tr>
<tr>
<td>Hip Fracture</td>
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</table>

$166 Billion

With Use of Natural Therapies including Supplemental Nutrients & Herbal Remedies

Townsend Letter for Doctors:

<table>
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<tr>
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<tbody>
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<tr>
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<tr>
<td>Ulcer</td>
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</table>

$9.6 Billion

TOTAL, SELECTED CONDITIONS = $196.1 BILLION
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<tr>
<th>DEATHS:</th>
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<tr>
<td>Adverse Drug Reactions</td>
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<tr>
<td>Food Contamination:</td>
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<tr>
<td>Charcoal Briquettes (Carbon Monoxide):</td>
</tr>
<tr>
<td>Household cleaners:</td>
</tr>
<tr>
<td>Pesticide poisoning:</td>
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<tr>
<td>Hair Dryers:</td>
</tr>
<tr>
<td>Iron poisoning:</td>
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<tr>
<td>All Plants (house plants, etc.):</td>
</tr>
<tr>
<td>All vitamins:</td>
</tr>
<tr>
<td><strong>Uncontaminated amino acids:</strong></td>
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<tr>
<td>Commercial Herbal Products:</td>
</tr>
</tbody>
</table>

Sources: Calculations based on data from the American Association of Poison Control Centers, National Center for Health Statistics, Journal of the American Medical Association, Centers for Disease Control, U.S. Consumer Product Safety Commission
Mr. Durbin, Mr. McNamara.

Mr. McNamara, Mr. Chairman, Members of the subcommittee, my name is Steve McNamara, and I am here as legal counsel for the Utah Natural Products Alliance. That is a coalition of companies in Utah that have worked together very closely with Senator Hatch on the development of his legislation, and they also are very supportive of the fine work undertaken by Congressmen Richardson and Gallegly.

We have prepared a fairly detailed written brief for your staff. As far as you are interested in the subject of dietary supplement regulation we have citations and copies of FDA documents attached to it. Rather than repeat here or summarize that document, since a number of issues have been raised today, let me respond to a couple of points that others have raised that seem to have been important to Members of the subcommittee and that I think it is important for you to hear about.

When I listened to FDA say they aren’t trying to take away substances from dietary supplement users and that they are really only applying existing law in a rational manner to go after products that present a safety concern I really wonder how they can say that with credibility, knowing the court cases that they have lost just this year.

I have attached to our statement that has been submitted to the committee copies of two different decisions by two different United States Court of Appeals, a total of six Federal judges, that have been approved by Congress. Rather than take my word for what FDA has been doing in regulating this industry, let’s look at these recent Federal court precedents.

The dietary supplement industry was selling a product called black current oil. Black currents are the same things used to make jam with. Black current oil became identified as a reasonable source of a substance called gamma linolenic acid people have decided they would like to use in supplementing their diets. I have met with Sir James Black, who won the Nobel Prize for medicine, who believes that it is a rational and safe substance to use in supplementing the diets.

The dietary supplement industry begins to distribute black current oil. FDA asserted that this substance could not legally be marketed at all because it was an unapproved food additive because you added it to a gelatin capsule. Listen to the United States Court of Appeals who have ruled about this subject. It is in the attachment to the statement.

The U.S. Court of Appeals ruled this year we hold that BCO encapsulated glycerin and gelatin is not a food additive. FDA has not shown that it is adulterated or unsafe in any way.

FDA's assertion that they are only going after unsafe substances is belied by a ruling in 1993 by a Court of Appeals. One said, the only justification for this Alice-in-Wonderland approach is to allow the FDA to make an end-run around the statutory scheme and take action that would put a dietary supplement product off the market. That is the kind of use and abuse of existing law to deny dietary supplement companies and users products that FDA has been following.
Don’t take my word for it. Ask your staff to read the document that we have submitted to you for the record and which I hope you will agree to include in the record and then tell me if you think I am distorting the truth or who is distorting the truth when they sit before you today.

Let’s talk about the labeling issues. It sounds so very reassuring when the Commissioner says, I only want to take action where there is an absence of significant scientific agreement. What does he mean by that?

Do you understand that among the ways in which FDA is applying that standard that they have told the industry you would not be able under that standard to publish a newsletter that truthfully and in a nonmisleading manner summarizes on a monthly basis the recent scientific literature because you won’t have gotten your labeling approved in advance by a FDA regulation?

By the way, that new literature probably can’t be approved anyway because it does not yet amount to significant scientific agreement.

What do we want to do with our government money? Do we want to prevent a company from distributing a truthful and nonmisleading monthly newsletter about recent nutritional and scientific literature? Do we want to set up a system whereby you can’t get that substitute until you get the FDA to agree in advance by publishing a regulation that your summary is a truthful characterization of the recent scientific literature?

Another twist is that their concept of significant scientific agreement is that you may not summarize controversial information and give a truthful and accurate summary of a controversy to your customers. You can only get approved to make a claim if you have proved to their satisfaction that there is ultimate proof of the ultimate question, i.e., that this material will indeed cure, treat or prevent a disease.

We have a number of other concerns.

I heard the bell. I will be quiet. Thank you.

[The statement of Mr. McNamara follows:]
Testimony of
Stephen H. McNamara
Hyman, Phelps & McNamara, P.C.
Washington, D.C.

Legal Counsel for
THE UTAH NATURAL PRODUCTS ALLIANCE (UNPA)
Salt Lake City, Utah

re

"WHY DIETARY SUPPLEMENTS NEED LEGISLATIVE RELIEF"

Mr. Chairman and Members of the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies:

The Utah Natural Products Alliance (UNPA) appreciates the invitation to testify at this hearing to review the regulation of dietary supplement products by the U.S. Food and Drug Administration (FDA). UNPA is an association of Utah companies that manufacture or distribute dietary supplement products. These companies have been working closely with the senior Senator from their state, Senator Orrin Hatch, on behalf of appropriate legislation for dietary supplement products. UNPA strongly endorses the concepts underlying S. 784, the "Dietary Supplement Health and Education Act of 1993," which was introduced by Senator Hatch, for himself and Senators Reid and Murkowski, on April 7 of this year, although UNPA members hope for certain refinements in S. 784 during the legislative process. We note that there are now more than 55 cosponsors of S. 784.

In addition, UNPA members greatly appreciate the interest and support of Congressman Bill Richardson of New Mexico and his colleagues, who have introduced H.R. 1709, also entitled the "Dietary Supplement Health and Education Act of 1993," and who clearly share with Senator Hatch, UNPA, and many Americans the desire to improve the current situation concerning regulation of dietary supplements. We note that H.R. 1709 now has more than 150 cosponsors.

UNPA urges the Members of this Subcommittee to support appropriate legislation to restrain FDA from expending any funds to issue or enforce any new regulations that would impose additional restrictions upon dietary supplement products until such time as the Congress has been able to complete action on the pending dietary supplement legislation, cited above. In this regard, we have been asked by the Subcommittee's staff to explain why UNPA believes dietary supplements are in need of legislative relief from excessive FDA regulation. We are pleased to have the opportunity to do so.
I. NEED FOR NEW LAW TO STOP FDA FROM TRYING TO IMPOSE "FOOD ADDITIVE" STATUS ON SAFE SUPPLEMENTAL FOOD SUBSTANCES

UNPA believes that Congress should amend the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 301 et seq., to make it clear that a food substance provided by a dietary supplement is not subject to regulation as a "food additive" by the FDA. This provision is needed because FDA has tried to prevent consumers from obtaining supplemental amounts of food substances that they want to consume by asserting that such substances are subject to the technical definition of "food additive." FDA has asserted that, as "food additives," food substances are banned from being included in dietary supplements without the prior issuance by FDA of a food additive regulation.1

UNPA believes food additive status for ingredients in dietary supplements should be reserved for chemical preservatives, solvents, processing aids, or other such technical or functional agents.2 FDA should not be permitted to assert "food additive" requirements to prevent consumers from obtaining safe vitamins, minerals, herbs, or other similar food substances that they knowingly want to consume and to add to their diets by means of a dietary supplement.

This is not just a theoretical concern. In recent years FDA has tried -- sometimes successfully -- to deprive dietary supplement consumers of a number of food substances -- including black currant oil, linseed/flaxseed oil, evening primrose oil, co-enzyme Q10, chlorella,


2/ Indeed, these kinds of additives are often not used at all in dietary supplements.
and even orotic acid (a substance found in milk) by arguing that the substances — food substances, desired by consumers in dietary supplement form — were "food additives."

A. Chromium

Indeed, in the recent past FDA even suggested that compounds of chromium were unapproved food additives and thus illegal3 when added to dietary supplements, even though it is clear that chromium is (1) a nutritionally essential mineral, (2) extremely safe (in the trivalent form commonly used in dietary supplements), and (3) not present in optimum amounts in all American diets.4 Instead of raising doubts about the legality of chromium, FDA should have been encouraging its inclusion in multimineral dietary supplement products.

This year, after Senator Hatch had spoken out on the floor of the Senate in 1992 about FDA over-regulation of chromium supplements (Congressional Record, S. 7983, June 11, 1992), FDA implied that it was no longer so concerned about chromium (58 Fed. Reg. 2212, 2170, January 6, 1993); but there is no guarantee that FDA will not revert to its former attitude with respect to this essential nutrient. UNPA believes that FDA should not be allowed to prevent consumers from obtaining supplements of chromium or other safe supplemental food substances by asserting that such substances are "food additives."

B. Black Currant Oil

FDA has asserted to Congress that in pursuing "food additive" allegations against dietary supplement ingredients, it is simply applying the current law in a reasonable manner and is restricting its actions to products that present serious safety concerns. Two very recent federal judicial decisions, however, show that in fact FDA has been distorting the law in its actions to

3/ E.g., see 56 Fed. Reg. 60382 (November 27, 1991) ("Dietary supplements of . . . chromium. . . are not permitted").

try to prevent the marketing of safe dietary supplement substances. We attach to this statement copies of unanimous decisions by three-judge-panels of two different United States courts of appeals, rejecting efforts by FDA to ban safe dietary supplements of black currant oil by means of the legal ruse of asserting that the black currant oil was a "food additive." *United States v. Two Plastic Drums... Viponte Ltd. Black Currant Oil... Traco Labs, Inc.*, 984 F.2d 814 (7th Cir. 1993) ("Traco") (Attachment A); *United States v. 29 Cartons of... an Article of Food... Oakmont Investment Co.*, 987 F.2d 33 (1st Cir. 1993) ("Oakmont") (Attachment B).

Both of these cases involved the same product, i.e., black currant oil intended to be used as a dietary supplement in gelatin capsules. As the Seventh Circuit noted, "FDA has not shown that BCO [black currant oil] is adulterated or unsafe in any way." (Traco, page 820.) Nevertheless, FDA attempted to cause this safe supplemental substance to be banned by asserting that it was a "food additive" (apparently, on the basis that the substance would be "added" to gelatin capsules). If the substance were a "food additive," it would become illegal by operation of law because the food additive provisions of the FDC Act provide that a food additive is "deemed to be unsafe" if it is not the subject of a regulation issued by FDA approving its use. 21 U.S.C. §§ 342(a)(2), 348(a)(2).

Fortunately, both courts unanimously rejected this FDA "food additive" interpretation, which was clearly an effort by FDA personnel to ban a safe dietary supplement by stretching the legal definition of a "food additive" beyond all reason. The decision by the Seventh Circuit Court of Appeals describes the FDA's effort as an "Alice-in-Wonderland" approach. (Traco, page 819.) The decision by the First Circuit describes FDA's approach as "nonsensical." (Oakmont, page 37.)

We understand that FDA recommended to the Department of Justice that petitions for certiorari be filed with the United States Supreme Court to try to have these decisions overturned. Fortunately, it appears that the Solicitor General declined to file such petitions. Nevertheless, we also understand that FDA personnel are now asserting: (1) that they may not
regard FDA as bound by the Traco and Oakmont decisions in other circuits, and that at some point in the future FDA may once again seek to enforce the view that even a single supplemental food substance sold in a gelatin capsule may be regulated by FDA as a "food additive"; and (2) that, notwithstanding Traco and Oakmont, if a company were to add an additional substance to black currant oil, e.g., vitamin E (a combination that dietary supplement products have sometimes provided in the past), such an addition of another substance would create a different set of facts and would enable FDA to assert all over again that the black currant oil in such a product is an unapproved, "illegal" food additive.

It is this sort of FDA action in using and abusing the food additive definition to try to stop the sale of safe dietary supplement products that has caused persons interested in dietary supplements to ask Congress to pass a law that would explicitly provide that FDA may not regulate supplemental substances as food additives. Such a provision is included both in S. 784 and in H.R. 1709. UNPA strongly encourages all Members of Congress to support such legislation.

C. Evening Primrose Oil

I have had a striking personal experience with what I believe is FDA misuse of the food additive definition in the case of dietary supplements. This concerned evening primrose oil. A few years ago, I accompanied Sir James Black, the highly respected British physician-researcher (who has won the Nobel Prize for Medicine), to a meeting with senior personnel at the FDA Center for Food Safety and Applied Nutrition. At that time, Sir James wanted to explain to FDA personnel why he believed that dietary supplements of evening primrose oil were both clearly safe and useful, as a source of gamma linolenic acid (GLA). In what was one of the most surprising and disturbing meetings that I have ever attended at FDA, Sir James was not allowed to explain to FDA personnel why he believed evening primrose oil was safe and appropriate for supplementation; instead, he was told that FDA would not permit such a
presentation and that the agency had already decided that evening primrose oil was an "unapproved food additive" and should not be sold as a dietary supplement.

The extent of FDA's subsequent determination to eradicate all dietary supplements of evening primrose oil from the United States market has also truly surprised me. The most recent (1993) FDA Annual Awards Ceremony provides some instructive insight in this respect: At this ceremony the FDA Commissioner presented a special award to more than 60(!) FDA personnel for pursuing regulatory actions against evening primrose oil. (See Attachment C.) Note that this crusade was taken against a product that I understand is readily available, with a substantial record of safety, to the general public in most of the rest of the modern world -- including, for example, in Canada, Great Britain, Germany, Scandinavia, and Israel. Why should FDA be so determined to deprive American citizens of such a supplemental food substance that they want to consume?

I am a lawyer and not a scientist, so I cannot, of course, speak as an expert about safety. However, FDA assertions that there are safety-related concerns about dietary supplements of evening primrose oil at reasonable potencies appear to me to be incredible. I have heard Nobel Prize-winner Sir James Black express just the contrary view; and, as noted above, the substance is widely available with a substantial record of safety in other sophisticated nations. The fact that FDA would give a major award to its personnel for preventing American consumers from obtaining a dietary supplement that is readily available elsewhere in the modern world is both instructive about FDA's attitude concerning dietary supplements, and, I believe, disturbing.

D. Preventing FDA From Regulating Food Substances In Dietary Supplements As "Food Additives" Would Not Deprive FDA Of Ample Authority To Protect Consumers From Unsafe Products

It is important to note here that preventing FDA from regulating food substances in dietary supplements as "food additives" would not deprive FDA of ample authority to protect
consumers from unsafe products. Section 402(a)(1) of the existing FDC Act, 21 U.S.C. § 342(a)(1), would continue to apply to dietary supplements. This section prohibits a food (including a dietary supplement) from bearing or containing any "poisonous or deleterious substance which may render it injurious to health." Under this section of the FDC Act, however, FDA must at least have some realistic basis to believe and show that a food substance is poisonous or deleterious and "may" render a product injurious to health before the agency can deprive consumers of foods that they want to purchase and consume — and that is just as it should be in a free society.

E. **FDA Disregard Of Its Previous Statements To Congress**

There is another point that UNPA wants to mention here because it should be of special interest to the Subcommittee — since it concerns the matter of adherence by a regulatory agency to laws enacted by Congress.

One of the problems that the dietary supplement industry faces when FDA asserts that an ingredient in a dietary supplement is an "unapproved food additive" is that FDA has interpreted the law in such a manner that, in most circumstances, such an assertion by FDA becomes a necessarily-self-fulfilling prophecy. In general, FDA asserts that the only way for the proponent of such a substance to avoid food additive status, and illegality, is to show that the substance is "generally recognized as safe" ("GRAS") — but FDA then asserts that if its experts state that a substance is not GRAS, then, as a matter of law, the substance cannot be "generally recognized" as safe and therefore must be deemed to be a food additive. E.g., FDA asserts that once a court is presented with affidavits by FDA witnesses stating that a material is not GRAS, there is not even any reason for the court to hold a trial on the subject, and that summary judgment should be granted for FDA.

We raise this matter here because such an argument by FDA — although it may meet with favorable acceptance in a court that does not particularly want to hear a long trial involving a
battle of scientific witnesses who disagree about GRAS status – is, UNPA believes, in flagrant disregard of the interpretation of the food additive definition that FDA conveyed to Congress that it would abide by when the Food Additives Amendment was enacted in 1958. At that time, the representatives of the Department of Health, Education, and Welfare who testified for FDA before Congress about the proposed legislation explicitly stated that no matter what definition of "food additive" was adopted, in an enforcement action the burden would be on FDA to prove that a substance was not GRAS! (See Attachments D and E.) Current FDA practice essentially renders that testimony a nullity. Instead, FDA argues that the burden of proof is on anyone who disagrees with FDA to prove that a substance is GRAS, and that a substance cannot be GRAS, as a matter of law, if FDA says it is not. FDA’s ability to manipulate the burden of proof and the meaning of the food additive definition in this respect is one more reason why the dietary supplement industry needs a clear statutory exception from food additive status for food substances provided as dietary supplements.

II. NEED FOR EXPLICIT LEGISLATIVE RECOGNITION THAT LABELING FOR A DIETARY SUPPLEMENT MAY PROVIDE TRUTHFUL HEALTH-RELATED INFORMATION WITHOUT FDA PRECLEARANCE

As Senator Hatch observed when the Nutrition Labeling and Education Act (NLEA) was passed in 1990, "By their very nature, the dietary supplements must be marketed so that the consumer is informed of the health or disease-prevention benefits that may be conferred." Congressional Record, S. 16611 (October 24, 1990). Nevertheless, since passage of that Act, FDA has repeatedly tried to impose severe restraints on the freedom of dietary supplement manufacturers efficiently to provide truthful health-related information in labeling. 56 Fed. Reg. 60537, 60583 (proposed 21 C.F.R. § 101.14(a)(1)) (November 27, 1991); 58 Fed. Reg. 33700, 33714 (proposed 21 C.F.R. § 101.14(a)(2)) (June 18, 1993). The dietary supplement industry needs enactment of legislation that clearly permits dietary supplement products to include in their labeling truthful information, including truthful information about the physiological properties or other health-related aspects of the products.
Of particular concern here is the matter of a prior restraint on free speech, which should be regarded as anathema by Americans: FDA has repeatedly proposed regulations that would not allow truthful health-related information to be included in labeling for dietary supplements until after FDA first issues a final regulation approving the information — a process that can be expected to take years to complete. 56 Fed. Reg. 60537, 60563 (November 27, 1991); 58 Fed. Reg. 33700, 33714 (June 18, 1993).

Let us be very clear here that UNPA is not arguing that companies should be free to make false or misleading claims. If a labeling claim is made that is false or misleading, or the claim otherwise violates a proper legal standard, FDA already has, should have, and would continue to have, ample authority to take action against the product, as a "misbranded" food. 21 U.S.C. § 343. FDA can initiate a civil seizure action, an injunction action, or a criminal prosecution in response to the marketing of a misbranded dietary supplement, 21 U.S.C. §§ 331-334, or it can request a recall of the product. 21 C.F.R. §§ 7.40-7.59. However, UNPA strongly believes that a dietary supplement distributor should not be required first to obtain FDA permission, including the issuance of a new regulation, before the company may begin to provide health-related information in labeling that the company is prepared to defend in court, if necessary, as truthful, not misleading, and supported by valid scientific evidence. Petitions to FDA to issue regulations can be extremely time-consuming and costly to prepare, and it typically takes FDA years to issue a new regulation. Labeling information about food substances should not be subject to such burdensome and delaying prior restraints. (Furthermore, enforcement convenience for FDA should not be given priority over freedom of speech!)

The extent to which FDA has been willing to go to try to prevent dietary supplements from providing truthful and nonmisleading information in labeling is instructive here. Let's consider just three examples:
A. **Nutrition Newsletters**

FDA regards a company newsletter that reviews the recent scientific literature on health-related effects of nutrients as "labeling" for company products that contain those nutrients. Under the terms of FDA's NLEA regulations, such a newsletter, as "labeling," could not be published without the company's first obtaining FDA approval (by means of the issuance of a new regulation) for every report in the newsletter about a study that would link a nutrient to a health-related condition.\(^5\)

The pragmatic "bottom line" of all of this is that, it appears, FDA's intentions for regulating the labeling of dietary supplement products would effectively prevent a company even from issuing a regular, timely newsletter that provides a truthful and nonmisleading review of the recent scientific literature concerning nutrients that the company sells. This would not only prevent the rendering of a valuable consumer service, it would be a serious breach of the freedom of speech.

B. **Labeling Statements About Evolving Science**

In the course of FDA's rulemaking proceeding on whether to allow health-related claims for omega-3 fatty acids in food labeling, at least one manufacturer filed comments with FDA in which it asked that food companies be permitted to make a truthful and nonmisleading, balanced statement in labeling about the nature and extent of evolving knowledge concerning possible benefits of fish and omega-3 fatty acids in the diet. The model labeling statement that the company's comments proposed reads as follows:

\(^5\) Furthermore, it appears that FDA would probably not be willing to issue a regulation approving such a newsletter *at all* because the recent scientific literature, even if truthfully reported, would probably not yet have reached the state that FDA would regard as "significant scientific agreement" about matters described therein!
There is considerable scientific interest in the subject of whether fish, or certain nutritional substances found in fish, including omega-3 fatty acids, may, when included in the diet on a regular basis, reduce the risk of coronary heart disease. At the present time, there is no established consensus that omega-3 fatty acids definitively have such an effect, but a number of researchers believe that such a relationship may exist, and research is underway to obtain further information.

(Comments by Zapata Haynie Corporation, dated February 20, 1992, filed in FDA Docket No. 91N-0103.)

So far, at least, FDA has refused to permit a statement of this type about omega-3 fatty acids to be used in food labeling — in part, it seems, because the agency appears to be opposed to any labeling at all, even truthful labeling, about evolving health-related knowledge that has not reached the point of (what FDA regards as) significant scientific agreement that a nutrient will inhibit a disease (as distinguished from significant scientific agreement about the current state of evolving knowledge concerning whether a nutrient may have that effect). See generally 58 Fed. Reg. 2478, 2682 (January 6, 1993). I am a lawyer and not a scientist, but I understand from some highly-qualified experts that the model labeling quoted above is a fair and reasonable brief summary of the current state of scientific knowledge and opinion on its subject. It saddens me to realize that my government has tried to put in place a new requirement of law that would prevent a food company from being able to provide truthful and balanced labeling information about evolving scientific knowledge.

If a company wants to make such a statement in labeling, on the premise that the statement is truthful and not misleading, and the company is prepared to defend the scientific validity of the statement, and is willing to assume the risk that FDA might bring regulatory action against the company in court if the agency should conclude that the company has made a false or misleading statement, why should the company not be free to make such a statement on its own responsibility? UNPA believes that a company should not need to wait, first, for the wheels of government at FDA slowly to grind out concurrence that such a statement is truthful
and not misleading, and then, for FDA to publish an authorizing regulation (which, inevitably, takes FDA years to accomplish) before such a statement may be made in labeling. Such prior restraints on speech should not be tolerated by Congress.

Moreover, UNPA believes that companies should not be subjected to a regulatory system where (as appears to be the situation here) FDA may even acknowledge that a proposed labeling statement is truthful, but nevertheless refuse to permit the statement because the agency takes the position that the only health messages it will approve for use in labeling are ones where the described nutrient has been proven to have disease-preventive benefit. Why should a company be denied the freedom to provide a truthful summary of evolving scientific knowledge about whether the nutrient may have such benefit? Is this the kind of law -- restriction on truthful speech about evolving scientific knowledge -- that we want to have in a free society? What kind of country are we creating for ourselves in the future?

UNPA believes that, in addition to the mandatory basic label information (e.g., statement of identity, net quantity of contents, list of ingredients, and name and address of the responsible company), and subject to the need to conform label statements to any pertinent definitions of terms that have been established by law (e.g., in a valid FDA regulation), in general, (1) any truthful and nonmisleading statement should be allowed, so long as it is not a drug claim (and we do not believe the model statement proposed by Zapata Haynie, for example, amounts to a drug claim), (2) such labeling should be subject to government policing and enforcement actions for violations (e.g., for false or misleading statements) but not to preclearance, and (3) a regulatory process that would chill truthful speech should not be tolerated.

C. Labeling Statements About Quantitative Content

As a third example of the extent to which FDA has been willing to go in trying to prevent dietary supplement companies from providing even truthful information in labeling, consider the fact that recent FDA regulatory correspondence has actually told some companies
that they should not state in labeling how much of a supplemental substance is provided by a tablet. For example, in correspondence issued on July 16, 1992, FDA told one company that a label text that the company had proposed to FDA was improper because "[i]nositol[,] choline bitartrate, para-aminobenzoic acid, citrus bioflavonoids and betaine hydrochloride are declared in milligram amounts on the label of this vitamin and mineral tablet." (See Attachment F.) FDA did not want the company to tell its customers how much of each of these substances was present in the product!

Do we really want the public's limited resources being spent by FDA on preventing a dietary supplement company from truthfully telling how much of a substance is present in a dietary supplement?

All of the foregoing examples underscore a continuing concern of the dietary supplement industry. The industry needs to be able to provide truthful and nonmisleading information to its customers. UNPA is full-willing for the industry to be held to a high standard of truthfulness in providing information, but companies should not be required to obtain FDA issuance of an approving regulation before using new labeling. Such a prior restraint on free speech would delay, or effectively prevent entirely, the communication of truthful information about products, and it would also build the size of an additionally-expensive regulatory bureaucracy.

D. The Proposed Legislation Would Not Authorize False Or Misleading Claims

We emphasize that the desired legislation would not authorize false or misleading claims. Whenever FDA believes that a false or misleading claim has been made in labeling for a dietary supplement product, or that a claim has been made that goes so far in providing health-related information that the product should be deemed to be a drug, the agency has ample power to take action in court — under the authority that it already has under existing law — to obtain seizure and condemnation, or to obtain an injunction, or to pursue criminal prosecution — subject to the burden, which FDA properly should bear, to show that the product is indeed in violation. 21
U.S.C. §§ 331-334, 343(a)(1). The federal courts, including even the United States Supreme Court, have affirmed FDA's power to stop improper claims for dietary supplements under existing law by initiating seizures or taking other punitive action when such claims have been made. E.g., Kordel v. United States, 335 U.S. 345 (1948) (criminal prosecution for improper claims for vitamin/mineral products).

Accordingly, if FDA should present to this Subcommittee some extreme or gross examples of products that appear to bear false or misleading claims, or improper drug claims, FDA should be told to exercise its existing authority to take regulatory actions against improperly-promoted products; but it should not be allowed to set in place new rules, as now proposed, that would require honest distributors of dietary supplements to obtain a new regulation from FDA approving each new health-related statement before the statement may appear in labeling. Such a prior restraint on truthful speech is unnecessary and inappropriate. An agency that has not properly exercised its ample existing authority to take action against wrongdoers should not be given new authority that would have the effect of restraining free expression of truthful information by honest citizens as well as the wrongdoers.

III. NEED TO BE ABLE TO OBTAIN JUDICIAL REVIEW OF FDA WARNING LETTERS

UNPA's third legislative goal is a simple request for fundamental procedural fairness in FDA regulation. FDA's primary form of initial regulatory action against allegedly improper dietary supplement products is the issuance of a "warning letter." Such a letter, usually addressed to the president of a company, is put on public display by FDA; and it routinely asserts that a particular product is in "serious violation" of the law — either because the product allegedly bears false or misleading labeling, or because it allegedly contains an "unapproved food additive," or because it allegedly bears labeling that constitutes an unauthorized drug claim. The warning letter also routinely threatens an action in court against the product or company. These letters are promptly put on public display at FDA headquarters, and they are frequently the subject of reports in the press or other media.
Such a warning letter can have a devastating impact upon a company, causing the business community, customers, stockholders, and others to believe that the company is in "serious violation" of law and in danger of an enforcement action in court.

If the points raised by FDA in a warning letter have merit, usually the addressee company will promptly take corrective action. However, in circumstances where a company believes that FDA's letter is in error, a most unreasonable situation currently applies. Even though the letter has been made public by FDA and states to the world that the agency has concluded that the company is in serious violation of law, nevertheless, FDA will not agree that the company can obtain judicial review of the merits of such a letter in court. Instead, FDA argues that such a letter is not technically "final agency action" (because the agency might possibly change its mind -- although the letter contains no hint of that). The effect is that a dietary supplement company can receive from FDA a formal public warning telling the company that it is in serious violation of law, and demanding that it cease marketing a certain product, and yet FDA will not allow the company to obtain judicial review of the merits of the assertion.

Such a situation is fundamentally unfair. FDA should not be allowed to issue threatening and disparaging warning letters, which are made available to the press and the public generally, without having the warning letter be subject to judicial review. UNPA believes that legislation is urgently needed to authorize a dietary supplement company to obtain judicial review of any public warning letter that is issued to it by FDA, asserting that the company is in violation of law. Both S. 784 and H.R. 1709 would have this favorable effect.

IV. CONCLUSION

UNPA hopes the foregoing comments are helpful. We will be pleased to try to answer any questions you may have.

* * * * *
The record supports the district court's finding that Rem did not actually intend to rush to the incoming Chicago train to quickly regain possession of the suitcase before the police found it. Notably, Rem arrived in Chicago and went to a motel to change his clothes and make several telephone calls. The district court stated: "I'm very puzzled in view of his explanation of what happened here that if he was concerned, as I believe he certainly would have reason to be concerned, about his safety that he would have stopped on the way from Midway airport to the Amtrak station and taken the time to check into a motel based on his explanation. I find that incredible."

In addition, when the police approached him, Rem denied having been on the train from Los Angeles—or on any train at all. He had been in Chicago two weeks; could not remember the name or location of his hotel; and was merely "visiting" and "looking around" at the train station. This is the equivalent to an oral disclaimer of ownership. See Tolbert, 692 F.2d at 1044-45 (court found the oral disclaimer showed abandonment). Aside from any issue of standing, at the very least, Rem's statements indicated that he had no expectation of privacy in the suitcase which did not have his name on it, and which was found on a train that defendant had never been aboard.

The district court did not err in finding that Rem had abandoned the suitcase and as a result had no legitimate expectation of privacy in it or its contents. The district court's denial of Rem's motion to suppress the evidence found is

Affirmed.

UNITED STATES of America, Plaintiff-Appellant,

v.

TWO PLASTIC DRUMS, MORE or LESS OF AN ARTICLE OF FOOD, LA. BELED IN PART: VIPONTE, LTD., BLACK CurrANT OIL BATCH NO. BOOFSF 039, etc., and Traco Labs, Inc., Defendants-Appellees.

No. 92-1172.

United States Court of Appeals, Seventh Circuit.


Rehearing Denied March 31, 1993.

The Government, acting through the Food and Drug Administration (FDA), commenced an in rem seizure action against drums of black currant oil (BCO). The United States District Court for the Central District of Illinois, Harold Albert Baker, J., 791 F.Supp. 751, granted the processor's motion for summary judgment. The Government appealed. The Court of Appeals, Cudahy, Circuit Judge, held that encapsulated BCO, with a single active ingredient, was not a "food additive" and, thus, the processor did not have burden of proving that BCO was generally recognized as safe (GRAS), even if BCO was merely a component of BCO dietary supplement capsules.

Affirmed.

1. Food = a "GRAS" food additive, and processor has burden of proving that it is generally recognized as safe (GRAS), even if component is principal component or ingredient sought when food is purchased. Federal Food, Drug, and Cosmetic Act, § 201(a), as amended, 21 U.S.C.A. § 321(a).

See publication Words and Phrases for other judicial constructions and definitions.

2. Food =

Even substances ordinarily considered "food" in common usage may become food

ATTACHMENT A
additives for which processor has burden of proving that they are generally recognized as safe (GRAS). Federal Food, Drug, and Cosmetic Act, § 201(s), as amended, 21 U.S.C.A. § 321(a).

3. Food = \( \frac{1}{4}, 5 \)

Black currant oil (BCO) is dietary supplement itself, not component of dietary supplement and, thus, is “food” and not “food additive,” for which processor would have burden of proving that it is generally recognized as safe (GRAS), when BCO is combined with gelatin and glycerin in capsule form; dietary supplement is BCO combined with inactive ingredients used to market BCO in capsule form. Federal Food, Drug, and Cosmetic Act, § 201(f, s), as amended, 21 U.S.C.A. § 321(f, s).

See publication Words and Phrases for other judicial constructions and definitions.

4. Food = \( \frac{1}{5} \)

For substance to become food additive, for which processor would have burden of proving that it is generally recognized as safe (GRAS), substance must not only be added to food, but must have purpose or effect of altering food’s characteristics; it is not enough for substance to become component of food. Federal Food, Drug, and Cosmetic Act, § 201(f, s), as amended, 21 U.S.C.A. § 321(f, s).

5. Food = \( \frac{1}{5} \)

Encapsulated black currant oil (BCO), the ‘single active ingredient of a dietary supplement, was not “food additive” and; thus, processor did not have burden of proving that BCO was generally recognized as safe (GRAS). Federal Food, Drug, and Cosmetic Act, § 201(f, s), as amended, 21 U.S.C.A. § 321(f, s).

6. Food = \( \frac{1}{5} \)

Congressional purpose of protecting public health did not permit Food and Drug Administration (FDA) to interpret “food additive” within meaning of Federal Food, Drug, and Cosmetic Act as including every

component of food, even single active ingredients, in order to shift burden to processors in all cases to prove that component is generally recognized as safe (GRAS). Federal Food, Drug, and Cosmetic Act, § 201(f, s), as amended, 21 U.S.C.A. § 321(f, s).

7. Food = \( \frac{1}{5}, 24(1) \)

Fact that black currant oil (BCO) was marketed in capsule form, rather than as bottled liquid, did not permit Food and Drug Administration (FDA) to treat BCO as food additive and require processor to prove that it was generally recognized as safe (GRAS); no difference existed between encapsulated BCO and BCO in bottled form. Federal Food, Drug, and Cosmetic Act, § 201(f, s), as amended, 21 U.S.C.A. § 321(f, s).

*The Honorable Hubert L. Will, Senior District Judge for the Northern District of Illinois, is

sitting by designation.


Robert Ullman (argued), Jacob Laufer, Steven Shapiro, Bass & Ullman, New York City, Marc Ansel, Erwin, Martinkus, Cole & Ansel, Champaign, IL, for defendants-appellees.

Before CUDAHY and EASTERBROOK, Circuit Judges, and WILL, Senior District Judge.*
I.

Black currant oil ("BCO") is extracted from the seeds of the black currant berry and is marketed as a dietary supplement for its unique fatty-acid structures. The FDA argues that BCO is a food additive not generally recognized as safe ("GRAS") and seeks to seize and condemn two drums of BCO pursuant to sections 334 and 342 of the Act. A food is adulterated and subject to seizure under section 384 "if it is, or it bears or contains, any food additive which [the Secretary has not recognized as safe pursuant to section 348]." 21 U.S.C. § 342(a)(2)(C). The determination of whether a substance is a food additive is critical in establishing the safety of the substance because, if the substance is deemed a food additive, it is presumed to be unsafe, and the processor has the burden of showing that the substance is GRAS. On the other hand, if a substance is not a food additive, but food in the generic sense, then the substance is presumed safe and the FDA has the burden of showing that the substance is injurious to health. United States v. An Article of Food ... FoodScience Labs., 678 F.2d 725, 739 (7th Cir.1982).

The Act defines "food additive" as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures ... to be safe under the conditions of its intended use....

21 U.S.C. § 321(a). The FDA contends that BCO is a food additive because it is a "component" of food when it is combined with the gelatin and glycerin used to market the BCO in capsules. The gelatin and glycerin encase the BCO to prevent it from becoming rancid. The FDA concedes that if the BCO alone was marketed in both for teaspoon consumption, it would not be a food additive, and the FDA would bear the burden of proving that BCO is injurious to health. But the combination of BCO with glycerin and gelatin, the FDA maintains, creates a food consisting of three components, and thus, three food additives.3 In this instance, therefore, the FDA would require the processor to prove that the substance is safe—something that Traco Labs, the claimant of the two drums of BCO, has not done.

The district court granted summary judgment against the FDA, holding that the FDA's definition of food additive "would obscure any distinction between "foods' under § 321(f) and 'food additives' under § 321(a)" contrary to the intent of Congress. United States v. Two Plastic Drums, More or Less of An Article of Food ... (Traco Labs), 791 F.Supp. 751, 754-55 (C.D.III.1991); see also 761 F.Supp. 70, 74 (C.D.III.1991) (order denying FDA's motion for summary judgment).

II.

[1, 2] We review the grant of summary judgment de novo. Ovejero v. Reilly, 977 F.2d 1120, 1123 (7th Cir.1992). Summary judgment is appropriate when there is a genuine issue of any material fact and the moving party is entitled to judgment as a matter of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250, 106 S.Ct. 2505, 2511, 91 L.Ed.2d 208 (1986). The sole issue presented in this action is whether BCO, when combined with glycerin and gelatin, is a food additive pursuant to section

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1. Because food additives can be thought of as a subset of food in the broadest sense, see Nutri- lab, Inc. v. Schweller, 715 F.2d 335, 337 (7th Cir.1983), reference to food in the generic sense refers to articles of food not considered food additives.

2. Because gelatin and glycerin are GRAS, they are not formally considered "food additives" under the statute.
In determining what is a food additive, we look first to the language of the statute itself, Consumer Product Safety Commission v. GTE Sylvania, Inc., 447 U.S. 102, 108, 100 S.Ct. 2051, 2056, 64 L.Ed.2d 766 (1980), and if the language of the statute is plain, then it is conclusive absent contrary legislative intent. United States v. Ron Pair Enterprises, Inc., 489 U.S. 235, 109 S.Ct. 1026, 103 L.Ed.2d 290 (1989). Section 201(s) defines a food additive as "any substance the intended use of which results in its becoming a component or otherwise affecting the characteristics of any food...." This language is very broad, and thus, the general rule is that a component of an article of food is a food additive, even if the component in question is the "principal component," i.e. the ingredient sought when purchasing the food. Food Science, 678 F.2d at 788. Moreover, even substances ordinarily considered "food" in common usage may become food additives in some circumstances. National Nutritional Foods Ass'n v. Kennedy, 572 F.2d 377, 391 (2d Cir.1978) (vitamins and minerals may be food additives when added to food). In addition, this court has held that DDT found naturally in fish is a food additive under the broad language of the Act. United States v. Ewing Bros. Co., 502 F.2d 715, 721-24 (7th Cir.1974) (Stevens, J.), cert. denied sub nom., Vita Food Prods. of Illinois, Inc. v. United States, 420 U.S. 945, 95 S.Ct. 1324, 43 L.Ed.2d 423 (1975).

[3] The FDA argues that the statutory language clearly indicates that any and every component of an article of food is a food additive. Although we are mindful of the deference due the FDA in construing the statute it administers, Young v. Community Nutrition Inst., 476 U.S. 974, 981, 106 S.Ct. 2360, 2364-65, 90 L.Ed.2d 959 (1986); Chevron U.S.A., Inc. v. NRDC, 467 U.S. 837, 843-44, 104 S.Ct. 2775, 2782, 81 L.Ed.2d 694 (1984); United States v. 25 Cases, More or Less, of An Article of Device, 942 F.2d 1178, 1182 (7th Cir.1991), deference here is unwarranted since its interpretation is contrary to the language and intent of the Act. Demarest v. Manspeaker, 498 U.S. 184, 111 S.Ct. 599, 112 L.Ed.2d 608 (1991) (administrative interpretation of statute contrary to plain language is not entitled to deference). As an initial matter, we question whether BCO can even be considered a "component" under the Act. The term "component," commonly understood and defined as a "a constituent part" or "ingredient," Webster's Third New International Dictionary 466 (1976), loses its meaning when applied to foods used in conjunction with inactive ingredients, as this case amply evidences. Here, the dietary supplement (the food) is nothing but BCO combined with glycerin and gelatin—two inactive substances used for marketing the BCO in capsule form. The gelatin and glycerin do not interact with or change the character of the BCO, but merely act as a container comparable to a bottle containing liquids marketed for teaspoon consumption. The BCO in question is the dietary supplement and the dietary supplement is the BCO. Therefore, to hold that BCO is a component of the dietary supplement would be to find that BCO is a component of itself. Such an interpretation would defy logic and common sense.

[4] But even assuming that a single active "ingredient" of food can be considered a component of the food, the statutory language does not indicate that every component of food is necessarily a food additive. The Act defines "food additive" as a substance "becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. § 201(s) (emphasis added). The FDA interpretation of this provision implies that the language, "or otherwise," is used disjunctively in such a way that a substance is a food additive if (1) it is a component of any food, or (2) affects the characteristics of a food. We think that this interpretation, however, distorts the plain meaning of the provision. The phrase "or otherwise," as employed here, is not used to express two alternative definitions of a food additive. Rather, it is used in a way to clarify or elaborate, such that "otherwise" is correctly read as "similarly." This view comports with established principles of statutory construction holding that courts should rein in broad and general statutory language when such language is
immediately coupled with more limiting language or a specific enumeration. 2A Norman J. Singer, Sutherland on Statutory Construction §§ 47.16, 47.17 (5th ed. 1932) (reviewing doctrines of nocestur a sociis (coupling of words denotes an intention that they be understood in same general sense) and ejusdem generis (general words coupled with statutory enumeration are construed only to embrace objects similar in nature); see also Toilet Goods Ass’n v. Gardner, 278 F.Supp. 786, 790 (S.D.N.Y. 1968) (employing doctrine of ejusdem generis to limit expansive application of color additive provision), aff’d in relevant part, rev’d in part sub nom., Toilet Goods Ass’n v. Finch, 419 F.2d 21 (2d Cir.1969).

The phrase “becoming a component” in section 321(a) is immediately followed by more descriptive language relating to the substance’s effect on food. Moreover, the examples of food additives then enumerated in the Act describe the substances by their function or by their effect on food. 21 U.S.C. § 321(a) (listing as examples of food additives “any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use”); cf. 104 Cong.Rec. 17,417 (remarks of Rep. Williams) (“substances which are used to improve the characteristics of our food are illustrative of the kinds of things this legislation deals with.”); Harry A. Touhmin, Jr., Treatise on the Law of Foods, Drugs and Cosmetics §§ 22.5—22.10 (2d ed. 1963) (grouping food additives according to function). Therefore, simply becoming a “component” of food does not, in and of itself, satisfy the definition of a food additive. To be a food additive, a substance must not only be added to food, but it must also have the purpose or effect of altering a food’s characteristics.

[6] When two or more active ingredients comprise a food, each component is arguably different from the food in such a way that the addition of each has affected the characteristics of the other components and of the food. Thus, courts faced with foods involving two or more active components have held that each component is a food additive. See United States v. 45/19 Kg. Drums of Pure Vegetable Oil, 961 F.2d 808, 812 & n. 3 (9th Cir.) (Evening Primrose Oil (“EPO”) held food additive when encapsulated with Vitamin E, since “EPO is not a single ingredient”—distinguishing the case of BCO encapsulated alone), cert. denied sub nom., B thematic Ltd. v. United States, — U.S. —, 113 S.Ct. 375, 121 L.Ed.2d 287 (1992); Food Science, 678 F.2d at 738 (principal ingredient of food a food additive if combined with another active ingredient); United States v. 41 Cases, More or Less, etc., 420 F.2d 1126, 1130 (5th Cir.1970) (medicated poultry feed found adulterated as containing two-three active ingredients held to be food additives); United States v. 42/19 Tablet Bottles, 779 F.Supp. 253 (E.D.N.Y.1991) (two active non-chemical ingredients of dietary supplement held food additives); United States v. 21 Approximately 100 Kg. Bulk Metal Drums, 761 F.Supp. 190 (D.Me.1991) (BCO held food additive when encapsulated with fish oil and various vitamins and minerals). But when there is only one active component, as is the case here, that single component does not affect the characteristics of the food in question—rather, it constitutes the food. Thus, even if we were to find that BCO was a component of the BCO dietary supplement capsules, the language of the Act indicates that it is not a food additive because it is the single active ingredient, it does not affect the characteristics of any food.


amounts to import or improve desirable properties or suppress undesirable properties.” Webster’s, supra, at 24.
Upon reviewing the structure and evolution of food regulation under the Act, it is clear that Congress intended to distinguish food additives from food in the generic sense. The original Food and Drug Act of 1906 required the government to prove that foods containing poisonous substances were unsafe. The addition of deleterious substances alone would not necessitate a finding of adulteration. *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 34 S.Ct. 387, 58 L.Ed. 658 (1914). The Act was revamped in 1938, adopting a “per se” approach: It prohibited the use of poisonous or deleterious substances unless the industry proved that the addition of the substances was safe. *See Evins Bros.*, 602 F.2d at 720; *Toulmin*, supra, §§ 1.5, 2.1, 2.3. The 1938 Act itself proved inefficient and Congress took steps to amend the Act in the early 1960’s. Congress perceived essentially two flaws in the regulatory scheme. First, the government had the burden of first proving that a food additive is poisonous or deleterious before it could prevent the industry from using it. This required substantial time, during which the industry could market the potentially injurious additives to the consuming public. The second problem was that the law prevented processors from using certain additives in harmless amounts that, if used, would increase and improve the food supply. S.Rep. No. 2422, 85th Cong., 2d Sess. (1958), reprinted in 1958 U.S.C.C.A.N. 5300, 5301; *Toulmin*, supra, § 22.3.

After six years of extensive hearings, Congress passed the *Food Additives Amendment Act of 1958*. The thrust of the amendments was to put upon processors rather than the government the burden of proving that a newly discovered substance added to food is safe if used within specified quantities. The Act, however, did not require processors to prove that all of their marketed food was safe, although Congress would have been free to enact such a requirement. Rather, the burden imposed upon processors applied only to food additives, and the government retained—as was the case prior to the 1958 amendment—the burden of proving that a given food was unsafe.

[6] Consequently, the Act distinguishes between food additives and food in the generic sense, and this distinction is critical in allocating the burden of proof. The FDA’s food additive definition is so broad, however, that it would blur this distinction. It would classify every component of food—even single active ingredients—as food additives. Thus, it would seem, even the addition of water to food would make the food a food additive. The only justification for this Alice-in-Wonderland approach is to allow the FDA to make an end-run around the statutory scheme and shift to the processors the burden of proving the safety of a substance in all circumstances. To be sure, the paramount objective of the Act is to protect the public health. But “[T]o our anxiety to effectuate the congres-sional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.” *62 Cases of Jam v. United States*, 340 U.S. 593, 600, 71 S.Ct. 515, 520, 95 L.Ed. 566 (1951).

[7] The FDA’s interpretation would also arbitrarily classify a substance as either food or food additive by how it is marketed rather than by the nature and use of the substance itself. The FDA concedes that BCO marketed in bottles instead of in capsule form is not a food additive, and that it would in that event have the burden of proving that the BCO is harmful or deleterious. Yet there is no difference between the BCO bottled for teaspoon consumption and the encapsulated BCO but for the way it is marketed. How a product is marketed is not a rational way of determining whether a substance is a food additive and which party—the FDA or the processor—bears the burden of proving its effect, if any, on the consuming public.

Therefore, although a component of food is generally a food additive, when the “component” is the single active ingredient and thus in all material respects is identical to the food of which it is supposedly a component but for certain, inactive additions, such as the gelatin and glycercin used for encapsulation here, the substance in
question is not a food additive. Our holding today is not inconsistent with FoodScience, the case on which the FDA relies. In that case, this Court held that the substance N,N-dimethylglycine hydrochloride ("DMG")—the lesser by weight and volume of two active components of the tablet Aangamik 15—was a food additive even though DMG was the "principal ingredient" of the tablets. 678 F.2d at 738. The DMG, even though it was the reason consumers would purchase Aangamik 15, comprised only 4 percent of the tablets' weight, and was mixed with another active ingredient (calcium gluconate) to form Aangamik 15. We did not reach the question presented here where the substance at issue is the single active ingredient of a marketed product. The district court in FoodScience enjoined the use of DMG "except when offered as a single ingredient for food use." But because the government did not cross-appeal from the exception, we refused to consider that question. Id. at 737 & n. 2. Indeed, if the majority opinion had held what the FDA alleges it held, the concurrence in that case, on which the district court below relied, would have been a dissent. The concurrence states:

I believe ... as did the district court, that this would be a far different case if DMG were being marketed as a single food ingredient. In that case, the FDA would not be entitled to rely on the "food additive" presumption to condemn plaintiff's product but would instead be obligated to shoulder its normal burden of proving, by a preponderance of the evidence, that DMG was an "adulterated food"....

Id. at 741 (Cudahy, J., concurring) (footnote omitted). In short, this case is different from FoodScience and other cases in which the substance in question was mixed with other active ingredients to form an arguably distinct article of food. See 45/194 Kg. Drums of Pure Vegetable Oil, 961 F.2d at 812 & n. 8; 41 Cases, More or Less, 420 F.2d at 1130; 42/30 Tablet Bottles, 779 F.Supp. at 258; 21 Approximately 180 Kg. Bulk Metal Drums, 761 F.Supp. at 180. In fact, the rule enunciated today is supported by every court that has addressed the pre-case question involved here. See United States v. 29 Cartons of An Article of Food ... Oakmont Inv. Co., 792 F.Supp. 139 (D.Mass.1992) (encapsulated BCO not food additive); United States v. Vitality Systems, Inc., Food Drug Cosm. L. Rep. ¶ 38, 251 (D.Or. August 6, 1991) (holding that methylsulfonylmethane ("MSM") marketed in pure form not food additive but MSM held food additive in multi-ingredient products containing other nutrients such as Vitamin C); United States v. Undetermined Quantities of Articles of Food ... Blue-Green Algae, No. 83-1180-FR, 1984 WL 788, 1981 (D.Or. November 8, 1984) (encapsulated Aphanozomenon flos-aquae (blue-green algae) not food additive because it was not intended to affect the characteristics of another food or become component of another food); United States v. An Article of Food ... L-Tryptophan, No. 77-687 (D.N.J. January 23, 1979) (L-Tryptophan tablets not food additive).

III.

Accordingly, we hold that BCO encapsulated with glycerin and gelatin is not a food additive. Because the FDA has not shown that BCO is adulterated or unsafe in any way, there is no basis to condemn the two drums at issue. If BCO is injurious to health, the statute requires the FDA to prove as much. Meanwhile, the Act's labeling requirements protect the consuming public to the extent mandated by Congress by enabling "persons to weigh for themselves the benefits and risks of consuming BCO." The judgment of the district court is therefore

AFFIRMED.
judge’s added statement that premeditation “excludes action which is taken so sponta-
neously that there is no time to think,” was
appropriate only because the judge earlier
stated that premeditation “may occur within
seconds.” The trial judge in this case
did not imply that premeditation could be
formed in seconds. In this case, Watkins
argued with the victim in the hallway out-
side the apartment, went to the kitchen to
get a knife, and returned to the hallway
where he fatally stabbed the victim. Wat-
kins had time to reflect.

The jury focused on the critical distinc-
tion necessary to find guilt beyond a rea-
sonable doubt of the crime of first degree
murder. It chose to convict Watkins. Again,
we do not find Watkins’ arguments
compelling and discard no “gross miscar-
riage of justice.” Hernandez-Hernandez,
904 F.2d at 763. Thus, we are not required
to considered the McCleskey exception. As
a final matter, we note that Watkins has
not made “a colorable showing of factual
innocence,” making the likelihood of suc-
cess on the exception exceptionally slim.

Because the district court properly dis-
missed Watkins’ new arguments as an
abuse of the writ, we affirm.

Affirmed.

UNITED STATES of America,
Plaintiff, Appellant,

29 CARTONS OF AN ARTICLE OF FOOD, ETC., Defendant.

Claim of OAKMONT INVESTMENT
CO., INC., Claimant, Appellee.

No. 92-1948.

United States Court of Appeals,
First Circuit.


Government sought to condemn car-
tons of encapsulated black currant oil, al-

ing that oil was “food additive” of ques-
tionable safety. The United States District
Court for the District of Massachusetts,
Joseph L. Tauro, Chief Judge, 792 F.Supp.
139, dismissed government’s complaint, and
it appealed. The Court of Appeals, Selya,
Circuit Judge, held that encapsulated oil,
which was “food” in its liquid form, in two
inert substances did not render oil “food
additive.”

Affirmed.

1. Food =⇒

Food and Drug Administration (FDA)
can prevent sale of “food” only if it proves
by preponderance of evidence that it is
injurious to health as substances classified
as “food” are presumed safe. Federal
Food, Drug, and Cosmetic Act, §§ 201(f),
§§ 321(f), (f)(1), 342(a)(1).

2. Food =⇒

Purpose of statute governing “food add-
itives” is to protect consumers against
introduction of untested and potentially un-
safe substances, such as flavor, texture, or
preservative agents, into food. Federal
Food, Drug, and Cosmetic Act, § 409, as

3. Food =⇒

Food and Drug Administration (FDA)
can prevent sale of products containing
“food additive” unless and until processor
shows that substance, when added to food,
is generally recognized as safe (GRAS)§17
Federal Food, Drug, and Cosmetic Act,

4. Food =⇒

Any substance that meets statutory
definition of “food additive” is presumed to
be unsafe until Food and Drug Administra-
tion (FDA) has promulgated regulations
prescribing conditions assuring safe use.
Federal Food, Drug, and Cosmetic Act,
§ 409(a)(2), as amended, 21 U.S.C.A.
§ 348(a)(2).
5. Food \(<\) Food

To be labeled as "food additive," substance must be intended, or reasonably expected, to become component of food or to otherwise affect characteristics of food, and not be generally recognized as safe (GRAS). Federal Food, Drug, and Cosmetic Act, § 201(s), as amended, 21 U.S.C.A. § 321(s).

See publication Words and Phrases for other judicial constructions and definitions.

6. Food \(<\) Food

Only component which, when added to food, effects, or could be expected to effect, some change in food, rather than any component of multicomponent substance, active or inactive, is "food additive," phrase "becoming a component or otherwise affecting the characteristics of any food" in statutory definition of "food additive" indicates that definition targets only those components that have purpose or effect of altering food's characteristics. Federal Food, Drug, and Cosmetic Act, § 201(f, s), as amended, 21 U.S.C.A. § 321(f, s).

7. Food \(=\) Food

Black currant oil encapsulated in glycerin and gelatin for easy ingestion as dietary supplement was not "food additive" within meaning of Federal Food, Drug, and Cosmetic Act, even though it was one of three edible ingredients in capsules; black currant oil in its liquid form was "food," whether substance is food additive depends on its use for its effect on food, oil was only active ingredient in capsules, and it was not being used for its effect on glycerin and gelatin. "Food, Drug, and Cosmetic Act, § 201(f, s), as amended, 21 U.S.C.A. § 321(f, s).

8. Food \(\equiv\) Food

Food processor's subjective determination of what constitutes "food" is not determinative of whether particular substance is "food" or "food additive." Federal Food, Drug, and Cosmetic Act, § 201(f, s), as amended, 21 U.S.C.A. § 321(f, s).

9. Statutes \(=\) Statutes

Purely legal question of statutory construction concerning whether particular substance was "food additive" within meaning of Federal Food, Drug, and Cosmetic Act, did not require court to defer to Food and Drug Administration's (FDA) expertise in interpreting Act. Federal Food, Drug, and Cosmetic Act, § 201(f, s), as amended, 21 U.S.C.A. § 321(f, s).

10. Statutes \(=\) Statutes

True measure of court's willingness to defer to agency's interpretation of statute depends on persuasiveness of that interpretation given all attendant circumstances.


Robert Ullman, with whom Jacob Lauber, Steven Shapiro, and Bass & Ullman, New York City, were on brief, for appellee.

Before SELYA, Circuit Judge, ALDRICH, Senior Circuit Judge, and CYR, Circuit Judge.

SELYA, Circuit Judge.

The government seized, and seeks to condemn, twenty-nine cartons of undiluted black currant oil (BCO), in capsule form, owned by claimant-appellee Oakmont Investment Co. (Oakmont), alleging that BCO is a food additive of questionable safety. Because we believe that encapsulated BCO, intended to be ingested as purchased, cannot properly be termed a food additive as defined in the Federal Food, Drug, and Cosmetic Act (the Act), as amended, 21 U.S.C. §§ 301 et seq. (1988), we affirm the district court's dismissal of the government's in rem complaint.

I. BACKGROUND

On October 11, 1988, the United States Food and Drug Administration (FDA) seized 200 bottles of encapsulated BCO, packed in twenty-nine cartons, and brought
U.S. v. 29 CARTONS OF "FOOD" AN ARTICLE OF FOOD

Cite to: 987 F.2d 13 (lst Cir. 1993)

"food" are presumed safe. Thus, the FDA can prevent sale of bottled BCO or any other "food" only if it proves by a preponderance of the evidence that the food is "injurious to health." 21 U.S.C. § 342(a)(1); see, e.g., United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 411, 34 S.Ct. 337, 340, 58 L.Ed. 658 (1914); United States v. An Article of Food [FoodScience Labs., Inc.], 678 F.2d 735, 741 n. 3 (7th Cir.1982) (Cudahy, J., concurring). Although the FDA suspects that BCO may be unhealthful, it is unable at the present time to translate this suspicion into legally competent proof.

[2-4] In addition to regulating the sale of food per se, the Act contains provisions anent food additives. These provisions are designed to protect consumers against the introduction of untested and potentially unsafe substances, such as flavor, texture, or preservative agents, into food. A gloss was added to the treatment of food additives in 1958. See Pub.L. No. 85-929, 72 Stat. 1784 (1958) (codified in scattered sections of 21 U.S.C.). Unlike section 342(a)(1), which places the burden of proving injuriousness upon the government in respect to foods, the food additives amendment allocates the burden quite differently: the FDA can prevent the sale of products containing a food additive unless and until the processor shows that the substance, when added to food, is generally recognized as safe (in the vernacular, "GRAS"). See S.Rep. No. 2422, 85th Cong., 2d Sess. (1958), reprinted in 1958 U.S.C.C.A.N. 5300, 5301-02 (explaining the processor's burden of proving that a newly discovered substance which . . . is added to the food we eat is safe"). Thus, in contrast to the Act's treatment of "food," any substance that meets the Act's definition of a "food additive" is presumed to be "unsafe" under 21 U.S.C. § 348 until the FDA, or more particularly, the Commissioner of Food and Drugs, has promulgated a regulation prescribing conditions assuring safe use. See 21 U.S.C. § 348(a)(2); 21 C.F.R. § 5.10(a)(1) (1992).

[5] The 1958 amendment defines a food additive in pertinent part as:

an in rem action contending that, under 21 U.S.C. § 342(a)(2)(C), the capsules should be condemned as "adulterated" food because they contain a "food additive," the BCO, that Oakmont had not proven to be safe.

At the ensuing bench trial, certain facts were uncontradicted. BCO is a liquid obtained by squeezing black currant berry seeds. It is composed of polyunsaturated fatty acids. In its pure liquid form, it can be ingested by the spoonful as a dietary supplement. However, Oakmont markets BCO in capsules which are to be swallowed whole. The capsules contain pure BCO—nothing more. They are made from gelatin and glycerin (or an equivalent plasticizer) and have no independent nutritional value. Rather, a capsule serves a dual purpose as a container (enabling consumers to ingest predetermined quantities of BCO in solid form) and as a prophylactic (protecting the BCO from rancidity).

On these and other facts, the district court dismissed the government's complaint and ordered the capsules released. See United States v. 29 Cartons, Etc., 792 F.Supp. 139, 142 (D.Mass.1992). The court reasoned that when, as in this case, BCO comprises the only active ingredient within a gelatin capsule, it can properly be classified as a "food," but not as a "food additive." See id. at 141-42. Accordingly, the FDA erred in seizing the bottles on the ground that they "allegedly contain[ ] an unsafe food additive." Id. at 142.

When the FDA appealed, the district court stayed its release order.

II. THE REGULATORY LANDSCAPE

[1] To put this case into workable perspective, we first review the relevant statutory provisions. The Act defines "food" as:

(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

21 U.S.C. § 321(f). The FDA concedes that pure BCO (sold, say, as a bottled liquid) falls within section 321(f)(1) and is, therefore, "food." Substances classified as...
any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures ... to be safe under the conditions of its intended use....

21 U.S.C. § 321(a). To be labeled a food additive, then, a substance must (1) be intended, or reasonably expected, to become a component of food or to otherwise affect the characteristics of food, and (2) not be GRAS.

The Act thus creates a distinction between foods and food additives which has meaningful consequences for purveyors and for the public. The distinction also significantly affects the ease with which the FDA may regulate a substance's sale.

III. THE ISSUE

This appeal revolves around the question of whether the FDA or Oakmont must carry out the research necessary to show that BCO is, or is not, GRAS. The issue reduces to whether pure BCO, when sold in encapsulated form, must be regulated as a “food” within the meaning of section 321(f), or as a “food additive” within the meaning of section 321(a).

The meat of the parties' disagreement lies in their differing interpretations of that portion of the Act which states that a substance can be a food additive if its intended use results, or may be expected to result, "in its becoming a component or otherwise affecting the characteristics of any food."

21 U.S.C. § 321(a). The FDA reads the quoted language as creating two independent and disjunctive standards: to satisfy the first prong of the food additive definition, a substance must either (1) be a component of food, or (2) otherwise affect the characteristics of food. Because each constituent part or element of a food (that is, each "component") necessarily affects the food's characteristics, the FDA considers every component, at least potentially, see infra note 3, to be a food additive. Drawing on this interpretation, the FDA asserts that the seized capsules are composed of three consumable components—BCO, gelatin, and glycerin—and that, therefore, each of these three ingredients is subject to potential regulation as a food additive.

As Oakmont parses the statute, it creates only a single, unitary food additive standard. The phrase "or otherwise affecting the characteristics of any food" signals that a component is potentially a food additive only if it affects the characteristics of some food to which it is added. Unlike the FDA's interpretation, Oakmont's interpretation attaches no significance to a substance's mere presence as a component of a whole. It focuses instead on the substance's affirmative use in a way that affects food.

Applying its interpretation of the statute to the facts at bar, Oakmont argued below, as it does here, that the BCO contained in the seized capsules is itself a food and not a component of some other food, that it is intended so to serve, and that its sale in a convenient carrier medium does not transmogrify it into a food additive. In holding are not constituent parts of a food, may nevertheless have deleterious effects on food. One example might be chemicals used in packaging food.

3. We use the adjectival modifier "potential" because gelatin and glycerin are conceded GRAS. Hence, these components cannot be classified as food additives because neither can fulfill the definition's second prong.
that food is defined "by its 'use[]' for food," 29 Cartons, 792 F.Supp. at 141 (quoting 21 U.S.C. § 321(f)), whereas a food additive is defined by its effect on another substance, see id., the district court substantially adopted Oakmont's reading of the law and its focus on a substance's intended function.

In specific terms, then, we must determine whether, as the FDA would have it, any element of any substance that has more than one component may be branded a food additive, or, rather, whether, as Oakmont urges and the court below believed, such treatment should be reserved for elements which, when so added, effect a change (or, at least, could be expected to effect a change) in some other active ingredient.

IV. FOOD FOR THOUGHT

[6] The Seventh Circuit has recently grappled with a factually similar case presenting this very issue. See United States v. Two Plastic Drums, Etc., 984 F.2d 814 (7th Cir.1993). Employing a perspicacious analysis of the Act's text and legislative history, the court rejected the FDA's notion that all components of a substance are necessarily food additives. The court observed that the "'or otherwise'" phrase contained in the statutory definition of a food additive targets only those components that "have the purpose or effect of altering a food's characteristics." Id. at 818. The subsequent enumeration of sample food additives, describing each substance by its "function or by [its] effect on food," makes it clear that an additive must stimulate some change in a food to which it is added. Id. at 818. Turning to the legislative history, the court observed that the FDA's broad definition of a food additive, which would apply to all components, even a substance which comprises the only active ingredient of the whole, subverts congressional purpose. Blurring the distinction between food additives and food in this way would permit the agency to tilt a delicately balanced statutory scheme that allocates the burden of establishing a food's safety with the FDA. See id. at 819.

[7] The Seventh Circuit also recognized the incongruity of categorizing a food's single active component as an additive. Because "that single component does not affect the characteristics of the food in question—rather, it constitutes the food," id. at 818, it has no place within "the common understanding of an additive, defined by Webster as 'a substance added to another . . . to impart or improve desirable properties or suppress undesirable properties.'" Id. at 818 n. 3 (citation omitted). Thus, in order to qualify as a food additive, a component must be added to a food in order to change that food's properties. See id. at 819. On that basis, pure BCO, in capsule form, is not a food additive. See id. at 820.

Judges should hesitate to write lengthy opinions merely for the sake of committing their own prose to posterity. Given the existence of a cogent, well-reasoned, eminently correct opinion closely on point, we embrace it. We will, therefore, affirm the judgment below for substantially the reasons elucidated in Two Plastic Drums.

We pause, nevertheless, to essay a few additional observations.

First: We are reluctant to believe that Congress traffics in absurdities. Since it defies common sense to say that a substance can be a "food additive" when there is no (other) food to which it is added, we think that the FDA's reading of the Act is nonsensical and, hence, must be incorrect. Moreover, classifying BCO as a "component" merely because it is combined with two totally inert substances serving collectively as a carrier medium would itself create a bizarre paradox: as the Seventh Circuit noted, "to hold that BCO is a component of the dietary supplement would be to find that BCO is a component of itself." Two Plastic Drums, 984 F.2d at 817.

[8] Second: In the FDA's estimation, a processor's "subjective intent" that only one of a product's components constitutes the food is irrelevant because "it is the objective intended use, i.e., the intent to combine two or more components, that
counts." Appellant's Brief at 11. But, this harangue misses the mark. We fully agree that a processor's subjective determination of what constitutes a food is not determinative in cases of this stripe—but neither is the naked fact that more than one component has been combined. In the final analysis, what counts is the use of an ingredient for its effect on food. Here, from an objective standpoint, BCO is not being used for its effect on gelatin and glycerine. Thus, contrary to the FDA's loudly expressed fears, eschewing its rendition of the statutory text will not supplant objectivity with subjectivity.4

Third: The FDA also maintains that because "the ingredients of multi-ingredient food products, such as cake mixes," indisputably fall within the food additive definition, the statute could not possibly contain a "requirement that a substance must be added to a preexisting food, which it must be shown actually to affect." Appellant's Brief at 9. We disagree. Cake mixes are foods composed of many interacting food additives, each with its particular effect on the whole.6 Absent any one ingredient, the concoction remains a cake mix, albeit one that may be short on sweetness or lumpy in texture. In that sense, cake mixes and products of that ilk are a far cry from a dietary supplement composed of a single active ingredient. What differentiates this case is that, if the BCO is removed, one is left with nothing but an empty capsule.

Fourth: We think it advisable to mention the FDA's insistence, citing Chevron U.S.A. Ind., Inc. v. NRDC, 467 U.S. 837, 843, 104 S.Ct. 2778, 2782, 81 L.Ed.2d 694 (1984), that we must obey its interpretation of the Act. In our estimation, the purely legal question facing us in this case presents no occasion for deference. In this realm of judicial expertise, the courts, not the agency, have the last word. See id. at 843 n. 9, 104 S.Ct. at 2782 n. 9 ("The judiciary is the final authority on issues of statutory construction..."); BATF v. FLRA, 464 U.S. 89, 98 n. 8, 104 S.Ct. 439, 445 n. 8, 78 L.Ed.2d 195 (1983) (observing that "deciding what a statute means is the "quintessential judicial function"); FTC v. Colgate-Palmolive Co., 380 U.S. 374, 85 S.Ct. 1035, 1042, 18 L.Ed.2d 904 (1965) (holding that "legal standard[s]... must get their final meaning from judicial construction"); Wilcox v. Ives, 864 F.2d 915, 924 (1st Cir.1988) (quoting BATF v. FLRA, supra).

At any rate, the true measure of a court's willingness to defer to an agency's interpretation of a statute "depends, in the last analysis, on the persuasiveness of the interpretation, given all the attendant circumstances." Massachusetts Dep't of Educ. v. United States Dep't of Educ., 837 F.2d 536, 541 (1st Cir.1988). "The simple fact that the agency has a position, in and of itself, is of only marginal significance." Mayburg v. Secretary of HHS, 740 F.2d 100, 106 (1st Cir.1984). When, as now, a court is persuaded neither by "the validity of [the agency's] reasoning," nor by the interpretive fit between the agency's rendition, on the one hand, and the language and structure of the statute, on the other hand, a court should not defer.5

4. Moreover, if the FDA worries that processors may muck the statutory classifications with convenient recitals of subjective intent, we question the agency's espousal of a rule that would "arbitrarily classify a substance as either food or food additive by how it is marketed rather than by the nature and use of the substance itself." Two Plastic Drum, 984 F.2d at 819. In the words of Sir Francis Bacon, the FDA's suggested remedy is worse than the disease.

6. We do not quarrel with those courts that have held, when confronted with multi-ingredient products containing two or more active ingredients, that each active ingredient is potentially a food additive. See, e.g., United States v. 48/194 Kg. Drums, Etc., 961 F.2d 808, 812 n. 3 (9th Cir. 1992); FoodScience, 678 F.2d at 738; United States v. 41 Cases, Etc., 429 F.2d 1126, 1130 (5th Cir.1970).

6. The longevity of an agency's position is often significant in assessing the degree of deference owed to it. See Brown v. Georgetown Univ. Hosp., 488 U.S. 204, 312, 109 S.Ct. 448, 473, 102 L.Ed.2d 493 (1988) (refusing to apply Chevron deference to "agency litigating positions that are wholly unsupported by regulations, rulings, or administrative practice"); Skidmore, 323 U.S. at 140, 65 S.Ct. at 164 (acknowledging the value of "consistency" in respect to gauging persuasiveness). Here, the FDA's position is of recent vintage. Indeed, the original complaint in this
UNITED ELEC. WORKERS v. 163 PLEASANT STREET CORP.
Cite as 987 F.2d 99 (1st Cir. 1993)


V. CONCLUSION

We need go no further. The proposition that placing a single-ingredient food product into an inert capsule as a convenient method of ingestion converts that food into a food additive perverts the statutory text, undermines legislative intent, and defenestrates common sense. We cannot accept such anfractuous reasoning.

Affirmed.

UNITED ELECTRICAL RADIO AND MACHINE WORKERS OF AMERICA (UE), et al., Plaintiffs, Appellants,
v.
163 PLEASANT STREET CORPORATION, et al.,
Defendants, Appellees.
No. 92-1865.
United States Court of Appeals,
First Circuit.

1. Federal Courts ☐=562

Although resolution of plaintiff's motion for reconsideration by margin order contravened separation of documents requirement, plaintiffs' appeal, which was timely when viewed against the date order was entered, would be deemed waiver of separate document requirement. Fed. Rules Civ.Proc.Rule 58, 28 U.S.C.A.

2. Federal Courts ☐=792

Where district court elects to dispose of motion for lack of personal jurisdiction without evidentiary hearing, "prima facie standard" governs review, under which it is plaintiff's burden to demonstrate existence of every fact required to satisfy both forum's long-arm provision and due process clause. U.S.C.A. Const.Amends. 5, 14.

See publication Words and Phrases for other judicial constructions and definitions.

3. Federal Civil Procedure ☐=1829

Prima facie showing of personal jurisdiction on motion to dismiss, being resolved without evidentiary hearing, must be based upon evidence of specific facts set forth in other foods or liquids, not because of its placement in gelatin capsules. See United States v. Articles of Food [Blue-Green Algae], No. 83-1180-FR, 1984 WL 1981, at *3-4 (D.Or. Nov. 8, 1984).
Evening Primrose Oil Litigation Team

For outstanding performance in the investigational and evidentiary seizure proceedings concluding EPO litigation in California and Maine.

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John D. Harris
Sara H. Henry, Ph.D.
S. Steven Hotta, M.D.
Hiljiie Irausquin, Ph.D.
Stanton W. Johnson
James M. Kewley
Camilla K. Kliner
Jean Knight
Charles J. Kokoski
Michael R. Kravchuk
Leslie Kuz
Margaret M. Laski
Ronald R. Laski
Marjane C. Lawson
Lawrence J. Lin, M.D.
Shelly L. Malforth
Barbara Marcelletti
Gerad L. McCowin

Francis G. McNerney
Daniel L. Michaels
Edith D. Miller
Richard C. Nelson
Louisa Nickerson
Frances V. Noyes
Janice F. Oliver
Mary K. Pendersgast
Richard H. Peretz
Antoinette M. Pusatiere
Ruth E. Rubino
James P. Reavey
Robert J. Reif
Peter A. Salsbury
Emil G. Siegmund
Manjeet Singh
Solomon Sobel, M.D.
John J. Stamp
Linda M. Stewart
Cynthia Stockberg
Donald W. Stresser
Pearl M. Tanjuaquito
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Amanda B. Pedersen
Chief Mediator and Ombudsman

For outstanding skills and exceptional performance as the Food and Drug Administration's Chief Mediator and Ombudsman.

ATTACHMENT C
FEDERAL FOOD, DRUG, AND COSMETIC ACT

(Chemical Additives in Food)

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON

INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

EIGHTY-FOURTH CONGRESS

SECOND SESSION

OF

H. R. 4475

A BILL TO PROTECT THE PUBLIC HEALTH BY AMENDING THE
FEDERAL FOOD, DRUG, AND COSMETIC ACT AS TO PROVIDE FOR THE SAFETY OF CHEMICAL
ADDITIVES IN FOOD

H. R. 7605, H. R. 7606, H. R. 8748

BILLS TO PROTECT THE PUBLIC HEALTH BY AMENDING THE
FEDERAL FOOD, DRUG, AND COSMETIC ACT TO PROHIBIT
THE USE IN FOOD OF NEW FOOD ADDITIVES WHICH
HAVE NOT BEEN ADEQUATELY TESTED
TO ESTABLISH THEIR SAFETY

H. R. 7607, H. R. 7764, H. R. 8271, H. R. 8275

BILLS TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT
FOR THE PROTECTION OF THE PUBLIC HEALTH, BY PROHIBITING
NEW FOOD ADDITIVES WHICH HAVE NOT BEEN ADEQUATELY TESTED TO ESTABLISH
THEIR SAFE USE UNDER THE CONDITIONS
OF THEIR INTENDED USE

JANUARY 21, FEBRUARY 1, 2, 3, AND 14, 1956

Printed for the use of the Committee on Interstate and Foreign Commerce

DEPARTMENT OF

UNITED STATES

HEALTH, EDUCATION, AND WELFARE

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WASHINGTON: 1956

ATTACHMENT D

SEE P. 226 (739)
must uphold the finding of the Administrator. You could change that act in many other fields, and perhaps make it work. But to select this highly technical field as an innovation, as a departure from the administrative act, it seems to me we would come unworn. If we are going to experiment and try to improve it—and I think we can improve the administrative act—I much prefer to try on something else, and something that is not as highly technical and does not involve the safety of so many people.

There is one question here about this standard that troubles me. As I interpret the act, the standard of whether a man has obeyed the act or not—the test whether has has violated a criminal statute—is not whether the additive is safe or not safe. The test is whether it is generally recognized by the experts to be safe.

If this were a purely simple matter, there might be some justification for that sort of a test. But where a man is put in jeopardy, it seems to me that he is entitled to some standard that is much safer and much more certain than that. In order to determine whether he is committing a violation of the penal code, he has to pass on the question of whether the experts generally recognize.

Mr. Goosney. Yes, sir.

Mr. Durr. He goes into the field of opinion and conflicting opinion and highly technical matters. I just don't think that is good, even though it is in the Drug Act. I can't believe that is good legislation. I am wondering why we simply don't make the test the safety of the matter. Then he can certainly make his decision. He is a manufacturer. He has his experts. Whenever he makes his decision, then he will have to accept the consequences of it. I am wondering what difference it would make if we substituted and changed that language and struck out the "generally recognized."

Mr. Goosney. We have in general language "generally accepted," because the committee over the years has never been willing to give the Food and Drug Administration the authority to make a list to say which products are in and which are out. This is what has been called here an objective standard.

We have the burden, no matter how this bill goes, of proving that a product is not generally recognized as safe among experts in the court.

Let us assume that this bill came out as we recommended it and company X had a chemical which had not been adequately tested, we thought it was not generally recognized as safe, the applicant thought it was generally recognized as safe. We would have the burden of going to court to seize, prosecute, or enjoin to prove that fact. That it was not generally recognized as safe.

We have in this food and drug law some general language. "Prepared under insanitary conditions," "it if it consists in whole or in part in filth," "if it is a poisonous or deleterious substance which may be injurious," all these generalities have been to the courts, and we have not had difficulty with vagueness knocking down the law. We have been singularly successful, I think.

Mr. Durr. Under the present law, what happens if a man does put on the market—I am not talking about civil liability, but criminal—a deleterious substance, something that causes great damage. Can he be criminally prosecuted?
FOOD ADDITIVES

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON

INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

EIGHTY-FIFTH CONGRESS

ON

BILLS TO AMEND THE FEDERAL FOOD, DRUG, AND

COSMETIC ACT WITH RESPECT TO CHEMICAL

ADDITIVES IN FOOD

JULY 15, 16, 17, 18, 19, 21, 22, 24, AUGUST 6, 7, 1957, AND

APRIL 18, 1958

Printed for the use of the Committee on Interstate and Foreign Commerce

UNITED STATES
GOVERNMENT PRINTING OFFICE
WASHINGTON : 1958

ATTACHMENT E
SEE P. 455 (617)
FOOD ADDITIVES

encourage the adoption of reasonably uniform laws. We need all the help they can give in controlling chemical additives, for the task is so big that combined Federal-State-city interest is imperative.

Last year the State of Utah enacted a new food, drug, and cosmetic law that contains an approach to the control of chemical additives not too different from the basic principles in some of the bills you are considering. The State of New York is considering new additives legislation now. New York City is considering a revision of its sanitary code with respect to food additives. And we understand that food-law enforcement officials of other States are considering the steps they should take to deal with residues of additives. If the Federal Government fails to enact legislation that can serve as a guide, the result may be the adoption of varying methods of State and local control.

In conclusion, the problem, the real hazard of the use of inadequately tested chemicals in food is very clear and is with us today. It is not, as some of the testimony last summer suggested, merely a theoretical problem. Inadequately tested chemicals are being used in food today and their use constitutes a real hazard to the public health.

(The information referred to follows):
July 16, 1992

Dear Mr.,

Your letter, written in response to the referenced Warning Letter, has been reviewed by the Agency.

We note the corrective actions which have taken regarding the inconsistencies noted between the immediate bottle label and carton. However, as stated in our Warning Letter, we do not agree that the product is labeled in accordance with §411 of the FDC Act. Inositol choline bitartrate, para-aminobenzoic acid, citrus bioflavonoids and betaine hydrochloride are declared in milligram amounts on the label of this vitamin and mineral tablet. Such declarations give prominence to these ingredients which are not vitamins, minerals, or sources of vitamins and minerals in violation of §411(b)(2)(B).

Also, we are unable to concur with your proposal that this issue be deferred until NLEA regulations become final since §411 has been in effect since 1976.

Sincerely,

Eugene C. Schults
Compliance Officer
Philadelphia District

ECS/bgp

ATTACHMENT
Mr. Durbin. I will try to hold myself to the same five minutes. Let me ask a few questions.

Mr. Kessler, this is your company?

Mr. Gerry Kessler. Yes.

Mr. Durbin. How big is your research staff?

Mr. Gerry Kessler. We have two or three people that promote products that are associated—

Mr. Durbin. Research scientists?

Mr. Gerry Kessler. Plus we have a staff of scientists who are in charge of the manufacturing of the products.

Mr. Durbin. How many?

Mr. Gerry Kessler. Seven, eight.

Mr. Durbin. How do you determine that something like this really is going to improve my potency as a male?

Mr. Gerry Kessler. If that product were promoted for potency, the product would have been our number one seller. That product is no longer on the market, hasn’t been for almost a year. The product is for male energy and for male stamina, and the product didn’t sell because we didn’t make any claim for it other than what we put on the label. It would have been our number one product if we had sold it for what you are saying we sold it for.

Mr. Durbin. It is called Virile Action, potent for men, and it has an arrow moving in the right direction.

Mr. Gerry Kessler. That product didn’t sell, so I guess the people—I am not going to answer that question. The product is not on the market because it was not a good seller because we made no claims for it. And what appears to be claims that are tremendous claims was apparently not enough to get the public to agree that it was the most wonderful product in the world.

Mr. Durbin. How did you come up with this list of ingredients and put it into this product?

Mr. Gerry Kessler. I am not one of those scientists, and I can’t answer the question. We have 500 products. I can’t answer the question on each one of those products.

I did submit on many of the products that are sitting in front of you to the Waxman hearing studies and research that appeared in medical journals that was about as high as that on those four products. I would be glad to submit it to this subcommittee so you can have a chance to look at it and see what are the reasons behind what is stated on the bottle.

Mr. Durbin. “Fuel For Thought.” This is the one we have been talking about today. Why don’t you tell me how did you come to the conclusion that these neuro-nutrition items help to provide fuel for thought?

Mr. Gerry Kessler. Number one, again, I am not a scientist, and I can’t go into the detail on that.

The fact is that the ingredients in that product help to support neurotransmitters within the brain. There is great research on that to demonstrate that it does do that.

Will that make you smarter than you are? That is not what it is to do. In other words, if you are not getting the necessary nutrients and, therefore, your neurotransmitters are not functioning the way they should be and they are not producing the neural hormones that are necessary to bring you to a level of normalcy, this
isn’t going to take any of us who are adult normal and make us superior intellects.

However, to be able for a dietary supplement to say that it changes a function of the body or the chemistry of the body is a category that is classified in Section 201(g)(1)(c) of the current law says that any product that claims to change the structure or function of the body is a drug, with the exception of foods. And under foods they include dietary supplements.

So if we can establish with truthful, nonmisleading claims that those products do exactly what they imply, to say—we would like to be able to say that on the label and then it wouldn’t be left open for Mark Silbergeld to say anyone can make assumptions as to what it is we are trying to say.

If the Richardson and Hatch bill were passed and we could make claims based upon reasonable science, I would be willing to live by that standard. That is not one of our products, but I would be glad to answer your question.

Mr. Durbin, Ms. Whittlekin, you made reference to Nature’s Response here. I will just tell you there are no two ways about it. This is a very misleading brochure.

For example, to suggest that this aloe vera extract inhibits the production of the HIV virus in vitro—in the Diet Pepsi ad it said, don’t worry because it can kill HIV in vitro. People may have hope that this is going to help cure cancer or a HIV-positive situation.

They could put this on the market, send the notice to FDA 30 days before it hits the market, and then it is up to the FDA to prove them wrong.

We are not going to be able to fund the FDA to meet the requirements of the Richardson-Hatch bill. It cannot be done. I have been through this with an administration that is freezing domestic spending. We are not going to have more employees to fund Richardson-Hatch. The net result is your industry will be deregulated. If that is what you are shooting for, I fear there are bad actors out there that will put you in hot water in a hurry.

Ms. Whittlekin. Looking at the Richardson bill you think it would take some staff to accomplish that. Think about the amount of staff it would take for pre-approval on thousands of products, a much, much greater burden.

What we have now is what the FDA has been working on. I think they have blown this so out of proportion that it looks like a huge job. If you look at their history of the number of products that they have been able to successfully conclude, mostly with warning letters, that is all they have to do is write a letter and people quake and change absolutely perfectly responsible labels just to make the FDA happy. They can today take that product off the market, and they probably should.

The things that are referenced there are not just made-up claims. They are cutting-edge research, that there is not probably enough now.

I am not talking in vitro. There are clinical studies underway to show that aloe vera—there is a germ there. It is not to the point where it should probably be on a label yet. When they put one or two like that and a bunch of others that have had to resort to cute names to give a hint what it might be about, they are subject to
misinterpretation because we cannot make a responsible statement there that fairly characterizes the science. A lot of misunderstandings happen.

Mr. Durbin. If there is somebody in your industry that has anything near a cure or palliative for AIDS, my guess is they would have moved a long time ago. There are pharmaceutical companies across the country investing millions of dollars in an effort to find that, realizing that if they were successful everyone would be so relieved.

If this is true, for goodness sakes do something about it through the ordinary channels. If it isn’t, don’t tantalize people with these kinds of brochures. A person who is suffering from cancer is going to take Nature’s Response here?

Ms. Whittlin. I understand your concern and agree about that product.

An example on the thing you are saying, most of this research is taking place in colleges and universities. One company did clinical studies over a long period of time. The results were so exciting they took it to FDA, and FDA came down and seized all their products. That was the answer they got.

I agree it should not be on literature for serious diseases like that until it is very well established. These things are not serious disease claims.

Mr. Gerry Kessler. Having to do with money and funding the FDA, if legitimate companies within the industry must submit to the Food and Drug Administration 30 days in advance of making a health claim, that information—and it is clear that the product that you submitted the information on does not have substantial information behind it, and it would not hold up in court—90 percent of the companies that would attempt to make such a claim would not make the claim because their product would be on the market by the time the Food and Drug Administration acted and more than likely, the product would have to be withdrawn in the market.

It costs a lot of money to manufacture and label a product, to distribute and promote a product. And you would not have to fund a great deal of money to the Food and Drug Administration to prevent false and misleading health claims from going on the market because, as soon as the FDA said I do not agree with this information, within the 30 days that they were given notification the company would have to take some action and would probably have to take the product off the market.

Mr. Durbin. Your bill also says for 60 days you can’t take the product off the shelf, so you have at least 90 days, as I read it.

Mr. McNamara. If there is a warning letter and you trigger the procedure for getting review of the warning letter, there would be a delay while the warning letter was reviewed.

Mr. Gerry Kessler. By the time you got distribution the product would be removed from the market.

Mr. Durbin. This fellow might.

Mr. Gerry Kessler. My company would never make those kinds of claims. I am not sure those claims should be—I am not sure that the Food and Drug Administration shouldn’t have acted on those claims. FDA admittedly uses 1 percent of its enforcement finances
to go after the dietary supplement industry. I would suggest they use more. It would be better to make a level playing field for everyone in the industry.

All the products that are there that are giving this industry a bad name could be eliminated. I think it would be good for the industry if they would use the power that they have and use the law to get rid of those products for everyone.

Mr. DURBIN. Mr. Skeen?

Mr. SKEEN. Mr. Cordaro talked about self-policing and enforcement through your association. Give me some idea how that works for you and cite examples. For instance, if the industry was interested in self-policing et cetera, would it be energized by that kind of situation that he has been showing you on that bottle? What would you do about it?

Mr. CORDARO. The counsel has a rigorous code of ethics. We can only deal with our members. We can’t do anything outside——

Mr. SKEEN. Are there other associations?

Mr. CORDARO. I think between the CRN—I think it is fair to say that with the CRN, the NNFA, the non-prescription drug manufacturers and a couple of herbal associations we have to cover 99 percent of the business wouldn’t you say?

Mr. SKEEN. Are they all interested in self-policing.

Mr. CORDARO. CRN is and we have a track record for that. NNFA has made extensive efforts in that direction.

Mr. SKEEN. The Chairman hits on a valid point. The funding necessary to do what the Richardson-Hatch bill does is going to be something to contend with. I would rather see the industry doing its own self-policing and enforcement if there is dramatic evidence that it does hold its own industry to strict standards.

Mr. CORDARO. We have a rather rigorous code of ethics. One part addresses the issue of claims. We do not have the ability to police the marketplace. What we do is that if a member company calls to our attention what it considers to be an inappropriate or a egregious claim by another member, then we have the power and the authority, and we have done this, is to ask for substantiation and to provide guidance as to how that should be dealt with. So on the claims area——

Mr. SKEEN. Only for your member companies?

Mr. CORDARO. Yes, sir.

Mr. SKEEN. Do other organizations do it for their membership?

Ms. WHITTEKIN. We also don’t cover all of the market. This book is a codification of some of the newest standards that are under way for our industry. For quite a while we have taken on individual projects and looked where we thought there might be a problem. We have a database that lists several thousand products that in case we need to have a recall we know what is in every one of them.

It is not as big as it is going to be because it is in everybody’s interest to get rid of fringe products. There will always be some little company that can decide to take advantage of the system and will be small enough that the FDA will have trouble finding them. They aren’t members of our association so you will never get 100 percent, but I think we are getting close to good control.
Mr. Skeen. But you are very sensitive to anybody that enters the market, so you know what is there, probably long before FDA does.

Ms. Whittekin. Yes.

Mr. Skeen. I would think that the most valuable thing these associations could do is have a very rigid self-policing system. Do you take them to court?

Mr. Cordaro. We don't have the authority to take them to court. What we do have is that we make a recommendation as to will and if so what changes they should make in their labeling. If they are not responsive and if we have repeated violations we can deny them membership in the association. That is the extent of what our—

Mr. Skeen. You don't do whistle blowing?

Ms. Whittekin. Bad publicity is one of the best motivators, because if we can get to the retailers and say this is a problem, they won't buy it. We can't afford the kind of government that would police every product coming off every production line.

Mr. Skeen. Somebody comes up with a situation that you are working with today and we give you a lot more government, that is not always the answer.

Mr. Gerry Kessler. We can stop or at least put pressure on to stop a company from being able to advertise their product that has not established that the product—in the magazines of the industry, they can be stopped from displaying the product at a health food show. A seal of approval by NNFA is being worked on where if they don't have the seal of approval the implication is that the product has not been approved.

My company spent over a million dollars in law suits against seven companies stopping them from making claims that we felt were damaging the industry.

Mr. Pastor. It has been asked a number of times how do you hold accountable what is on the value of the product and each time the response was that the label, whatever the contents of the label, must be upheld in a court of law. So I would ask you who takes these manufacturers, when the value of the product may be questionable, who takes them to court? Whose job is it to take them to court?

Mr. McNamara. FDA has multiple options of enforcements. There seemed to be confusion in the earlier discussion about whether the new law would require truthfulness in labeling. The existing law provides that a food including a dietary supplement will be misbranded if its labeling is false or misleading. And as far as one is talking about health claims, the text varies a little between Senator Hatch and Congressman Richardson, but since this is a congressional committee in the House, Congressman Richardson's bill, label of a supplement about a disease or other condition of the body, if such characterization accurately represents the current state of scientific evidence, an elaboration pinning down that definition.

Nothing in the existing law or in the new law which adds additional restraints would have the effect of allowing anyone to make a false or misleading claim. If one does that under current law, the FDA may bring a civil seizure action against the products, which happens very quickly.
The agency may bring an injunction action against the responsible company, may bring a criminal prosecution, and there is a Supreme Court case upholding a criminal prosecution of a vitamin mineral company for making unsubstantiated claims, and the FDA may request a recall.

It has an ample number of responses that it can bring when there are false or misleading claims. I hope you are considering in addition to whatever FDA recognizes is a small segment of the industry, one has honest people who are working hard and are trying to pay salaries of their employees and to remain in business. Those people are people we need to consider as well.

Do you want to set up a system of government at this time when we have limited resources in which every new claim about a health or disease-related condition will have to be approved by a new FDA regulation before the statement may be made and then whenever you want to change it, you will have to go back to the same bureaucracy to get a new regulation approved to change that approval?

I would suggest that in a free society where we want to we ought to set up a system saying make a false or misleading claim and there are a whole set of prosecutorial options to the FDA, and let them hit the people who made false claims. But that allows the honest purveyor of product who puts out product that he cares about an opportunity to decide what is truthful and not misleading and to go to market to defend it if the government wishes to challenge it.

In an area with precious resources it is not the time to create a permanent bureaucracy that is going to review everybody's health claim as it comes down the pike.

Mr. SKEEN. I agree. Those people still have a basic responsibility in their industry and who do they talk to? They eventually, as I understand—it is your question—it finally winds up in the purview of the FDA to do something about final action?

Mr. McNAMARA. Yes, sir.

Mr. DURBIN. Ms. DeLauro.

Ms. DeLAURO. Mr. Cordaro, I think you said that dietary supplements were food. Then why not continue to deal with them with regard to the FDA as food, and that is a relaxed law in the 1906 FDCA and the purpose of the NLEA was to, if you will, lessen the restrictions and that it does now treat dietary supplements as food. Why a separation out?

Mr. McNAMARA. There are multiple aspects to the answer to that kind of question. It is a very fair question. Number one, dietary supplements are a subcategory of food. Under the general heading of food there are various kinds of foods. The Food Drug and Cosmetic Act passed in 1938 provides for foods for special dietary use.

It is interesting that FDA declines to mention that it has a regulation that defines foods for special dietary use. Let's look at this definition that is in the code of Federal regulations today.

Two parts of interest. Foods for special dietary uses include substances that are for uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral or other dietary properties. Sounds like it fits the kind of products we sell.
What else it says you do in terms of intended use, they may be for uses for supplying the particular dietary needs which exist by reason of a physical, physiological, pathological or other condition including but not limited to the conditions of diseases, allergic hypersensitivity to food, underweight or overweight, et cetera.

I would submit to you that for foods for special dietary use, including dietary supplements, there has been a long-standing practice to treat them differently and when the Nutrition, Labeling and Education Act was passed there was an understanding on the part of the industry that they would continue to be treated separately.

The legislative history is the statement that appears in the history which says, of course, dietary supplements by their very nature need to convey information about their health and disease-related benefits. At that time Congress authorized FDA, but did not require that FDA could have a different standard and procedure for dietary supplements than it had for conventional foods.

FDA chose at that time, much to the surprise of the dietary supplement industry, much to the surprise of Senator Hatch and Congressman Richardson—the FDA’s response at one point was insulting. In fact, it chose instead to impose on dietary supplements for the first time uniformity with what had been done for conventional foods. FDA is making the change and I think they should account to that.

Ms. DeLAURO. But the Congress also instructed—charged FDA to come up with a standard. They have.

Mr. McNAMARA. What we are asking the Congress to do is now to be very clear to FDA what they were expecting was that dietary supplements would be able to make truthful and nonmisleading statements that are appropriate for diet supplements and whack somebody who doesn’t make a good claim.

Ms. DeLAURO. If a manufacturer has valid claims, why not get FDA approval so that consumers have the confidence of knowing—

Mr. McNAMARA. You know, anyone who has had to deal with the Food and Drug Administration in terms of bureaucratic review of any kind of petition learns that nothing ever happens on time or promptly.

The Congress writes deadlines into the act for action on food additives. Does FDA ever meet them? No. Deadlines for new drug approvals are supposed to occur within 180 days. Does that ever happen? No.

You contemplate writing a law as though FDA will execute it.

Ms. DeLAURO. No. I have been here long enough, participated in the process long enough to know that deadlines come and go in a variety of instances. But the fact is that, and you know, we can get back to Commissioner Kessler, that over I guess a two-year period of time they dealt with about 8 of the 10 areas that the NLEA had laid out.

Clearly we will have an opportunity to find out if that is the case and go back to take a look at it. The other thing that was important in the point that Commissioner Kessler made was that the Congress, in its infinite wisdom, did not talk about increased resources in any way or financial resources or personnel resources.
I have a question, the same question I asked of Senator Hatch. Assuming we could put a health claims standard in place, one that would be acceptable to all sides, would you be agreeable to a health claim approval process that would require the manufacturer to put evidence as to basis of the proposed claim and require FDA to rule on the claim within a certain time frame?

Mr. MCNAMARA. I would not. I think it would develop into an elaborate, delaying, expensive process.

Mr. CORDARO. I would like to answer the question and give you two examples. One is the relationship between folic acid and neural tube defects and the antioxidant vitamins and the prevention of cancer. I don't know if it is because I am the oldest of 11 children or it is because of the work that I did for several years with AID or because I worked for Senator Hubert Humphrey and was with him when he was helping develop the WIC program, but I am appalled by the way that FDA has handled the approval process for folic acid and neural tube defects.

If you wanted to use that as an example of everything that is wrong with the process, I think that would underscore it in spades. The Congress identified four specific claims in the supplement area that they asked FDA to look at just as supplement claims. One of those was folic acid and neural tube birth defects.

What FDA did was they immediately decided to—they had to try to link this together with a food fortification policy. Secondly, somehow the issue of safety concerns got into the equation. Thirdly, they decided they couldn't handle it through the normal way so they had to pull together an advisory committee.

Thirteen months after the Center for Disease Control and Prevention made a recommendation to women who were at risk of becoming pregnant that they should be using folic acid, months after associations like Spina Bifida Association and March of Dimes have supported such a claim, after the government of the U.K. has supported such a claim, FDA is still fiddling with this claim.

Meanwhile, while they are fiddling with this, there are 2,500 children born every year that have neural tube birth defects. I would respectfully disagree with Commissioner Kessler, who I know is a doctor, who I know is a lawyer and I am neither, but I would respectfully disagree with him that the data is not good in this area.

He suggested that all of the data wasn't that good that we were going to give this claim. All the scientists I have talked to have said if the data is good in any one area it is in this area. Meanwhile, a percent of those 2,500 children every year would have a chance of not having this neural birth defect.

If you multiply that by the time it takes and the years, I think that the point that Steve is making about the bureaucracy underscores the problem.

In anti-oxidants and vitamins and cancer prevention, FDA has approved a claim for vitamin C and beta carotene as found in food, and then they have turned around and denied that claim in a dietary supplement form on the grounds that they are not sure it is the beta carotene and the vitamin C.

I am saying, if you are not sure, then why say that you are approving it in food because of those two nutrients?
I can understand if they said there is something in this stuff, we are not sure what it is, so we are approving it for food. But don't stay it is the beta carotene and the vitamin C.

So what are they going to do now? They are going to put this lumbering cumbersome long process in motion again and they are going to have a three-day conference starting September 1st, 2nd, and 3rd and bring a bunch of scientists together and to start kicking the data around. And we are still not going to be able to make the claim.

Those two examples underscore why we have a problem that needs to be fixed.

Mr. McNAMARA. If there is that much of a problem when your data is as good as this and endorsed by another government agency and in the public spotlight, God help you if you are a little company trying to get something that is just going to help your sales.

Ms. WHITTEKIN. I wanted to give you a real practical answer. The practical answer to your question is it would not work because in three years we have one supplement claim that has squeaked through. We asked for four. There should be hundreds, but only one squeaked through, even though we are talking about folic acid, they don't talk about the fetal deaths.

In the last two years while they have been fumbling around with this claim, there have been 3,000 miscarriages or stillborns, because of the folic acid, and 1,000 infants have died.

There are some serious side effects to the inaction as well. Even the claim they are getting around to finally proposing, the March of Dimes says is an inadequate claim and it is not strong enough to get the point across and the fortification guidelines are too conservative to get the job done. The problem is the system just doesn't work.

Mr. DURBIN. Mr. Walsh.

Mr. WALSH. I appreciate the witnesses' testimony. I am not going to ask any questions. However, I would exercise my prerogative that as we get further and further into the dinner hour, witnesses refrain from using the word "food".

Mr. DURBIN. Thank you very much for your patience in waiting to testify.

Mr. WALSH. We would like to thank you. We have attended quite a few hearings. I think the questions here were very provocative, were very well thought out.

I think that there is a true desire to get an understanding of what is going on here. I just want to thank you very much. That is why it has taken this long and we appreciate it.
WITNESSES

STEPHEN BARRETT, M.D., NATIONAL COUNCIL AGAINST HEALTH FRAUD, INC.
JOAN PRIESTLY, M.D., EXECUTIVE VICE PRESIDENT, CITIZENS FOR HEALTH

Mr. DURBIN. Our next panel consists of Dr. Stephen Barrett with the National Council Against Health Fraud and Dr. Joan Priestly, Executive Vice President of Citizens for Health.

So there is no misunderstanding, they have opposing viewpoints on the issue, but they are called in the same panel. We have the testimony of both witnesses, which will be made part of the permanent record.

Now, we invite for the purposes of oral testimony Dr. Barrett. We are putting you on the flexible five schedule here.

Please do your best.

Dr. BARRETT. I am Dr. Stephen Barrett. I am a psychiatrist from Allentown, Pennsylvania who spends most of his time investigating health frauds and quackery. I have been doing it for about 25 years.

Two weeks ago I published what is probably the largest collection of information on quackery published in the last 60 years. It is called the Health Robbers.

I think credibility is very important. I am going to cut right to the heart of the matter as far as credibility is concerned. The document that I gave you lists a number of companies that have been involved in law violations.

My collection of illegal claims for products probably numbers around 3,000 violative products over the last 10 or 15 years.

The reason why the FDA has not been able to clean up the marketplace is extremely complex and far beyond what I have time to discuss. I will sum it up by simply saying that there are so many violative products out there and the FDA has so many things it has to do, that it simply has not had the resources to clean up the marketplace.

Therefore, if you make a law that weakens the FDA's enforcement ability, you are just going to make things worse. I think the Hatch-Richardson bill will make things worse.

I wish I had the time to rebut what I consider to be about 50 half truths and frank lies that I have heard here today. I don't have time to do that, but I will tell you a little bit about the law violators.

My exhibit contains a list of 25 enforcement actions that Federal and State agencies have taken against General Nutrition Corporation which of course is a member of the Council for Responsible Nutrition and a member of the National Nutritional Foods Association, although it was not a member when some of these things were taken.

(223)
That has not stopped GNC from making deceptive statements in its store by its clerks or in the way in which it markets its product. It has made a change. There are fewer therapeutic claims now that GNC has had a criminal prosecution against it.

I have also listed 28 companies and the claims they made that were illegal for LT. I have collected literature, catalogs, material from health food stores, from manufacturers, 28 companies I identified and I was not doing it systematically, I did not at that time have a way of doing it systematically. I did it rather haphazardly but my files contain 28 examples of false, illegal and therefore criminal claims.

Now, let's turn to the company of Mr. Kessler who testified a few minutes ago. I did not know he was teaching today, but I thought it was interesting to see what his company was doing. I have a file on his company that goes back over 20 years and over 20 products that have been marketed with false or misleading claims. I have 11 products identified in my report with the literature.

Here is one: Cardiomaxim, cardiovascular diseases in the vital organs is an essential part of preventive health. It would appear to me that this product Cardiomaxim has some therapeutic purpose related to the heart.

Now, if the ingredients could indeed exert a therapeutic purpose, maybe there would be some justification for making these kind of statements. But I am afraid they don't. Niacin is mentioned. Niacin is a marvelous drug for the heart, however the dosage that is in the product will do nothing. Vitamin B-6, taking 10 times or more of the RDA of vitamin B-6 won't do anything. That is on the low threshold of toxicity for long-term use.

I don't know about carnatene, but the other five ingredients don't have therapeutic value. This product is illegal. I don't know if it is still being marketed. My brochure is a few years old. Now, CRN talked about, and I believe it was Mr. Skeen who asked about the voluntary regulation. None, zero, zip. They gave you some examples.

Anyone with two eyes during the 1980s could see that there were hundreds of illegal claims being made for supplement products in the trade literature. I have collected it and filed it. CRN talked about, I am sorry, it was mentioned that the National Nutritional Foods Association has calls for a voluntary recall of germanium. They did not mention that the FDA has been concerned about germanium, had any number of seizures and court cases where it was taken off the market.

FDA didn't think it should be marketed at all. In 1986 they instituted an import ban. It was not legal to bring it into this country to be used as a supplement product. I think the recall is a little late. It came as the result of deaths. There have been a lot of deaths and cases of kidney injury.

Now, let's talk about how the mail was generated. Ladies and gentlemen, you are being subjected to the biggest snow job in American history. People are not writing because they want protection. Most of the people are writing because they really have a basis to believe that the FDA is going to take away their supplements.
What has happened is that the industry has been saying amongst itself and to the public, fight for your family’s rights, the FDA is attempting to take away your family’s right to choose safety and beneficial nutrition at supplements. Baloney. Here is another “Don’t let the FDA take your vitamins.”

Here is another one, “Write to Congress today or kiss your vitamins good-bye.” I ask you this: Is the FDA really going to do anything that is going to impact on the majority of those 100 million people who are taking vitamins, most of whom take it because they are not sure they get enough in their diet, the answer is no, the FDA never has and never will attempt to restrict the use of moderate vitamins used for nutrition.

This is a disinformation campaign. I have walked into General Nutrition stores. They have letter writing booths where they say write now or you will lose your vitamins.

So most of the people who are writing to you from the consumer side are people who have been scared into believing they are going to lose something if they don’t write to you.

They don’t understand what they have been writing about. They have been misled.

Now, I have one other item which I am going to give to the subcommittee. This is a videotape to promote the vitamin bills. It is a one-minute tape. It shows Mel Gibson, the actor, and the tape opens with a SWAT team coming in with appropriate music, and I guess it is infrared devices and descending on his home. The women see Mel Gibson in handcuffs and he says, gee, fellows, all it is is vitamin C. Then he says they have already raided doctors’ offices and health food stores, will your home be next.

That is nonsense. The FDA is not about to invade people’s homes. But this kind of promotion is stirring people up to write to you.

Now, I hope that—well, I guess it is hard to turn down or push away the thousands of letters. If you really want to represent consumers, ignore that because people are writing to you for two reasons: They are either in the supplement business selling as retailers, clerks, multi-level distributors, and there are about 1 million people doing this, or people have been misled into thinking they are going to lose something.

Several people have a vested interest in the product and they want to get rid of FDA supervision and the rest of the people have simply been misled.

Mr. Durbin. Thank you.
TESTIMONY BEFORE THE HOUSE OF REPRESENTATIVES
APPROPRIATIONS SUBCOMMITTEE ON AGRICULTURE,
RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION,
AND RELATED AGENCIES, OCTOBER 18, 1993

Statement of Stephen Barrett, M.D.
National Council Against Health Fraud, Inc.
P.O. Box 1747
Allentown, PA 18105
215-437-1795

Mr. Chairman and members of the subcommittee:

The dietary supplement industry is fighting to weaken FDA regulation over its products. The industry would like you to believe that the issue involved is "freedom of choice" and that consumers need protection from the FDA. Nothing could be further from the truth! What industry leaders really want is the freedom to mislead to consumers without government interference.

The groundwork for the massive letter-writing campaign that Congress now faces was laid in February 1992 at a meeting of supplement industry leaders. Two bills, then pending in Congress, would have greatly strengthened our government's ability to combat health frauds. H.R. 2597/S. 2135 would have increased the FDA's enforcement powers as well as penalties for violating the Food, Drug, and Cosmetic Act. And H.R. 1662 would have amended the Federal Trade Commission Act to make it illegal to advertise nutritional or therapeutic claims that would not be permissible on product labels. The industry also feared that the FDA would stop the sale of amino acids, herbs and various other "supplements" that have no proven value. The meeting's outcome was formation of the Nutritional Health Alliance (NHA) to enable manufacturers, suppliers, distributors, retailers, consumers, and other supplement industry allies to coordinate their efforts. (See Attachment A.)

To launch its disinformation campaign, NHA advertised in trade publications that "The FDA wants to put you out of business. Every health food store is under immediate threat of siege. Congress wants to give the FDA police powers so they can seize products without notification and use heavy fines and court penalties to close you down. The FDA wants to destroy your supplement business by making many items prescription only. The FDA wants to make it illegal to sell the majority of your best selling products. . . . If current FDA and Congressional actions are passed and enforced, the nutritional supplements industry as we know it will vanish within the next 12-18 months—and most health food stores will be out of business." (See Attachment B.)

In addition to blocking bills to strengthen government regulation, the supplement industry is campaigning to weaken it. In April 1993, bills titled the Dietary Supplement and Health Education Act of 1993 were introduced by Senator Orrin Hatch (R-UT) and Representative Bill Richardson (D-NM). Senator Hatch's version (S. 784) defines "dietary supplements" as vitamins, minerals, herbs, amino acids, and other substances intended "to supplement the diet by increasing the total dietary intake." (This definition covers everything the health-food industry would like to call a supplement.) The bill would also (1) prevent the FDA from classifying such products as drugs or food additives, regulating their dosage, or making them available only by prescription; (2) permit manufacturers to make therapeutic claims based on flimsy evidence; and (3) stall most FDA regulatory actions by permitting manufacturers who receive a warning letter to protest to the Department of Health and Human Services or seek court review. Representative Richardson's version (H.R. 1709) is similar but not quite as restrictive. If either bill passes, the FDA's ability to protect consumers from fraudulently marketed "nutrition" products will be
severely weakened. The New York Times has called these bills “The 1993 Snake Oil Protection Act.” (See Attachment C.)

To support these bills, proponents are generating mail from "health food" manufacturers, retailers, and distributors, as well as from health-food store shoppers, customers of mail-order companies, multilevel distributors, "natural health" practitioners, and bodybuilding and fitness enthusiasts who use supplements. To fire up their troops, proponents are portraying the FDA as a Gestapo-like agency and are urging consumers to "write to Congress today or kiss your vitamins goodbye!" (See Attachments D and E.) The campaign's leaders want legislators to believe that the outpouring of mail represents a "grass-roots" effort by consumers who wish to preserve "freedom of choice." Most of the mail, however, is coming from individuals who profit from the sale of supplements or who have been misled by those who profit.

Another misleading tool used by the bills' proponents is a videotaped 60-second public service announcement intended to dramatize government interference with people's freedom to take vitamins. The video shows footage from a television program showing a SWAT team, guns drawn, raiding a private home to arrest the owner (played by Mel Gibson), who is located in the kitchen holding a bottle of vitamin C. "It's only vitamins," Gibson protests as he is handcuffed, "vitamin C, you know... like in oranges." During the "arrest," viewers are told: "The federal government is actually considering classifying most vitamins and other supplements as drugs. The FDA has already conducted raids on doctors' offices and health food stores. Could raids on individuals be next? Protect your right to vitamins. Call Congress now." The scenario, of course, is no more realistic than the claims that the "health food" industry makes for most of its products.

In a speech from the Senate floor, Senator Hatch stated that the FDA has "repeatedly attempted to impose unnecessarily stringent standards that would leave many if not most supplement companies with no practical choice but to close their doors." As a result, he claimed, "consumers are left uninformed and the nation pays millions of dollars for health care that could have been saved through disease prevention."

The idea that FDA regulation leaves consumers uninformed is ludicrous. The supplement industry maintains a never-ending flow of information (most of it misleading) through talk shows, books, health-food magazines and newsletters, public relation firms, oral claims by retailers, and other channels. The idea that its strategies would lower health-care costs is even more ridiculous. Although some constituents recommend a sound diet that is low in fat and high in fiber, others recommend diets that are unbalanced or nutritionally inadequate. Although some people can benefit from taking supplements, virtually everyone connected with the industry recommends them unnecessarily and/or inappropriately. In fact, having observed the health-food industry for many years, I consider it a form of organized crime.

During the past twenty years I have collected advertisements and product literature containing false, misleading, and unsubstantiated claims for thousands of products sold through health food stores, multilevel (person-to-person) companies, and the offices of unscientific practitioners. Every one of these documents is evidence of violation of federal and state criminal laws. I have also collected hundreds of reports and other documents related to government regulation of supplement manufacturers. Here are some examples:

• General Nutrition Corporation (GNC), the nation's largest chain of health-food stores, has been subjected to at least 25 regulatory actions involving unsubstantiated claims made for supplement products. (See Attachment F.)

• I have collected evidence that, during the 1980s, at least 26 manufacturers, including GNC, marketed L-tryptophan products with illegal claims. L-tryptophan supplements have killed at least 28 persons and caused thousands of others to become seriously ill. (See Attachment G.)

• Nature's Plus, whose president, Gerald Kessler, is also president of the Nutritional Health Alliance, has marketed more than twenty "dietary supplement products" with false and misleading claims. (Attachment H contains eleven examples.)

2
• Many investigators have reported that health-food retailers are prone to “prescribe” products to their customers. In 1989, for example, volunteers of the Consumer Health Education Council (CHEC) telephoned 41 Houston-area health food stores and asked to speak with the person who provided nutritional advice. The callers explained that they had a brother with AIDS who was seeking an effective alternative against the HIV virus. The caller also explained that the brother’s wife was still having sex with her husband and was seeking products that would reduce her risk of being infected, or make it impossible. All 41 retailers offered products they said could benefit the brother’s immune system, improve the woman’s immunity and protect her against harm from the HIV virus. Thirty said they sold products that would cure AIDS. None recommended abstinence or use of a condom. (See Attachment I)

• In July 1993, FDA Commissioner David Kessler, M.D., J.D., released Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace, a 110-page report documenting widespread criminal activity by health-food industry manufacturers and retailers. The report listed (1) more than 500 “dietary supplements” and the unsubstantiated claims made for them in company catalogs and other product literature; (2) FDA enforcement actions (seizures and warning letters) taken against 188 dietary supplements from November 1990 through June 1993; and (3) a list of oral representations that supplement retailers made for specific products for high blood pressure, immune system problems, and cancer. The list was compiled by FDA personnel in each of the FDA’s 21 district offices throughout the United States who visited local health-food stores, posing as prospective customers. The investigators asked “What do you sell to help high blood pressure?” “Do you have anything to help fight infection or help my immune system?” and “Do you have anything that works on cancer?” Of 129 requests for information summarized in this section of the FDA report, 120 resulted in recommendations of specific dietary supplements. On six occasions, employees merely provided references from reading materials on dietary supplements. Store employees declined to make recommendations in only three cases. In 21 cases, employees made direct use of Prescription for Nutritional Healing, a 384-page book—filled with unsubstantiated therapeutic claims—whose publisher promises that the book will increase their sales. (See Attachments J and K.)

The public needs protection, not from the FDA, but from those who exploit misinformation and false hope. The Hatch/Richardson bills will not protect consumers but will make it easier for them to be exploited.

Stephen Barrett, M.D., who practices psychiatry in Allentown, Pennsylvania, is a nationally renowned author, editor, and consumer advocate. An expert in medical communications, he is medical editor of Prometheus Books and edits Nutrition Forum, a newsletter emphasizing the exposure of fads, fallacies and quackery. His 35 books include The Health Robbers: A Close Look at Quackery in America; Vitamins and “Health” Foods: The Great American Hustle; and four editions of the college textbook Consumer Health: A Guide to Intelligent Decisions. One book he edited, Vitamins and Minerals: Help or Harm?, by Charles Marshall, Ph.D., won the American Medical Writers Association award for best book of 1983 for the general public and is now a special publication of Consumer Reports Books. Dr. Barrett is a board member of the National Council Against Health Fraud, a Scientific Advisor to the American Council on Science and Health, and a Fellow of the Committee for the Scientific Investigation of Claims of the Paranormal (CSICOP). In 1984, he received an FDA Commissioner’s Special Citation Award for Public Service in fighting nutrition quackery. In 1986, he was awarded honorary membership in the American Dietetic Association. In 1987, he began teaching health education at The Pennsylvania State University. His recent projects include Dubious Cancer Treatment, published by the Florida Division of the American Cancer Society; Health Schemes, Scams, and Frauds, published by Consumer Reports Books; Your Guide to Good Nutrition, published by Prometheus Books; and Reader’s Guide to “Alternative” Health Methods, published by the American Medical Association.
Commentary

A Lasting Dilemma

R. Howard had a terrific commentary all written up last week about the organic food movement and about the survey for this issue and then I attended an Industry summit that convinced me that nothing could be more important than telling you what occurred this past weekend (Feb.21-23).

About 30 individuals representing different facets of the health food industry were invited by the Dietary Supplement Coalition (DSC) to an Industry summit at the J&R Double Arch Ranch in San Ynez, CA to learn more about the legislative issues threatening our Industry. What we heard was that it was do or die time. The enormity of the situation shocked those present into creating a New World Order for our Industry.

People who were enemies, people who had filed lawsuits against each other, people who had written nasty letters to each other, people who would never consider even being in the same room with each other, all got together and decided to put past animosities aside and work together to confront a set of legislative and regulatory issues, that if enacted, could ruin this industry.

We all arrived with different perspectives on the battle ahead. But we all left with one goal: to work together to save this industry and to work fast. That’s why I decided to “hold the press” and get this information out now.

“There is major legislation on several fronts that if passed as proposed will mean the end of 50 percent of this industry in the next couple of years,” proclaimed Scott Bass, legal counsel for both the NFPA and the DSC, but who spoke at the meeting as an expert in the industry, “I’m not talking about actions that we don’t like. I’m talking about issues out there that are so serious and life threatening that if we’re not unified will go through.”

With this message the meeting began. The issues facing this industry in the next few months are a result of converging movements in Congress and in the Food and Drug Administration that by coincidence or design are gathering momentum, much like a tornado about to strike.

What is happening is not easy to explain in just a few words, but basically the following is my understanding of the issues. We are being threatened on several fronts:

1. The FDA Enforcement Amendment of 1991, H.R. #3642, sponsored by John Dingell (D-MI) and Henry Waxman (D-CA) and Senate Bill #2135 sponsored by Sen. Edward Kennedy (D-MA). In brief, this bill would give the FDA, a regulatory agency, parity with other enforcement agencies. Using military terms, it would serve to give atomic age equipment—in the form of increased embargo, subpoena and inspection powers and civil penalties of up to $1 million—to an agency which up to now had been only a Third World power.

2. Distortions of the Nutritional Labeling and Education Act (NLEA). The NLEA, passed in the Fall of 1990, basically was a mandate from Congress to provide more honest food labeling to consumers so that they could better select foods that were good for them. It was a pro-consumer law that validated the industry’s long held belief that foods do affect our health. But the FDA, it appears, is resolved to change the intent of Congress and actually drastically restrict the flow of information.

This is how they will do that. By limiting the number of health claims that can legally be made to four and by treating vitamins as either foods or drugs. Simply put, what FDA has said is either a dietary supplement has a potency level close to that found in conventional foods and is thereby regulated as a food or it is above that amount, and therefore classified as a drug.

And perhaps most distressing of all, according to reliable sources within Washington, the Task Force on Dietary Supplements headed by Gary Dykstra (FDA’s deputy associate commissioner for regulatory affairs), will come out with a report that will categorize supplements into three groups:

A. A-Z vitamins and the major minerals
B. Amino Acids
C. Herbs and all other nutrients such as CoQ10, selenium, chromium, etc.

Based on where our sources say the Task Force is heading, the last two categories will be removed from the market... period. Aminos will be classified as drugs and taken away from us and class three items will be “vigorously enforced.” The report is expected to come out this month (it was originally scheduled for December).

Scared enough? There’s more... The proposed switch away from RDAs (Recommended Daily Allowances) to RDIs (Reference Daily Intakes) as the FDA proposed as part of the NLEA, would further decrease the level of nutrients in multivitamin and multimineral formulations. (See Commentary, Jan. 1992)

And, in addition to these problems, a third bill, #1662 the Nutrition Advertising Coordination Act introduced by Rep. Joe Moakley (D-Mass) will coordinate action between the FDA and the Federal Trade Commission. It will most likely result in more restrictive advertising guidelines to match the rules on labeling.

Faced with these rapid-firing assaults on several fronts, leaders within the health food industry have been struggling to fight this onslaught of legislation. There have been letters sent by the hundreds of thousands, articles written, lobbying done, petitions

(Continued on page 23)

Do or Die Time

(Continued from page 2)

HEALTH FOODS BUSINESS/March 1992

Attachment A
The FDA wants to put YOU OUT OF BUSINESS

Every health food store is under immediate threat of siege. Congress wants to give the FDA police powers so they can seize products without notification and use heavy fines and court penalties to close you down.

§ FDA wants to destroy your supplement business by making many items prescription only.

§ FDA wants to make it illegal for you to sell the majority of your best selling products.

§ FDA wants you to only sell A's, B's, C's etc.in low potencies knowing this will not allow your business to survive.

If current FDA and Congressional actions are passed and enforced, the nutritional supplements industry as we know it will vanish within the next 12-18 months—and most health food stores will be out of business.

No one can afford to ignore this imminent danger—your future and the future of the entire health food industry is in YOUR hands.

If you don't do something about it, NO ONE ELSE WILL.

The NHA is a non-profit coalition that is supported by the entire Health Food Industry—manufacturers, distributors, retailers, health care professionals, associations, and consumer groups.

Contributions are urgently needed for the survival of our industry. Please send whatever you can afford today!

How the FDA Intends to Eliminate our Industry...

● The FDA Task Force Report due to be released in April allegedly contains a recommendation to circumvent the existing Proxmire Law.

● H.R. 3642/S. 2135 are bills before Congress that will empower the FDA with police powers and authority to impose heavy civil penalties that could be used to destroy our industry.

● Possible legislation such as former H.R. 1662 which could ban virtually all health claims and choke the flow of nutritional information to the public.

● The FDA interpretation of the NLEA (Nutrition Labeling & Education Act of 1990) seeks to restrict all health claims and allow the FDA to severely limit the potency of safe and beneficial products you have sold for years.

● The NLEA also contains a provision to give all State Food and Drug Agencies enforcement powers to impose the same severe civil penalties as the Federal FDA.

● In anticipation of increased enforcement activities, the FDA has just hired 100 new criminal investigators. The new director of this Office of Criminal Investigation is said to be a former Secret Service agent... you are their target.

Nutritional Health Alliance ... We're fighting back!!

● By preventing the FDA Task Force from undermining the Proxmire Law and attacking nutritional supplements such as herbs, amino acids and trace minerals.

● By clarifying the NLEA regulations to guarantee the right to make valid health claims and sell beneficial dosages of nutritional supplements.

● By lobbying against H.R.3642/S.2135 to prevent oppressive FDA police power from destroying our industry.

● By removing R.D.I. from the NLEA regulations to ensure beneficial potencies for dietary supplements.

● By supporting the Proxmure Bill of the 90's to eliminate all present and future attacks on nutritional supplements.

● By mounting the largest Congressional letter writing campaign in history, which will make the FDA and Congress understand that this industry means to survive and prosper.

Nutritional Health Alliance
Protecting Your Right to Choose

Tel: 516 249 7070

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The 1993 Snake Oil Protection Act

Forget health care reform or reinventing government. The biggest volume of mail being logged in many Congressional offices these days calls on lawmakers to block action by the Food and Drug Administration to ban the sale of vitamins and other dietary supplements. The only problem is, the agency has no such proposal.

Using scare tactics and misinformation, the dietary supplement industry has managed to rally thousands of health-minded Americans to support legislation that would actually deprive consumers of reliable health information.

Displays in health-food stores across the nation—-equipped with sample letters, envelopes and stationery—alert citizens about the F.D.A.'s mythical vitamin ban and urge citizens to write to Congress to support legislation sponsored by Senator Orrin Hatch, Republican of Utah, and Representative Bill Richardson, Democrat of New Mexico. Without such legislation, a brochure warns, consumers can "kiss your supplements goodbye."

The industry's goal is to get Congress to exempt supplements permanently from the new food labeling law. That law sensibly requires that all health claims for food and supplements be supported by "significant scientific agreement."

Under the new food labeling rules, products that claim to contain essential ingredients to, say, cure baldness or male impotence might have to change their labels. But contrary to the industry's disinformation campaign, the products themselves wouldn't be banned.

The Hatch-Richardson legislation would lower the new labeling standard to allow health claims for supplements supported only by unconfirmed preliminary studies not subjected to any meaningful scientific peer review. It would also make it harder for the F.D.A. to seize products promptly, or demand proof of safety, where there is mounting evidence that a product may be dangerous.

This fight, in other words, really isn't about keeping supplements on the shelves. It's about the right of unscrupulous companies and individuals to maximize profits by making fraudulent claims.
Time is running out.
Get Congress to act now!

Don't let the FDA take away your safe and beneficial dietary supplements! Learn the best ways to reach lawmakers — what to say in a letter, postcard or phone call, and when to visit your representative in Congress. NHA's Political Action Guide will help you understand the issues and how to convince Congress to act now.

Call today or send in the coupon below to order your
NHA Political Action Guide
Campaign '93
1-800-289-0033, Ext. 950

Nutritional Health Alliance
NHA
Protecting Your Right to Choose

100% of all proceeds will go to grass roots and lobbying efforts to protect your nutritional rights.

Nutritional Health Alliance • P.O. Box 267 • Farmingdale, NY 11735
The Nutritional Health Alliance is a nonprofit coalition of consumers, health care professionals, health food retailers and dietary supplement manufacturers.
ACTION ALERT

DON'T LET FDA TAKE YOUR VITAMINS AWAY!

Tell your Senators and Representative in Washington, D.C. to cosponsor the Dietary Supplement Health and Education Act and protect your access to beneficial vitamins, minerals, herbs and other dietary supplements, as well as information about their important health benefits!

Don't let the FDA turn your safe and beneficial dietary supplements into prescription drugs. Don't let them keep you in the dark about the role supplements can play in preventing disease and promoting good health.

Ask both of your U.S. Senators to cosponsor S. 784, Introduced by Sen. Orrin Hatch (R-Utah) and Sen. Harry Reid (D-Nev.). Ask your Representative to cosponsor H.R. 1709, Introduced by Congressman Bill Richardson (D-New Mex.).

You can find the names of your Washington representatives in the government section of your telephone book or by calling the League of Women Voters.

The address for all Senators is:
Senator_________________________
United States Senate
Washington, DC 20510

The address for all Representatives is:
Representative__________________
U.S. House of Representatives
Washington, DC 20515

WRITE TO CONGRESS TODAY

Protect your right to choose wellness over illness. Support the Nutritional Health Alliance. Our Campaign '93 Political Action Guide will provide you with complete addresses and phone numbers for Congress, tips on communicating with lawmakers, background information on the issues, and much more. The Action Guide is yours when you make a donation to the NHA of $25 or more. Order yours today by calling 1-800-289-0033, Ext. 950!

WHAT THE BILLS WOULD DO:

√ Allow health claims that (1) accurately represent the current state of scientific evidence; (2) accurately describe the ability of the supplement to prevent or repair damage from environmental factors; or (3) duplicate claims already approved for conventional foods.

√ Prohibit dietary supplements from being regulated as drugs or food additives, and prohibit restrictions on potencies and combinations.

√ Establish an Office of Dietary Supplements within the National Institutes of Health to coordinate and promote research and advise FDA on dietary supplement issues.

NHA Call The NHA Hotline For A Legislative Update: 1-800-226-4NHA
Administrative Office: (516) 349-2070 - Box 327 - Farmingdale, NY 11735
Almost from its inception, the FDA has voiced AMA policy in attacking preventative health care and in particular, nutritional supplementation.

The results are 2 billion dollars a day in health care costs and millions of concerned Americans who cannot afford health insurance.

The American family with its back to the wall, is struggling to pay sky-rocketing health care costs. How anguish will they be when they discover that most of the pain, suffering and dollars spent might well have been avoided.

How is the FDA attempting to take away your family's nutritional rights?

§ If the current FDA and Congressional actions are passed and enforced, 50% of all nutritional supplements will no longer be available to Americans within the next 12 to 18 months. Indeed, your family's right to choose safe and beneficial nutritional supplements may cease to exist.

§ The FDA Task Force Report released in April may undermine the existing Proxmire Law, which protects nutritional supplements from overregulation by the FDA.

§ HR 3642/S. 2135 are passed, the FDA will be empowered with police powers and the ability to levy heavy civil penalties that will be used indiscriminately against dietary supplements and force most health food stores out of business.

§ The new NLEA regulations give each of the 50 states the same enforcement powers as the FDA to also indiscriminately impose and enforce severe penalties against honest suppliers of quality nutritional supplements.

§ In preparation for increased enforcement activities, the FDA has hired 100 criminal investigators led by a 20-year veteran of the U.S. Secret Service. These new G-men will be unleashed on the supplement industry to enforce unwarranted restrictions designed to limit your access to preventative health care.

Protecting your health care rights

The Nutritional Health Alliance (NHA) is an organized coalition of manufacturers, retailers, health care professionals and concerned consumers who are committed to protecting your nutritional right to choose wellness over illness.

What the NHA is doing to protect your family's nutritional rights

- Preventing the FDA Task Force from undermining the Proxmire Law and attacking nutritional supplements such as herbs, amino acids and trace minerals.
- Lobbying against HR 3642/S. 2135 to prevent oppressive FDA police powers from destroying our country's nutritional supplement industry.
- Clarifying the NLEA regulations to guarantee your right to receive valid health claims and beneficial dosages of nutritional supplements.
- By supporting legislation to enhance the Proxmire Bill which will eliminate all present and future attacks on nutritional supplements.
- With your help, the NHA will organize the largest Congressional letter writing campaign in history. The FDA and Congress will see that the people's right to choose dietary supplements will once again continue to survive.

This coordinated effort promises to be the most effective grass-roots lobbying campaign in history, surpassing even the battles of the 70s which led to the passage of the Proxmire Law by a unanimous vote. The Proxmire Law is intended to prohibit the FDA from overregulating nutritional supplements.

Tel: 516 249 7070

Nutritional Health Alliance

NHA

Protecting Your Right to Choose

What you can do to protect your family's nutritional right to choose wellness over illness!

Send your donations to the NHA to protect your family's nutritional rights. The NHA will send you information on key issues, a list of the key legislators who are against your nutritional rights and sample letters to help you influence these Congressmen to protect your rights.

- $20  - $30  - $40  - $50  - $100

Send your donations to:

Nutritional Health Alliance

P.O. Box 267, Farmingdale, NY 11735

The Nutritional Health Alliance is a non-profit organization. Contributions may not be tax deductible.
ATTACHMENT F: REGULATORY ACTIONS
AGAINST GENERAL NUTRITION CORPORATION

1-2. FTC (1969): False advertising charges were brought regarding claims for Geri-Gen ("therapeutic tonic") and Hemotrex. Settled by consent decree.

3. FDA (1974): A supply of vitamin C tablets was seized and destroyed under a consent agreement. The FDA had charged that the labeling of the tablets, which contained bioflavonoids, made false and misleading nutritional claims.


6. FDA (1981): GNC agreed to drop claims that lysine cured genital herpes. However, the company continued to circulate literature suggesting it would.

7. USPS (1982): Complaint charged that advertising for Advantage Starch Block contained false representations that the product blocked the absorption of calories from starch-containing foods. A false representation order was issued in 1983. The California Dept. of Health issued an embargo.

8-20. USPS (1984): GNC was charged with making false representations for 13 products: Risk Modifier (a nutrient mixture claimed to decrease cancer risk); Life Expander Choline Chloride (claimed to improve memory); Mental Acuity Formula (supposedly able to prevent or retard memory loss due to aging); Life Expander Fat Fighter (containing DHEA, claimed to cause weight loss without dietary modification); Challenge Maximum Body Builder (claimed to have special muscle-building properties); L-Glutamine tablets (claimed to "keep you mentally and emotionally in balance"); Lipotropic Fat Fighter Tablets (a nutrient mixture that supposedly could reduce body fat); Spirulina (which supposedly will "turn off your brain's appetite control center"); the 24-Hour Diet Plan and the Practical Diet Plan (both "guaranteed" to produce weight loss of "up to 10 pounds in two weeks"); Life Expander Growth Hormone releaser (claimed to cause weight loss without dieting); Herbal Diet Formula (supposedly capable, by itself, of causing weight loss); and Inches BeGone (a body-wrapping cream claimed to reduce any area where you want to lose inches). The complaints were settled with a consent agreement.

21. FTC (1984): An administrative complaint charged GNC with making deceptive claims that its Healthy Greens might help people prevent cancer. In 1986 an Administrative Law Judge concluded that "GNC's unconscionable, false and misleading advertising found in this case is not an isolated incident but in fact is a part of a continuing pattern. . . . GNC's false and deceptive advertising in this case may be seen as an indication of GNC's propensity to employ false and misleading advertisements."

22. FDA (1984): Criminal prosecution charging that GNC, three of its officers, and two retail store managers had violated the Federal Food, Drug, and Cosmetic Act by conspiring to promote and sell an evening primrose oil product with claims that it is effective against high blood pressure, arthritis, multiple sclerosis and other diseases. In 1986 the company pled guilty to four counts of misbranding a drug, and former president Gary Daum pled guilty to one misbranding count.

23. FDA (1985): Appetite Control Factor with CCK was recalled after the FDA informed the company that claims made for the product made it an unapproved new drug.

24. FDA (1985): Life Expander Fat Fighter was recalled after the FDA informed the company that claims made for the product made it an unapproved new drug.

25. Pa. Dept. of Health (1989): A consent agreement stopped allegedly false representations for a Helsinki formula hair treatment. The product had been marketed with false claims that it was a proven treatment for thinning hair and that the vitamin supplement contained "those special nutrients that have been proven helpful in an overall hair-care regimen."

In 1986, I observed that the actions of the FDA, FTC and USPS appeared to have had considerable impact on General Nutrition's marketing practices. During 1986, the stores continued to misrepresent the need for people to take supplements for "insurance" or for the ordinary stresses of life, but I encountered no illegal therapeutic claims for GNC products. The company did continue to make false and illegal claims for other brand products sold through its stores. The stores still convey misleading messages about the need to take supplements, and several investigators have noted unsubstantiated (and illegal) claims made by clerks to prospective customers.
### ATTACHMENT G: DUBIOUS CLAIMS FOR L-TRYPTOPHAN

Some of these companies habitually and flagrantly make illegal therapeutic claims for many products. Some have been subjected to regulatory actions unrelated to tryptophan.

<table>
<thead>
<tr>
<th>Company</th>
<th>Claim</th>
<th>Where Made</th>
</tr>
</thead>
<tbody>
<tr>
<td>AARP Pharmacy Service</td>
<td>Helps to minimize the effects of stress, anxiety, depression and insomnia in the body.</td>
<td>Mail-order catalog*</td>
</tr>
<tr>
<td>Alacer Corporation</td>
<td>Trypotimies Stress Formula [Contains 150 mg L-Tryptophan]</td>
<td>Catalog</td>
</tr>
<tr>
<td>Barth’s Nutritional Supplements</td>
<td>Nutri-Val ... drug-free way to aid natural relaxation [contains 50 mg tryptophan]</td>
<td>Mail-order catalog</td>
</tr>
<tr>
<td></td>
<td>Trypo-Best. L-Tryptophane is an essential amino acid that works in the brain to make “Serotonin,” a natural tranquilizer substance that may help induce sleep. ... See how these tablets can help you get a good night’s sleep. Nutri-Active Trypotraphan Plus ... to induce better sleep. L-Tryptophane 500 mg. Nature’s aid to safe, restful sleep.</td>
<td></td>
</tr>
<tr>
<td>Bedford Vitamins Co.</td>
<td>NeuroComp, a potent natural tranquilizer ... uniquely formulated with high potencies of known calmatives. Acts to reduce irritability and relax the central nervous system. Safe and non-habit-forming. Contains L-Tryptophane renowned for its tranquilizing properties and effectiveness in the treatment of insomnia...</td>
<td>Catalog. Company also published a newsletter about amino acids</td>
</tr>
<tr>
<td>Country Life</td>
<td>L-Tryptophane helps promote restful sleep. Aids in mood stabilization and assists in countering nicotine and carbohydrate cravings. ... Avoid if pregnant.</td>
<td>Flyer</td>
</tr>
<tr>
<td>Dietic (Division of FreshTops)</td>
<td>Helps to minimize the effects of stress, anxiety, depression and insomnia in the body</td>
<td>Product reference guide*</td>
</tr>
<tr>
<td>Doctor’s Mutual Service Co.</td>
<td>Tryptophane ... has been found helpful for some insomniacs.</td>
<td>Wholesale price list</td>
</tr>
<tr>
<td>Doctor’s Pride Inc.</td>
<td>L-Tryptophane Tablets - L-Tryptophane has come to be known as “Nature’s Tranquilizer. It is the precursor of serotonin, a chemical messenger of the brain. Serotonin has been found to be useful as an aid for relieving depression and inducing sleep.</td>
<td>Catalog</td>
</tr>
<tr>
<td>General Nutrition Corporation</td>
<td>L-Tryptophane Tablets ... “Nature’s tranquilizer” and as “the precursor of serotonin, a chemical messenger of the brain ... found to be useful as an aid for relieving depression and inducing sleep.”</td>
<td>Mail-order catalog</td>
</tr>
<tr>
<td>General Research Laboratories</td>
<td>Sommiphane. Each tablet contains 600 mg of L-Tryptophane</td>
<td>Catalog</td>
</tr>
<tr>
<td>Good N’ Natural Vitamins</td>
<td>L-Tryptophane Tablets - “Nature’s tranquilizer. This important amino acid is probably the most researched of them all. The body converts L-Tryptophane into Serotonin, a chemical messenger of the brain that acts as a natural tranquilizer.</td>
<td>Catalog</td>
</tr>
<tr>
<td>Great Earth International</td>
<td>Distributed three information sheets written by Earl Mindell which contain many claims for L-tryptophan.</td>
<td></td>
</tr>
<tr>
<td>Linblads, Inc.</td>
<td>(Distributed Nutri-Dyn products)</td>
<td></td>
</tr>
<tr>
<td>Makers of KAL</td>
<td>Supplemental tryptophane ... should then result in increased mental acuity and improves thought processes. ... Tryptophane supplements have become so popular not only because they improve your “thinkability,” but also because large doses of 500 to 1,000 mg are so effective in inducing sleep.</td>
<td>Self-education flyer</td>
</tr>
<tr>
<td>Nat-Rul Health Products</td>
<td>L-Tryptophane. ... Nutritionists and physicians have used it to help cure insomnia, depression, and mental stress.</td>
<td>Mail-order catalog</td>
</tr>
<tr>
<td></td>
<td>MaxiPhane - Natural drug-free aid to relaxation and sleep.</td>
<td></td>
</tr>
<tr>
<td>Company</td>
<td>Description</td>
<td>Catalog Location</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Natrol, Inc.</td>
<td>calms kids - a nutritional formula for the active child. [Contains 800 mg L-Tryptophan] Designed to combat the nutritional demands placed on children by stress</td>
<td>Rio Grande catalog</td>
</tr>
<tr>
<td>Nature's Bounty (Puritan's Pride)</td>
<td>L-Tryptophan Tablets . . . “Nature’s tranquilizer” and as “the precursor of serotonin, a chemical messenger of the brain . . . found to be useful as an aid for relieving depression and inducing sleep.”</td>
<td>L&amp;H Vitamins catalog</td>
</tr>
<tr>
<td>Nutri-Dyn</td>
<td>Tryptodyn #534 (Natural Relaxant)</td>
<td>Catalog</td>
</tr>
<tr>
<td>Nutrition Headquarters</td>
<td>L-Tryptophane Tablets Science continues to study this amino acids to see what effect it has in helping to give folks a good night’s sleep. L-Tryptophane also is important in the formation of enzymes that can help turn fats into energy.</td>
<td>Mail-order catalog</td>
</tr>
<tr>
<td>Nutritional Factors</td>
<td>Amino-Mate Sleep-Mate. L-Tryptophan is a well known relaxant, that, when chelated with magnesium, becomes a powerful sleep aid. Sleep-Mate provides the optimum sleep-inducing formulation of magnesium. L-Tryptophan . . . safe, effective, drug-free, and nonaddictive.</td>
<td>Flyer distributed to health food stores</td>
</tr>
<tr>
<td>Schiff Corporation</td>
<td>Tryptophane . . . helps induce normal sleep to most people, including chronic insomniacs. It has been reported that elderly persons suffering from senility problems such as forgetfulness, disorientation, hallucination, depression, argumentativeness, and similar states were relieved when Tryptophan was administered. Tryptolyn (a combination of tryptophan and lysine) . . . more effective than drugs in lowering blood cholesterol.</td>
<td>Flyers distributed to health food stores</td>
</tr>
<tr>
<td>Source Naturals</td>
<td>NutraSleep. Are You Sleeping? Lots of things can keep you awake . . . But where is something natural that really works, and won’t leave you groggy the next morning? NutraSleep is a safe, natural formula to help you relax, sleep well and wake up refreshed . . . Take NutraSleep and rest assured.</td>
<td>Ad in Health World</td>
</tr>
<tr>
<td>Synergy Plus</td>
<td>Special Stress. The Ultimate Stress Formula [Contains 100 mg L-tryptophan]</td>
<td>Ad in Let’s Live</td>
</tr>
<tr>
<td>U.S. Health Club</td>
<td>NatureSleep. Now . . . sleep restfully without depending on habit-forming drugs . . . NatureSleep tablets help you get the amount and kind of sleep you require . . . Now you can say goodbye to tossing and turning, and rely on NatureSleep to stop “bedtime blues.” . . . Restful sleep can . . . help prevent lowered resistance . . . Each tablet contains 500 mgs of L-Tryptophane . . . reported to have safe calming benefits that can help promote restful sleep.</td>
<td>Mail-order catalog</td>
</tr>
<tr>
<td>Vitamin Factory</td>
<td>L-Tryptophane Capsules for sleep. L-tryptophan is an amino acid that is an effective natural treatment for insomnia. Many people find that taking high doses of L-Tryptophan before bedtime helps them get to sleep.</td>
<td>Mail-order brochure</td>
</tr>
<tr>
<td>Vitamin Power</td>
<td>L-Tryptophane calms you down when you’re nervous and helps you sleep like a baby. It’s safe, effective and not a drug. Perks you up when you’re blue. Trypto-Calm Complex . . . to help you sleep better and help relieve simple nervous tension . . . A safe alternative to the synthetically-produced sleep aids on the market today . . .</td>
<td>Mail-order catalog.</td>
</tr>
<tr>
<td>Vitamin Specialties</td>
<td>L-Tryptophane. Aids in relaxation and helps to induce sleep naturally. There is overwhelming evidence that L-tryptophane has a positive effect on sleep.</td>
<td>Catalog</td>
</tr>
<tr>
<td>Western Vitamins &amp; Health Products</td>
<td>L-Tryptophane - “Nature’s Tranquilizer . . . an essential amino acid that works in the brain to make “Serotonin,” a natural tranquilizer substance that has been found useful as an aid for depression and possibly helping to induce relaxation! If nature’s aid to safe, restful sleep is what you are looking for, L-Tryptophan 500 mg tablets may be nature’s answer for you.</td>
<td>Mail-order catalog</td>
</tr>
</tbody>
</table>
CARDIO-MAXIM
MAXIMUM STRENGTH COMPLEX

Cardio-vascular disease is the number one killer in America. Therefore, strengthening the body's vital organs is an essential part of preventative health.

Nature's Plus introduces CARDIO-MAXIM, a sophisticated foundation of nutrients for those who are interested in this very special supplementation. No other formula of its kind offers nutrients which represent the latest advances in this area of nutritional research.

Two Protein Coated Tablets Contain:
- L-Taurine (free form amino acid) ........ 500 mg.
- L-Carnitine (free form amino acid) .... 200 mg.
- Bromelain (600 GDU/gram) ........... 140 mg.
- Magnesium (aspartate) ............... 100 mg.
- Potassium (aspartate) ............... 40 mg.
- C.S.A. (chondroitin sulphate A) ........ 25 mg.
- Vitamin B-6 (pyridoxine HCl) ........ 25 mg.
- Niacin ................................ 25 mg.

Product No. 5086 - 60 Tablets
Product No. 5087 - 90 Tablets
MEGA-TROPIC™
Fat Buster Formula
For Muscle Definition

MUSCLE MASTERS has formulated MEGA-TROPIC, the most complete and effective fat burning formula ever developed.

MEGA-TROPIC CONTAINS:
- CARNITINE: an amino acid that transports fat into the cell to be utilized for energy.
- CHOLINE & INOSITOL: fat emulsifying agents.
- METHIONINE: essential amino acid which prevents fatty degeneration of the liver.
- VITAMIN B6: essential for the metabolism of methionine and carnitine.
- BRINCALL BERRY EXTRACT: reduces the body’s ability to manufacture cholesterol, fat, and triglycerides.
- LEMON GRASS OIL: 90% citral, a natural cholesterol lowering agent.
- PHOSPHATIDYL CHOLINE: a patented fat and cholesterol emulsifier.
- Betaine HCL: important stomach enzyme for protein digestion.

The unique combination of nutrients, vitamins, amino acids, and enzymes in MEGA-TROPIC is a must for all bodybuilders desiring that CUT OUT LOOK OF A PRO.

Two Proteins Coated Tablets Contain:
- Choline Bitartrate .................................. 2128 mg (equivalent to 1000 mg elemental choline)
- Inositol ................................................. 500 mg
- L-Methionine (free form amino acid) .......... 500 mg
- L-Carnitine (free form amino acid) ........... 100 mg
- Betaine HCl (Beet molasses) ................. 100 mg
- Beta Sitosterol Complex (from natural soybean phytosterols) ........... 100 mg
- Vitamin B-6 (pyridoxine HCl) .............. 50 mg
- Brincall Berry Extract (with naturally occurring (-)-hydroxycinnamate) ...... 50 mg
- Lemon Grass (with naturally occurring citral) .................................................. 50 mg
- Phosphatidyl Choline (from natural soybean phospholipids) ....... 50 mg
- In a natural herbal base of Barberry Bark, Dandelion Root, Fennel Seed, Golden Seal, Capsaicin and Ginger.

Product # M82420 - 60 capsules
Product # M82421 - 90 tablets

ANABOLIC IMPULSE™
For Mental Determination and Physical Intensity

MUSCLE MASTERS ANABOLIC IMPULSE supplies nutrients which are known to stimulate the production of excitatory and inhibitory nerve transmitters. When the brain is supplied with a proper balance of these neuro-nutrients, the bodybuilders’ performance will be enhanced by the regulation of energy, electrolyte balance and impulse rate. This will allow the bodybuilder to train at a heightened capacity and to accelerate the recovery process while maintaining peak mental and physical intensity.

Two Capsules Contain:
- Aspartic Acid ...................................... 300 mg
- Glysine ............................................. 300 mg
- Choline Bitartrate ................................ 200 mg
- DLPA (D-phenylalanine) .......................... 200 mg
- L-Glutamine ........................................ 100 mg
- Pancreatonic Acid ................................ 100 mg
- GABA (gamma aminobutyric acid) ............ 50 mg
- L-Glycine ............................................ 50 mg
- RNA (ribonucleic acid) ......................... 50 mg
- Vitamin B-6 (pyridoxine HCl) ............... 20 mg
- DNA (deoxyribonucleic acid) ................... 5 mg

Product # M8265 - 60 capsules
Product # M8266 - 120 capsules

SMILAX Plus DMG
For Peak Muscular Growth and Increased Energy

MUSCLE MASTERS SMILAX Plus DMG offers the highest potency of the purest herbal extract of sarsaparilla available. Numerous publications and bodybuilding testimonials have indicated that SMILAX can produce the same beneficial effects as steroids without the harmful side effects. These benefits include increased muscular size and density, decreased body fat percentage, increased strength, increased recuperative abilities, and increased endurance.

MUSCLE MASTERS SMILAX also contains the addition of DMG, making our formula unique and far superior to any other on the market. DMG, the active component of vitamin B14, is an intermediary metabolite, aiding in the conversion of carbohydrates, proteins and fats into ATP.

MUSCLE MASTERS Maximum Strength SMILAX is a powerful blend of pure solid root extract of SMILAX officinalis and DMG (N-Dimethylglycine).

Ingredients contained in a natural blend of purified water, sorbitol, glycerine, and sarsaparilla flavor.

Product # M8271 - 2 oz. Bottle
**STRESS PLEX**

Stress PLEX is also ideal for those who experience a moderate amount of stress, and wish to take more frequent lower potencies throughout the day.

**Two Protein Coated Tablet Contains:**
- Vitamin C (Cold Rose Hops) 300 mg
- Pancreatinic Acid 100 mg
- Lactase (Lactase) 100 mg
- Oatmeal (Oatmeal) 100 mg
- Vitamin B-6 (Riboflavin) 10 mg
- Vitamin B-2 (Riboflavin) 10 mg
- Vitamin B-1 (Thiamine HCl) 10 mg
- Biotin 10 mg
- PABA 10 mg
- (Para Aminobenzoic Acid) 10 mg

In a fortified Rice Bran base.

**SSENSI-STRESSCAPS**

Sensi-Stress is the perfect stress formula for all sensitive people, and for anyone who prefers a pure and natural capsule form for best and efficient results.

**Two Capsules Contain:**
- Vitamin C (Eco Farm) 500 mg
- Pancreatinic Acid 200 mg
- Lactase (Lactase) 125 mg
- Oatmeal (Oatmeal) 75 mg
- Vitamin B-6 (Riboflavin) 75 mg
- Vitamin B-1 (Thiamine HCl) 60 mg

In a natural herbal base containing Valerian Root and Chamomile.

**ULTRA STRESS WITH IRON SUSTAINED RELEASE**

Ultra Stress is a Mega Potency Stress Formula designed for those who experience an extreme amount of physical stress. Ultra Stress is for those "workaholics" who need an overactive life and require an extreme amount of energy and endurance to get them through the day.

For those who need to work down and feed from their hectic pace. Ultra Stress will provide a superior formula to offer you the strength, energy, and endurance to be alert, aware and able to handle the day's activities with energy and ease.

**One Protein Coated Tablet Contains:**
- Vitamin C (with Rose Hips) 500 mg
- Pancreatinic Acid 300 mg
- L-Cystine 100 mg
- Iron (Iron Ascorbate Complex) 25 mg
- Vitamin B-2 (Riboflavin) 10 mg
- Vitamin B-6 (Riboflavin) 125 mg
- Niacinamide 125 mg
- Choline (Choline) 75 mg

In a fortified Rice Bran base.

**MEGA STRESS COMPLEX SUSTAINED RELEASE**

For those who experience anxiety and nervous energy as a result of extreme stressful or emotional conditions, Mega Stress Complex was designed "Just for You." Mega Stress Complex contains Tryptophan, Valerian Root and Chamomile to provide a calming influence on the nervous and body.

Mega Stress Complex is "Your Frost" and can be taken by those who cannot tolerate yeast.

**One Protein Coated Tablet Contains:**
- Vitamin C 500 mg
- Tryptophan 500 mg
- Pancreatonic Acid 500 mg
- Magnesium 125 mg
- Biotin 100 mg
- Vitamin B-6 100 mg
- Calcium 100 mg
- Zinc (Cysteine Complex) 25 mg
- Choline (Choline) 75 mg
- Vitamin B-1 (Thiamine HCl) 60 mg
- Vitamin B-2 (Riboflavin) 60 mg

In a fortified Rice Bran base.

**EXEC-U-STRESS SUSTAINED RELEASE**

With the health of the business executive in mind, Nature's Plus has developed Exec-U-Stress, containing a distinct blend of ingredients which offer specific benefits to relieve irritability and anxiety and allow you to perform at the highest level of mental capacity possible.

**Three Tablets Contain:**
- Vitamin C 500 mg
- Tryptophan 500 mg
- Pancreatonic Acid 300 mg
- Zinc (Cysteine Complex) 125 mg
- L-Cystine 100 mg
- Iron (Iron Ascorbate Complex) 75 mg
- L-Tryptophan 200 mg
- Selenium 200 mg
- Biotin 100 mg
- (Para Aminobenzoic Acid) 100 mg
- Biotin 100 mg

In a fortified Rice Bran base.

**YEAST FREE • Vegetarian • Sugar and Bacterial Free**

Bottles of 30 - 60 - 90
AIDS FRAUD RAMPANT IN HOUSTON
Nicolas Martin

Between September 20 and October 12, 1989, the Consumer Health Education Council (CHEC) surveyed 41 Houston-area health food stores to determine the extent to which bogus treatments for AIDS are recommended. CHEC volunteers telephoned the stores and asked to speak with the person who provided nutritional advice. Each volunteer caller then explained that he had a brother with AIDS who recently was hospitalized with AIDS-related pneumonia and was now at home with his family. The brother was said to not be taking AZT (the only approved AIDS drug) but was seeking a more effective alternative against the HIV virus. The caller explained that he was the family member given the responsibility for locating the ‘alternative’ treatment and would forward information or products to his brother. The caller also informed the health food store employee that the brother’s wife had sex with her husband and was seeking products that would reduce her risk of being infected, or make it impossible.

Despite the illegality of their actions, all 41 retailers gave what amounted to medical advice for treating or preventing AIDS. Twenty-nine did so over the phone, while twelve asked the caller to visit the store. None referred the caller to a physician, clinic, or any organization that assists people with the disease. All stated that AIDS affects the immune system of the infected person and that they sold products that could “boost,” “enhance,” “improve,” or otherwise benefit the bodys system. While several expressed minor uncertainty about the wife having sex with her infected husband, none suggested that she be advised to cease such a practice or be told of her high probability of becoming infected by HIV. None advised using a condom. All said that their stores sold products that would improve the woman’s immunity and protect her against possible harm from the HIV virus. Twenty-seven claimed that if the wife took certain supplements she would be protected against infection.

Our callers emphasized that they were seeking a genuine cure for AIDS, not simply a way to prolong lifespan marginally. Thirty of the employees said they sold products that would cure AIDS. When this was questioned by the caller, most stood firmly by this claim. Some expressed slight reservations, like “I’m pretty confident it will work,” and some assured the caller that “people are having good luck” with whatever they recommended.

Many of the employees emphasized the influence of the mood on the susceptibility to infection or bodily reaction to HIV. Several said the products would be more effective if meditation or other ways to induce “positive thinking” were also utilized. One health food store “nutritional counselor,” to whom our volunteers were referred by the AIDS Foundation and other local AIDS support groups, said by phone that “people doing drug therapy are not doing well at all” and that it would be better to turn to “natural healing.” Several health food stores suggested referrals to herbalists or “nutritional” consultants in private practice. One employee, who recommended hydrogen peroxide, other products, and literature, said that her sister-in-law had died of AIDS.

The recommended products included: vitamins (41 stores); vitamin C (38 stores); immune boosters (35 stores); coenzyme Q10* (26 stores); germanium* (26 stores); lecithin (19 stores); ornithine and/or arginine (9 stores); gamma-linoleic acid* (7 stores); raw glandulars (7 stores); hydrogen peroxide (5 stores); homeopathic salts (5 stores); Bach flower remedies (4 stores); blue-green algae* (4 stores); cysteine (3 stores); and herbal baths (2 stores). [Editor’s note: Those marked with an asterisk (*) have been subjected to federal regulatory actions but are still being marketed.]

Several subjects were pessimistic about the benefits of using AZT, and some discouraged its use. CHEC knows of cases in which infected individuals decided to take “natural” treatments instead of AZT, a decision that can shorten their life.

Unfortunately, the Houston news media have shown little interest in what we did. Only United Press International and a weekly paper in Houston’s heavily homosexual district ran stories based on our survey. One television station used a hidden camera to film a health food store employee claiming to be able to cure AIDS, but the story was not aired. The media seem to view criticism of AIDS product fraud as an attack upon the victims rather than the perpetrators.

Mr. Martin is executive director of the Consumer Health Education Council, a nonprofit agency located in Houston.

QUESTION BOX

Q. What is “alternative agriculture”?

A. A recently released report by a committee of the National Academy of Sciences states that it is not a single system of farming practices. Rather, “it includes a spectrum of farming systems, ranging from organic systems that attempt to use no purchased synthetic chemical inputs to those involving the prudent use of pesticides or antibiotics to control specific pests or diseases. Alternative farming encompasses, but is not limited to, farming systems known as biological, low-input, organic, regenerative, or sustainable. It includes a range of practices such as integrated pest management; low-density animal production systems; crop rotations designed to reduce pest damage, improve crop health, decrease soil erosion; and, in the case of legumes, fix nitrogen in the soil; and tillage and planting practices that reduce soil erosion and help control weeds.” In simpler terms, it appears to be a loosely defined philosophy and set of practices aimed at minimizing the use of pesticides, antibiotics, and synthetic chemical fertilizers while protecting soil quality and remaining profitable. The 404-page NAS report Alternative Agriculture is available for $19.95 (softcover) or $29.95 (hardcover) from the National Academy Press, 2101 Constitution Ave., N.W., Washington, DC 20418.
Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace

Department of Health and Human Services
Public Health Service
Food and Drug Administration

July 1993
Introduction

This report demonstrates the pervasiveness of unsubstantiated claims currently being made for dietary supplements in the U.S. marketplace and reviews health hazards associated with dietary supplements.

FDA is issuing this report so that consumers have accurate information about the dietary supplement marketplace. The report has four sections:

- a list, with more than 500 entries, of dietary supplement products and the unsubstantiated claims currently being made for those products
- a representative list of recent FDA enforcement actions against dietary supplements
- a list of oral representations made for specific products for hypertension, immune system problems, and cancer by employees of stores selling dietary supplements
- a narrative report describing serious adverse reactions associated with selected ingredients marketed as dietary supplements.

Products with Unsubstantiated Claims

To gain an understanding of the current dietary supplement marketplace, FDA has compiled examples of dietary supplements and the claims being made for those products. Only printed claims have been included in this list; pamphlets and brochures, leaflets, point-of-purchase materials, and product advertisements were the primary sources of the claims.

Whenever possible, each dietary supplement product on the list is classified according to the following code: (AA) signifies an amino acid product; (G) signifies a glandular product; (H) signifies an herbal product; (Combo H) signifies a combination herbal product; (M) signifies a mineral product; and (V) signifies a vitamin product.

Each product makes at least one unsubstantiated claim; most make several. The claims range from treatment of such chronic diseases as cancer, emphysema and multiple sclerosis to the elimination of such disorders as incontinence and varicose veins. Some promise prevention of heart disease and cataracts. Others promise cures: "removal of kidney and gallstones." Some claim very specific outcomes, such as the product that "inhibits platelet aggregation" or the one that works against "diabetic vascular damage." Others promise relief from "infection."

Unsubstantiated claims being made for dietary supplements in the United States today include claims for treatment of such infectious diseases as AIDS, chickenpox, cholera, and dysentery; they range from the general ("infection" and "sepsis") to the specific ("ringworm" and "impetigo").

These products may be making a wide variety of claims, but they have one thing in common: Not one of the claims has been substantiated by FDA before their appearance in the marketplace.

FDA Enforcement Actions, November 1990 through June 1993

Because of the current legal and regulatory framework, FDA exercises oversight on the dietary supplement industry on a case-by-case basis. Each case is extremely resource-intensive. This section of the report lists representative FDA regulatory actions, between November 1990 and June 1993, against 188 dietary supplement products that made unsubstantiated claims about serious medical conditions. It includes only actions taken under the drug provisions of the Federal Food, Drug, and Cosmetic Act by FDA's health fraud program. Items in this section marked by an asterisk are product seizures; all other listings are warning letters. As the other sections of this report make clear, this investment of resources has failed to stem the tide of unsubstantiated claims.

Oral Claims for Dietary Supplements

As the long list of printed claims shows, unsubstantiated claims currently are pervasive in the dietary supplement industry. No picture of the current situation would be complete, however, without an understanding of oral representations being made about these products. To complete this picture, earlier this month personnel in each of FDA's 21 district offices across the nation informally visited local stores that sell dietary supplements.

During their visits, they asked salespeople the following questions about the use of dietary supplements for specific serious and life-threatening diseases:
• "What do you sell to help high blood pressure?"
• "Do you have anything to help fight infection or help my immune system?"
• "Do you have anything that works on cancer?"

The results of those visits are presented by disease category. Of the 129 requests for information summarized in this section, 120 resulted in recommendations of specific dietary supplements. In three instances, store employees declined to make recommendations. On six occasions, employees merely provided references from reading material on dietary supplements.

The oral representations of dietary supplements demonstrate the pervasiveness of unsubstantiated claims for serious diseases being made for these products across the nation.

Health Hazards Associated with Dietary Supplements

Unsubstantiated claims now being made for dietary supplements represent only part of the picture: In addition, some of these products present health hazards that can be serious and are sometimes fatal.

The report on health hazards focuses on selected ingredients currently available in dietary supplement products: nine herbal substances, two amino acids, four vitamin and mineral products that can be toxic at higher doses, and one other product. This list is not intended to be all-inclusive.

Conclusions

Roughly 80 percent of the dietary supplement marketplace consists of vitamins and minerals that are marketed at reasonable potencies and make no unsubstantiated health claims. The conclusions of this report do apply, however, to the other 20 percent of the marketplace: those dietary supplement products that present safety concerns or make unsubstantiated claims.

Thousands of unsubstantiated claims are being made about hundreds of dietary supplements. Some ingredients marketed as dietary supplements have demonstrated serious and even life-threatening hazards.

As a result, millions of Americans are spending billions of dollars every year on dietary supplement products, many of which have shown little or no evidence of either safety or effectiveness. In this blizzard of claims for dietary supplement products, valid claims are currently indistinguishable from invalid claims. Moreover, people may be replacing legitimate treatments of demonstrated effectiveness with unproven and questionable remedies. For example, high blood pressure is a well-understood condition that is readily treatable. Left untreated, or improperly treated, it can be life-threatening.

This report suggests that the success of FDA’s rather modest enforcement actions of the past few years has been limited. The samples collected—along with oral representations of uses for dietary supplements—show that in nearly all cases unsubstantiated claims are moving off the product label and into catalogues, brochures, and oral sales pitches.

The history of health quackery in this century demonstrates that enforcement actions may cause manufacturers to remove claims from the label—but the products stay on the market. Even without claims on the label, sales literature and salespeople continue to make unsubstantiated claims. Moreover, products continue to be bought and used because of the original unsubstantiated claims made on their behalf.

The bottom line is this: The marketplace has changed little over the years despite FDA’s efforts. If anything, unsubstantiated claims are becoming more exaggerated, more products of unknown effect are available, and their use is escalating.

When it comes to dietary supplements, the position of the Food and Drug Administration is straightforward: Dietary supplements should be safe, and any health claim on their labels or in promotional literature should be scientifically valid.

Many of these products can be beneficial. FDA has prepared this report so that consumers will have information about the broad range of claims being made for them. We will have learned little from the turn-of-the-century days of the traveling medicine show if the proliferation of unsubstantiated claims for dietary supplements is allowed to continue.
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Mr. DURBIN. Dr. Priestly.

Dr. PRIESTLY. Thank you.

Well, two things: First, Dr. Barrett is absolutely correct. You have been told lies and half truths today. I guess I should be polite and call them a material misrepresentation of fact which were made to you by the FDA officials who were here today.

I would like to take the time to give two sentences for their one without the clock running because we should not have to spend our time before you correcting lies and misstatements that you have been told.

Shark cartilage, Kessler said there is no evidence and there is one lonesome study. Someone in his position cannot be unaware of a multitude of studies that have been performed on shark cartilage in human and animal subjects. We will put for you a computer list.

He cannot be unaware that the national institutes in NIH are funding studies on this product in human and animal level for patients with aids. David Kessler said there is far from conclusive evidence on folic acid. I was peripherally involved in this.

The CDC, his parent organization, has said the position on folic acid has been well discussed here. I was involved in another attempt to do a final study on folic acid and the CDC said the overwhelming preponderance of evidence was they would not allow us to do a blind study on the grounds that it would be unethical to withhold it from women.

He said that they would hold supplements to standard food. That is not true. In their advance notice of proposed rules, they are trying to sneak in dietary ingredients as food additives.

You have heard that has vast implications for where the burden of proof lies. He said there is no evidence for the claims to be made on these products pointing to a vast array. That is grossly untrue. We are systematically going through each product and categorizing the number of research studies published on these products.

They said they would review claims in a timely fashion and to the extent of science. I want to explain that that is categorically not true based on their previous history.

In 1991 they sent an aloe vera company a standard regulatory letter. This is aloe. It has always been used. It is as old as the hills. The University of Texas has been researching aloe for the last 10 years also on AIDS patients and they have published their findings. One can decrease the dose of AZT by 90 percent while taking aloe vera because aloe seems to be such an excellent anti-viral. It does block the AIDS virus in the test tube.

There are trials sponsored and funded by our government right now, using oral and intravenous aloe extract on AIDS patients. It may not be as preposterous as it sounds on face value. However, the FDA wrote them a letter and said they were unaware of any substantial scientific evidence that documents that these products were generally recognized as safe or effective.

In response to which, the Aloe Vera Company, which I know and deal with, dispatched a truck. They sent a truckload of boxes filled the available aloe studies from around the world for the last generation, in response to which the FDA returned the truck and the boxes unopened and sent them a one paragraph letter that said:
Our office has neither the time or resources available to review this material.

This is not the way to pursue this if you are going to claim credibility. There on a unsubstantiated claims documents published two years later the same aloe vera company shows up under unsubstantiated claims. I don't think it is possible to fulfill any standard for substantiation when this is what a company attempts to do and is totally rebuffed.

Dr. Kessler said we know that drugs work. Excuse me, I think he has been away from medical practice for too long. Drugs have very serious side effects and often do not work for diseases. That is why we keep developing new ones with a multitude of drugs for the same problems.

GAO did a study in 1985 that demonstrated that only 15 percent of the available drugs on the market have ever been truly found to be effective by scientific published literature. He said it is only labeling, a company can keep selling the product, they have to just change the label. I cannot believe Dr. Kessler is not aware of the enforcement actions of his agency.

If you read one thing from the enclosures I have for you, please read this, FDA versus the People of the United States. It documents raid after raid, when agencies go in with guns drawn, confiscate literature and confiscate and destroy the product, because something on the label indicates that it might be beneficial medically in their eyes. It is not always true that all you have to do is change the label.

At the bottom most of the time, it says the company has filed suit against the FDA and no charges have been filed by the FDA against the company or clinic to date. This has happened again and again. That is absolutely not true. They simply send a polite letter and the company can continuing manufacturing the product.

He said we have no intention of limiting access or takings product off the market. That is not true. I will address that in my testimony.

Thank you.

Now we will start over. We should not have to spend our time reuping the lies that you have been told.

[The information follows:]
Testimony by Joan Priestley, M.D.
Before the House Subcommittee on Agriculture, Rural Development, FDA and Related Agencies
Monday, October 18, 1993, 1:30 PM
For further information and briefing, call (202) 737-1909

Congressmen and Congresswomen, Good afternoon. My name is Joan Priestley. I am a medical doctor with a large private practice in California. I use a wide variety of natural and standard therapies to treat patients with immune system problems. It is a privilege and an honor to be able to speak with you in favor of the dietary supplement acts of 1993 (HR 509 and HR 1709). I'm here today because I am very concerned about:

1) recent excessive and unjust FDA enforcement actions,  
2) the true magnitude and ramifications of their present regulatory intentions, and  
3) adverse public health consequences and increased health-care costs for all Americans if these bills as currently written do not become law.

In 1990, Congress passed a well-intentioned bill, the Nutritional Labeling and Education Act, or the NLEA. It was designed to provide consumers with better information about the contents, health benefits and quality of the products and supplements we consume. Unfortunately, the FDA has subverted the original intent of this legislation. They have made unwarranted interpretations that have led to overly restrictive regulations. Instead of expanding consumer access to valid health information, the FDA's NLEA regulations severely restrict consumer education about the benefits of dietary supplements. If the FDA prevails, the NLEA will actually stand for 'Nearly Losing Every Alternative.'

I will explain. The FDA is saying to Congress, the media and public that they have no intention of taking vitamins off the market. But on July 23rd, I attended a 4-hour meeting with more than a dozen top FDA officials, at which they reluctantly admitted that they do intend to:

1. remove all amino acids from the over-the-counter market (and allow them to be approved as drugs perhaps years later)  
2. severely limit the amount per tablet of vitamins and minerals which have an RDA (recommended dietary allowance), and  
3. eliminate most other products, including all medicinal herbs, plant oils, and many other minerals and nutrients.

These severely restrictive actions are based on the FDA's flimsy and unsubstantiated speculations about the safety of these supplements. In fact, the FDA has squandered taxpayers' money by sending teams of agents to Congressional offices to spread what amounts to deliberate disinformation about their intentions regarding supplements and the practical effects of these bills. The FDA continues to make the assertion that they have no intention of taking these products off the market.
These propaganda tactics have dubious legality and are completely devoid of integrity. It is especially ominous that this disinformation campaign has originated from the highest levels of the FDA. Congress must fundamentally reestablish FDA accountability for public health policy. I highly recommend that any such remedial legislation include provisions for both Congressional oversight and judicial review of FDA actions, until such time as the FDA can reestablish its credibility with Congress. The FDA is publicly making three additional false assertions which I will address briefly:

I. Safety and Toxicity of Supplements

FDA is strongly emphasizing its concerns about the safety of dietary supplement products. Their rhetoric is completely inconsistent with the scientific evidence (and historical evidence) which overwhelmingly indicates that these products are extremely safe. Based on data from American Poison Control Centers, we can say with certainty that these products are many thousands of times safer than drugs. In ten years of collecting data, they have documented 3500 deaths from prescription and over-the-counter drugs and only one death possibly related to the use of an uncontaminated nutrient. If I recruited all of the Americans who have suffered severe disabling side effects from prescription drug use, they would not be able to fit in this conference room, or in all of the conference rooms throughout this building. This is not the case with nutrient supplements. Formerly, I used to freely prescribe drugs to my patients. I relieved calls all night long from patients suffering side-effects. Now that I prescribe nutrients and diet changes, I always get a full night's sleep. The FDA's concern for the safety of dietary supplements is a non-issue. FDA alarm about the toxicity of nutrients represents just one more scare tactic, and is another wasteful diversion of finances and manpower.

II: Claims

The FDA wants the exclusive and final authority to control information about these products. FDA Commissioner David Kessler said recently on national television, "The FDA is the arbiter of truth trust us. We will tell you what is good for you I'm a baby doctor," indicating that the American public doesn't have the ability to make health care decisions. Personally, I am not convinced that Commissioner Kessler knows or understands the differences between disease care and health care. The FDA misused its funds and resources to compile this book of unsubstantiated claims for products which in reality are validated by thousands of studies. A substantial percentage of these claims are fully documented by any medical and scientific definition of substantiated. The most conspicuous unsubstantiation is the information in the booklet itself. Just last week, the FDA even decided to not allow claims about anti-oxidants and cancer. There have been 17,106 studies on vitamin E and over 4800 studies on vitamin C during the last 30 years, demonstrating both safety and effectiveness. When will there be enough credible data for the FDA? How many thousands more studies are necessary to satisfy this agency? More importantly, how many people will be needlessly placed at risk and how many will die waiting for an FDA edict about the value of these safe antioxidant products? The FDA has had sufficient information about folic acid's benefits in preventing birth defects for 11 years now. During that time, over 13,000 preventable cases of neural-tube birth defects occurred. While the FDA is still trying to get it right with this inexpensive, safe and effective nutrient, other Western countries incorporated folic acid into their public health policy two decades ago. In the absence of FDA credibility and leadership in this area, American consumers would be far better served by allowing companies to make truthful and non-
misleading claims without prior FDA approval. Because of its pervasive institutional bias against supplements, the FDA has failed Americans. It is time to use another system. It is, in my opinion, tantamount to fraud for the FDA to obscure the full scientific record regarding the medical and health benefits of these safe and effective dietary supplements. This includes fiber and beta-carotene in reducing cancer risks, antioxidants such as ascorbate and vitamin E in reducing cardiovascular risks, and folic acid for neural-tube defects. The unnecessary billions spent on suppressing the signs and symptoms of ill health create substantial, avoidable human suffering and will lead, in the words of Dr. George Lundborg (Editor of the Journal of the American Medical Association), to an imminent operational and financial meltdown of America's health-care system. Given the original mission of the FDA, it is indeed ironic that this agency has become the single biggest obstacle to medical progress in America today.

III: Enforcement Powers

The bills of Congressmen Gallegly and Richardson will allow the FDA to retain all the legitimate enforcement authority they need to control truly adulterated, misbranded, contaminated and unsafe products, and to proceed against truly fraudulent claims. Their present unscientific bias and anti-supplement policies are medically senseless. In fact, the First and Seventh Federal Circuit Courts have found that FDA policies are utterly nonsensical and follow an Alice-in-Wonderland logic. This is hardly what America deserves from its primary health regulatory agency. Other judges have ruled against the FDA in cases involving extreme and unwarranted armed attacks directed by the FDA on sincere and honest businesses. Moreover, multi-million dollar lawsuits are now pending against FDA for their extreme tactics and absurd policies.

Ultimately, taxpayers will have to pay these enormous legal fees and judgments as well. As a doctor knowledgeable about the role of nutrition in preventive medicine and disease treatment, I know that FDA policies about dietary supplements don't have much to do with medicine or public health. In my opinion, this is just an arrogant power grab by an agency which is not adequately supervised and is careening out of control. The economic factors which may underlie this power grab are directly stated in the Dietary Supplement Task Force Report. According to the FDA, they will ensure that the existence of dietary supplements on the market do not act as a disincentive to drug development.

David Adams, FDA Assistant Deputy Commissioner for Policy, echoed the same sentiments when he said, Pay careful attention to what is happening [with dietary supplements] in the legislative arena...if these efforts are successful, there could be created a class of products to compete with approved drugs...the establishment of a separate regulatory category for supplements could undercut exclusivity rights enjoyed by the holders of approved drug applications. [at the Drug Information Association Annual Meeting, July 12, 1993]. I think that the FDA has realized that the elimination of economically competitive natural products will definitely clear the way for more drug development, but the health and well-being of Americans will suffer as a consequence of this misguided and self-aggrandizing approach by the FDA. Therefore, it seems that the FDA is really interested in protecting the 58 billion dollar drug and disease-management market enjoyed by the pharmaceutical industry.
Conclusion: What Do We Want?

In summary, this issue is not just about vitamins. This is clearly a medical, public health, and economic issue. At stake are billions of health-care dollars, the quality of life that we enjoy, our freedom to speak the truth about the medical and health benefits of supplements, and our freedom to choose the kind of health care we want. Yes, we need consumer protection.

We need:

- Truthful and non-misleading claims
- Safe products,
- Pure ingredients at Full potency,
- Manufacturers standards of identity,
- Nutritional good manufacturing practices, and
- Full disclosure labels.

We favor clear and prominent warnings on labels about scientifically established toxicities to humans, to assist consumers in their decision-making. We want the FDA to prosecute real fraud, but deep FDA bias against supplement products has corrupted the agency's ability to impartially determine real risks. We can no longer trust the FDA to honestly implement consumer protection legislation that has come from Congress. In fact, FDA bias is now so deep and intractable as to necessitate Congressional intervention. American consumers now need protection from an agency of our own government that is trying vigorously to eliminate our health freedoms and informed choice. Please consider carefully the FDA's recent history of subverting legislative intent of Congress before trusting the FDA to implement Congressional intentions yet again.

Thank you for this opportunity to present on behalf of myself, my 700 patients and thousands of members of Citizens for Health. I will be happy to answer any questions you may have. Thank you.
Mr. DURBIN. I am sorry, but you have used your time and we will have some questions.

Dr. PRIESTLY. You have my written statement which summarizes what I have to say.

Mr. DURBIN. Can a person take too many vitamins in terms of dietary supplements. Is it possible to take too much?

Dr. PRIESTLY. I don’t think that is the issue.

Mr. DURBIN. No. It is yes, no, or I don’t know?

Dr. PRIESTLY. If I drank two gallons of water I would die tomorrow. It is possible to take too much of anything.

Mr. DURBIN. Is it possible to take too many vitamins where it could become toxic for a normal individual?

Dr. PRIESTLY. In selected cases. People have attempted to commit suicide with vitamins and aspirin and other drugs. It is possible to take too much of anything.

Mr. DURBIN. Isn’t it possible that the FDA should set limits on drugs and the potency.

Dr. PRIESTLY. Yes.

Mr. DURBIN. Why is it unreasonable? If it is dangerous for a person to take too much of a vitamin, why is it wrong for the FDA to establish a maximum limit on the potency of any dietary supplement.

Dr. PRIESTLY. We have maximum limits on many products already. There are people who are being helped and their lives are being extended, including my 700 AIDS patients, by taking very high dosages of nutrients. Nutrients in high doses have pharmacologic effects. You do not see these affects kick in at recommended dietary allowance levels. Therefore, we need to have the option of choosing the health care treatments for ourselves.

Mr. DURBIN. I am sure it is an experimental effort on your part and I hope it is successful. But as a normal individual, I should know if I take too many of a certain vitamin, it might be dangerous and certainly it might be dangerous for my young children. That does not seem like an unreasonable thing to ask. Yet the Hatch–Richardson bill prohibits the FDA from setting that limit.

Dr. PRIESTLY. They have been doing it on limited claims of safety. We if we look at the poison control center reports of deaths due to ingestion of vitamins over the past decade, we have had possibly one. If we look at the same cases of the poison control centers of deaths due to inappropriate use of pharmaceutical drugs, that has grown exponentially. Therefore the concerns about safety are vastly overrated.

Mr. DURBIN. We also would agree that those who go about getting approvals on prescription drugs, go through a long process, constant review and are subject to many more regulations than faces the dietary industry. I think you would agree to that.

The question is not whether they should be held to a higher standard. The question is whether the dietary supplement industry should be held to a standard. You have worked with a lot of dietary supplements. I notice you had the same affection for garlic that my grandmother had for Vicks Vapor Rub. Both have one thing in both, you can smell them a mile away.
Have you looked at these dietary supplements and found any health claims you have found unreasonable or outrageous exaggerated?

Dr. PRIESTLY. I am in a different position because I go to every conference that I can find where these companies exhibit. Some product lines only sell to physicians like me. They do laboratory quality analysis on their batches of products which I have pulled many times. Their quality control is excellent.

They put out excellent monographs, they have educated us on the available reserve which we can pull and look at for ourselves in the medical library.

Mr. DURBIN. I am not asking you about that part. Have you found any that you thought have misled people? We have talked about Nature's Response all day. They made some suggestions here that even some folks from the industry thought went over the line.

Dr. PRIESTLY. If I did, I would call the company. I am not aware of the available research.

Mr. DURBIN. Do you understand the difficult choice we have to make in this committee, if it turns out to be the FDA's responsibility to challenge those claims? That is a pretty expensive undertaking.

Dr. PRIESTLY. I think it is too expensive in terms of needless deaths or hospital costs to deny people the information about these products.

Mr. DURBIN. How would you pay for it? Do you think a user fee on the industry is reasonable?

Dr. PRIESTLY. No. Many of these are mom and pop industries. They employ two people. Where are they going to get the money for this?

Mr. DURBIN. You are like my constituents. They want it done, but they don't want to pay for it.

Mr. Skeen.

Mr. Skeen. Let's summarize a little bit. From the tenor of the testimony, one of you favors what FDA has been doing and the other is not enamored of the practices of the Food and Drug Administration. Dr. Barrett, tell me what you think, in summary, of how FDA could do a better job?

Dr. Barrett. To regulate the industry?

Mr. Skeen. Yes.

Dr. Barrett. I have been very outspoken on this and have been an extreme critic of the FDA, but not since Commissioner Kessler took over. I think Congress has to do something. Despite all the talk about the FDA being big and powerful, I think they lack a few teeth.

I have seen hundreds of times that companies can market products long enough to make a lot of money, even though the products are worthless. They made therapeutic claims. The FDA has to detect it, line up witnesses and bring out all sorts of potential heavy machinery in order to take on a company, and in the meantime, the company can make money. Congress has to pass a law that would give the government some ability to penalize lawbreakers financially.

The Food and Cosmetic Act does not allow for that in civil actions. The Federal Trade Commission does. The FTC has been able
to deter many people from making false claims. The thing the FDA has to do is make routine use of criminal prosecution. Marketing a product with a therapeutic claim that is not generally recognized as safe, as effective, is two Federal crimes.

The FDA rarely uses criminal prosecution, partly for political reasons and partially because it is labor intensive. I believe what is needed is a shift in regulatory posture and an improvement in law so that illegal claims can be deterred. Right now, there is almost no deterrence.

Mr. SKEEN. No teeth and no deterrence?
Dr. BARRETT. I have collected 3,000 violations. The FDA may have more. I don’t know. I may have more than the FDA, I am not sure.

Mr. SKEEN. What do you find that is right with the FDA, if anything, Dr. Priestly?

Dr. PRIESTLY. There are certain regulatory abilities we want them to have. We want them to have the ability to take away from us truly adulterating foods, rotting seafood food, which they are doing very well. Truly misbranded items, things that contain a drug that it does not make mention of that on the label. Truly fraudulent claims where the fraud statutes come into play and the FTC can get into the fact. We want to retain those regulatory abilities.

Mr. SKEEN. Do you have them now?
Dr. PRIESTLY. Yes. What is right with them, that aspect of the regulatory ability.

Mr. SKEEN. I want to know, because it gives me some idea of your basic thinking. I know you both are very dedicated to your viewpoints and you express them very well. We have to take the attitude, too, how do we rig this thing up so we have all the wrenches tight and all the nuts and bolts, because we need your input.

Also, I would like to get some feeling for what the industry really thinks about itself and this self-policing and self-enforcement.

Dr. PRIESTLY. What was the first part of your question?

Mr. SKEEN. The question is what do you think is right with the FDA? You got one point in.

Dr. PRIESTLY. How could they do things better and what does the industry feel? How could they do it better?

I think that Americans health would be better served by having a different agency oversee supplements. There has been too much of a long-standing historical institutional bias in this area.

The FDA has its hands tied. They have these absurd theories that they have to apply to dietary supplements because they are only given foods or drugs. Other countries have a third category called “nutraceuticals” and a different agencies regulates them, one that is more unbiased and neutral about them.

It is proposed to transfer that area to the NIH and it has been proposed to transfer that area to the USDA, which are agencies that have carried out research on these products and is in general considered to be more neutral towards them.

Mr. SKEEN. You think basically they have a primary bias?

Dr. PRIESTLY. I think they have an incredibly entrenched bias that will not be easy to overcome. How does industry feel? The peo-
ple I talk to on a weekly basis, suppliers of products, they are running scared. They are very concerned that the FDA is going to conduct an armed raid on their office next, as are holistic physicians. This is not the America that we want. This is more Germany 1938, and that could happen in our country.

Mr. Skeen. Thank you.

Mr. Durbin. Ms. DeLauro.

Ms. DeLauro. I think it is a little bit of what my colleague Mr. Skeen was asking; but what role do you see for the FDA in this, or do you see any role for the FDA when, in fact, they have been, and we have heard testimony, some testimony, and there is a difference of view that dietary supplements are food?

The FDA oversees food. Congress charged FDA to come up with a standard. What role do you see for the FDA in this effort?

Dr. Priestly. I hope it would be more limited. They did tell us point blank at a major meeting we had, that they do intend to take amino acids off the market and soon and regulate them as drugs. They do intend to limit the potencies of vitamins and minerals and they do intend to eliminate herbs and other products, based on, I think, specious arguments about safety. I would rather see them do what they do better, which is regulate drugs. Perhaps this has become too overwhelming a burden to have such divergent areas under the jurisdiction of one agency.

They have a much longer history of a close cooperation with the drug industry and oversight of drugs, and I might add, have been much kinder to their clients.

Ms. DeLauro. Dr. Barrett, what is your view of their role?

Dr. Barrett. I think the health industry wants to have no oversight whatsoever and has carefully disguised this in the Hatch—Richardson bill. I would like to see a very stringent regulation.

I think that the supplement marketplace includes probably about 20,000 products. I am in the process of trying to count them. I don't think anyone ever has before. I believe that the vast majority of them are worthless for any purpose. There are a couple of good ones and they focus on that. Folic acid which has potential, niacin is a marvelous drug under supervision. And calcium, the benefits are pretty clear. Beyond that, I am not sure that anything sold in the health food store has much value.

We are talking about an industry that is selling products that doesn't have much value. Most people who buy it, buy it to be sure they have enough in their diets.

The supplements they want to protect are things like shark cartilage. That is not a dietary supplement. It is a pseudo-medicine. It is being marketed for cancer.

The manufacturer will not put it on the label. 60 Minutes put it on the air. It is now a household word.

Ms. DeLauro. When you treat patients with dietary supplements, Dr. Priestly, what is your criteria? What is your standard?

How do you make a determination that you are looking at something that is of no use at all or something that has value to whatever illness you are trying to treat? How do you make your own determination of these products, if there are 20,000 on the market?

Dr. Priestly. I was trained as a scientist as well as Dr. Barrett, and we try to be scientific about it. I will call my friends that I
have cultivated in university centers that I know are involved in research in various areas, and ask them how is it going. We all talk together. I have a library of several thousand volumes of published literature, as well as bulging file cabinets with articles of all descriptions, clinical prose is excellent. That is the huge green book that we showed you. I do medical searches. I have nutritional researchers who work for me.

I look at what all holistic doctors look at, which I think we would be better served if traditional pharmaceutical companies looked at, and that is outcome. How do things work? How do people say they feel differently after using this? How do their laboratory tests change? What subjective and objective criteria do we have?

I want to take the opportunity to tell this body that I started as a traditional physician. I was trained in one of the top 10 medical schools in America. We had 45 minutes on nutrition and two years on pharmacology three days a week complete with dog lab. So we kind of come out with an inherent bias that there is only a certain way to approach disease. I have since come to feel, since sort of jumping ship, if you will, that what we are taught is a standard western model is a myopic approach, it is only a shadow of what constitutes real healing.

It has been my pleasure and privilege to practice this kind of medicine. I have never had a practice that has been so effective and satisfying for me and for my patients. Since I stopped doing that, what I call a “symptom drug next” approach and starting using nutrients and started focusing on an integrated holistic approach, it is standard in my office for patients to come back for their next visit and start gushing about how much better they feel and how transformed their lives are, using the simplest cheapest, safe nutrient products which, unfortunately, their insurance companies will not pay for. I have people who fly in from out of state, and that is standard experience for holistic doctors. People are determined to get this kind of care for themselves. They would not flock to our offices if they were not getting better results and are more satisfied with the system than they are with western medicine.

I look at outcome and the available medical research. When you go right and everybody else goes left, especially in a licensed profession, we better have a great deal of research and scientific backing to justify our position.

Ms. DeLAURO. Thank you.
Mr. DURBIN. Thank you.
Mr. Walsh.
Mr. WALSH. There have been some published reports that say there have been approximately 40 products, claiming to have Ginseng in them, and a number of those have no Ginseng in them. How would the FDA deal with a manufacturer who made these misleading claims?

Dr. BARRETT. You mean, if the product was misbranded and the FDA could use any amount of regulatory machinery. As far as I know, I don’t know if there have been any, but I don’t think there have been many involving that. They went after a product that said it had apple juice and it did not and they got a whopping conviction.
Mr. WALSH. So it is a violation of the law.
Dr. BARRETT. If you said something is in the product and it is not, that is a crime called misbranding.

Mr. WALSH. If we did nothing more and we stiffened the penalties for that sort of thing, would that be effective?

Dr. BARRETT. If you left the law alone and stiffened the penalties for misbranding and for marketing a unapproved new drug and you kept David Kessler as Commissioner the industry would get cleaned up. That is what they are scared to death about.

Mr. WALSH. Commissioner Kessler said he is only concerned about the labels on these products. He held up the shark’s cartilage, as an example. I asked him, “Does it say it is going to cure cancer and tumors?” He said, “No.” Then he started talking about the brochures and so on.

What if we all agreed that there should be no false claims on any of these things unless there is a standard scientific body of evidence that agrees that this will cause the cure for cancer? So they just say what is in the bottle, basically, and then you go into the health food store and you have a very aggressive store owner who becomes the snake oil salesman and says, “This, my friends, will cure anything,” just to make a sort of wild statement.

How do you deal with that individual? I ask Dr. Priestly that one.

Dr. PRIESTLY. The FDA told us at their meetings that they will include anyone, including an employee of a health food store, to be a retailer of the product and then subjected to the full prosecutorial system that they have taken for themselves in the proposed rules, including asset seizure, criminal sentences in prison, phenomenal fines of $250,000.

They have created a Draconic way of choking off the flow of information. They have already confiscated books from health food stores claiming the books were too close to the products.

Mr. WALSH. So there are laws that would deal with that as we speak.

Dr. BARRETT. There is no provision for fines in civil cases, only in criminal cases. The situation you described is the situation as it is today, that most products are not marketing with claims on the label. Labeling includes any statement made in the context of a sale.

If the claim can be traced to the manufacturer through literature or through an oral claim of a retailer and so on, some manufacturers give seminars for retailers where they give out the claims. If you can trace a claim, you establish an intended use. And if there is an intended use, the product has to have adequate directions. If you don’t have adequate directions, then that is that crime. So the law is okay, except it doesn’t have a penalty.

Mr. WALSH. We have been talking a lot about shark’s cartilage and I would be the last person in the world to buy shark’s cartilage. But if someone told me to chew the bark of a Pacific yew tree to cure cancer, I would have laughed. Now, Bristol-Myers in my hometown is spending millions of dollars in my hometown to synthesize Pacific yew tree bark to cure cancer. We have a real dilemma here.
We cannot preclude anything in terms of cures just because the body of knowledge that physicians are working with today does not back up the claim that shark’s cartilage doesn’t cure cancer.

Mr. DURBIN. Dr. Barrett, do you take vitamins?

Dr. BARRETT. I take niacin because I have a life-threatening cholesterol problem and I published a very detailed report of my experience with it which has been highly favorable.

Mr. DURBIN. Dr. Priestly, do you take vitamins?

Dr. PRIESTLY. For someone who is a holistic physician—and my AIDS patients take large quantities of these—I am not a great vitamin taker. The vitamins I think are important for women, especially, are calcium in correct form, B vitamins for stress, and antioxidants, vitamin C, E, zinc, and selenium.

Mr. DURBIN. Thank you very much.
WITNESSES
MARK SILBERGELD, CONSUMERS UNION
MARY ELLEN CAMIRE, M.D., INSTITUTE OF FOOD TECHNOLOGISTS, UNIVERSITY OF MAINE
JO REED, ON BEHALF OF GERALD JAMES, AMERICAN ASSOCIATION OF RETIRED PERSONS
FRED BINGHAM, CONSUMER COALITION FOR HEALTH CHOICES

Mr. Durbin. Our last panel—God bless them for their patience—is Mark Silbergeld for the Consumers Union; Mary Ellen Camire, Institute of Food Technologies, the University of Maine; Gerald James, American Association of Retired Persons; and from the Consumer Coalition for Health Choices, Fred Bingham.

I believe this panel is also somewhat divided in its opinions.

Mr. Silbergeld. I will not summarize my testimony. I would rather make some observations.

Mr. Durbin. Please do. I read your magazine all the time.

Mr. Silbergeld. I compliment you for holding this hearing and which I hope will shed more light on. You have served your constituents well on your work on public health. One of the problems with this product is jurisdictional, of course.

The issues of safety and the issues of health claims must be judged product by product and not all of them necessarily fall into either the category of food or drugs. The issues are complex, and they are made more complex by the question of what is the product, but of what claims are made for that substance which is the product.

If the standards are set for the large number of products on the market, which I think everybody concedes are harmless, the daily multivitamin, et cetera, we like the ability to deal effectively with the products that are not harmless and may be neither harmless nor efficacious. We will also end up with some strange anomalies if we go to the root of the Richardson/Hatch legislation.

You look at a situation where the manufacturer of pumpkin, the traditional pumpkin prepared and sold in a can to make pumpkin pie is subject to the health claim limitation of the NLEA and cannot claim that pumpkins reduce tumors, but the mom and pop who takes that pumpkin and reduces it to a pill should be able to back up that claim and have a very expensive set of medical tests starting with medical and going into clinical trials in order to prove that it is not true.

To the American consumer, I would consider that anomaly not only strange but unacceptable from both a health and an economic viewpoint. Public health must continue to rely on science. So the question is whose science?

Today we have been presented with three of those possibilities: FDA, the sponsors of the legislation, or the industry that makes and sells so-called food supplements. Given what I heard this after-
noon, I would by far prefer to rely on the FDA as a source of science. Also, science may not be good in every last instance. It may not be perfect in many instances, but neither is science in many other places like universities or, for that matter, in private corporate laboratories.

Some of what I heard about this industry's science this afternoon is extremely unsettling. And with respect to the witnesses on the last panel, I would have to say that if there are some of these companies that are mom and pop, two-employee industries, I have to ask myself: Do I want to buy a cancer cure or a cholesterol lowering cure from a company with two employees? Who is doing the research? Who is making sure the product works? Who is doing the quality control?

We know what they are doing, they are doing the promotion and sales and accounting. So certainly if we are given those choices, I would say that by far, by light-years, consumers would prefer to rely on the FDA's science in these questions and not the science of either the industry or, with all due respect, the very respected Members of Congress who have proposed this legislation.

I have not heard anything that was on the one hand or another. My wife is a scientist and I can tell you I hear "on the one hand and on the other hand" all the time about scientific issues. I did not hear that from the authors of the legislation.

People think that the FDA is assuring the quality of products that are out there and especially if they make health claims or if they claim to be food or supplement their diet. If that is not truth, then to me that is the problem, not how to maintain employment in an industry that cannot support its claim for many of its products.

We have had no quarrel with most of the products by a number of brand names and volume. But with the products that are the problems, it is not how to maintain the investment or the employment.

The most important problem is how to meet the public's expectation, if those products are out there, and especially if they have had health claims, that in fact those products will meet those claims and not harm people in other ways.

At the very latest, I am not satisfied with Commissioner Kessler's assertion that he is willing to have those claims out there as long as they can be justified. I think he did not mean to stop there, but he did. I want to know on a package of those products the same thing I know on a traditional medicine.

I want to know what are the indications for it. I want to know what are the contraindications, what are the side-effects and, what is the proper dosage and what to do if there is a problem.

I can tell you, and you will see in my testimony, we have looked at a number of these products and the FDA book. Many of the problem products do not have that basic information on it. It is not enough to say, let them make the claim if they can substantiate it. The label has to have proper instruction and usage information or they could be harmful to consumers.

Thank you, Mr. Chairman.

[The information follows:]
TESTIMONY OF MARK SILBERGELD
Director, Washington Office
CONSUMERS UNION

on

DIETARY SUPPLEMENTS

before the

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT,
FDA AND RELATED AGENCIES

COMMITTEE ON APPROPRIATIONS,
U.S. HOUSE OF REPRESENTATIVES

October 18, 1993
Mr. Chairman, Consumers Union1 appreciates the Subcommittee's invitation to testify on the important issue of how the Food and Drug Administration should regulate dietary supplements. At this time, we offer no judgment on dietary supplements as a product class. The number and variety of products offered to the public is far too varied to permit general judgments, positive or negative, about the entire class of product or about its marketing.

However, there most certainly are particular products and product claims that raise serious concerns for consumers. Some products may present potential health problems, either used as directed or used in the face of a lack of adequate directions and precautions. Other products may make claims for treatment or cure of medical conditions, the reliance upon which is not demonstrably justified. These problems arise particularly with respect to some herbal extract and amino acid products.

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1 Consumers Union is a nonprofit membership organization, chartered in 1936 under the laws of the State of New York to provide information, education and counsel about consumer goods and services and the management of family income. Consumers Union’s income is derived solely from the sale of Consumer Reports and its other publications and from member donations. Expenses of occasional public service efforts may be met, in part, by nonrestrictive, noncommercial grants and fees. In addition to reports on Consumers Union’s own product testing, Consumer Reports, with approximately 4.9 million circulation, regularly carries articles on health, product safety, market-place economics and regulatory actions which affect consumer welfare. Beginning with the first issue of Consumer Reports in 1936, Consumers Union has reported on hazards of lead exposure from various sources on numerous occasions. Consumers Union’s publications carry no advertising and receive no commercial support.
The issue goes beyond the general economic concern as to whether or which dietary supplements are sound purchases. It goes to the question of whether dietary supplements have the potential to improve or damage people's health. This question is within the jurisdiction of the U.S. Food and Drug Administration. The public relies upon the FDA to monitor the marketplace and to remove or adequately regulate those products and those product claims that are false or potentially injurious. The public should be able to assume that the government assures that foods offered for sale, and health claims made for products, would not be there or would be acted against by the government if harm were threatened.

Consumers Union believes it to be essential that the FDA have full authority and resources to prevent potentially dangerous food and drug products, including dietary supplements, from reaching the consumer. And we believe that the FDA must also be able to regulate health claims for foods and diet supplements. I do not want to get caught up in the distinction between regulation of foods and regulation of drugs. There appears to be sufficient authority under the Food, Drug and Cosmetic Act and the Dietary Supplement Act of 1992 for FDA to deal with these products and product claims. If any of these products falls between the cracks of current laws, due to a lack of clarity as to whether a product is a food or a drug, that lack of clarity should be addressed by the Congress in a manner that leaves the FDA fully able to carry out the responsibility to assure safety and the accuracy of health claims.
Congress only recently affirmed its intent that the FDA assure that health claims for food be rigorously regulated, when it enacted the Nutritional Labeling and Education Act. It should continue that policy with vigor.

However, legislation that has been introduced that would alter that course. H.R. 1709 would shift the burden of proof, requiring the FDA to prove lack of safety, rather than the manufacturer to prove safety, when health claims are made for dietary supplements. A practical effect of this may be that where the evidence of safety is unclear, public policy will shift from the current preference of risk aversion to a policy of risk-taking. This undoubtedly will allow unsubstantiated and unsubstantiable claims to burgeon. The policy of risk aversion would better serve the public health.

H.R. 1709 also would prevent FDA from requiring prior approval of dietary supplements that make health claims. This would be very unsound public health policy. It is sound and very recently-enacted federal policy under the Nutritional Labelling and Education Act that FDA prior approval be required for health claims on food labels. There is no reason what this policy should apply to dietary staples but not to dietary supplements. If anything, there is less concern when consumers are encouraged to consume milk, bread, citrus and other standard dietary components without "indications", "precautions" and dosage recommendations than there is when they consume willow extract, blue or black cohosh,
germander, chapparal, comfrey or amino acid supplements, without such accompanying information.

Consumers Union opposes H.R. 1709 and supports H.R. 2923, which would help to increase our knowledge of the role that dietary supplements play in health while preserving the power of the FDA to deal with products and claims that are of health concern.

Numerous examples of hazardous dietary supplements offered in the marketplace today, even with the present degree of FDA regulation, illustrate why FDA should be more, not less aggressive. Some supplements threaten the consumer's health due to a lack of warning or dosage information while others make unsubstantiated claims which are indirectly threatening.

Among the examples we have identified is the lack of an FDA-required Reye's disease warning on the label of a product containing a naturally occurring form of aspirin, which may be hazardous if administered to children under the age of 16 with colds, flu, or the chicken pox. The product is indicated for use by children with cold symptoms. We also are concerned about the marketing of "blue cohosh" an herbal extract marketed as an aid for "female problems" that contains a chemical administered by physicians to induce labor. A similar concern exists regarding "black cohosh". Neither of these products bears any contraindication for use by pregnant women.
The FDA has documented a long list of "Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace", which appears in a publication bearing that title dated July, 1993. It is impossible to read the list of hundreds of unsubstantiated claims that appears at pages 2-40 of that book without concluding that strict standards and greater regulatory resources are required to deal with the problem that exists in the marketplace today.

These examples illustrate the need for increased FDA action, not a reduction in agency authority as proposed by H.R. 1709. Presently, the FDA is stressing the need for "scientific agreement" before a health claim can be made. We will oppose any proposal that would eliminate this assurance to the user of FDA-regulated products. Consumers deserve safe products, as well as information concerning the appropriate dosage and use of a product, and warnings alerting to possible hazards.

Proponents claim H.R. 1709 would allow for consumer freedom. This is not so and it would drastically reverse federal health policy in this regard. Freedom of choice requires an informed choice and there is no informed choice when there is a lack of evidence that the product will do what is claimed for it, or where there is a lack of indications, contraindications, warnings, dosage recommendations and other use instructions.
The same "freedom of choice" arguments were made when laetrile was being touted as a miracle cancer cure. The argument was offered that no harm could be done by cancer patients trying the unproven "remedy". In fact, harm is done when consumers are urged to rely on unsubstantiated health claims, and especially when those claims go to prevention or cure, rather than to general good health. For one thing, consumers may rely upon the unproven claim instead of approaches to prevention and cure that have a better chance to produce the intended effect. Distract from appropriate treatment or prevention is not merely a matter of "choice". For another, the harm may be compounded when the purported preventive or cure has potentially significant side effects, as is the case with many of these products.

The FDA is not inflexible in dealing with these issues. As the FDA itself stated in its June 18, 1993, Federal Register advanced notice of proposed rulemaking on dietary supplements, "What is safe at low levels in foods may not necessarily be safe at higher levels or in more concentrated forms. The chemical form of the substance in dietary supplements may also differ from that commonly used in foods in conventional food form." At the very least, it is important that the FDA assure the labelling of appropriate consumption parameters for products that are presumed safe to consume.

It also should be noted that the FDA is about to approve
health claims for folic acid under appropriate conditions and is considering approval of claims for anti-oxidants. What these prior approval processes assure the public is important: that the health claims have a sound scientific basis for concluding efficacy and that the form and conditions of consumption offered to the consumer be appropriate to assure safety.

Consumers Union hopes that the Subcommittee will agree that it is important for the FDA to retain and expand a vigorous program to assure that dietary supplements offered to consumers are safe and that health claims are soundly based in science and accompanied by appropriate information for use of the product. Whatever benefits these products may hold for consumers should not be overwhelmed by the risks of inadequate regulation.
Mr. Durbin. Ms. Camire you are next.

Ms. Camire. I am an assistant professor of the University of Maine Department of Food Science and Human Nutrition. I would like to correct the witness list. I am a Ph.D., not a M.D. I am a scientist, not a physician.

Today I am representing the Institute of Food Technologists which is a society of over 20,000 members, food scientists, and people working in food and nutrition. As a member of the Nutrition Division of IFT, I would like to discuss some of the problems we have with dietary supplements.

Our biggest concern is the safety of the supplements. The legislation raises questions about the adequate protection of consumers from overdoses, from toxic contaminants and from natural components which may be toxic. Supplement manufacturers, not the FDA, should bear the burden of assuring that these products safety. We have talked about Vitamin A, niacin, iron, and selenium can be toxic. Excess vitamin C can cause birth defects and miscarriages.

The National Research Council, which sets RDAs, the legal dose of ferrous sulphate, is 3 grams for a two-year-old child. It is something you could easily have ingested and it looks like candy. This is easily ingested by toddlers who can get into mothers' supplements.

Iron has been cited as the most frequent cause of pediatric deaths. Minerals, if you have too much of one. It creates malnutrition of the others.

The safety problems occur with consumption of nutrients that did not have RDAs. Purified forms of soluble dietary fiber have blocked the intestines of people who don't drink enough water, cause diarrhea, gas, and possibly interfere with absorption. Maximum safe levels would help protect consumers from overconsumption. IFT agrees with the FDA that safe levels for vitamins, minerals, amino acids, and other nutrients must be established based upon a preponderance of sound scientific evidence.

Several natural products such as bone meal and seaweed can be contaminated with heavy metals. These should be analyzed so consumers can avoid these toxins. Herbal preparations often contain toxic natural compounds. Consumers are unaware of this, particularly if they have Chinese or foreign names.

Herbs are not regulated as drugs. They don't have warning labels, but they contain pharmacologically active chemicals. While some responsible manufacturers do label their supplements with warning labels—do not take if you are pregnant, et cetera—many others do not. The chemicals found in herbal products are particularly hazardous to pregnant women and people with circulatory disease and kidney disease.

A history of years does not guarantee the safety of an herbal preparation. Herbs vary in potency on how much of the active chemical they have. Different parts of the plant may have different concentrations. The roots are different from the leaves. Herbs can also provoke allergic responses in people. They have been traditionally used as folk medicines. But American consumers often do not have an herbalist to consult.
Senator Hatch kept bringing up 4,000 years of use. 4,000 years, minus 100, we have had herbalists. In American culture today we do not have an herbalist who knows what you have eaten, your family life style, everything about you to prescribe the right herbs for you. You go to the store and you buy a concentrated pill off the shelf. It is totally different.

The FDA must have the authority to guarantee the safety and efficacy of these products. Also H.R. 1709 would prevent the FDA from protecting consumers from health risks posed by herbal products and also from the long-term problems incurred when you substituting herbs for more effective medical treatment.

We are also concerned that the proposed guidelines for supplement health claims. H.R. 1709 would seriously undermine nutrition education programs of the USDA and other agencies. As proposed, this bill would permit supplement manufacturers to make health claims not currently allowed for foods containing the same nutrients.

We have a lot to learn about the role of nutrient interactions and the role of nonnutrient food chemicals in maintenance of health and prevention of disease. Large doses of isolated nutrients may not have the same health benefits as smaller quantities present in their natural form in foods. Health claims for dietary supplements, like those for foods and drugs, must be based upon scientific consensus, not anecdotal reports.

In summary, IFT supports the safe and appropriate use of dietary supplements, but we feel that the FDA should be given greater authority to regulate these supplements. The Nutrition Division of IFT has prepared a 12-page commentary on the issues raised by H.R. 1709, and copies of this document are provided for the record and available for you to read.

I would be happy to answer your questions.

[The information follows:]
Testimony of
The Institute of Food Technologists

by
Dr. Mary Ellen Camire

before the
Subcommittee on Agriculture
Committee on Appropriations
U.S. House of Representatives

October 18, 1993
Testimony of the Institute of Food Technologists

before the
Subcommittee on Agriculture
Committee on Appropriations

October 18, 1993

Good afternoon, I am Mary Ellen Camire, Assistant Professor in the Department of Food Science and Human Nutrition at the University of Maine at Orono. Thank you for the opportunity to speak to you today as a representative of the Institute of Food Technologists (IFT). IFT is a scientific society of over 26,000 food scientists, technologists, nutritionists, and others working in the areas of food and nutrition. IFT members are employed in academia, industry, and government agencies. As a member of the Nutrition Division of IFT, I would like to address several issues regarding dietary supplements.

Our primary concern is the safety of such supplements. H.R. 1709 raises serious questions regarding the adequate protection of American consumers from overdoses, toxic contaminants or potentially hazardous components. Supplement manufacturers, not the FDA, should bear the responsibility for ensuring the safety of their products. Several important nutrients, including vitamin A, niacin, iron, and selenium, can be toxic in large doses. Excess vitamin A or related substances during the first few weeks of pregnancy may result in miscarriages and severe birth defects. According to the National Research Council, the lethal dose for ferrous sulphate, a common form of iron in supplements, is 3 grams for a two year old child. This quantity may be easily ingested by toddlers who have access to their mothers' supplements. Iron has been cited as the "single most frequent cause of pediatric poisoning deaths" (V. Herbert in Journal of the American Dietetic Association 92: 1502, 1992). Minerals in particular can interfere with each other's absorption, resulting in imbalances.

Safety problems also occur with consumption of nutrients which do not have Recommended Dietary Allowances. Purified forms of soluble dietary fiber have blocked the intestines of people who did not drink sufficient water with these supplements. Some concentrated sources of fiber may cause diarrhea and gas and possibly interfere with absorption of other nutrients. Maximum safe levels would help protect consumers from over-consumption. IFT agrees with the FDA that safe levels for vitamins, minerals, amino acids and other nutrients must be established, based upon a preponderance of sound scientific evidence.

Several natural products including bone meal and seaweed may be contaminated with heavy metals such as lead. Such products must be analyzed by
manufacturers and must meet established safety criteria so that consumers can avoid these poisons. Herbal preparations often contain toxic natural compounds, yet consumers are unaware of this potential danger. A greater concern is the lack of warning labels for herbal products. Herbs are currently not regulated as drugs, yet they contain pharmacologically active chemicals that often are sold as drugs in a purified form. While some responsible supplement manufacturers voluntarily label their herbal products with warning labels and contraindications, many others do not. The chemicals found in herbal products can be hazardous to pregnant women, and persons with kidney, liver or circulatory diseases.

A history of use does not guarantee the safety of an herbal preparation. Herbs vary in potency, and different parts of a plant may have different concentrations of active ingredients. Herbs may also provoke allergic responses in some people. Although many herbs have been used traditionally as folk medicines, American consumers do not have a knowledgeable herbalist to consult for proper dosage; they just buy a concentrated product off the store shelf. The FDA must have authority to guarantee the safety and efficacy of herbal products. H.R. 1709 would prevent the FDA from protecting consumers from health risks posed by herbal products and also from the long-term problems incurred by substituting herbs for more effective treatments.

We are also concerned with the proposed guidelines for supplement health claims. H.R. 1709 seriously undermines the nutrition education programs of the USDA and other agencies. As proposed, this bill would permit supplement manufacturers to make health claims not currently allowed for foods containing the same nutrients. We have much to learn about the importance of nutrient interactions and the role of minor non-nutrient food chemicals in maintenance of health and prevention of disease. Large doses of isolated nutrients may not have the same health benefits as smaller quantities present in their natural form in foods. Health claims for dietary supplements, like those for foods and drugs, must be based upon significant scientific consensus, not anecdotal reports.

In summary, IFT supports the safe and appropriate use of dietary supplements, but recommends that the FDA be given greater authority to regulate these products. The Nutrition Division of IFT has prepared a 12-page commentary on the issues raised by H.R. 1709, and copies of this document are provided for the record and are available for your perusal. I would be happy to provide additional information upon request.
Commentary on the Scientific Issues Raised by
H.R. 1709, "Dietary Supplement Health and Education Act of 1993"

by

The Nutrition Division

of

The Institute of Food Technologists

July 28, 1993
Commentary on the Scientific Issues Raised by
H.R. 1709, "Dietary Supplement Health and Education Act of 1993"

by
The Nutrition Division
of
The Institute of Food Technologists

July 28, 1993

Executive Summary

Nutrition scientists from the Nutrition Division of the Institute of Food Technologists (IFT) have reviewed the dietary supplement bill H.R. 1709, "Dietary Supplement Health and Education Act of 1993" and offer comments on the scientific issues raised by this proposed legislation. IFT is a 26,000-member scientific society of food scientists and technologists.

Although the IFT’s Nutrition Division (IFT-ND) supports the safe and appropriate use of dietary supplements, it finds that the proposed legislation would undermine the provisions of the FDA procedures intended to ensure the safety of dietary supplements. H.R. 1709 would not provide the American public with sufficient protection from known dangers posed by excessive nutrient intake, toxic substances associated with certain supplements, or false health claims.

Generally, H.R. 1709 would: (1) Prohibit FDA from regulating potency of supplements; (2) require that dietary intake standards be declared as a percent daily value per serving and specifies how daily values would generally be determined; (3) shift the burden in regulating the safety of ingredients from industry to FDA with respect to supplements; and (4) establish a lower standard of substantiation for health claims than applies to foods.

IFT-ND’s specific concerns regarding H.R. 1709 are:

• An inadequate recognition of the inherent toxicity of certain nutrient supplements;
• A failure to ensure the safety of amino acid supplements;
• No safeguards against harmful nutrient interactions;
• An erosion of the scientific basis for determining safe and adequate levels of nutrient intake;
• No protection of consumers from known health risks from excessive intake of certain forms of dietary fiber and some herbal supplements;
• An inadequate scientific basis for supporting health claims; and
• An increase in the potential for misleading health claims about dietary supplements.

Supplements should not be permitted to bypass established FDA procedures for safety assurance or be permitted to make health claims that cannot be made for foods containing the same nutrient. The IFT-ND believes that, as with foods and drugs, the supplement industry should bear the burden of proof that their products are safe and health claims not misleading.
Introduction

The following commentary addresses key scientific issues in food safety and public health raised by H.R. 1709, the "Dietary Supplement Health and Education Act of 1993" for the purposes of regulating dietary supplements. This document was prepared by the Nutrition Division of the Institute of Food Technologists (IFT-ND). IFT is a 26,000-member scientific society of food scientists and technologists. The Nutrition Division includes some 1,400 members whose work in food and nutrition ranges from basic and applied research to consumer education.

IFT-ND acknowledges and supports the safe and appropriate use of dietary supplements. The primary interests IFT-ND has regarding dietary supplements are consumer safety and public health issues. IFT-ND is also concerned about the potential erosion of the scientific basis for regulating both foods and dietary supplements.

IFT-ND believes that H.R. 1709 would prohibit FDA from regulating the potency of dietary supplements thereby risking consumer safety with regard to nutrient toxicity, potential imbalances, and harmful nutrient interactions. It is concerned that shifting the responsibility for ensuring the safety of dietary supplements from industry to FDA would overburden FDA and risk public health with regard to certain herbal preparations. IFT-ND also questions the appropriateness of creating a less stringent scientific standard for health claims about dietary supplements than applies to foods.

Risk of Toxicity of Vitamin and Mineral Supplements

Issue: Many vitamins and minerals are toxic when consumed in excess amounts.

Rationale: Safety is a matter of great concern because of the toxicity of many nutrients when consumed in excessive amounts. Nutrient toxicity is clearly recognized and documented in the National Research Council’s publication, Recommended Dietary Allowances, 10th edition, 1989. In addition to direct toxicity, excessive intake of certain nutrients may also exert indirect adverse effects by interfering with the absorption, metabolism, or function of other nutrients. Excessive intake of certain nutrients may also mask another nutrient deficiency.

Although there is a role for nutrient supplements for specific segments of the population, the risks of toxic effects of certain nutrients are real and scientifically well documented. For this reason, it is imperative that the FDA have the authority and ability to regulate dosages, i.e., "potency." In addition, many instances of toxicity have been due to excessive intake caused by a lack of understanding of the risks and benefits of a particular nutrient. In this regard, effective regulation of labeling information, including health claims as defined and restricted by the Nutrition Labeling and Education Act (NLEA), child-proof
packaging, warning labels, and limitations on potency as are required for prescription drugs will help reduce the hazards of toxicity from overdoses.

The following examples of nutrient toxicity illustrate the risks of unregulated supplements. These are more thoroughly described and annotated in *Present Knowledge in Nutrition*, 6th ed., 1990, ILSI-Nutrition Foundation, M.L. Brown, ed. and elsewhere as noted.

- Excessive intake of zinc can induce a severe copper deficiency by interfering with copper absorption. Severe anemia and death have been induced by abuse of zinc supplements.

- Iron supplements pose a severe risk when consumed in excess by children and those genetically at risk from iron overload or hemochromatosis (National Research Council, Recommended Dietary Allowances, 10th ed., 1989). Iron toxicity from consumption of supplements is one of the most common forms of poisoning in preschool children. Five children in Los Angeles County recently died from an overdose of a prenatal vitamin-mineral supplement (Food Chemical News, June 7, 1993). Iron has been identified as the "single most frequent cause of pediatric poisoning deaths" (Herbert, V. in: J. Am. Diet. Assoc. 92: 1502, 1992).


- Vitamin B₆, in the form of supplemental pyridoxine hydrochloride, causes neurotoxicity when consumed in excessive amounts. Although the exact toxic dose has not been precisely determined, the prolonged consumption of supplements containing between 100 and 1000 mg vitamin B₆/day has caused toxic effects.

- Folic acid is relatively nontoxic in its own right. Excessive folic acid intake, however, can mask the neurological problems associated with vitamin B₁₂ deficiency. Thus, excessive folic acid supplementation of vitamin B₁₂-deficient individuals indirectly can cause irreversible nerve damage.

- Vitamin D toxicity can occur mainly through excessive consumption of supplements, although an error in fortification of milk was responsible for a recent episode of vitamin D toxicity. Vitamin D toxicity causes abnormal calcium metabolism and can, ultimately, lead to death.

- Vitamin A has both acute and chronic toxic effects when consumed in excess. Of particular concern is the teratogenic effect, i.e., the induction of birth defects, caused by excessive vitamin A intake during pregnancy or just prior to conception.
Water-soluble vitamins have been shown to have harmful side effects, e.g., kidney damage, when consumed in very large doses for long periods of time.

**Risks Associated with Amino Acid Supplements**

**Issue:** Amino acids consumed in excess may be harmful and compromise consumer safety.

**Rationale:** Food proteins provide amino acids which are required by the body for the synthesis of body proteins and as a source of nitrogen for the synthesis of other tissue, metabolic and hormonal constituents. Little, if any, evidence, however, suggests that there is a nutritional or drug-like benefit in healthy individuals who consume excessive amounts of proteins or individual amino acids. In fact, the consumption of isolated amino acids may be harmful, as suggested recently with the outbreak of Eosinophilia-Myalgia Syndrome (EMS) associated with the consumption of L-tryptophan. Whether the outbreak was due to a contaminant in the amino acid supplement or the amino acid itself remains unclear, but either suggests possible public health concerns since 38 deaths have been associated with the consumption of the amino acid supplement. This occurrence supports the need for clear and definitive regulations and the need for total quality standards.

The safety of excess consumption of individual amino acids has not been established. In a recent review of the safety of amino acids, the Federation of American Societies for Experimental Biology (FASEB) concluded that not enough evidence exists to establish safe upper limits of consumption for amino acid supplements. In addition, FASEB acknowledged that certain groups of people, e.g., the young, elderly, women of childbearing age, and people with suppressed immune systems, may be at increased risk from amino acid supplementation and should only use amino acid supplements under medical supervision.

Further, the consumption of amino acids may lead to adverse health effects such as:

- amino acid toxicity, e.g., tryptophan
- amino acid imbalance(s), e.g., excess threonine may precipitate tryptophan deficiency
- amino acid antagonism, e.g., excess lysine or arginine antagonize the metabolism of each other

Amino acids are primarily, if not exclusively, promoted for therapeutic benefits in ways similar to the promotion of drugs. Because excess consumption may be harmful, the safe use of such products can best be fostered if they are regulated as drugs.
Nutrient Interactions

**Issue:** Excess consumption of certain nutrients may create adverse nutrient interactions leading to serious health problems.

**Rationale:** In addition to the overt toxicity of some nutrients (particularly the fat-soluble vitamins A and D), there are many examples of potentially dangerous interactions between minerals, vitamins, amino acids, and other dietary constituents. These interactions are generally of little practical significance in balanced diets composed of traditional foods. The potential for excess nutrient intake leading to nutrient imbalances is enhanced with the consumption of isolated nutrients.

For example, zinc, copper and iron interact with one another in a predictable way. A diet with excess amounts of any one of these nutrients affects the absorption and metabolism of the other two. Therefore, diets with excess zinc can result in what appears to be iron-deficiency anemia, and diets high in iron can result in an apparent deficiency of zinc and copper.

The interaction of zinc, copper and iron is of particular significance in light of a current theory that ischemic heart disease is related to diets low in copper. More than enough evidence exists to support a health claim for copper under H.R. 1709. However, consumers who take large amounts of copper in an effort to reduce the risk of heart disease run the real risk of compromised iron and zinc status. This consequence is of special concern among children and women of childbearing age who are already at significant risk of iron deficiency.

Other nutrient interactions for potential concern with large doses include:

- vitamin E increasing the requirement for vitamin K
- polyunsaturated fats (e.g., fish oils) may increase the requirement for vitamin E
- copper may increase the need for vitamin E and pantothenic acid
- many minerals, e.g., copper, zinc, iron, and manganese can interfere with the absorption of riboflavin
- creation of a nutrient imbalance - supplements containing single nutrients often do not provide the entire complement of nutrients required for optimal health or a specific targeted function. For example, calcium supplements may not contain other nutrients (protein, phosphorus, magnesium, zinc, vitamin C, and vitamin D) required to build bones.
Nutrient supplements make valuable contributions when used appropriately. The IFT-ND is seriously concerned, however, that misuse of such products, fueled by compelling and misleading health claims, will result in nutritional imbalances and other toxic effects that could seriously undermine public health.

Risks Associated with Fiber Supplements

_Issue:_ There is a potential health risk in consuming excess dietary fiber, especially soluble fiber, as a supplement.

_Rationale:_ While there is widespread scientific support for increasing the consumption of dietary fiber by Americans, recommendations to do so refer specifically to foods rich in dietary fiber, not to the use of supplements. For two of the most prevalent and costly diseases to individuals and the nation, cancer and heart disease, increased dietary fiber consumption has been extensively associated with their decreased incidence. There is insufficient evidence, however, that dietary fiber _per se_ is the food component affecting these diseases. The overwhelming evidence suggests that it is the combination of nutrients obtained in a low fat, high dietary fiber diet that is collectively contributing to these health-protective effects observed in people consuming abundant dietary fiber.

The use of isolated dietary fibers added back to foods, however, such as wheat, corn and oat bran, soy fiber, cellulose, and pectin, has found wide application. As food additives, the inclusion in foods of these isolated sources of dietary fiber is limited by the acceptability of the foods. Although wheat bran, a popular and rich source of dietary fiber, is often used in scientific studies and has been shown to have beneficial effects, its consumption is best achieved through incorporation into foods. Consumption of too much isolated fiber not incorporated into food may reduce the absorption of other essential nutrients. This problem could be overcome with vitamin and mineral supplements, but with this strategy, people may be avoiding real foods, missing the most healthful food choices available, and risking nutrient imbalances or unfavorable nutrient interactions.

In addition, there is a health risk in consuming soluble dietary fiber as a supplement: soluble fiber may not become totally hydrated before being consumed. Consumed, inadequately hydrated, soluble fiber only becomes fully hydrated in the stomach and intestine, where its greatly increased bulk can lead to intestinal obstructions and excess fermentation. Severe gastrointestinal illness has been documented with the use of guar gum supplements and some such products have had to be recalled from the marketplace and destroyed (Food Chem News, May 10, 1993).

The IFT-ND supports the proposed health claims of FDA for dietary fiber and cancer and heart disease. It seems inappropriate and unscientific, however, to restrict the health claims labeling of foods that are naturally rich in dietary fiber, or high in added dietary fiber, but allow such claims on isolated sources of dietary fiber for which demonstrated health risks
exist. In addition, IFT-ND finds no scientific basis for supporting the use of dietary supplements that would supply complex carbohydrates and/or sugars and advises caution on the use of supplements containing soluble dietary fiber. IFT-ND is concerned about the health risks associated with the consumption of supplements containing soluble dietary fiber and with the potential for nutrient imbalances that may result from the use of dietary fiber supplements.

Risk of Toxicity and Pharmacologic Effects of Some Herbal Preparations

**Issue:** Some herbal preparations contain naturally occurring toxic chemicals.

**Rationale:** Although many ingredients of dietary supplements pose no risk to consumers under normal usage, some herbal preparations contain naturally occurring toxic chemicals. Certain preparations, such as those recommended for allergies, contain arsenic salts and other poisons as active ingredients.

The FDA proposal for regulation of dietary supplements cites several herbs, notably lobelia (Indian tobacco) which may cause coma, and chaparral (creosote bush) which produces toxic hepatitis. Many herbs contain chemicals that have the following medicinal effects and possible adverse reactions:

- **Purgatives, cathartics:** habitual use leads to chronic diarrhea; weakened adults and young children may lose vital fluids and minerals, resulting in severe dehydration.

- **Blood thinners including coumarins:** persons taking prescribed blood-thinning drugs risk excessive bleeding.

- **Licorice root and its principal active chemical, glycyrrhizin** (used as a natural high-intensity sweetener): water and sodium are retained, causing blood pressure to rise. These products should be avoided by people with cardiac or kidney disease, or hypertension, and those who are overweight or pregnant.

The part of the plant used in a supplement must be clearly identified because toxicity varies with each part (leaf, root, flower) and with stage of development. For example, raspberry fruit is widely consumed and is used in many herbal products for its flavor. Raspberry **leaves** are also a common ingredient in herbal teas. Traditionally, tea made with raspberry leaves is purported to ease childbirth, and is thus recommended for pregnant women. Some herbalists, however, advise their clients to avoid raspberry leaves because they stimulate uterine contractions, leading to premature labor, and possible miscarriage. Babies born to mothers who consume large amounts of raspberry leaf tea prior to delivery may be at higher risk of jaundice.
H.R. 1709 seeks to prevent regulation of dietary supplements as drugs, despite the admission by several companies that their products are medicines. Consumers expect to be warned about possible side effects and contraindications for herb consumption, just as they are now protected with drug labeling. Some supplement manufacturers already label their products with such warnings. Herbs contain chemicals that are drugs; that is one reason why consumers use them. Further, the dose of pharmacologically active substances may vary widely among different herbal products and therefore may have widely differing and potentially harmful effects among various consumers. Safety cannot be guaranteed solely on the basis of a history of usage.

For example, ephedra or ma huang is a Chinese herb popular in many preparations, especially weight loss pills. The active ingredient in ephedra is ephedrine. Purified ephedrine and its synthetic derivatives such as pseudoephedrine are used in prescription and over-the-counter (OTC) drugs. Ephedrine dilates the bronchioles of the lungs, stimulates heart muscles, contracts the uterus, and acts as a diuretic. Typical side effects of ephedrine use are dizziness, nervousness, headache, and chest pain. OTC nasal decongestant tablets contain 30 milligrams of pseudoephedrine hydrochloride and are required to state on their package the following or similar warning:

"Do not exceed recommended dosage because at higher doses nervousness, dizziness, or sleeplessness may occur. Do not take this product for more than 7 days. If symptoms do not improve or are accompanied by fever, consult a doctor. Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product."

Dried ephedra contains about 1% ephedrine. About 3 grams of ephedra contain 30 milligrams of ephedrine; 24 grams of ephedra is equivalent to the maximum dose for the OTC drug. Without guidelines, consumers can easily take too much ephedra and suffer its unpleasant side effects.

Consumers often confuse "natural" with "safe" but natural products can be harmful. Proper labeling will protect consumers from inadvertent use of a natural drug that could harm them, while safeguarding their right to use herbal medicines.

Scientific Basis for Daily Values and RDAs

**Issue:** Adoption of the highest RDAs as Daily Values impedes the application of new scientific information.

**Rationale:** Legitimate scientific uncertainty exists about the safe and appropriate intake of many nutrients for all healthy individuals. For some nutrients insufficient information is
available to determine nutrient needs; for others, the range of appropriate intake is very large. Another difficulty in recommending a safe intake of such nutrients for virtually everyone is that scientific knowledge changes, sometimes rapidly. For these reasons, wise public health policy permits flexibility in adopting new scientific information as it becomes established.

A tremendous amount of work has been accomplished to determine the essential nutrients and the amounts necessary to achieve good nutrition and health. Although precise nutrient requirements remain to be established for some nutrients and certain groups of people, there is abundant scientifically sound information for establishing appropriate and practical dietary guidelines for the American people. A major problem has been to adequately disseminate this information and for people to adhere to these well-researched and formulated dietary guidelines.

Recommended Dietary Allowances (RDAs) exist for most essential vitamins, minerals and energy. Because insufficient scientific information is available for biotin, pantothenic acid, copper, manganese, fluoride, chromium and molybdenum, recommended intakes for these nutrients are provided as ranges. RDAs are "the levels of intake of essential nutrients that, on the basis of scientific knowledge, are judged by the Food and Nutrition Board to be adequate to meet the known nutrient needs of practically all healthy persons." In meeting these RDAs individuals can make a significant contribution to the maintenance of their good health. It is acknowledged that numerous other factors, i.e., excess weight, exercise, control of stress, and smoking, can affect an individual's ability to maintain good health and reduce the likelihood of disease.

The Food and Drug Administration (FDA) had established a set of Daily Values (DV) for all vitamins, minerals, fats, carbohydrates, and dietary fiber. DV are drawn from the RDAs where data are available and from significant scientific agreement about appropriate nutrient intakes for other nutrients without RDAs, e.g., dietary fiber, fat, etc. The FDA first suggested DV for all macro and micro nutrients in its proposed regulations in response to the NLEA of 1990. These proposed values, however, were rejected as being too low. Most health professionals and nutritionists agreed with this decision.

The DV selected in the current regulations on nutritional labeling are those first suggested in 1973 and previously referred to as the U.S. Recommended Daily Allowances (U.S. RDA). The U.S. RDA values were the highest RDA values established in 1968. It is vital to the concept of DV that the actual numbers suggested be viewed as approximate. They are not minimum requirements and may vary widely for different population groups. Foresighted public policy allows for adaptations to new knowledge when current scientific understanding recognizes wide variation in what appropriate intakes may be. For example, the usual American diet containing nearly 40% of its energy from fat may have been thought appropriate 20 or 30 years ago but now we know that this intake is too high for the optimum health of most people. Legislation specifying absolute nutrient intakes would be an impediment to the implementation of new scientific knowledge as it is acquired.
Scientific Basis for Health Claims

**Issue:** The "totality of scientific evidence" approach as the scientific basis for establishing a health claim undermines the scientific method as a means of evaluating evidence.

**Rationale:** Under the NLEA, the scientific basis for establishing a health claim is based on "significant scientific agreement among qualified experts." This is the standard that comes closest to scientific consensus on the validity and interpretation of all existing, publicly available, scientific evidence. The specification of "scientific evidence" is important for it distinguishes objectively obtained data such as that from clinical trials, epidemiological observations, biochemical research studies, and the like, from opinion, testimonials, and anecdotal evidence. This standard has the merit of emphasizing scientifically sound data and rejecting flawed or poorly designed studies in an effort to assess and interpret scientific findings. The intent is to bring the best scientific evidence to decision-making and incorporate the assessment of the available scientific evidence by those trained and experienced in science. Where data are inadequate for making judgements or reaching agreement, the "significant scientific agreement" process calls for health claims to be rejected on the basis of insufficient or inadequate evidence.

This process is most often flawed by the lack of adequate or sufficient data, and sometimes, by differing interpretations of what the evidence means. While this approach may be imperfect, it is by far the best tool available for rational decision-making where scientific issues are involved. Substantial deviation from this process or the rush to judgement with inadequate information can be expected to foster serious misjudgements, compromise public safety, and undermine the trustworthiness of scientific research.

Changing the "significant scientific agreement" standard for decision-making to one based on the "totality of scientific evidence" carries with it the implication that all evidence may be valid and worthy of inclusion in decision-making. In fact, some types of scientific evidence are not as reliable as others. Studies without controls or inappropriate control groups, invalid experimental models, insufficient numbers of observations, inappropriate methodology, and serious design flaws, should be rejected outright or given little weight in the overall assessment of the scientific evidence. Shifting the decision-making process to include the "totality of scientific evidence," would give inappropriate emphasis to untrustworthy reports.

Potentially Misleading Health Claims

**Issue:** A less stringent standard for nutrient requirements and health claims than is permitted for foods delivering the same types and levels of nutrients undermines nutrition education and raises public health concerns.
Rationale: H.R. 1709, if enacted, would permit marketers of dietary supplements to position and describe their products as superior to foods containing a similar nutrient profile. Under the NLEA, however, similar foods would be proscribed from making the same claim. Such a contradiction undermines rational education efforts supported and undertaken by the USDA and other government and private agencies, that consistently emphasize total diet as the means to good nutrition.

The NLEA is a stunning example of effective government action. It strives to make nutrition information more accessible and useful to the general public. The principles of the NLEA have wide support from government, industry, consumer advocates, academia, and the public. The NLEA is the product of years of effort and cooperation by these groups to improve both the scientific rationale in food labeling and the science base for providing information. The NLEA has earned the whole-hearted support of government legislators and the public. Many private organizations and government agencies have committed substantial resources to public education about the NLEA. The IFT-ND believes that different labeling and scientific standards for foods and dietary supplements would undermine the important progress achieved by the NLEA.

Further, the classification of dietary supplements as a separate category distinct from foods or drugs, with a different and less rigorous scientific standard for health claims, will create confusion among consumers and permit the promotion of some dietary supplements with dubious benefit and possible risk. For example, under H.R. 1709, dietary supplements would be permitted to claim that they "prevent or repair damage caused by diet or other environmental factors." Such claims imply that dietary supplements are drugs or achieve drug-like effects, but unlike drugs, dietary supplements would not have to demonstrate either safety or efficacy. On the other hand, a food with a similar nutrient profile is prohibited from making such claims under the NLEA. The IFT-ND believes that such a policy not only puts public safety at risk but also undermines consumer education and the ability to make informed food choices.

Summary

The IFT-ND supports the safe and appropriate use of dietary supplements but finds that H.R. 1709 would undermine the provisions of the NLEA intended to ensure the safe use of foods and dietary supplements. The proposed legislation does not provide the American public with sufficient protection from known dangers posed by excessive nutrient intake, toxic substances associated with some dietary supplements, or false and misleading health claims. The IFT-ND believes that, as with foods and drugs, the supplement industry, not the FDA, bears the burden of proof that supplements and their manufacturing processes are safe.
It would impede the application of new scientific knowledge if Congress were to legislate specific Daily Values for nutrients or dietary components where scientific evidence is inadequate or optimum nutrient intakes vary greatly. All recommendations for adequate nutrient intake must be based on sound scientific information. IFT-ND supports the application to both foods and dietary supplements of the same, stringent, scientific standards in determining the basis for health claims. IFT-ND supports the labeling of dietary supplements containing pharmacologically active compounds to warn consumers of potential side effects.

The IFT-ND's concerns with H.R. 1709 are:

- An inadequate recognition of the inherent toxicity of certain nutrient supplements;
- A failure to ensure the safety of amino acid supplements;
- No safeguards against harmful nutrient interactions;
- An erosion of the scientific basis for determining safe and adequate levels of nutrient intake;
- No protection of consumers from known health risks from excessive intake of certain forms of dietary fiber and some herbal supplements;
- An inadequate scientific basis for supporting health claims; and
- An increase in the potential for misleading health claims regarding dietary supplements.
Mr. Durbin, Ms. Reed.

Ms. Reed. I wanted to start by thanking you for your leadership on expanding the low-income rural home repair program in recent action by the subcommittee. This will mean a lot to a lot of older people in providing better living conditions.

Mr. Durbin. They still have to sign the affidavit that they will not sell narcotics on the premises.

Ms. Reed. Thank you again. I will summarize our remarks.

Science has made great strides in finding the link between diet and health. Studies show that certain vitamins and minerals have a positive correlation with lower incidences of cancer and other diseases. Some research is finding that supplement use may be particularly beneficial for older Americans. For these reasons, AARP supports the right of consumers to have access to safe and effective dietary supplements, and we believe such access must be preserved. Indeed we don’t believe it to be in jeopardy.

Supplement manufacturers have capitalized on studies showing links between diet and health. There is a significant industry focus on the health concerns of older Americans. Health food stores sell products with names like ArthPlus and magazines include full-page ads for OcuGuard caps, showing a silver-haired couple that presumably takes this product to improve their aging eyes. Senior citizens suffer disproportionately from diet-related diseases. Because seniors read labels more often than other age groups and are more trusting of salespersons, they are ripe for being defrauded. As a membership organization, AARP shares a responsibility to educate and inform its members on these issues.

Most supplement products are harmless under normal circumstances. Some may not be safe, however, and many of them include unsubstantiated and downright false health claims on their labels.

We are concerned that the inconsistencies and gaps in the current law do not adequately ensure the safety of dietary supplements and protect against deception and frauds.

AARP believes it is time for Congress to amend the Food, Drug and Cosmetic Act to make sure that supplements are safe and accurately labeled. A comprehensive approach is needed. Supplement labels should comply, where appropriate, with the requirements of the Nutrition Labeling and Education Act, especially its requirements for health claims, and in addition we believe they should include expiration dates, full ingredient listings, and adverse reaction warnings.

In developing labeling requirements, FDA should be particularly attentive to implied claims that appear in product names like Bone-Up and OcuGuard.

Another important labeling concern for AARP members is readability. FDA can make it easier to read labels through addressing other factors—that is to say, other than the problem with the small size of containers. Other factors like type style and color contrast can make a real difference.

The issue of ensuring the safety of dietary supplements has prompted significant controversy. While it would be unrealistic and unsuitable for FDA to treat most supplements as “drugs,” AARP
believes better mechanisms are needed to ensure safety, quality and purity.

Among bills introduced so far, only H.R. 2923, the Dietary Supplement Consumer Protection Act of 1993, introduced by Representative Cardiss Collins would promote safe, effective and quality supplements that are accurately labeled. Other legislative alternatives establish a lower standard of evidence for health and nutrition claims than allowed for commonly eaten foods containing the same nutrients. Moreover, they fail to adequately address misleading and deceptive claims. Under those alternative bills, FDA would have to prove a product dangerous to public health before action could be taken. This means that hair growth, vision restoration or cancer prevention would not have to satisfy the same scientific standards required of common foods as long as FDA could discern no pattern of public harm.

In conclusion, AARP views Federal regulation of dietary supplements as an issue of consumer health and safety and consumer protection from frauds. We are deeply concerned about the scare tactics employed by some members of the supplement industry to convince vulnerable consumers that FDA regulations would result in a ban of all supplements. AARP would oppose a policy intended to limit access to all or most supplement products.

Again, AARP urges Congress to amend the FDCA to clarify ambiguities related to dietary supplement products so that consumers, industry and regulators are clear on what standards apply to specific types of supplement products. We stand ready to work with Congress and all interested parties in this efforts.

Thank you.

Mr. Durbin. Thank you very much.

[The information follows:]
STATEMENT

OF

GERALD JAMES
MEMBER, BOARD OF DIRECTORS
OF THE
AMERICAN ASSOCIATION OF RETIRED PERSONS
ON
REGULATION OF DIETARY SUPPLEMENTS
BEFORE THE
SUBCOMMITTEE ON AGRICULTURE
OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES HOUSE OF REPRESENTATIVES
OCTOBER 18, 1993

For further information, contact:

Larry White
(202) 434-3800
The American Association of Retired Persons (AARP) appreciates this opportunity to present our views regarding federal regulation of dietary supplements -- vitamins, minerals, herbs, and other nutritional substances.

Many consumers, including a significant number of older Americans, take dietary supplements. While vitamin and mineral deficiencies are not a widespread problem in this country, many older Americans do not get enough essential nutrients because some of the medicines that they take hinder vitamin absorption. Also, the sense of taste diminishes with age, so many older persons don't have a good appetite and therefore do not eat sufficiently for proper nutrition. AARP supports the right of consumers to have access to safe and effective dietary supplements, and we believe that such access must be preserved.

Science has made great strides in uncovering the link between diet and health. Studies, reported in the popular press and on television, show that certain vitamins and minerals can correlate with lower incidences of cancer and other diseases.

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1 A 1986 survey conducted among residents in a retirement community found that 53 percent of those surveyed used nutritional supplements, with 91 percent of supplement users taking them daily and 61 percent for more than five years. Sobel, J et al.: "Use of Nutritional Supplements in a Retirement Community." Gerontologist 1986; 26:187-191.
Some research is finding that supplement use may be particularly beneficial for older Americans. One major study found that supplements can boost the immune systems of older people and decrease their risk of infection.²

Supplement manufacturers have capitalized on these developments and on Americans' -- particularly older Americans' -- increased interest in health. Health food stores sell products like "ArthPlus" and magazines include full-page ads for "OcuGuard" caps, showing a silver-haired couple that presumably takes this product to improve their aging eyes.³ Senior citizens suffer disproportionately from diet-related diseases and read labels more often than other age groups. Surveys also indicate that they are more trusting of salespersons and do less research than younger consumers.⁴ Put these factors together and you have consumers who are ripe for being defrauded.

The vast majority of supplement products are harmless under normal circumstances. Some of these products, however, may not be safe and many of them include unsubstantiated and downright false health claims on their labels.

³ See Attachment 2.
We are concerned that the inconsistencies and gaps in the current law — where supplements are sometimes considered "food," sometimes "food additives," and sometimes "drugs" — do not adequately ensure the safety of dietary supplements and protect against consumer deception and fraud.

In view of these concerns, AARP believes that it is time for Congress to amend the Food, Drug, and Cosmetic Act to make sure that supplements are both safe and accurately labeled.

SUPPLEMENT LABELING

With respect to labeling, the Association supports a comprehensive approach. Labels should not only comply with the requirements of the Nutrition Labeling and Education Act (NLEA), but also provide additional essential consumer information. For instance, when appropriate, the label should identify special populations that may be particularly sensitive to possible adverse effects. Labels should indicate the effects of widely used drugs on vitamin absorption, or indicate the side effects of taking excessive amounts of certain supplements. Some research, for example, indicates that older persons may be especially vulnerable to the effects of very high dosages of Vitamin A, which can cause liver and bone damage.5

5 See e.g., Krasinki SD, Russell RM, Otradovec CL, et al.: Relationship of vitamin A and vitamin E intake to fasting plasma retinol, retinol binding protein, retinyl esters, crotene, alpha-tocopherol, and cholesterol among elderly and young adults: increased plasma retinol esters among Vitamin A supplement users.
In developing labeling requirements, FDA should be particularly attentive to implied health claims that appear in product names, like "Bone-Up" and "OcuGuard."

Another important labeling concern for AARP members is readability. FDA did the right thing in the food labeling area when it prescribed type size and style features that would enhance the readability of the food label. While the small size of supplement containers presents a major obstacle to readability, FDA can prescribe other readability factors -- like type style and color contrast -- to help ensure that people can read product labels.

SAFETY, QUALITY AND ACCESS

The issue of ensuring the safety of dietary supplements has prompted significant controversy. While AARP agrees with the industry that dietary supplements, for the most part, are not "drugs," we believe there should be better mechanisms in place to ensure their safety. For instance, FDA should review the safety of dietary supplements, particularly herbs, amino acids, and other supplements that are less well studied than essential nutrients. AARP could support a requirement that all FDA reviews (whether for safety or to permit a health or nutrition claim) comply with reasonable procedures and timelines. This would

require that Congress also make available the resources FDA needs to conduct its work on a timely basis.

We also encourage FDA to adopt quality and purity standards (such as disintegration and potency standards) for supplement products to ensure that people are getting what they pay for. For example, if a consumer buys vitamin E capsules that are labeled as containing 400 international units each, every capsule should contain that amount. A recent broadcast on supplements found that some products contained as little as 57% of the potency cited on the label.

The Association supports consumer access to dietary supplements and opposes any effort to make them available only by prescription. A safe but unproven supplement should remain on the market as long as it does not make health or nutrition claims. In order to make such a claim, however, we believe the product should have to satisfy the same standard used for common foods -- "significant scientific agreement."

LEGISLATION

H.R. 2923, the "Dietary Supplement Consumer Protection Act of 1993" introduced by Representative Cardiss Collins, is the only bill currently introduced that promotes safety and efficacy of dietary supplement products, along with accurate, non-misleading labeling.
The Association is pleased that H.R. 2923 maintains a consistent standard for health and nutrition claims for both the food industry and the dietary supplement industry, i.e., "significant scientific agreement." In addition, AARP supports provisions requiring supplement labels to include expiration dates and information regarding any possible adverse effects. The bill also defines the terms "dietary supplement" and "dietary ingredient," which should help to resolve a significant policy debate. Finally, we are heartened by the bill's proposals to ensure the good quality of supplements, expand research on these products, and establish an objective body to advise federal officials regarding these products.

AARP does not support H.R. 1709, the "Dietary Supplement Health and Education Act of 1993". This legislation would establish a lower standard of evidence for health and nutrition claims than is allowed for foods eaten on an everyday basis although most dietary supplements are processed from those same commonly consumed food sources. Moreover, the bill fails adequately to address misleading and deceptive health and nutrition claims on dietary supplements.

Under H.R. 1709, any claim made about a supplement would be legal provided the manufacturer gives FDA 60 days notice prior to marketing. FDA must then prove that the product is dangerous to public health before any action could be taken. The product
would not have to be effective or accurately labeled as long as no harm or danger to public health is discerned. Therefore, supplements that promise hair growth, vision restoration, arthritis therapy, cancer prevention, cholesterol reduction, or bone restoration would not have to satisfy the basic standards required of common foods containing the same nutrients.

This means that under H.R. 1709, no action could be taken against a fraudulent or mislabeled product unless it harmed or killed enough individuals to establish a pattern discernible by the FDA. Even then FDA would be limited to taking action against only a particular company’s product. That same product could be sold by other companies, for many different purposes, under different names. Companies bent on maintaining their profits could continue to market a fraudulent, substandard or dangerous product indefinitely by simply changing its name and stated purpose (health or nutrition claim).

AARP does not agree that this approach constitutes true freedom of choice for the vast majority of consumers who expect products sold in the public domain to meet some standard of safety, quality and effectiveness.

In conclusion, AARP views federal regulation of dietary supplements as an issue of consumer health and safety, and consumer protection from fraud. We are deeply concerned about
the scare tactics employed by some members of the supplement industry to convince vulnerable consumers that FDA regulation would result in a ban of all supplements. AARP would oppose a policy intended to limit access to all or most supplement products.

Again, AARP urges Congress to amend the FDCA to clarify ambiguities related to dietary supplement products so that consumers, industry and regulators are clear on what standards apply to specific types of supplement products. AARP stands ready to work with Congress and all interested parties in this effort.
Mr. DURBIN. The last witness on this panel is Fred Bingham.

Mr. BINGHAM. I am Fred Bingham. I am a person with AIDS, and I am Executive Director of Direct AIDS Alternative Information Resources called DAAAIR a nonprofit buyers club in New York City. I speak today as a spokesperson for the Consumer Coalition for Health Choices, a national association of consumer advocacy groups that oppose FDA plans to restrict access to dietary supplements under the guise of safety and labeling regulations.

At our July 23, 1993 meeting between community activists and senior FDA personnel, we were told explicitly that the FDA's proposed regulations, if fully implemented, would result in the removal of all amino acids, most if not all medicinal herbs and many high-potency vitamins from the over-the-counter market. This is exactly what Gary Dykstra, Mike Taylor—this admission from FDA officials was not made easily. They started off the meeting repeatedly denying that they had any intention of taking supplements off the market. But when questioned about specific provisions in the regulations, they were forced to admit, quite reluctantly, that these products would not be in compliance with their proposed regulations and would therefore be subject to removal from the market.

We very much want safe products, pure ingredients, full potency, manufacturers' standards of identity, nutritional good manufacturing practices, full disclosure labels and truthful and nonmisleading claims.

We favor clear and prominent warnings on labels about scientifically established or epidemiologically observed toxicities to assist consumers in their decision-making.

An egregious example of unscientific bias from the FDA is their present policy towards amino acids. They assert that amino acids pose significant safety concerns to the agency, but there is a dearth of scientific evidence of toxicity, danger and hazard to the public health. In fact, amino acids are so safe that scientists can't determine upper safety limits as concluded in the FDA-sponsored Life Science Research Organization/FASEB report. In disregard for scientific integrity, the FDA states that this lack of an upper safety limit is reason to classify all amino acids as drugs because safe upper level limits are not known. The FDA is not protecting the public from danger, they are handing a plum to the people holding use-patents on amino acids. Without substantial reform—and there is deep institutional bias within FDA—the FDA can no longer be entrusted with regulation of our food supplements or our foods. As an HIV-infected individual, I use amino acids and herbal concentrates as my chosen treatment to keep my immune system strong. These treatments have restored my immune system from a low of 100 T-cells to my present nearly 800 T-cells. I have gained nearly 50 pounds and am now able to walk long distances without difficulty, and all this because of an aggressive alternative protocol. My successes are representative of such experiences worldwide. Unfortunately, given FDA's looming restrictions on nonmisleading health information there are no mechanisms in place to bring about our successful experiences to the consumer.

All of my oldest friends who have chosen to use orthodox treatments with long-term cumulative toxicity—all are now dead. For me, the prospect of losing access to amino acids and herbal con-
centrates is a life-and-death proposition. I helped found the Consumer Coalition for Health Choices to oppose these new FDA regulations and to keep access open.

We are very interested in eliminating real fraud and there is a sizable amount of it out there. But a deep bias against supplement products has distorted the FDA's ability to recognize fraud when they see it. In their ignorance, they toss the baby out and keep the bath water.

Nowhere is the FDA's pro-drug/anti-supplement bias more evident than the statement by the FDA Dietary Supplement Task Force report, stated on page 2 and repeated on page 71, that the FDA's mission is to ensure that the existence of dietary supplements on the market do not act as a disincentive for drug development. The FDA has spent considerable resources to try to convince Congress and the media that what they said was not what they meant, but it is what they meant. Although we can understand the political and economic motivations of the FDA in suppressing supplements to protect drugs, we cannot afford to condone it.

The FDA has become a threat to the public health they are charged with protecting. At the July 23rd meeting, one official expressed dismay that the popularity of alternative medical therapies in the United States was driving clinical studies of unapproved drugs into Europe where access to such therapies is more restricted. As a patient and consumer advocates, we must question the wisdom of FDA promotion of drug development at the expense of patients' informed choice.

According to data from the American Association of Poison Control Centers, over 3,500 people died over a 10-year period from prescription and over-the-counter drugs. During the same period, only one died from nutrients, specifically a 28-year-old schizophrenic IV-drug user known to horde and abuse medications, given niacin on prescription by his physician. Further, the American Medical Association's Council on Drug Effects estimates that in the same 10-year period between 800,000 and 1,300,000 people died due to adverse effects of medications. The FDA currently considers anything that is used in the cure, treatment, prevention or mitigation of disease to be a drug. Most foods have some preventive influence on disease. Does FDA intend for foods to be regulated as drugs? Does FDA intend to apply an "Alice in Wonderland logic" to how it decides what is and what is not a food supplement?

Concerning the food supplement safety as exemplified by eosinophilia myalgia syndrome, my heart goes out to the victims of EMS and their families. They don't deserve the suffering they have endured. But the FDA is as much responsible for their plight as Showa Denko, which mismanufactured the contaminated tryptophan.

The FDA was informed of the Contamination problem by November of 1989 according to FDA logs obtained under the Freedom of Information Act. Why did they allow these Americans to take what they knew was impure tryptophan? Why did they risk the lives of American consumers? Was it for political gain? During and after the EMS outbreak the FDA tried very hard to convince Congress, the press and the public that tryptophan was responsible. I have got to add, on the tryptophan issue that the FDA has spent a lot
of time focuses on that tragedy as being an blatant example of how dangerous these nutritional herbal supplements can be. However, what they have failed to do is to accept that the primary responsibility for ensuring the safety of this product was the FDA's. They do not mention L-tryptophan supplements are manufactured by pharmaceutical companies, the most intensely regulated industry under FDA's jurisdiction. They fail to mention that in a majority of the EMS cases the contaminated tryptophan was described by physicians. They also do not mention that the contamination occurred because of changes in the manufacturing process, processes involving genetically-altered manufacturing techniques, techniques which were approved by FDA. Likewise the contaminated L-tryptophan was an imported product which means that FDA had the ability to stop the product before it could cause a problem. Product contamination happens whether it be with alar apples, Chilean grapes or Jack in the box contaminated meats. This is one reason we support H.R. 1709, the Dietary Supplement Health And Education Act now pending in Congress. The bill does indeed require that manufacturers inform FDA of any significant changes in manufacturing procedures specifically to prevent EMS-like problems from happening again. But rather than being an indictment of the integrity of supplements, in reality the EMS tragedy is an indictment of FDA's own failure to protect the public in this instance. I could go on but I won't.

[The information follows:]
Testimony of Fred Bingham before Representative Durbin and members of the House Appropriations Subcommittee, 18 October 1993, 2:30 PM.

My name is Fred Bingham and I am Executive Director of Direct AIDS Alternative Information Resources (DAAIR), a non-profit buyers club in New York City. I speak today as spokesperson for the Consumer Coalition for Health Choices, an national association of consumer advocacy groups which oppose FDA plans to restrict access to dietary supplements under the guise of safety and labeling regulations.

At our July 23rd, 1993 meeting between community activists and senior FDA personnel we were told explicitly that the FDA's proposed regulations, if fully implemented, would result in the removal of all amino acids, most if not all medicinal herbs, and many high-potency vitamins from the over-the-counter market. This admission from FDA officials was not made easily. They started off the meeting repeatedly denying that they had any intention of taking supplements off the market. But when questioned about specific provisions in their regulations, they were forced to admit, quite reluctantly, that these products would not be in compliance with their proposed regulations and would therefore be subject to removal from the market.

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Fred Bingham Testimony before the House Appropriations Subcommittee
As an HIV-infected individual, I use amino acids and herbal concentrates as my chosen treatment to keep my immune system strong. These treatments have restored my immune system from a low of 100 T-cells to my present 700+ T-cells. I have gained nearly fifty pounds and am now able to walk long distances without difficulty, and all this because of an aggressive alternative protocol. All of my friends chose to use orthodox treatments of AZT, ddC and ddi. All are now dead. For me, the prospect of loosing access to amino acids and herbal concentrates was a life-and-death proposition. I helped found the Consumers Coalition for Health Choices to oppose these new FDA regulations and to keep access open.

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Concerning food supplement safety as exemplified by eosinophilia myalgia syndrome (EMS), my heart goes out to the victims of EMS and their families. They don't deserve the suffering they have endured. But the FDA is as much responsible for their plight as Showa Denko which mis-manufactured the contaminated tryptophan.
The FDA was informed of the contamination problem by November of 1989 according to FDA logs obtained under the Freedom of Information Act. Why did they allow these Americans to take what they knew was impure tryptophan? Did they risk the lives of American consumers for political gain?

During and after the EMS epidemic, the FDA tried very hard to convince Congress, the press and the public that tryptophan was responsible. This campaign was not founded on scientific information. It was mainly political. When the CDC and other medical authorities unanimously concluded that a contaminant from one company was responsible, they refused to accept the finding again without scientific evidence. They started suggesting that tryptophan contributed to the toxicity of the contaminant, and initiated research studies to prove this contention. By administering massive doses of insoluble tryptophan and using seriously flawed methodologies, they were able to conclude that tryptophan cannot be ruled out as a contributing factor in EMS. All in all, it was a stellar example of scientific obfuscation.

Now the FDA solicits EMS victims and their families for news conferences and congressional hearings as if they were the protectors of the victims, instead of being accessories-after-the-fact. If the FDA had acted to protect the public health when they first were informed of Showa Denko's contaminated tryptophan, many EMS victims would be alive and healthy today. Their suffering was largely preventable, and the FDA failed in their responsibility.

We do know that uncontaminated tryptophan has been used to treat EMS, and has been patented for that purpose. What public-health reason would the FDA have for banning beneficial tryptophan along with the contaminated product? The FDA's actions regarding tryptophan denied EMS victims and their families a therapeutic remedy, and denied the rest of American consumers a safe and valuable food supplement, all because of a series of incredible mistakes and/or some purpose that only the FDA knows.

These decisions were made at the top levels of the FDA. Americans deserve better conduct from their primary public-health agency. We deserve to know what happened and what the FDA did and did not do to protect public health. It is time for a full-scale Congressional investigation of this tragedy.

The tryptophan case is but the tip of the iceberg of the FDA's deep institutional bias against dietary supplements. This pervasive bias has corrupted recent Congressional attempts to expand access to truthful health information through the Nutritional Labeling and Education Act (NLEA). Instead of more and better information for consumers, we get less and worse information. This bias has resulted in the FDA telling Congress that they have serious safety concerns about rare vegetable oils when their own scientific experts testified, under oath in court, that they had no such safety concerns, and didn't know any other scientist who did (FDA vs. Traco). The FDA's unscientific bias and political opportunism is singularly inappropriate for a public health agency, and it indicates a critical lack of oversight from the Commissioner's office.

Fred Bingham Testimony before the House Appropriations Subcommittee
At the July 23rd meeting with the FDA, their experts were unprepared to deal with our detailed questions regarding amino acids. At our insistence, the FDA agreed to a subsequent meeting, to deal exclusively with amino acid safety. We have made arrangements for academic, medical and industry experts to attend the meeting and meet with selected FDA, CDC, NIH and Mayo Clinic experts to discuss the scientific realities of amino acid safety. Although we have formally requested this meeting and specified the experts needed to discuss relevant topics, the FDA has declined our dates and it now looks like we may not have another opportunity to resolve this issue in 1993. Whether or not the FDA's failure to accommodate this meeting is in violation of Congressional intent and the 1992 Moratorium is for you to decide.

Regarding consumer advocacy, I would like to contrast our coalition with other consumer groups we actually use the supplement products that the FDA is attempting to regulate. CSPI (Center for Science in the Public Interest) and AARP (American Association of Retired Persons) have taken public stands in support of FDA on behalf of consumers, yet they have not polled their members about this issue. In fact, many CSPI and AARP members are quite upset about this policy. They should be. For the over-100 million Americans who rely on nutrient supplements, losing access would be catastrophic. For all Americans, restrictions on supplements would increase the cost of healthcare while reducing our collective health.

Thank you for this opportunity to speak with you today. I would be happy to address any questions you might have.
Mr. DURBIN. If I might ask a few questions. I will try to be as brief as I can.

Mr. Silbergeld, I read your magazine and buy my cars according to your standards and charts and a lot of other things.

Has Consumers Union done a study along the lines that Ms. Meyers discussed earlier? I suppose the word is the efficacy of the dietary supplements and vitamins, solubility and that sort of thing?

Mr. SILBERGELD. No. Those would require laboratories that—we don’t test medical products. If we wanted to judge that, we would do a secondary literature search and see what the literature showed.

Mr. DURBIN. It would seem to me that everybody should agree with that standard, that the product as advertised, no matter where you stand on this issue, is in this bottle.

Mr. SILBERGELD. It should contain what it claims to contain and should meet certain biological standards for absorption.

Mr. DURBIN. I think also when you talk about contraindications and side effects and interactions with other drugs, that strikes me as the kind of basic information you can find on most bottles of aspirin.

Mr. SILBERGELD. Any medicine.

Mr. DURBIN. And in that respect should not be too great a hurdle for the folks in this industry to meet that.

I might say to a Ph.D., Dr. Camire, your 15-page or 12-page analysis of the bill through your Institute was excellent. I read it in preparation for this.

Can I ask you perhaps to join in a conversation with Mr. Bingham about the amino acid question? Because some of the statements made in the analysis came to an opposite conclusion about efficacy of amino acids, particularly in people with suppressed immune systems.

On page 4, the Federation of American Societies for Experimental Biology concluded that amino acids for certain people such as a gentleman in Mr. Bingham’s situation may be at an increased risk situation. He has come to the opposite conclusion.

Ms. CAMIRE. I don’t think so. We want the same thing. It didn’t reach a maximum amount which is what he said, but for certain groups it was a risk. People with suppressed immune systems should be using amino acid supplements under medical supervision, which is what he is doing.

Mr. DURBIN. I take it you are?

Mr. BINGHAM. Yes, except my physicians don’t know quite what to do with me.

Mr. DURBIN. She is looking for results from other people. I assume that is what is going on in the treatment of HIV positive individuals. They are taking a look at impact of dietary supplements on patients?

Mr. BINGHAM. AIDS, if nothing else to me, who is a researcher—I do a lot of research; I am very aggressive, obviously—is, if nothing else, it is an amino acid dysfunction. I don’t want to get into that.

I just want to let you know that we have requested—the Consumer Coalition for Health Choices has requested a meeting with FDA on the issue of amino acid safety. We wanted it to hap-
pen at the end of this month. They conveniently turned it over to someone’s responsibility in the agency, Donald Hull in the Office of AIDS Coordination, who was on vacation for three weeks. He just came back, and I have assembled the top scientists and researchers in this area to come and address point by point Dr. Laurie Love’s studies.

The CDC came to the opposite conclusion as FDA. We are very concerned, particularly people with AIDS, that they intend to remove these from the market, all amino acids, and my life depends on them.

Everyone seems to not have mentioned today——

Mr. DURBIN. I can’t believe there is anything we haven’t mentioned.

Mr. BINGHAM. Everyone here, I have been really impressed with you, that you really want to know, you are really concerned. I am impressed with the depths of this and the lateness of this meeting.

But with—many of the substances—the minute we use them therapeutically they transmute from a food to a drug, in FDA jargon, but there is no mechanism in place to study these, to spend the $275 million because there is no patent available for many of these substances. They are natural compound drugs of the public domain. There is no method for them to get a protected marketing right for companies to pursue the studies that need to be done to prove these are efficacious. The deck is stacked against nutrients in this way that there is no mechanism in place.

I have been thinking a lot about it. You say should we take how many vitamins? People can take too many. I think a fish can drown in water if too much water goes through its gills. Would a reasonable person take that many vitamins if there was a limit on the label, a dosage on the label? I am not sure they would.

Ms. CAMIRE. One of the things that struck me today is that—this has been a little bit with the idea we need different nutrient levels whether you are a healthy person, how old or what sex you are, on whether you are pregnant or not. But they don’t address disease. We have to separate how much of a nutrient you need when you have cancer or—et cetera.

Our concern wasn’t the anecdotal few papers, that we had a variety. And by reviewing the literature I don’t think we need a lot of studies but that we have somebody sit down and look at everything together. It has all been pushed on the FDA, and they can’t right now. Different bills have been proposed. I suppose we will end up with a hybrid bill anyway.

Mr. BINGHAM. You keep coming back to the cost of this. If you were to use—if most Americans—elderly Americans—were to use 400 to 800 IU’s of vitamin E a day you would save $30 billion a year in this country. You are saying we are not going to spend this money to do these studies because it would cost too much, but the cost in preventive health care is enormous.

Mr. DURBIN. We run into this situation all the time. There are many, many things we can do that are good that aren’t done and end up costing us more later on. That is one of the unfortunate aspects of our current budget situation.

Ms. Reed, thank you for pinch hitting. I have to say to the dietary supplement industry, if you don’t get AARP on your side you have
a big problem because her members are some of your big users. If they don’t happen to believe this is a good idea, you have a sales job to do.

We have received lots of letters, but I respect the fact that your organization looks beyond the letters and has come to the conclusion that there are things you want to see as part of this package that are not included. Some are very practical.

Here I am struggling with my reading glasses. When it comes to labeling and information, the folks I represent, my mother, she wants that kind of information, too. That is what they are looking for.

Ms. REED. The polling that we have done of our membership, while we do not have a lot of specific information yet, although it is underway on dietary supplements, we have a great deal of information as to older persons’ feelings about truth in advertising and truth in labeling. They feel very strongly about that and that is a big part of what we have presented.

Mr. DURBIN. Mr. Skeen.

Mr. SKEEN. I want to thank you folks that have endured with us. We have chewed this bubble gum just about long enough. I want to say that we appreciate so much the input because we are not experts in these fields and don’t pretend to be. We have to make the system work.

The frustrating part of it is that when you give the job to a government entity it becomes a bureaucratic approach and it is difficult to make it fit the circumstances you are talking about in your particular case. We are very conscious about what illness does. We don’t want people to be sick. We want them to have every opportunity, and I think we afford them an opportunity, but we want it done right and for them to have assurance we have given thought about how efficacious it is and that it is not fraudulent.

We are trying to protect the consumer, and I think that we do a pretty good job of it all in all. But there is a lot of criticism to be made. We appreciate the opportunity to visit with you folks because you help us arrive at some of these answers, if there are any answers. I want to thank all of you. If you have endured as long as I have you are numb from the hips down at least. I don’t know what kind of a vitamin you can take. Another 10 or 15 minutes I am going to find some. Thank you, Mr. Chairman.

Mr. DURBIN. Ms. DeLauro.

Ms. DEAULO. I want to thank all of you for your testimony and for hanging in. Is this a record, Mr. Chairman?

Mr. DURBIN. It better be.

Ms. DEAULO. One thing I would like to have done and ask if this can happen, Mr. Chairman, is both Dr. Priestly and Fred Bingham talked about in conversation with the FDA and it is in Dr. Priestly’s testimony that the admittance, that removing all amino acids from the over-the-counter market is removing minerals—I would like to, just for the record, have the FDA address that issue and see what—

Dr. PRIESTLY. We have a transcript of the meeting.

Ms. DEAULO. To know what they have to say about that. I had one question for Jo in terms of the kinds of outreach that you may be doing with your membership on the issue, outreach and edu-
cation, if you will. You mentioned two products, OcuGuard and another—I don't know if you are suggesting other supplements or any other products to them.

Just in terms of what your education process is and your outreach process on this because it appears to me that that is a group of folks who are frightened very easily about what is going to happen. I know that is the case in terms of their health insurance and medicare and whether or not it is going to be there, and I am certain in terms of any medications they may be taking.

Ms. REED. Yes. We have been experiencing deluges of mail on this issue. But we have ongoing consumer education programs with our membership and as regards this particular issue, we have had some articles, at least one article in our news bulletin, which goes to our entire membership. I think the task is still looming large before us. There is lots more to do.

Ms. DeLAURO. Do you make recommendations to them on dietary supplements or eye products?

Ms. REED. We have in our program division people who do focus on areas where there are frauds, particular frauds affecting older persons that particularly target them and information that will go out on a consumer alert. But we don't make recommendations of particular products certainly.

If we think that they are at risk and we have reason to provide some warning, we might do that.

Ms. DeLAURO. I would just like to conclude by saying that I—this is only my second term here, but it has been probably the most thorough review of an issue, at least in terms of the questions, and I know people have been reading on both sides of the table because when you do get the volume of inquiry and mail or phone calls from constituents, you don't sit back and say this is not an issue. This is not a concern.

It has to be a concern, and you are trying to make the best possible determination, because we do have to make some sort of a determination, and it has been said in a number of different ways, and I said earlier, what I want to be able to do is to have the people that I represent and people all over this country have the opportunity to know what it is that they are taking, how much of it they are taking, what goes into it, what they can anticipate in terms of side effects or—and understand what it is that they are dealing with.

I think that is what the goal is for all of us up here and that is the kind of, if you will, the focus and that we are going to be trying to determine, and by the time we end this process and make some sort of a conclusion. So I thank you very, very much for your help and your enlightening us and talking with us about this issue today. Thank you very much, Mr. Chairman.

Mr. DURBIN. Mr. Walsh.

Mr. WALSH. Thank you, Mr. Chairman. I would like to thank the witnesses for their very thorough, intelligent testimony. I think the Chairman has done a very good job of bringing in people with all different points of view and I think that way we get a full presentation of the issue from all sides.

From my perspective, the discussion we are having today on this industry is very typical of discussions that Congress has had over
the years on all industries. There are situations where we, the government, need to stand behind the consumer or protect the consumer, as the government is perhaps in some cases more informed than the consumer. All those things come into the decision whether to regulate or not to regulate.

One of the things that our constituents will tell us is that American society is overregulated. This is an area of our society which some people feel is not regulated enough. Others would tell us it is overregulated and as usual we are reacting to a situation, I think, instead of being proactive. But that is basically our role, it seems, in these sorts of issues. So we have to weigh whether or not the public good is done by promulgating more regulation or not to.

The difficulty for me is that the FDA who is empowered with a lot of this regulation has created real problems for themselves in other areas where they are working, so there is a trust factor there because I think in a lot of instances they have lost the trust of the American public.

If it is not the FDA, then, who is regulating this industry? It is that easy, but I think we should be careful not to err on the side of overregulation. I will just leave it at that for now. I congratulate the Chairman. I think this was a great hearing even though it was awfully long.

Mr. DURBIN. I want to thank the witnesses and the audience for sticking around for six-and-a-half hours. We will continue our debate and I want to apologize to the herbalist in the back of the room. If anyone wants to add testimony for the record we would be happy to have them do so.
The Food And Drug Administration, L-Tryptophan, Eosinophilia Myelagia Syndrome, And Showa Denko: A Public Deception

Prepared by
Cynthia Riddle
Investigative Journalist
Topanga CA 90290-1008

for a hearing on Dietary Supplement Regulation before the

House Appropriations Subcommittee on Agriculture
2362 Rayburn House Office Building, Washington DC 20515
Honorable Richard Durbin, Chairman

October 18, 1993
The Food and Drug Administration is using false allegations about one particular nutritional supplement as an opportunity to expand its regulatory control of the entire dietary supplement (vitamins, minerals and amino acids) and herbal market.

In the fall of 1989, there was an outbreak of a rare blood disorder, Eosinophilia Myalgia Syndrome (EMS) which caused 38 deaths and various flu-like symptoms in over 1500 individuals using L-tryptophan or products containing L-tryptophan. In response to the outbreak of EMS, the FDA pulled L-tryptophan off the market and banned its sale and distribution.

Amino acids are essential components of the protein found in foods. L-tryptophan is an essential amino acid that was used safely as a nutritional supplement by over thirty million people from the late 1960's until the fall of 1989. The world wide amino acid production is mostly dominated by a "cartel" of Japanese manufacturers, Mitsui, Ajinomoto, Kyowa Hakko, Tanabe and Nippon. Until 1988, the majority of the L-tryptophan market was controlled by Mitsui, Ajinomoto and Kyowa Hakko. In 1988, Showa Denko, a five billion dollar a year manufacturer of petrochemicals, entered the market of L-tryptophan produced for human use. In most cartels, the amount of production and sales by each of the members is governed by the collective. Within two years of introducing L-tryptophan to the market, Showa Denko achieved a 60% market share by undercutting the prices of the other manufacturers and bypassing distributors. Surely this must have upset the rest of the "cartel."

The lower prices Showa Denko offered may have also been possible due to cheaper production methods. Showa Denko, in adapting their laboratory process to produce L-tryptophan in large quantities, made changes to their protocol which are unthinkable to those familiar with scientific methodology and production. They simultaneously altered three elements in their manufacturing process, including eliminating a reverse osmosis filter, reducing the amount of carbon in another filtration step and the introduction of a new strain of genetically altered bacteria.

The Center for Disease Control and the Mayo Clinic both investigated and found that EMS was not caused by L-tryptophan, but rather by contaminants produced only by Showa Denko during the time when they had changed their manufacturing protocols. Despite identifying which company had produced the tainted
batches of L-tryptophan, the FDA refused to allow uncontaminated L-tryptophan back on the market. FDA Commissioner David Kessler introduced the Dietary Supplement Task Force in April, 1991, with these comments, "The recent problems with L-tryptophan ... unequivocally demonstrates that dietary supplements, whose regulatory status has been in limbo, can harm people." Despite evidence to the contrary, both the Commissioner and his staff continue to imply that pure L-tryptophan was responsible for EMS. Their refusal to allow it back on the market is especially strange when one considers other tainted foods and over-the-counter drugs that have been returned to the market as soon as the contaminated source had been identified and isolated.

It is not quite so strange, however, when you understand a little more about L-tryptophan. L-tryptophan produces serotonin, an important brain neurotransmitter. Some of its effects in the human body include: desensitization to pain, facilitation of sleep, and relief of PMS and depression. In addition, it is an essential part of all body proteins. It was an all-natural remedy that was available to millions of consumers at relatively low cost. Before the 1989 recall of L-tryptophan, U.S. sales of L-tryptophan were approximately 180 million dollars per year. It was a very lucrative market which was outside the control of the pharmaceutical industry.

While withdrawing L-tryptophan from the market in 1989, the FDA has allowed unhampered sales of two pharmaceutical products which are serotonin enhancers. Prozac, a chemical anti-depressant, is marketed by Eli Lilly at the suggested cost of $1.60 per capsule for annual sales of over $1 billion. (Compare this with the cost of L-tryptophan at $.25/500 mg.) Prozac has been shown to have a number of negative side effects, including headache, nervousness and gastric upset. It has also been implicated in a number of suicides and violent assaults. During the time it was being tested for market approval alone, 15 patients using it committed suicide.

Given that the FDA has recalled some products, such as weight control products containing guar gum, after a report of one associated death, it seems strange that they would have granted approval to Prozac. As of June 1992, after four and a half years on the market, Prozac use had been associated with 840 deaths by suicide. This has caused some to ask whether this product might still be available were it not one of the most lucrative drugs ever
marketed by Eli Lilly, a profitability greatly increased by the withdrawal from the market of L-tryptophan.

Exactly three months after the FDA pulled L-tryptophan off the shelves, they granted distribution rights in the United States for another chemical anti-depressant, Anafranil, manufactured by the pharmaceutical giant, Ciba-Geigy. Like Prozac, Anafranil is a serotonin enhancer but, unlike L-tryptophan, it does not actually produce serotonin. Also, unlike L-tryptophan, which has no negative side effects, Anafranil can produce headaches, dizziness, insomnia and nervousness.

Even though they know otherwise, the FDA continues to publicize L-tryptophan as a dangerous supplement. Why would they promote pharmaceutical products at the expense of naturally occurring substances such as vitamins and amino acids? The FDA openly stated in their recently released Dietary Supplements Task Force Report that:

"The Task Force considers various issues in its deliberations, including... what steps are necessary to ensure that the existence of dietary supplements on the market does not act as a disincentive for drug development."

The FDA Dietary Supplements Task Force, chaired by Associate Commissioner for Regulatory Affairs Gary Dykstra, in their Final Report issued on June 15, 1993, recommends the classifying of all amino acids sold in tablet or capsule form as prescription drugs. If they succeed in doing that, there are several possible scenarios of what could occur.

One possibility is that nobody will be able to get amino acid supplements anymore, just as has happened with L-tryptophan. They will not be available by prescription because the high costs of receiving FDA approval (new drug approval costs average $230 million and take approximately 12 years) will discourage any company from investing this money in a drug that cannot be patented. Amino acids would simply disappear from the market and those using them would have to switch to alternatives, such as powerful prescription drugs, illicit drugs, such as anabolic steroids, or black market amino acids which would be produced without the quality control which currently govern their production.
Another possibility is that they will be available, but at greatly increased costs to the consumer. Without the ability to patent nutrients such as amino acids, Dr. Brian Leibovitz, Editor-in-Chief of the Journal of Optimal Nutrition, suggests that the pharmaceutical industry has little incentive to thoroughly investigate their benefits.

However, therapeutic applications of nutritional supplements are patentable (so-called "use patents"). Dr. Richard Wurtman, of MIT, holds 37 use patents on various medical applications of supplementary amino acids. In what appears to be a conflict of interest, Wurtman testified before Congress last year, imploring them to ban OTC sales of amino acids, stating that all amino acids are toxic and should be available by prescription only. Should amino acids actually be recalled, as appears likely, Wurtman will receive 25% of the royalties that MIT will receive for the duration of the patent. Wurtman is not the only one in this whole situation who appears to be compromised.

Showa Denko, without acknowledging culpability, sent letters dated December 17, 1989 to all of its customers (supplement manufacturers) recalling unformulated L-tryptophan and offering, on an interim basis, to "Provide reimbursement of certain litigation defense costs ("the offer")." The supplement manufacturers were assured that Showa Denko would "promptly discharge all legal obligations that we have as your supplier of L-tryptophan." Furthermore, Showa Denko offered to pay for up to 100% of all legal costs incurred by the supplement manufacturers who were being sued by persons who had contracted EMS as a result of L-tryptophan containing products made exclusively with Showa Denko's L-tryptophan. The offer was contingent upon the supplement manufacturers, among other things, not bringing any action against Showa Denko during an interim period, and turning over the defense of all claims to Showa Denko attorneys to handle at Showa Denko's expense.

The supplement manufacturers, eager to be released from the liability and potential lawsuits over EMS, readily agreed. But, that was not the entirety of the offer. Showa Denko sent all of their customers who had received the tainted product a Joint Defense Agreement. Reportedly, that agreement requires their consent not to speak publicly about the matter of L-tryptophan.
The National Nutritional Foods Association (NNFA) is a trade association which represents supplement manufacturers among others. In response to pressure from its members who had signed the Joint Defense Agreement with Showa Denko, the NNFA has recently eliminated L-tryptophan from an industry-wide study designed to prove the safety of all amino acids. Sources report that Showa Denko is now trying to engineer a study which will prove that L-tryptophan is the causative agent in EMS.

Showa Denko, in the meantime, is quietly and quickly settling many of its lawsuits out of court. To date it has paid out over one billion dollars in settlements over EMS. Showa Denko stands a greater possibility of settling the remaining cases for seven to eight hundred million dollars instead of three to four billion dollars if the issue of culpability over EMS is still vague, with questions being asked whether it is caused by L-tryptophan as opposed to a contaminant generated by their own manufacturing process.

The pharmaceutical industry stands to gain if legislation can be enacted that, as in Canada, regulates amino acids as prescription drugs. However, even doing just that is no guarantee of quality and purity. The Canadian government, which initially held that their country suffered few cases of EMS due to the fact that L-tryptophan was available by prescription only, now admits that the low incidence of EMS in their country was because all of the L-tryptophan imported to their country was manufactured by sources other than Showa Denko. The few cases they did report were from L-tryptophan bought in the United States and carried across the border.

Stating that "side effects from (L-tryptophan) are considerably less than those of traditional drug therapies for insomnia and depression," one Canadian pharmaceutical manufacturer generated 1992 sales of L-tryptophan in excess of two million dollars, a 30% increase over the previous year, the same growth pattern it enjoyed in the United States prior to its withdrawal.

Initial research which originally alleged that L-tryptophan was the causative agent in EMS has been refuted by its authors, colleagues of Dr. Wurtman's at MIT. Another recent study of L-tryptophan, which showed it to have negative effects on the pancreas but no causative relationship to EMS, has significant design flaws and has yet to be retested by other experts in the field.
There is actually strong evidence that L-tryptophan is in no way related to EMS. L-tryptophan has even been found to be effective in the treatment of EMS. Dr. Christopher Caston, a South Carolina psychiatrist and L-tryptophan researcher, reports that he has successfully used a combination of L-tryptophan, vitamin C, vitamin B6, and minute doses of corticosteroids to treat EMS. If L-tryptophan were indeed the cause of EMS, how could further consumption of this alleged toxin effectively treat the very symptoms it was said to have caused?

Furthermore, researchers at Georgetown University Medical Center have reported that EMS has occurred in individuals using nutritional supplements other than L-tryptophan (lysine, niacin), and even in individuals not using supplements of any kind. This research, which supports a contaminant theory, suggests that the cause of EMS is due to something other than the nutritional supplements themselves, and the culprit is actually an unknown toxin to which certain individuals react.
BEFORE THE SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES
COMMITTEE ON APPROPRIATIONS
UNITED STATES HOUSE OF REPRESENTATIVES

Testimony Submitted for the Record of the

Hearing on Dietary Supplements
October 18, 1993

by

Jerome A. Halperin
Executive Director

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The United States Pharmacopeial Convention (USP), is a not-for-profit scientific body, composed of almost 400 delegates representing colleges and state associations of pharmacy and medicine, national professional scientific and trade associations, and agencies of the federal government. The USP was founded in 1820 in the old senate chamber of the Capital building, and is a private voluntary organization whose sole mission is to promote the public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and related articles by health care professionals, patients and consumers. The USP, the only non-governmental pharmacopeial body in the world, publishes the United States Pharmacopeia and the National Formulary (USP-NF). Congress first officially recognized the U. S. Pharmacopeia in the Drug Import Act of 1848 and recognized the USP and NF in the Pure Food and Drugs Act of 1906. Today these compendia and their supplements are recognized as official compendia under Section 201 of the Federal Food, Drug and Cosmetic Act of 1938. The USP now also publishes the USP Drug Information (USP DI®), a compendium of the information on the use of drugs and related articles by health care professionals, patients and consumers, recognized under the Medicaid and Medicare provisions of the Omnibus Budget Reconciliation Acts of 1990 and 1993.

In response to a resolution adopted at the 1990 meeting of the USP Convention, which encouraged USP to expand its programs for developing public standards and information for practitioners and consumers for combinations of vitamins and minerals used as nutritional supplements, USP has developed and adopted official compendial standards for several classes of nutritional supplements. A binder containing a compilation of the official standards established by the USP Committee of Revision as well as an update on the status of the standards currently under development has been provided to the Subcommittee for review. Also included in our written submission to the Subcommittee is a copy of the publication, The U. S. Pharmacopeial Convention, Inc., People, Policies, and Procedures, which describes in detail the composition and governance of the USP and the procedures, mechanisms and safeguards associated with its standards and information setting processes.

Compendial standards are developed by an elected scientific body, the Committee of Revision, established in 1830 to revise the Pharmacopoeia. The current Committee of Revision consists of 114 experts in pharmaceutical sciences (including nutrition), and the health professions, elected on the basis of their qualifications, not as representatives from any particular interest area. Sixteen subcommittees of the Committee of Revision comprise the Standards Division. One of these subcommittees is devoted solely to developing and establishing standards for vitamins, minerals and enteral products. The Information Division, comprised of 33 advisory panels, consists of approximately 700 physicians, pharmacists, other health care professionals, scientists and consumers – all of whom volunteer their time to prepare information on the proper use of medicines and nutritional supplements. Proposals are published for public review and comment prior to official adoption. The Nutrition and Electrolytes Advisory Panel has primary responsibility for
information relating to vitamins, minerals and nutritional supplements. Other panels, including the Consumer Interest and Health Education Panel participate in the process of developing information on these articles.

The public standards for nutritional supplements established by the USP were developed by the USP Subcommittee on Vitamins, Minerals and Enteral Products with the assistance of a specially appointed expert advisory panel consisting of scientific experts from the nutritional supplements industry, government agencies including the U.S. FDA, and Health Protection Branch of Canada, and others from both the United States and Canada.

The USP nutritional supplements standards adopted officially thus far take into account the fundamental differences between drug products and nutritional supplements and reflect the advice and counsel received during the development and proposal stages, from experts in health and human nutrition, the nutritional supplement industry, governmental agencies, and other interested parties from the U.S., Canada, and other countries. The standards adopted officially include (a) labeling and packaging requirements, (including expiration dating); (b) tolerances for vitamins and minerals contained therein; (c) methods for potency determination; (d) disintegration and dissolution standards for tablets and capsules; and (e) good manufacturing practices guidance for nutritional supplements. Before adoption, all of these standards were published for public notice and comment in Pharmacopeial Forum, USP's journal of standards development and official compendium revision. Pharmacopeial Forum is USP's analog to the Federal Register.

A separate section titled, "Nutritional Supplements" has been created within the Pharmacopeial Forum and the USP-NF book to distinguish the standards for nutritional supplements from those for drugs.

The Congress recognized similar USP efforts for drugs when it enacted legislation in 1906 and 1938. Since then the congressionally recognized system of public, enforceable standards for drugs established by a voluntary, nongovernment, scientific body and enforced by the Food and Drug Administration has given the American people the highest quality drugs and drug products in the world. We believe a similar system can exist for nutritional supplements. In this era of heightened consciousness of health care costs, we believe this system is cost-efficient by avoiding the need for public funds to establish standards.

In order for the U.S. government, the American public and the industry to take maximum advantage of our efforts to date, the USP believes that any legislation in this area should incorporate provisions similar to those in the Federal Food Drug and Cosmetic Act relating to drugs and drug products.

Specifically, we recommend the following principles be incorporated into any legislation governing vitamins, minerals and nutritional supplements:
• Section 201 (j) of the Federal Food Drug and Cosmetic Act already provides that the official United States Pharmacopeia and official National Formulary or any supplement to either of them, is an official compendium; for drugs. We believe the USP–NF should be recognized as official compendia for vitamins, minerals and nutritional supplements.

• If a nutritional supplement purports or is represented to be a nutritional supplement, the name of which is recognized in the official United States Pharmacopeia or the National Formulary, then its strength should not differ from, nor should its quality or purity fall below the standards set forth in the compendium, unless such difference in strength, quality, or purity is plainly stated on the label. This would enable manufacturers that do not wish to produce a product in compliance with USP requirements the flexibility to label their product truthfully in order for the consumer to determine which product to purchase.

• If a nutritional supplement is not recognized in the USP or NF and thus not subject to the standards of the official United States Pharmacopeia or the National Formulary it should meet the standards of strength, purity, or quality that it purports or is represented to possess. This would be determined by a product’s labeling and regulatory requirements.

• If a nutritional supplement purports or is represented to be a nutritional supplement recognized in the official United States Pharmacopeia or the National Formulary it should be packaged and labeled as prescribed in that compendium, unless otherwise modified with the consent of the Secretary. USP contains storage, packaging and expiration dating requirements and these help to ensure continued potency and quality throughout the life of the product.

• Nutritional supplements should be manufactured in accordance with current recognized principles of good manufacturing practices to ensure the article meets appropriate requirements. A description of such manufacturing practices is contained in the official United States Pharmacopeia or the National Formulary and should constitute evidence of their current recognition. Currently, the FDA has not published Good Manufacturing Practice requirements for nutritional supplements. USP has incorporated guidelines for manufacturers to follow until more specific requirements are published by a federal agency, should there be a need to do so.
In conclusion, the *U. S. Pharmacopeia* has served the American public well for over 170 years by establishing public standards and information for medicines that are recognized and enforced by government. We appreciate the Committee's consideration of USP programs and proposals with regard to nutritional supplements and hope that the Committee will see the wisdom of continuing the precedent of Congress and recognition of USP standards and information by mandating their enforcement by federal regulators. We would be pleased to provide further information about the *USP* or to respond to any questions.

Respectfully submitted,

Jerome A. Halperin  
Executive Director
Statement of

The American Heart Association

Submitted to the

Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies
Committee on Appropriations
U.S. House of Representatives

Concerning

Dietary Supplement Regulations

October 18, 1993
The American Heart Association appreciates the opportunity to submit testimony to the Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies concerning the need to improve the regulation of dietary supplements.

In 1990, the Congress enacted the Nutrition Labeling and Education Act which had as its goal the improvement of nutrition labeling on food products. The American Heart Association actively supported that legislation because it believed that in order to assist the public in making educated choices about the foods it consumed, there needed to be accurate, truthful, nonmisleading, and consistent labeling. It was presumed at the time that dietary supplements would fall under major provisions of the act.

The AHA’s mission is to reduce disability and death from cardiovascular diseases and stroke, this nation’s number one and three killers of Americans. Part of that mission includes supporting programs and other efforts that help people to live healthier, more productive lives. Primary efforts are directed at controlling high blood pressure, ceasing smoking, and eating foods low in fats, sodium, and cholesterol. Many products on the market are technically neither foods nor drugs under the Federal Food, Drug, and Cosmetic Act. While some statutory authority is vested in the Food and Drug Administration for regulating vitamins, minerals, and supplements, the law is outdated and very insufficient in protecting the public from unsafe products and ensuring that products are properly labeled. Although a large number of the vitamins, minerals, and dietary supplements pose no safety risks to the public, there has clearly been an increase in the number of dietary supplement products on the market, many of which make health related claims that the products
will prevent or mitigate a myriad of diseases and some of which do pose safety threats. Often such claims are based on no or minimal scientific evidence.

As the American public continues to be more and more health conscious, and as more and more products appear on the market, it is important for there to be some way of sorting out safe and effective products from what the New York Times recently referred to as "snake oils."

The American Heart Association is not opposed to the presence of dietary supplements in the market place and in fact the AHA would encourage the use of dietary supplements if and when such supplements can scientifically be established to provide the health benefits claimed. The AHA believes the public is entitled to assurances from the federal government that the products that they are consuming are in fact safe. They are entitled to know that a claim made in the labeling and advertising of a dietary supplement is based upon sound scientific evidence. Dietary supplements should be held to the consistent standards to which other products which are ingested are held.

As during the debate about nutrition labeling, the AHA believes that the reputable dietary supplement manufacturers would welcome federal regulatory oversight which would reassure the public that products are not only safe, but have the expected effects.

Therefore, the AHA suggests that the Subcommittee consider the following recommendations to be included in any legislative proposals:
1. That the FDA be given a specific mandate for regulating the dietary supplement industry. This could be accomplished by formally establishing an Office on Dietary Supplements within the Center for Food Safety and Applied Nutrition.

2. That the Office on Dietary Supplements be specifically charged with reviewing over a period of time all dietary supplements on the market. This review should focus first on supplements considered potentially unsafe, and then those considered to be safe. This process would ensure that the public is protected from the most hazardous products on the market while at the same time giving the dietary supplement industry the permission to continue to sell products that are deemed safe and effective as shown by sound scientific evidence. Finally, a third category to be reviewed includes all dietary supplements for which little or no safety or effectiveness data exists. These products could remain on the market pending FDA review. Until reviewed, such products should carry a statement on the label that the product is under review by the FDA. To assist the Office on Dietary Supplements the AHA recommends the establishment of appropriate scientific advisory panels comparable to the types of panels used by the FDA in other areas. FDA should be given full enforcement authorities to remove a product from the market found to be unsafe. The burden should remain on the manufacturer to establish that a product believed to be unsafe is in fact safe when used as intended. Any products appearing on the market after a specific date, which contain new or modified dietary supplements, should be subject to a petitioning review process designed to establish safety and efficacy.

3. That health claims should be subjected to the same standards and regulations that are applied to food products under the Nutrition Labeling and Education Act. If the Subcommittee does not subject dietary supplements to the
same health claim requirements as those required for foods, then the FDA should use its full authorities governing health claims under its drug authorities. It is inappropriate for dietary supplements to be held to standards less than the standards applied to foods.

4. The Office on Dietary Supplements should be required by law to develop and implement guidelines and/or regulations governing good manufacturing practices, labeling of ingredients, expiration dates, other labeling requirements, and warning statements such as "TAKE ONLY AS DIRECTED."

It is clear that some in the dietary supplement industry are waging a misinformation, propaganda campaign to convince the public and the users of dietary supplements that the FDA, Congress, and consumer and health organizations want to ban dietary supplements. Nothing could be further from the truth.

It is no wonder that this issue has been elevated to such a "controversial" status. Deceptions and distortions have become the norm. Fact and rationality seem to be all but forgotten. The irony is that it is the consumer who in the name of consumer protection is being hurt by the dietary supplement industry's scare tactics. Dietary supplement companies have yelled "fire!" in order to draw attention away from the fact that they are the ones who may be misleading consumers with unsubstantiated health claims that have little in the way of scientific evidence to support them. We would encourage the reputable manufacturers to rise above the snake oil salesmen and to support legislation that will continue to allow for the sale of all dietary supplements that are safe, to allow claims to be made when the claims are based on sound scientific evidence, and to remove those products that are determined to be unsafe, adulterated, or misbranded.
The American Heart Association therefore believes that the public health interest will be served best if statutory action is taken by Congress that ensures that dietary supplements are both safe and effective. The public looks for the government to provide assurances so that they can make truly informed choices about habits affecting their health and well being. FDA Commissioner David Kessler stated it best, "FDA’s goal is simple: We want people to have access to products that are safe, and we want to assure consumers that claims made about the health and nutritional benefits are truthful. We recognize that the body of knowledge about the benefits and risks of many of these products is growing and changing each day. We will take advantage of that knowledge, but hype cannot overwhelm science."
U.S. House of Representatives
Committee on Appropriations

Appropriations Subcommittee on Agriculture, Rural Development
Food and Drug Administration, and Related Agencies

Richard J. Durbin, Chairman

Hearing on Dietary Supplements

Washington, D.C.
October 18, 1993

Submitted Testimony by:

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U.S. House of Representatives Committee on Appropriations
Appropriations Subcommittee on Agriculture, Rural Development
Food and Drug Administration, and Related Agencies
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Hearing on Dietary Supplements
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Testimony of:
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I hereby submit to this Subcommittee my views on one of the issues critical to
a national public health program which emphasizes health promotion and the
prevention of chronic diseases through proper dietary practices and other rational
nutritional interventions. I am a Professor of Nutrition at Tufts University in
Boston where I conduct both basic and clinical studies on the role of diet and
nutrient supplements to help further our understanding of how they contribute to
the maintenance of physiologic function during aging and the protection against
associated degenerative conditions.

It is interesting to note that in 1941 President Roosevelt challenged the
National Nutrition Conference for Defense "to explore and define our nutrition
problems and to map out recommendations for an immediate program of action
[with an aim to] buoyant health [and] the building up of our people to a level of
health and vigor never before attained or dreamed of". These were high
expectations indeed, but during the last fifty years, and particularly during the last
two decades, nutrition scientists have made great strides toward this goal. For
example, research now shows that many vitamins and minerals possess important
roles beyond their classically recognized function in preventing deficiency diseases
and their biochemical action as coenzymes. Rigorous scientific studies have now
demonstrated that micronutrients also serve in "non-classical" roles as biological
regulators and modulators such that they can act to maximize physiologic function,
promote health, counter the adverse impact of environmental toxicants, and delay
or prevent the onset of many prevalent chronic diseases. Importantly, this
information can now be utilized through dietary recommendations and specific
nutrient interventions to promote public health.

National Research Council review of Diet and Health: Implications for Reducing
Chronic Disease Risk reveal a general consensus regarding the efficacy of nutrition
as a tool to improve public health. Indeed, the U.S. Department of Agriculture and
U.S. Department of Health and Human Services have already promulgated their
consensus on this matter in the 1990 Dietary Guidelines for Americans which are
proffered as effective in reducing the risk of obesity, heart disease, high blood
pressure, stroke, Type II diabetes, and some forms of cancer. Within the last few
years we have begun to recognize a further convergence of the scientific data regarding individual nutrients and their role in many chronic diseases. For example, generous intakes of calcium and vitamin D have been associated with decreased risk of osteoporosis, hypertension, colon cancer, and lead poisoning. Dietary antioxidants including vitamins C and E and beta-carotene have been associated with decreased risk of some cancers, cataract, infectious disease, and heart disease as well as injury from pro-oxidant environmental pollutants like smog and cigarette smoke. Vitamins B6, B12, and folic acid are associated with reduced risk of some cancers, cognitive impairments, and heart disease.

How do we begin to translate these scientific findings into public health recommendations? Congress has already recognized one effective means through its Nutrition Labeling and Education Act which permits health claims about the benefits of nutrients on packaging. The matter of how to decide which health claims are sufficiently substantiated to allow them to be advertised has presented both scientists and legislators with a challenge. That many health claims for nutrients supported by compelling scientific evidence continue to be rejected by the Food and Drug Administration (FDA) suggests to me that all the factors which should be part of such a decision analysis have not been considered. Whether for an individual or a population, the potential benefit of implementing a dietary change by selecting specific foods or choosing nutritional supplements is dependent upon several key factors:

1. The probability that the disease will occur. The risk factors for chronic diseases are many and include both genetic and environmental determinants. The major public health problem today is the prevalence of chronic diseases such as cancer, cardiovascular diseases, diabetes, osteoporosis, and infectious diseases. While the probability that any individual will suffer from one or more of these conditions can be assessed with some degree of accuracy, such calculations can also be applied to the general population. We are already acutely aware of the impact these diseases are having on our health care system.

2. The probability that the intervention is efficacious. Given that nutritional status represents only one of many risk factors, the relative degree of risk reduction (efficacy) by nutritional intervention(s) may be small, moderate or great. For example, recent studies suggest that vitamin E supplementation may reduce the risk of heart disease in women by 40%. While this is a significant reduction, it is important to recognize that no supplement or dietary pattern will ever guarantee the prevention of any chronic disease. On the other hand, the existence of other nutrients working in a complex and incompletely understood manner to reduce disease risk should not be a reason to reject a claim for a partly effective intervention which contributes to prevention efforts.

3. The probability that the scientific evidence is correct. In science there is rarely any situation where no uncertainty exists and every piece of data is consistent with the hypothesis. However, with important matters of public health, decisions are required today even though some questions remain and
more research is clearly necessary. You will note that recommendations are being made today about smoking and health while major studies continue to be conducted to better define and refine our understanding about this relationship. The same is true for calcium and osteoporosis and other nutrient-disease relationships but this should not mean the public cannot yet be informed. It is unrealistic and unnecessary to wait until the strictest standards for medical evidence, e.g., prospective, double-blind, placebo-controlled clinical trials employing chronic disease as the outcome variable, are complete before health claims are allowed. In many cases, these tests are so prohibitive in terms of cost and time that they will never be undertaken. Further, it is important to recognize that foods and their components are not new chemical entities like drugs and thus should not be treated as such. Evaluation of the evidence between nutrients and health should include the entire spectrum of available scientific evidence - from cell biology, animal studies, clinical trials, and epidemiological surveys - and its quality, strength, biologic plausibility, and consistency.

4. The probability that the food/nutrient is toxic. While there appears to be little reason for concern about toxicity resulting from dietary intake of nutrients, the common practice of nutrient supplementation warrants an indication of toxic levels where data are sufficient to establish an upper acceptable limit. However, the absence of any documented serious toxicity of many nutrients which are generally recognized as safe should not lead to suggestions that it is not safe because it is impossible to identify a safe upper level of intake.

5. The cost of intervention. Whether making public health recommendations for selecting a particular type of food (e.g., seafood, fruits, vegetables) or a nutrient supplement, the cost to the individual or health care provider is not an unimportant factor. Thankfully, relative to drug and other medical therapies, nutritional interventions are very inexpensive.

6. The impact of delaying a potentially beneficial recommendation. Recommendations to wait until every conceivable study has been designed and conducted to achieve a level of absolute certainty about the evidence will result in the continuing cost of the disease to the individual and to society. This burden is already unacceptably high so every reasonable attempt should be made to reduce the time necessary to translate good science into public health policy.

In summary, a benefit to cost ratio formula for a dietary or nutrient supplement intervention can be illustrated (where Pr = probability) as:

\[
\text{Benefit} \quad = \quad \frac{\text{Pr [event]} \times \text{Pr [efficacy]} \times \text{Pr [correctness of evidence]}}{\text{Pr [toxicity]} \times \text{Pr [cost]} \times \text{Pr [impact of delay]}}
\]

Recognition of each of these factors in FDA’s decision making process will help Americans to move forward more rapidly in improving their diet and in making rational decisions about nutrient supplementation. In this process, FDA
should reach out to take advantage of the expertise and stimulation to action found in the nutrition science and public health communities. Such an effort may help to shorten the interval between general recommendations available in the scientific community and government sanctioned recommendations. For example, in 1984 a National Institute of Health Consensus Development Conference recommended that increased intakes of calcium could reduce the risk of osteoporosis; in 1994 we will finally see a health claim allowed for calcium. Will it be another decade before health claims are allowed for dietary fiber, antioxidant vitamins, omega-3 fatty acids, and other nutrients which appear effective in reducing the risk of disease?

FDA should also explore ways to work with the food and supplement industries to promote approved health claims. An interesting model in this regard is the cooperative effort between the National Cancer Institute and the produce industry (Produce for Better Health Foundation) in developing the "Strive for Five" program to increase consumption of fruits and vegetables to at least five servings a day to improve the health of Americans.

While not a factor in this decision analysis, it is worthwhile to note that these issues are relevant to the conception in the United States of a new industry in "nutraceuticals". Such programs are already underway in Germany and Japan but can only begin to flourish here if the regulatory environment will allow it.

Ensuring that all the factors I have discussed are fairly evaluated by the FDA, in conjunction with a structure for allowing appropriate input by "outside" experts in nutrition science and public health, will contribute to an effective and timely translation of scientific data into valid health claims. With this information consumers can then better empower themselves to adopt healthy dietary and nutrient supplement practices to reduce their risk of disease.

Thank you.

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Personal Testimony to the House Appropriations Committee Hearing regarding the Dietary Supplement Health and Education Act HR 1709

by Roy Upton
October 19, 1993

Dear Committee Members,

I was present for the entire October 18th hearing regarding the Dietary Supplement Health and Education Act. Though the people who put this together should be commended on a job well done, my feelings were mixed with regards to the testimony presented, ranging from disgust to frustration to a little bit of hope because you as members were clearly interested to separate the wheat from the chaff on this issue. As this is the primary health care issue for myself, members of my family and many in my community, I would like to clarify some key issues that I feel were either under-emphasized or mis-represented by the presenters on both sides of the issue.

For the past two years my life has been almost totally consumed with this issue, though previous to that I have worked exclusively as an herbalist in different capacities for thirteen years. This work began as a student studying the ethnobotanical herbal traditions of Shoshone and Tewa peoples, and the ethnobotany of the United States Virgin Islands followed by completion of a three year state of California-recognized clinical internship in traditional Chinese medicine that included Western pre-medical studies. I have worked in varying aspects of the "health food industry" including in health food stores, and for a manufacturer of herbal products, and also have seven years of clinical experience. More recently, I was one of only two herbalists who were contracted by the National Institutes of Health to help in the evaluation of grant proposals regarding research in herbal medicine. But as I mentioned, most of my personal and professional time more recently has been taken up by this political battle that I sincerely believe is a necessary but unfortunate waste of time and resources of all involved. The health benefits and safety of nutrition and nutritional supplementation are reported so widely in the scientific literature that its seems counterproductive to expend so much to educate people of such obvious truths. Similarly, the value of herbal medicine is acknowledged in virtually every nation with the exception of Italy, Canada and the United States. Unfortunately, this is the state of people's understanding today.

My involvement began when FDA in their 1991 Nutrition Labeling and Education Act proposals stated that "herbs whose only known use is as medicines, such as belladonna, Rauwolfia and yellow dock, would be regulated as drugs." Nobody in the herb industry utilizes the herbs belladonna and Rauwolfia because of their inherent dangers, but yellow dock is commonly used. However, it is as far from a pharmaceutical drug as an herb can be. On one
reservation I lived, we would wrap buffalo meat in yellow dock leaves to help tenderize it. The women would take the seeds and winnow them in the wind and grind it for use as a protein-rich meal. A tea of the root was commonly used by women, predominantly to enrich the blood, even during pregnancy. And it was used as a medicine for skin conditions such as acne or boils. Herein lies the first basic problem. The Federal Food and Drug Administration, based on the Code of Federal Regulations considers any substance that is used in "the diagnosis, treatment, prevention or mitigation of symptoms or disease in man or animal..." as a "drug". Because of this, it approaches every therapeutic substance according to the same drug-approval parameters as those used for synthetic pharmaceuticals and medical devices. This means that using Garlic to help lower cholesterol is held to the same standard of evaluation as an artificial heart. Herein lies the second problem. As mentioned by some presenters, this drug approval process costs approximately $359 million dollars (according to 1993 estimates) per drug.

The overwhelming majority of medical research in this country is driven by economics, not by medical need. Congressman Ron Wyden, during hearings on the anti-cancer drug Taxol, went so far as to say that the National Institutes of Health was acting as a "tax-funded laboratory for the pharmaceutical industry". Drug development is driven by a company's ability to produce a patentable product that can capture a marketing niche that allows the manufacturer to recoup the huge amount of financial resources expended in the drug approval process. Without this patent protection, it is not economically feasible for a manufacturer to prove a substance is "safe and effective" unless they are assured of patent protection. Congress has faced this issue on other occasions, one of which lead to the Orphan Drug Act. At face value, it would seem reasonable to require the same amount of safety and effectiveness criteria when evaluating the therapeutic benefits of nutrients and herbal medicines. But, when we consider that the majority of such products, such as vitamin C, beta carotene, chamomile and peppermint tea or the hundreds of other commonly used herbs, are difficult to patent, we can begin to understand why there is not a greater acceptance of such medicines in the United States. If someone invests the costs needed to get FDA approval, and can now state on their label that chamomile tea is safe and effective as a sleep aid, anyone could grow it in their yard, or simply buy it as a tea. You must first understand the immense value of having access and information about such substances in order to know why it is such an important and emotionally-charged issue. And, you must look beyond the microscopic details and smoke screens that prevent a real grasp of these issues to be achieved.

FDA's Preventive Health Track Record

In the 50 years of FDA's history prior to Congress enacting NLEA, FDA has only approved two preventive health substances; fluoride for preventing cavities, and sunscreen for preventing sunburns (which they now attest are worthless). Our entire medical system has been driven by the economies of the pharmaceutical and medical device industries who race to develop new drugs or devices to "treat disease", not "promote health". Similarly, physicians are not trained in nutrition nor are they reimbursed for providing preventive health services and so preventive health information is virtually non-existent in the American medical system. Herein also lies the root cause of the so-called "health care crisis" facing us today. And, this is what lead to people like me to seek better systems of health care than those generally offered. It is a misnomer to call what America is facing as a "health" care crisis. It is in reality, a "disease" care crisis. As President Clinton has stated on several occasions; "the American public spends more on health care than any other nation but are not any healthier". In point of fact our health is worse. We rank 24th in infant mortality behind virtually every other technologically-developed nation, and we are 16th in longevity. One in eight women will develop breast cancer and one in three Americans will develop some form of cancer. Women in America are thirty times more likely to develop breast cancer than women in Thailand where diets are lower in fat, and higher in antioxidant nutrients. You must realize there is something drastically wrong with this picture.

I am 36 years old. I am a consumer of nutritional and herbal supplements. I have not needed the services of a medical doctor for 16 years. I have a 9 year old daughter who has never had so much as an aspirin or anti-biotic, not because we are against conventional medicine, but because the majority of everyday illnesses can be safely and effectively managed through less invasive means such as vitamins, herbs, proper nutrition and rest. Such experiences are also
representative of a large percentage of my colleagues and friends who likewise turn to less invasive therapies before resorting to the more powerful pharmaceutical and surgical interventions. But of course, this is somewhat of an intangible concept for people to understand so I will put it in more definitive terms.

An article in the January, 1993 New England Journal of Medicine stated that consumption of Vitamin E can reduce the risk of heart disease in men and women by as much as 40%. This correlation was greater in those people taking supplemental Vitamin E. There are 43 million heart disease sufferers in the United States at a cost burden of more than $100 billion per year. A therapeutic dose of Vitamin E costs approximately $1 per day and is safe. Yet there are no regulatory provisions for bringing such information to the marketplace (unfortunately the primary medium for consumer and health professional education). Numerous researchers have found that approximately 6% of Zinc supplementation and other antioxidant nutrients can reduce the incidence of macular degeneration by as much as 60%. Surgeries to correct such eye disorders are the number one therapy reimbursed under Medicare and is partly responsible for bankrupting this system. The health food industry has been recommending antioxidants since the 1950's. The benefits of herbs are innumerable. Chamomile tea is accepted worldwide as a safe and effective sleep and costs approximately 9¢ per cup. Contrast this with the number one sleeping agent Halcion which costs 89¢ per dose, includes liver and kidney failure and impotence as side-effects and is what ex-President Bush was using when he vomited on the Japanese Prime Minister. Lastly, as was referred to in the hearing, there are literally thousands of scientific research papers on the health benefits of garlic which has been shown to effectively lower cholesterol. Contrast this with Lovastatin, the primary anti-cholesterol drug sold in America at $2.89 per dose and also includes liver and kidney failure as side effects. Yet, Americans are denied access to this information in the marketplace because of an entrenched regulatory system that has based on a approval process to evaluate the unique needs of synthetic chemicals that have no history of safety or effectiveness. Everyone of us loses out.

Regarding Safety Issues

I address this to Mr. Durbin specifically. It appeared to me that you came to this table with a pre-conceived notion that the health food industry was not very ethical or that supplements pose a great threat to the American public. Unfortunately, I do not believe any of the panelists made any strides in dispelling this impression. I also want to state that I feel it was shameful that Mr. Kessler could not stand up for the therapeutic merit of his product. Undoubtedly, it was a Saw Palmetto/Zinc compound, both of which have been proven to be beneficial for prostate health. I was personally embarrassed as I feel everyone who makes products should be able to defend them responsibly. You continually referred to not wanting to take away FDA's ability to establish potency limits on nutritional supplements. However, you seem to be mis-informed regarding this issue. FDA has not had the legal authority to limit the potency of safe nutrients since the passage of the Proxmire amendment in 1976. This was a result of a previous attempt by FDA to regulate higher than RDA potencies of nutrients as drugs. You seemed to imply that this was a new provision of the Hatch/Richardson legislation when the inclusion of this language is simply a reaffirmation of Proxmire. This was deemed necessary because FDA has again proposed to establish such limits, not based on scientific fact or documentable safety concerns, but to conform with the RDA's, which one nutritionist (opposing the legislation) testified did not take into account optimal health or disease-preventive levels of nutrients. This issue remained unclear all day.

You raise a justified concern when you repeatedly asked (and the testifiers responded extremely poorly) "can a person take too much vitamins". The answer is "of course". I do not know why these supposed experts were not able to answer this affirmatively. However, as was mentioned, anything can be toxic in excess amounts. Excess water will drown you. Too much salt will contribute to hypertension. Too much fat will cause heart disease. Too many radishes can lead to thyroid dysfunction. Too much prune juice will cause diarrhea? When talking about toxicity of anything we must acknowledge that toxicity is relative. The real question to ask is "are supplements safe to take as they are intended to be taken?" or "can adequate labeling instructions be provided so that consumers can use such supplements safely?" In these instances
is an equal affirmative, of course. A review of the accumulated scientific data is a true measure of worth as compared to theoretical assumptions.

Given that the FDA has not regulated nutrient potencies for the past 17 years, and given the fact that almost 50% of the American public uses some type of nutritional supplement, we would logically assume that if nutrient excesses were a problem, the scientific or clinical data would support this. It does not. In twelve years of statistics of the American Association of Poison Control Centers a nutrient was implicated in only one case of toxicity, and this was in a schizophrenic, i.v. drug user. No reporting of herbal toxicities were noted. Though this point was presented it did not have the emphasis it deserved. The Centers for Disease Control likewise, have little evidence of any problem associated with vitamins and herbal products. This is hard facts and reality. FDA presented a synopsis of herb toxicities but a review of the scientific literature reveals that references to herb toxicity are extremely rare, and even in the majority of these cases, a direct correlation between herb ingestion and toxicity could not be affirmed. For example, one woman supposedly poisoned by the herb Chaparral Larrea divaricata died after an unsuccessful liver transplant. However, her medical records (obtained from FDA under FOI) revealed that she consumed almost a pint of alcohol an a regular basis for the past twenty years. In another incidence of supposed Comfrey toxicity a woman was taking Comfrey for "severe liver distress" and consumed daily doses of valium and acetaminophen, two known primary liver antagonists, for one year prior to ever consuming any Comfrey. With few exceptions, this is the way FDA has approached issues regarding herb toxicity. They have gotten a tremendous amount of lobbying and media mileage from a few isolated and exaggerated cases. Please refer to the attached paper for a more detailed commentary on these toxicities.

One panelist from the Consumers Union recommended that complete information about the supplements be required and included: uses and benefits; contraindications; cautionary notes; dosage levels, etc. His point was to insure that supplements are used safely. This is exactly the reason why we are trying to enact HR 1709. Under current regulations, manufacturers are prevented from including such "prescriptive" information on non-drug products. This point was also made, but under-emphasized. Everyone that I know would love to have such information on the label. In other countries such as Germany, France and the United Kingdom, such information is required. FDA is actually inhibiting information by which such products can be used in the safest way possible (FDA charged that Garlic capsules were drugs because the bottle stated the term "dose"). Yet, despite this, the scientific data is still showing that these products are not problematic. This in itself should attest to supplement safety. Please take note that at least 15 people die each year of allergic reactions from peanuts. More than this have died from anaphylactic shocks from sulphonates on salad bars. You cannot find a single herbal or vitamin supplement that has been implicated in 15 deaths, or that is consistently or prevalently involved in any sickness. Ask FDA to produce all the data on vitamin and herbal toxicity they have for the past 40 years. It will not amount to more than 100 cases of toxicity and fewer deaths. Again, for a perspective, contrast this to 100,000 fatalities each year due to FDA approved drugs, or thousands being born deformed because of FDA's Folic Acid inaction and millions suffering from cancer and heart disease, again partly because of FDA inaction. (Ms. Whittlekin submitted a chart that stated that FDA-approved drugs were responsible for 60,000-140,000 "adverse reactions". The original citation stated "fatalities, not adverse reactions, Nov 27, 1991 Journal of the American Medical Association)

Also, look real closely at what Dr. Kessler stated. He said "just clean up the labels claims" and he doesn't have a problem with those products. However, FDA's primary indictment of supplements was based on raising "safety" concerns. Why would FDA indict supplements on the basis of safety, and in the same testimony say that his only issue is claims? Taking claims off a label does not make a product any safer. An example was the shark cartilage which had no claims but was obviously a problem to Dr. Kessler. He sputtered and did not answer Mr. Sween's question about whether or not associated literature made claims about the product. I believe Mr. Sween, Mr. Meyers and Mr. Welch were trying to clarify this point, but it never quite got out. The reason is that safety is not an issue. Please believe me when I tell you that FDA did not represent themselves truthfully or honorably in this regard.
The EMS tragedy provides compelling reasons for taking all of these supplements off the market. But as was stated (though very hurriedly) by Mr. Bingham, the primary responsibility for this tragedy is with FDA and they are not accepting this. Rather they are using it to paint the entire health food industry as "snake oil" purveyors of dangerous products. FDA approves of genetic-engineering which was the cause of the L-tryptophane problem. They can stop any product at point of entry but did not stop this tryptophane. Dr. Vanderveen of FDA previously stated that even had strict United States Pharmacopoeial analysis been done on the contaminated L-Tryptophane it still would have been accepted because the analytical difference between contaminated and uncontaminated tryptophane was so small it would not have been identified unless someone knew what to look for.

Mrs. DeLauro truly feels the verdict is not in on L-tryptophane, but the Centers For Disease Control and nutritionists nationwide differ in their opinion. The rationale is easy to understand. L-tryptophane is essential for human life. How can an element that is essential for human life be toxic in the same amounts as that charged with causing EMS. It defies physiological reality. This is similar to saying that "because water has been implicated in causing death (drowning), it is poisonous". Even the EMS victims themselves state that it was definitely a contamination. More than anyone else, they have a vested interest in knowing what happened and they acknowledge a contaminant.

Mr. Durbin, I also want to address the pre-conceived notions you displayed about the Aloe Vera product. I totally agree that no product should imply any treatment for HIV or AIDS unless it is accompanied by a huge body of information that places the use of the product within the context of a comprehensive HIV regimen. This to me would be the epitome of labeling: i.e. to require that information such as "Vitamin E supplementation in conjunction with a low fat high fiber diet may reduce your risk of heart disease..." However, as Mr. Walsh stated, ten years ago no one would ever believe that a cancer treatment could come from a bark of a tree (Taxol). Is the potential of Aloe for inhibiting HIV any more dramatic or unbelievable than moldy bread for infections (penicillin), a tree bark for malaria (quinine), pine needle tips for scurvy (vitamin C). Scurvy was an incurable, fatal disease. Hundreds of thousands of early Americans died from it. Undoubtedly, people at that time said the same thing "come on now, limes for this deadly disease". Never underestimate the depth of ignorance of people who accept current knowledge as if it is an accumulation of all the wisdom that exists in the world. And, never underestimate the healing potential that can be found in nature. Life itself is a miracle. I believe people in Congress have a hard time remembering this.

Regarding FDA Mis-Representations
FDA has mis-represented themselves in additional ways. As Dr. Kessler stated "take the claims off and I don't have problems with the products." However, their Advanced Notice of Proposed Rulemaking of June 18, 1993 states the following:

Pg. 33698—"Many of these substances ("herbs without a history of documented traditional food use, and plant extracts") have no recognized nutritive value or technical effects."

Pg. 33699—"For many of these ingredients, there are no GRAS (Generally Recognized As Safe) or food additive regulations in effect, and FDA has no basis on which to determine if the ingredient is GRAS."

Pg. 33708—"When herbs are consumed primarily for their taste, aroma, or nutritive value, they are foods. If the herbs are intended (emphasis added) to be consumed for their medicinal effects, however, they are drugs."

Pg. 33709—"A product whose intended use is as a drug will continue to be subject to regulation as a drug."
Pg. 33710—"the fact that some herbs have been used for thousands of years does not necessarily justify a conclusion by FDA that their use is safe." (The World Health Organization differs in this opinion)

FDA is using the guise of consumer safety to justify their classifying of non-GRAS (Generally Recognized As Safe) substances (herbs) as unapproved "food additives". A food additive must be prior approved by FDA before it can be in commerce. FDA is attempting as a matter of law that herbs are no longer to be classified as foods or dietary supplements but as food additives thereby giving the FDA legal authority to remove all non-GRAS herbs and nutrients for no reason other than they have not been prior approved. To understand the ridiculousness of this is to note that neither mangos, papayas or kiwi fruits are classified as GRAS. In the proposed regulations (pg. 33699, 33707 & 33709), FDA is attempting to contend that only herbs with documentable "food use", or that are defined as "conventional" foods are eligible for consideration as being GRAS. This in conjunction with the types of attacks outlined in Mr. McNamara's testimony demonstrate a desire to restrict herbs. Likewise, only substances which fit FDA's definition of a conventional food (i.e. something that contributes taste, aroma or nutritional value to the daily diet) will be eligible for consideration of a health claim under the Nutrition Labeling and Education Act making it impossible for the American public to learn about the health promoting benefits of the majority of nutritional supplements (such as vitamin E) and herbal products in the marketplace. This definition appears to be sound. However, for example, neither fiber nor garlic oil in capsules meet FDA's criteria as a food. Fiber is neither nutritious nor does it contribute taste or aroma to the diet. Neither does Garlic in capsules. Capsules and tablets are specifically used to avoid such aromas or tastes. These are examples of commonly accepted "foods" that do not meet FDA's definitional criteria. Therefore, how are people to learn of the therapeutic value of such supplements.

They also contest that thousands of years worth of experience with herbs is not a conclusion of safety. However, thousands of years of reported safe use should. If there is no record of toxicity associated with a substance that has been in continued use for hundreds or thousands of years this should imply safety unless new findings suggest otherwise. The World Health Organization asserts that history of safe use, in absense of any information to the contrary does in fact imply safety. Beyond this, the majority of the most commonly available herbs are listed in officially-accepted Pharmacopoeial compendiums throughout the world, and they were listed in the official Pharmacopoeias and National Formularies of the United States up until the 1950's when there was a greater move toward synthetic drugs.

Contrary, to what Dr. Kessler said about cleaning up claims and leaving such products alone, again the ANPR states "A product whose intended use [emphasis added] is as a drug will continue to be regulated as a drug." The word "continues" in this sentence would make it appear as if this is current law. However, this is in fact a deviation of current policy. Presently, FDA takes action against a product that is marketed with an unapproved claim. Again, remember that Dr. Kessler had a problem with shark cartilage despite the fact that there were no claims on the labels. Whether you agree with the merits of shark cartilage or not, the issue remains, why isn't Dr. Kessler answering Congress honestly. Now they state that the intended use of the product can constitute defining such a product as a drug. FDA was able to get around a lot of decent questions through rhetoric. As legal council Steven McNamara pointed out, FDA is indeed spending a lot of resources in attempting to remove a number of, as the courts ruled" "safe" products off the market. Please look over these court decisions closely. Again, this is reality, not rhetoric and shows FDA's true intentions.

I will end this discussion on safety by providing a different perspective. Despite any history, or scientific documentation of safety, FDA has approved of genetically-engineered food manufacturing techniques creating what are being called "Frankenstein foods". They approved of the sweetening agent Aspartame despite recommendations by their own review panel members to disapprove it. In addition, according to the FDA Consumer, Aspartame remains the primary source of complaints regarding food additives. In 1989 it was responsible for 80% of FDA complaints with approximately 1500 complaints registered implying there are perhaps tens of.
Contrast such substances or techniques that have no history of use with the fact that the sedative qualities of Valerian Root were first written about in the sixth century, and that today, it continues to be used worldwide as a sedative, and has been scientifically validated. Note that more than a million cups of Chamomile Tea are drunk in Germany every day with only two reports of mild allergic reactions listed in the world's literature. Compare these newly-developed food additive and techniques with the fact that the literal written history of traditional Chinese herbalism is 3600 years old. Ayurvedic herbal traditions—5000+ years old. And, also note that herbal medicines have remained the primary form of medicines relied upon by the majority of the world's population. Please help me to understand why there appears to be a double standard. There are more people whose health is at risk from consuming FDA-approved food additives and food processing techniques than from supplements which have an exhaustive accumulation of both domestic and international information regarding both their safety and effectiveness.

Regarding Truth in Labeling

I would like to specifically address this to Mrs. DeLauro. You kept mentioning that you wanted to assure that people could be confident in knowing that what was on the label was truly in the package. This is already provided for in existing law, but was never addressed by any panel member. Any deviation in the declared content of a product is in violation of current "truth in labeling" laws. Please ask this of FDA because they appeared to blatantly mis-represent the facts by saying it is an unregulated industry. They also have the legal right to take any product off the market that possesses an unapproved health claim. The fact that misbranded products remain on the market is because FDA has spent the limited resources allocated to dealing with supplement issues going after what is good in the industry, they have ignored the bad. In a meeting I had with Mr. Taylor and a representative from the National Nutritional Foods Association I stated, "if you were going after the bad stuff in the industry, nobody would mind. But you are not. You are going after some of the best stuff."

Mrs. DeLauro you also made a statement about health information that "not even consensus would be used". This sounded as if consensus was a reasonable standard to use. There was consensus that the world was flat; that the sun evolved around the earth; that man would never fly, or land on the moon. When a physician named Semmelweiss found that washing his hands before delivering babies (learned from midwives) dramatically cut down the incidence of blood poisoning that claimed the lives of as many as 45% of delivering mothers, there was not consensus in his time. Consensus was not reached in birthing practice for another 100 years and hundred-of-thousands of deaths. When reflecting upon these issues please weigh this question. "what is the relative benefit vs. the relative risk of this decision?" i.e. what harm would have been done for people to follow the preliminary data about the benefits of washing their hands? What harm would have occurred had FDA not waited thirty years before allowing information about the correlation between fat intake and heart disease? What harm would have occurred for FDA to allow the health claim for Folic Acid? Antioxidant nutrients? Zinc? Unsaturated Fatty Acids? Chamomile Tea? Garlic?

As you mentioned, why should supplements have a different standard than food? For only one reason. The standard used by FDA, which lead to the initial disapproval of the fiber,
folic acid, antioxidant, etc. claims was closer to a drug standard than a standard appropriate for foods. But if FDA says they want to hold supplements to the same standard as foods, then why are health claims only allowed on antioxidants as found in foods, and not in antioxidant supplements? The answer is simple. They only looked at research regarding antioxidants as they occur in food because their mentality is that supplements represent "pharmacologically-active, drug-like effects". Again as the nutritionist from Maine pointed out, the definition of a food is based on RDA-like nutrient levels that do not take into account the increased nutrient needs of those suffering from disease. The fact remains, the evidence is there, and antioxidant supplements are safe. They are inexpensive and they can help prevent, and lessen the severity of many forms of cancer and heart disease and the American public desperately needs this guidance.

The EMS daughter told of her feelings of watching her mother suffer. I have similar feelings. Always in the work I have done with herbs, I have never pushed what I have learned on other people. If people want to know something and they ask, I will do my best to tell them. My mother developed breast cancer. In talking with her about it she said she was open to learning about things that could help. I sent her information about antioxidant nutrients, and the herbs Reishi Mushroom and Astragalus. To make a long story short, the bottom line was that if these things could help in cancer Dana Farber [medical center] would know about them (these words of wisdom came from my step father) and so she ended up not taking care to insure her nutritional levels were up. Such antioxidants is a primary way to prevent a reoccurrence of cancer. But, how will people learn about these if the information can not be disseminated in the marketplace.

The National Cancer Institute almost five years ago published a 350 page addendum to their annual conference proceedings on the use of antioxidants in cancer. Astragalus and Reishi are scientifically documented immune-potentiating herbs that are routinely given in conjunction with chemo-and radiation therapy to increase survival rates and decrease side-effects. My Acupuncture teacher, as I did, almost cries not understanding why physicians do not use them here. Please, please understand the pain of people like me who try so hard to make Congress understand these issues. Whether it is fighting for the ability to access acupuncturists or midwives, or being able to access truthful information about supplements, we are looking for a more humane form of healing that changes our state of "disease" care into "health" care. Not everyone has devoted their lives to this issue as much as I have, but the people who are writing each of you are principally, if not meticulously, correct. Do not believe for a minute that this has been a misinformation campaign, and that the hundreds of thousands of people responding to this issue are being fooled by a profit-motivated industry as Ms. Abbe Meyers implied. Mrs. DeLauro, I believe your constituency reflects a high level of commitment very well as I know you have been approached by people who do know the issues better than most. If each of you truly want to understand this issue, watch the video Lorenzo's Oil. Not meaning to sound too dramatic, this issue is our Lorenzo's Oil and we will not let it go away.

I would like to make a note to Mr. Walsh. You mentioned that this reminded you somewhat of the "snake oil" era of yesteryear. I beg to differ on a point of clarification. The so-called snake oil medicines were considered such because nobody knew what was in them because they were proprietary blends. Today, labeling laws require a full disclosure of ingredients from the most predominant to the least. This is the primary difference. Any American has the chance to learn about each of the ingredients in a nutritional or herbal formula, as in any food. In this way, consumer protection is insured and consumer education encouraged. There is a huge difference between the two.

Burden of Proof

What was also a major concern to panel members was the issue surrounding the burden of proof on safety. Again, this was mis-represented by FDA and not addressed by any panelist. Because no specific category exists for most supplements to fit in, they are by default, classified as foods. This is understandable for nutritional supplements but is a leap of faith with many herbs. Unfortunately, this is the regulatory reality right now, and so herbs are also classified as
foods (many of us would like to see the development of a "Traditional Medicines" category for herbs to fit in, as it is done in other countries.) Under present regulations, the manufacturer bears a burden of proof, as does every food manufacturer, to assure a product is safe before marketing it. This was totally ignored by FDA and failed to be mentioned by any panelist. FDA has the legal authority to request such data by which a manufacturer affirms safety. Upon providing such data, the burden of proof then switches to FDA to state the reasons why they feel the data does not affirm safety satisfactorily. If the manufacturer fails to produce such data, FDA has the authority to prohibit the sale of a product until such time as a manufacturer petitions for an official GRAS or Food Additive ruling. This mechanism has existed since the "Prior to 1958" use provision was enacted 35 years ago. Neither the Hatch or Richardson bills change this. They only reaffirm existing statutes. The reason for this is because FDA has been arbitrarily taking actions against supplements on the "food additive" theory without having any safety reason for doing so (Nutri-Cology vs. USA/Traco vs. USA/Elamol vs. USA).

I understand that most of us are not experts in Food and Drug law. However, I request that you get the opinion of an authority who is to clarify these positions and you will find that neither Dr. Kessler nor Mr. Taylor represented the present state of regulations honestly. This committee, until the very last panelist, was still making an issue about potencies and truth in labeling as if the Richardson legislation changes this which it does not.

Conclusion: The Real Health Food Industry

FDA and opponents of natural health care (natural health care includes: Acupuncture, Midwifery, Naturopathic Medicine, Chiropractic, Herbalism, Bio-Feedback, etc.) would like to portray people like me as quacks and charlatans. The fact is, that most of the concepts that were first expounded in the health food industry are now being accepted as healthy fact. The health food industry has been recommending a low-fat, high-fiber, high-antioxidant nutrient-rich, high folic acid diet for approximately 100 years when the first store opened its doors. It was the health food industry who has always emphasized a "holistic" approach to healing that encompasses diet, lifestyle, rest, exercise, as well as the herbs and nutrients. The health food industry has always been at the vanguard of encouraging people to take a more active role in their healing process, rather than simply relying on a pill, or turning that responsibility over to someone else. It was the health food industry who began the organic foods movement and have warned people incessantly about the dangers of pesticides, antibiotics and hormones used in commercial meat production while FDA has all but ignored this crisis. Much of the fitness movement began with the health food industry. The safety of foods, herbs and supplements as well as the information promoted by the health food industry has been absolutely awesome when compared to the tragedies associated with FDA actions and in-actions. Unfortunately, not one of the people testifying on our behalf, with the exception of Fred Bingham who because of his disease embodies this message, and was able to articulate any of the real issues. We are not politically savvy as some would make us out to be. People were talking how this is a huge industry at $4 billion. Since when is a $4 billion industry considered huge. One single pharmaceutical drug can yield annual sales in excess of $1 billion. Our strength is in conviction, dedication and people. We are getting thrashed in these hearings because of people who do not know how to work the political system and get our position across, or otherwise can not articulate who we are and what we represent. And, we are going to pay for it as are other Americans because you are going to go away with a misconception of what we represent. The people who are often there are those who have the financial resources to be "a player". The true message gets lost.

I want to thank you for the opportunity to present this testimony. I wish I had the opportunity to present it in person. I do not have corporate funds. I don't pay the lawyers and lobbyists to draft legislation or contribute to PAC funds. This is simply an issue that is near and dear to my heart that I want to see addressed responsibly and with clarity, not smoke screens from either side. The crew of people who put this hearing together should be sincerely congratulated for doing such a fine job. Please thank them for me. I thought the panels were extremely well-balanced even if I felt that most of the testifiers did not do justice to the issues. I would be happy to provide further information or ideas about these issues.
Sincerely, and with warm regards.

Roy Upton
3411 Cunnison Lane
Soquel, Ca. 95073

I would respectfully request that you ask the FDA the following questions:

1. Under NLEA, "high" potency nutrients are not eligible for health claims. If there was compelling evidence to suggest that amounts of Vitamin E in excess of what was achievable through a normal diet was effective for lowering the risk of heart disease, what mechanism is in place for bringing that information to the marketplace?

2. Under existing law, does FDA have the authority to take action against a product that makes a false statement of content on the label? If so, why have you asserted the supplement industry is unregulated?

3. Under existing law, does FDA have the authority to take action against unsubstantiated health claims? If so, why have you asserted the supplement industry is unregulated?

4. If a product complies with all labeling laws, and does not possess a claim on it, is FDA intending to take such a product off the market if it is in fact being used for its medicinal purposes? If so, why did FDA assert they have no intention of taking such products off the market?

5. People in the health food industry suggest that FDA uses a double standard regarding how FDA makes a safety determination of certain substances or processes: They cite approval of food irradiation, agricultural additives, and genetically-altered foods which have no evidence of long-term safety. They cite an acceptance of food additives such as MSG and Aspartame which have been a source of thousands of consumer complaints. They cite FDA's refusal to accept the herbal sweetening agent Stevia. How does FDA make a safety determination on foods, food processing techniques as compared to food supplements?

6. Why hasn't FDA taken a leadership role in bringing preventive health substances, or information about preventive health to the American public?

I would make the following recommendations with regards to regulation of dietary supplements and passage of the Dietary Supplement Health and Education Acts.

1. Even if health information is not allowed, allow manufacturers to put proper usage/dosage information on products without FDA from branding such information as being drug-like.

2. Require childproof caps/children warnings for all applicable supplement packaging.

3. Drop the health claims provisions of the legislation if people are undecided on it. (Americans have been denied this information for the past 50 years. We won't die any faster if we don't have it for another 5-10 years.)

4. Absolutely insist that manufacturer have the opportunity for "due process of the law" judicial review.

5. Absolutely require that FDA have sound reason to take action against a supplement.

6. Individually support additional funding of the Office of Alternative Medicine within NIH.
The American Dietetic Association (ADA) is pleased to submit testimony to the House Appropriations Subcommittee on Agriculture regarding the regulation of dietary supplements. Our 63,500 members serve the public through the promotion of optimal nutrition, health and well being. Our members are concerned about the lack of regulation of dietary supplements and the effects that this can have on the health of consumers. ADA is pleased that Congress is addressing this issue.

Registered dietitians have extensive education and training in the scientific knowledge of nutrition and its application in disease prevention and treatment. Dietitians are an important part of the health care team. In their work, they see appropriate and inappropriate use of dietary supplements. Our testimony is based on this knowledge and experience.

ADA believes that the nutrient needs of healthy children and adults are best met by consuming a variety of foods rather than by eating a poor diet fortified with supplements. However, ADA knows that dietary supplements can play a useful role in dietary patterns and access should not be limited. In order for consumers to get the most benefit from dietary supplements, they must be used on an individual basis since there is not one "right" dietary supplement for the diverse health care needs of consumers. In order to accomplish this, dietary supplements must be labeled in such a way that consumers have access to safe products that are completely and accurately labeled. Consumers need to know what is in the product, the toxicity levels, adverse side effects, and that any health claims are based on significant scientific agreement.

ADA believes that all dietary supplements should be subject to the labeling requirements specified in the Nutrition Labeling and Education Act of 1990 (NLEA). Dietary supplements, which have the potential for greater toxicity than food, should be accorded an equal, not a more lenient, standard. The concerns regarding labeling and health claims
on dietary supplements are the same concerns that the 103rd Congress reviewed during the NLEA discussion. Congress recognized these concerns and included dietary supplements in NLEA legislation.

ADA also believes that the burden of proof regarding safety of these products must be on the manufacturer, rather than on the Food and Drug Administration. Last of all, consumers should have the freedom of choice to make educated decisions on safe products, based on complete and accurate information.

Use of Dietary Supplements

ADA is concerned about the impact of dietary supplements on the health of consumers. The use of dietary supplements, primarily vitamins and minerals, has been increasing during the last half century. This phenomenon reflects the development of our knowledge of nutrition science and our capability of isolating and/or synthesizing vitamins and purifying mineral components. It also reflects the growing recognition of the potential role of nutrients in health promotion and the prevention of many of the chronic diseases such as cardiovascular disease, osteoporosis and certain cancers. Last of all, with the growing trend for people to take responsibility for their own health, many are self-prescribing nutrient therapy.

An estimated 60 million Americans are spending $4 billion dollars a year on products sold by mail order, door-to-door, through health food stores, grocery stores, department stores and pharmacies. These numbers emphasize the need for a new regulatory framework for dietary supplements that would protect the consumer from unsafe products, prevent the use of misleading health claims and provide the consumer with accurate information regarding ingredients, toxicity levels, side effects and dosage levels for all products.

Case Studies

ADA members work in a variety of health care settings including hospitals, outpatient clinics, public health clinics and nursing homes. They have reported numerous incidents of patients with renal disease, cancer, diabetes and other diseases, coming to them with medical conditions that have been brought on, or aggravated by, dietary supplements. These patients not only include healthy individuals who want to insure that they stay healthy, but also individuals who have chronic diseases, and are looking for a cure.

Renal Patients

Our members who work with renal (kidney) dialysis patients have been especially concerned. In the dialysis population, some vitamins and minerals are toxic even at small doses due to impaired utilization and excretion by the kidneys. Potassium is the most lethal to dialysis patients because elevated serum potassium can cause instant death from a heart attack.

End stage renal disease signals the final stages of renal failure and can be fatal if not treated properly. As a result, some patients look to dietary supplements for “cures.” Dietary supplements have become hazards to this population because some of them contain potassium. In addition, vitamins A and C, and magnesium pose risks to the dialysis population. Registered dietitians see the results of patients using dietary supplements without the consultation of the dietitian.

Registered dietitians working in dialysis units have identified the following examples of harm done from the consumption of a variety of dietary supplements:
1. A male dialysis patient in Maryland, against the advice of his doctor, dietitian and nurse, has been taking garlic to control his blood pressure and oyster shell calcium and "other things" to get his sex drive back. He is taking these on the advice of someone in the health food store who told him that the health professionals are wrong.

He has several problems in addition to his renal failure. His triglyceride level fluctuates from a normal of 200 mg/dl to over 3,000 mg/dl. The dietitian who is providing medical nutrition therapy for him has determined that the extremely high levels occur when he is taking dietary supplements, the names of which he refuses to divulge. In addition, he is taking a calcium supplement that contains magnesium which can result in dementia in dialysis patients. The dietitian has recommended that he take a different calcium supplement that is safe for renal dialysis patients. The patient refuses to adopt the recommendations and his condition is deteriorating quickly. He is now confined to a wheelchair.

2. In Landover, Maryland, a female dialysis patient with cancer tried bee pollen "out of desperation." She knew she was allergic to bee pollen but tried bee pollen tablets that the health food store employee said she wouldn't be allergic to because they were different from other bee pollens. She went into anaphylactic shock and almost died.

3. Also in Maryland, a 40 year old male with a kidney transplant was drinking aloe vera juice and taking herbal products that he himself was selling to others. He began to have mild rejection of his transplanted kidney and was told by his doctor that he may lose the kidney if he continued to take the supplements. The herbal products he was taking were interfering with the drug, cyclosporin, which works to prevent rejection of his transplanted kidney. The aloe vera juice increased his potassium levels which could lead to arrhythmia (an irregular heart rhythm) and a major heart attack.

The dietitian did a nutrition assessment and gave him two options: 1) continue his intake of dietary supplements and lose his kidney and go back on dialysis, or 2) discontinue the supplements and keep his transplant. He chose the second option and is improving. His transplant was saved.

Other Medical Conditions
Dietitians have worked with many other patients and have forwarded the following stories:

1. An elderly man from Ohio, whose wife died of lung cancer, began taking 25,000 to 50,000 IU of vitamin A daily (RDA is 1,000 IU) in addition to 50 to 100 mg of beta carotene on the advice of friends who said to him "if you don't want to succumb to the same disease that took the life of your wife, you should take these supplements." He did, and came to Ohio State University Hospitals because he had developed an orange pigment to his skin, symptomatic of beta carotene toxicity. He also developed headaches, high inter-cranial pressure, bulging eyes, tenderness of feet and palms of hands, and hair loss because of vitamin A toxicity. He also had a long history of moderate alcohol intake which probably contributed to the liver damage he sustained.
2. Kathy, a registered dietitian in Dallas, Texas, agreed to test the effects of fish liver oil tablets on reducing cholesterol levels. She did this test in conjunction with a sports medicine center. The dietitian was a healthy woman of 105 pounds. The salesperson she purchased the fish oil tablets from told her that she also had to take a multi-vitamin and mineral supplement in order for the fish oil to work properly. In this supplement, there were several vitamins that were over 3,000 times the RDA. Kathy was concerned about this and was referred to the company's biochemist who reassured her that these large vitamin levels were okay to take. She also questioned the dosage for someone her size and the biochemist told her that everyone, no matter what size, should take the same dose.

After taking these two products a short time, she developed flu-like symptoms of nausea, vomiting, and upset stomach. She stopped taking the supplements for four days. When she started feeling somewhat better, she started the supplements again to continue the test. One morning she forgot to take the two supplements and felt much better. She then took the two supplements and within 45 minutes, she was feeling the flu-like symptoms again.

At the same time, other consumers in the Dallas area were also experiencing similar problems with the same products. A pyramid marketing scheme was successful in selling a large quantity of the products before the problems were made public. Soon after, the problems were made known on a national scale, the company took the product off the market.

This is a clear example of a company going out and selling a product that was untested and reinforces the need for federal regulations that allow only safe products on the market. Kathy was a healthy woman to begin with, so the problems she experienced did not do serious harm. However, frail elderly individuals or someone with chronic disease would not do so well and could end up requiring medical care and hospitalization for dehydration and other related problems.

3. A dietitian in Tulsa, Oklahoma, provided nutrition therapy to a 40 year old male who had hemochromatosis (a disorder of iron metabolism) and liver problems. The man had no prior health problems and was concerned about making sure he remained healthy. In addition to a balanced diet rich in iron and vitamin C, he had been taking a multi-vitamin with iron for over ten years.

The physician diagnosed his problem and discovered that the patient's father and brother had had the same disease and that an uncle had died of it earlier. The patient was taken off the supplement, his doctor withdrew a pint of his blood every week for three months and he is working with the dietitian to follow a low iron diet. This is another example of why supplements, even at minimal doses, are not for everyone.

4. A female patient with brittle diabetes who was quite ill was referred to the Gainesville, Florida, Clinical Research Center (CRC) because her diabetes and triglyceride levels were out of control. She had been in other hospitals before coming to CRC but none were successful in diagnosing her problem and getting her diabetes and triglycerides under control.
The registered dietitian, who was part of the medical team at CRC, did a nutrition assessment and discovered that the woman was not following her diabetic diet and was taking at least 28 different dietary supplements each day. The woman had been directed by a person she called a "nutritionist physician" to take these supplements. She followed his advice and had to re-mortgage her house to finance the supplements and the care she received from him.

The dietitian at CRC stabilized the patient by eliminating the dietary supplements and providing a carefully controlled metabolic diet. After two weeks, the woman's diabetes was under control and her triglyceride levels were normal.

Summary
Although there is no systematic review of the safety of dietary supplements on today's market, there is growing documentation that there are hazardous ingredients in dietary supplements. The Food and Drug Administration published in July 1993 the report "Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace." This report outlines 16 ingredients in dietary supplements that have been associated with adverse medical problems. Some of these reflect the same problems that are identified in the examples listed above. It is time for untested dietary supplements to be regulated in a manner that will protect the American consumer. Consumers can no longer be used as an unofficial testing ground.

ADA believes that consumers should have access to dietary products that are safe and appropriately labeled. The federal government must regulate dietary supplements in a manner that provides the consumer with accurate information to choose the dietary supplements that are appropriate for him/her. ADA believes that consumers will be quick to hold the government accountable for supplement products that cause harm or illness when taken according to label recommendations, whether from too large a dosage (without a warning) or impurities in the product sample. The Food and Drug Administration should be given the enforcement ability to take prompt action to protect the public from unsafe and deceptive or fraudulently marketed dietary supplements.
Agriculture Subcommittee
House Appropriations Committee
U.S. House of Representatives
Washington, D.C.

October 21, 1993

The following is a statement submitted by ACT UP San Francisco Alternative Treatment Committee, concerning the hearings conducted October 18 on the FDA’s regulation of dietary supplements. We request that this statement be included in the record of the hearings.

In speaking for the Food and Drug Administration, Commissioner David Kessler says that the Agency does not intend to remove dietary supplements from the market except for reasons of safety. This is the same agency which tried to make an “end run” around the statutory scheme by improperly shifting the burden of proof in the Food and Drug Administration vs. Traco Labs Inc. case (Seventh Circuit Court of Appeals, no. 92-1172, the quote is from page 9 of the decision, enclosed) The FDA argued that black currant seed oil was an unapproved food additive and therefore presumptively unsafe. It was regarded as an “unapproved food additive” because it was to be enclosed in a gelatin capsule which could be regarded as a “food substance”. Given FDA’s past actions, it appears likely that the Agency will use “safety concerns” to make an “end run” around the Proxmire Amendment, using the proposed Dietary Supplement Limit. (See page 33694-33695, Federal Register, June 18, 1993, for an explanation of the DSL to be used in limiting vitamin potencies). Can we trust this agency to deal properly with “safety concerns” when it so improperly misused the food additive theory?

As an example of FDA’s presumable bias against dietary supplements, Commissioner Kessler, in his testimony before the House Subcommittee on Health and the Environment, July 29 (page 20-21) says “...ingredients that are naturally occurring in conventional foods often are concentrated in supplements, making it easy to greatly exceed the normal intakes from conventional foods...” and thus raising safety concerns. We tend to forget that such products as butter, lard, and salt fit the description Kessler gives above of “supplements”. Butter, lard, sugar and salt are concentrated ingredients which naturally occur in much less concentrated form in conventional foods. In the case of butter and lard, at least, we have an example of concentrated ingredients that are known to be harmful. These are concentrated sources of saturated fatty acids which raise blood cholesterol levels and lead to cardiovascular disease. By Kessler’s own logic, these
concentrated “food supplements” of saturated fatty acids that are known to be harmful should be removed from the market. They are by implication harmful drugs. A drug is defined as a substance which alters the physiological functioning of the body. Concentrated sources of saturated fatty acids alter the functioning of the liver, causing it to increase production of blood cholesterol. Obviously no one, including the FDA is demanding that butter and lard be removed from the over the counter market. The Agency is proposing to limit choice in the area of dietary supplements but not with regard to concentrated foods. FDA is employing a double standard here.

The contrast between the Federal Government’s treatment of the dietary supplement industry and of the tobacco industry is both obvious and outrageous. Dietary supplement products arguably have killed no one, except as the result of contaminants or accidental overdose. Tobacco annually kills over 400,000 consumers. And yet the Federal Government wants to remove dietary supplements from the market because of “safety concerns”, whereas tobacco products are rapped on the knuckles with warning labels. Although we are not calling for the removal of tobacco from the market, this situation is intolerably hypocritical and Congress had better resolve it one way or the other. Warning labels allowing “informed choice” are appropriate for tobacco products. They may be appropriate for a limited number of dietary supplements which are alleged to be harmful.

The FDA exploits the tragedy of EMS victims in calling for the removal of so-called “unsafe” amino acids. Apart from the FDA, there is significant scientific agreement that EMS is caused by a contaminant or contaminants, and not by pure L-tryptophan. Currently, the FDA allows pure and safe doses of L-tryptophan to be administered intravenously to patients who cannot digest and assimilate certain nutrients. Tryptophan is added to infant formulas and to animal feed. For these uses to be authorized, the FDA must legally have determined that pure L-tryptophan is safe. Even more ironic is the fact that a use patent (# 5,185,157) has been issued for the treatment of EMS with one to three grams of pure L-tryptophan. The FDA seems more concerned with control than with safety. The Agency has formed a partnership with the medical/pharmaceutical industry to exert full control over all health choices.

On the matter of claims, we in the AIDS community are constantly exposed to claims concerning possible treatments for AIDS related conditions. There must be some reliable mechanism whereby plausible claims can be separated from implausible claims. The FDA’s “significant scientific agreement” standard does not accomplish this. The FDA has only two categories concerning claims: substantiated and unsubstantiated. We in the AIDS community and all consumers want to know which claims within the “unsubstantiated” category are plausible.
After all, every claim is unsubstantiated before it is substantiated. Unsubstantiated is not the equivalent of "false", and therefore not the equivalent of "snake oil". "Snake oil" had no support in the medical literature of its day. We would like to know which claims, within the category of "unsubstantiated", nevertheless have support in the scientific community. In this way we can begin to distinguish them from claims which are totally unsupported. The FDA's "snake oil" rhetoric is not helpful in this regard. HR 1709 will allow claims which have scientific support, even though they are not yet sanctified by the FDA. The Agency must not be the sole gatekeeper for health information. The FDA asserts that allowing accurate information concerning scientific support for health claims is too confusing to consumers or too expensive to taxpayers. It is the equivalent of admitting that the FDA cannot afford to be honest about scientific support for claims, presumably because FDA does not respect the intelligence of consumers. Apparently the Agency, in its paternalism, is asserting that honesty is not the best policy. If the FDA believes this, what reason do we have to trust it?

The system of FDA substantiated-unsubstantiated claims is simple and retains absolute Agency control over health information, but it can ultimately lead to the untimely deaths of people with chronic and life-threatening illnesses. Some recent examples are: folic acid and neural tube defects, antioxidants and cancer, fiber and colon cancer.

Sincerely,

Michael Onstott
Alternative Treatment Committee
ACT UP San Francisco
THE FOOD AND DRUG Administration
v.
TRACO LABS INC.

In the
United States Court of Appeals
For the Seventh Circuit

No. 92-1172

United States of America, Plaintiff-Appellant,

v.

TWO PLASTIC DRUMS, MORE OR LESS
OF AN ARTICLE OF FOOD, LABELED IN PART:
VIPUNE LTD. BLACK CURRANT OIL
BATCH NO. BOOSF 039, etc.,
and TRACO LABS, INCORPORATED,

Defendants-Appellees.

Appeal from the United States District Court
for the Central District of Illinois, Eastern Division.

No. 88 C 1286—Harold A. Baker, Judge

AROUND OCTOBER 21, 1992—DECIDED JANUARY 27, 1993

Before CUDAHY and EASTERBROOK, Circuit Judges, and
WILL, Senior District Judge.*

CUDAHY, Circuit Judge. The Food and Drug Admin-
istration ("FDA") brings this in rem seizure action under
("Act"), seeking to condemn and destroy two drums of black

* The Honorable Hubert L. Will, Senior District Judge for the
Northern District of Illinois, is sitting by designation.

Counselors for TYRCo
Bass and Udin
Robert Udin
John A. Udin
currant oil as adulterated under 21 U.S.C. § 342(a)(2)(C) for being a food additive not recognized as safe. The district court granted summary judgment against the FDA, and the government appeals. We affirm.

1. Black currant oil ("BCO") is extracted from the seeds of the black currant berry and is marketed as a dietary supplement for its unique fatty-acid structures. The FDA argues that BCO is a food additive not generally recognized as safe ("GRAS") and seeks to seize and condemn two drums of BCO pursuant to sections 334 and 342 of the Act. A food is adulterated and subject to seizure under section 334 "if it is, or it bears or contains, any food additive which [the Secretary has not recognized as safe pursuant to section 348]." 21 U.S.C. § 342(a)(2)(C). The determination of whether a substance is a food additive is critical in establishing the safety of the substance because, if the substance is deemed a food additive, it is presumed to be unsafe, and the processor has the burden of showing that the substance is GRAS. On the other hand, if a substance is not a food additive, but food in the generic sense,1 then the substance is presumed safe and the FDA has the burden of showing that the substance is injurious to health. United States v. An Article of Food . . . FoodScience Labs., 678 F.2d 735, 739 (7th Cir. 1982).

The Act defines "food additive" as

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufactur-

1 Because food additives can be thought of as a subset of food in the broadest sense, see Nutralab, Inc. v. Schweiker, 711 F.2d 335, 337 (7th Cir. 1983), reference to food in the generic sense refers to articles of food not considered food additives.

ing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use.

21 U.S.C. § 321(s). The FDA contends that BCO is a food additive because it is a "component" of food when it is combined with the gelatin and glycerin used to market the BCO in capsules. The gelatin and glycerin encase the BCO to prevent it from becoming rancid. The FDA contends that if the BCO alone was marketed in bottles for teaspoon consumption, it would not be a food additive, and the FDA would bear the burden of proving that BCO is injurious to health. But the combination of BCO with gelatin and gelatin, the FDA maintains, creates a food consisting of three components, and thus, three food additives.2 In this instance, therefore, the FDA would require the processor to prove that the substance is safe—something that Traco Labs, the claimant of the two drums of BCO, has not done.

The district court granted summary judgment against the FDA, holding that the FDA's definition of food additive "would obscure any distinction between 'food' under § 321(f) and 'food additives' under § 321(s)" contrary to the intent of Congress. United States v. Two Plastic Drums, More or Less of An Article of Food . . . (Traco Labs), 791 F. Supp. 751, 754-55 (C.D. Ill. 1991); see also 761 F. Supp. 70, 74 (C.D. Ill. 1991) (order denying FDA's motion for summary judgment).

2 Because gelatin and glycerin are GRAS, they are not formally considered "food additives" under the statute.
II.

We review the grant of summary judgment de novo. Overton v. Reilly, 977 F.2d 1190, 1191 (7th Cir. 1992). Summary judgment is appropriate when there is no genuine issue of any material fact and the moving party is entitled to judgment as a matter of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986). The sole issue presented in this action is whether BCO, when combined with glycerin and gelatin, is a food additive pursuant to section 321(a). In determining what is a food additive, we look first to the language of the statute itself, Consumer Product Safety Comm'n v. GTE Sylvania, Inc., 447 U.S. 102, 108 (1980), and if the language of the statute is plain, then it is conclusive absent contrary legislative intent. United States v. Ron Pair Enters., Inc., 489 U.S. 235 (1989). Section 321(a) defines a food additive as "any substance the intended use of which results . . . in its becoming a component or otherwise affecting the characteristics of any food . . . ." This language is very broad, and thus the general rule is that a component of an article of food is a food additive, even if the component in question is the "principal component," i.e. the ingredient sought when purchasing the food. Food Science, 678 F.2d at 738. Moreover, even substances ordinarily considered "food" in common usage may become food additives in some circumstances. National Nutritional Foods Ass'n v. Kennedy, 572 F.2d 377, 391 (2d Cir. 1978) (vitamins and minerals may be food additives when added to food). In addition, this court has held that DDT found naturally in fish is a food additive under the broad language of the Act. United States v. Ewig Bros. Co., 502 F.2d 715, 721-24 (7th Cir. 1974) (Stevens, J.), cert. denied sub nom., Vita Food Prod. of Illinois, Inc. v. United States, 420 U.S. 948 (1975).

The FDA argues that the statutory language clearly indicates that any and every component of an article of food is a food additive. Although we are mindful of the deference due the FDA in construing the statute it administers, Vought v. Community Nutrition Inst., 476 U.S. 974, 981 (1986); Chevron U.S.A., Inc. v. NRDC, 467 U.S. 837, 843-44 (1984); United States v. 25 Cases, More or Less, of An Article of Device, 942 F.2d 1179, 1182 (7th Cir. 1991), deference here is unwarranted since its interpretation is contrary to the language and intent of the Act. Demarest v. Mantez, 498 U.S. 184 (1991) (administrative interpretation of statute contrary to plain language is not entitled to deference). As an initial matter, we question whether BCO can even be considered a "component" under the Act. The term "component," commonly understood and defined as a "a constituent part or "ingredient," Webster's Third New International Dictionary 466 (1976), loses its meaning when applied to foods used in conjunction with inactive ingredients, as this case amply evidences. Here, the dietary supplement (the food) is nothing but BCO combined with glycerin and gelatin—two inactive substances used for marketing the BCO in capsule form. The gelatin and glycerin do not interact with or change the character of the BCO, but merely act as a container comparable to a bottle containing liquids marketed for teaspoon consumption. The BCO in question is the dietary supplement and the dietary supplement is the BCO. Therefore, to hold that BCO is a component of the dietary supplement would be to find that BCO is a component of itself. Such an interpretation would defy logic and common sense.

But even assuming that a single active, "ingredient" of food can be considered a component of the food, the statutory language does not indicate that every component of food is necessarily a food additive. The Act defines "food additive" as a substance "becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. § 321(f) (emphasis added). The FDA interpretation of this provision implies that the language "or otherwise" is used disjunctively in such a way that a substance is a food additive if it (1) is a component of any food, or (2) affects the characteristics of a food. We think that this interpretation, however, distorts the plain meaning of the provision.
tive ingredient, it does not affect the characteristics of any food.

This interpretation is buttressed by the structure and history of the Act. The language of the Act must be read in the light of the statute as a whole: its design, objectives and policy. Crandon v. United States, 494 U.S. 152 (1990); Illinois EPA v. United States EPA, 947 F.2d 283 (7th Cir. 1991). Upon reviewing the structure and evolution of food regulation under the Act, it is clear that Congress intended to distinguish food additives from food in the generic sense. The original Food and Drug Act of 1906 required the government to prove that foods containing poisonous substances were unsafe. The addition of deleterious substances alone would not necessitate a finding of adulteration. United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914). The Act was revamped in 1938, adopting a “per se” approach: It prohibited the use of poisonous or deleterious substances unless the industry proved that the addition of the substances was safe. See Ewing Bros., 502 F.2d at 720; Toulmin, supra, §§ 1.5, 2.1, 2.3. The 1938 Act itself proved inefficient and Congress took steps to amend the Act in the early 1950’s. Congress perceived essentially two flaws in the regulatory scheme. First, the government had the burden of first proving that a food additive is poisonous or deleterious before it could prevent the industry from using it. This required substantial time, during which the industry could market the potentially injurious additives to the consuming public. The second problem was that the law prevented processors from using certain additives in harmless amounts that, if used, would increase and improve the food supply. S. Rep. No. 2422, 85th Cong., 2d Sess. (1958), reprinted in 1958 U.S.C.C.A.N. 5300, 5301; Toulmin, supra, § 22.3.

After six years of extensive hearings, Congress passed the Food Additives Amendment Act of 1958. The thrust of the amendments was to put upon processors rather than the government the burden of proving that a newly specified quantity. The Act, however, did not require processors to prove that all of their marketed food was safe, although Congress would have been free to enact such a requirement. Rather, the burden imposed upon processors applied only to food additives, and the government retained—as was the case prior to the 1958 amendment—the burden of proving that a given food was unsafe.

Consequently, the Act distinguishes between food additives and food in the generic sense, and this distinction is critical in allocating the burden of proof. The FDA’s food additive definition is so broad, however, that it would blur this distinction. It would classify every component of food—even single active ingredients—as food additives. Thus, it would seem, even the addition of water to food would make the food a food additive. The only justification for this Alice-in-Wonderland approach is to allow the FDA to prevent the manufacturer from marketing a food additive. In sum, the statutory scheme and all it encompasses create a burden of proving the safety of a food additive in all circumstances. To be sure, the paramount objective of the Act is to protect the public health. But “[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.” 62 Cases of Jam v. United States, 340 U.S. 593, 600 (1951).

The FDA’s interpretation would also arbitrarily classify a substance as either food or food additive by how it is marketed rather than by the nature and use of the substance itself. The FDA concedes that BCO marketed in bottles instead of in capsule form is not a food additive, and that it would in that event have the burden of proving that the BCO is harmful or deleterious. Yet there is no difference between the BCO bottled for teaspoon consumption and the encapsulated BCO but for the way it is marketed. How a product is marketed is not a rational way of determining whether a substance is a food additive and which party—the FDA or the processor—bears the burden of proving its effect, if any, on the consuming public.
Therefore, although a component of food is generally a food additive, when the “component” is the single active ingredient and thus in all material respects is identical to the food of which it is supposedly a component but for certain inactive additions, such as the gelatin and gelatin used for encapsulation here, the substance in question is not a food additive. Our holding today is not inconsistent with Food Science, the case on which the FDA relies. In that case, this Court held that the substance N,N-dimethylglycine hydrochloride (“DMG”)—the lesser by weight and volume of two active components of the tablet Aangamik 15—was a food additive even though DMG was the “principal ingredient” of the tablets. 678 F.2d at 738. The DMG, even though it was the reason consumers would purchase Aangamik 15, comprised only 4 percent of the tablets’ weight, and was mixed with another active ingredient (calcium gluconate) to form Aangamik 15. We did not reach the question presented here where the substance at issue is the single active ingredient of a marketed product. The district court in FoodScience enjoined the use of DMG “except when offered as a single ingredient for food use.” But because the government did not cross-appeal from the exception, we refused to consider that question. Id. at 737 & n.2. Indeed, if the majority opinion had held what the FDA alleges it held, the concurrence in that case, on which the district court below relied, would have been a dissent.

The concurrence states:

I believe... as did the district court, that this would be a far different case if DMG were being marketed as a single food ingredient. In that case, the FDA would not be entitled to rely on the “food additive” presumption to condemn plaintiff’s product but would instead be obligated to shoulder its normal burden of proving, by a preponderance of the evidence, that DMG was an “adulterated food”...

Id. at 741 (Cudahy, J., concurring) (footnote omitted). In short, this case is different from FoodScience and other cases in which the substance in question was mixed with other active ingredients to form an arguably distinct article of food. See 45/19; Kg. Drums of Pure Vegetable Oil, 961 F.2d at 812 & n.3; 41 Cases, More or Less, 420 F.2d at 1130; 42/30 Tablet Bottles, 779 F. Supp. at 253; 21 Approximately 180 Kg. Bulk Metal Drums, 761 F. Supp. at 180. In fact, the rule enunciated today is supported by every court that has addressed the precise question involved here. See United States v. 29 Cartons of An Article of Food... Oakmont Inv. Co., 792 F. Supp. 139 (D. Mass. 1992) (encapsulated BCO not food additive); United States v. Vitality Systems, Inc., Food Drug Cosm L. Rep. § 38,251 (D. Or. August 6, 1991) (holding that methylsulfonylmethane (“MSM”) marketed in pure form not food additive but MSM held food additive in multi-ingredient products containing other nutrients such as Vitamin C); United States v. Undetermined Quantities of Articles of Food... Blue-Green Algae, No. 83-1130 FR, 1984 WL 1801 (D. Or. November 8, 1984) (encapsulated Aphanizomenon flos-aquae (blue-green algae) not food additive because it was not intended to affect the characteristics of another food or become component of another food); United States v. An Article of Food... L-Tryptophan, No. 77-887 (D.N.J. January 3, 1979) (L-Tryptophan tablets not food additive).

III.

Accordingly, we hold that BCO encapsulated with gelatin and gelatin is not a food additive. Because the FDA has not shown that BCO is adulterated or unsafe in any way, there is no basis to condemn the two drums at issue. If BCO is injurious to health, the statute requires the FDA to prove as much. Meanwhile, the Act’s labeling requirements protect the consuming public to the extent mandated by Congress by enabling persons to weigh for themselves the benefits and risks of consuming BCO. The judgment of the district court is therefore

Affirmed.
Dear Members of the Subcommittee:

I request that the attached statement be included in the record of the Subcommittee Hearings of October 18, 1993, concerning FDA regulation of dietary supplements.

Sincerely,

Michael Onstott

Michael Onstott
Alternative Treatments Committee
ACT UP San Francisco
Agriculture Subcommittee
House Appropriations Committee
U.S. House of Representatives
Washington, D.C.

Dear Members of the Subcommittee,

In the battle against AIDS, as in all struggles against life-threatening illnesses, we must pursue a course which includes all potentially viable options for treatment. People with AIDS and other life-threatening illnesses must be consulted, included, and empowered during the process of developing new or individualized therapies. Given the results of the Concorde Study and other research indicating that anti-retrovirals are less efficacious than previously believed (especially with regard to early intervention) alternative options such as antioxidants, amino acids, and herbs become even more crucial.

Access to natural, traditional, and alternative treatments is an absolute right which activists, patients, and consumers will not give up. On June 15, 1993, the Food and Drug Administration released the final "Dietary Supplements Task Force Report" which calls for regulating amino acids, herbs, and other supplements in ways that could dangerously restrict access. Although many of the task force's proposals are rational and reasonable, some recommendations will lead motivated PWA's and other consumers to seek products and treatments in the underground market place.

Under FDA proposed guidelines all medicinal herbs could potentially be classified as "unapproved food additives". Further, a recommendation that the agency adopt a "Dietary Supplement Limit" (DSL) could ultimately lead to restrictions on vitamin and mineral potencies which would jeopardize access to optimal nutrient replacement therapies for People with AIDS and drive up costs for all consumers of nutrients. All amino acids are to be regulated as drugs including NAC (N-Acetyl Cysteine) and L-glutathione which are used to raise deficient levels of glutathione for people with AIDS/HIV; thus, FDA policy jeopardizes and increases the costs of nutrient replacement therapies utilizing amino acids. FDA proposals would hand free form amino acids over to the medical pharmaceutical industry and individuals who hold "use patents" on these same nutrients which will then become lucrative sources of excessive profits.

Many FDA employees are recruited from and retire to the pharmaceutical industry and many come from the law enforcement field. Over the years the Agency has developed a negative and combative kind of "drugs and guns" philosophy. In its
attempts to “protect” consumers, the Dietary Supplement Task Force considered “what steps are necessary to ensure that the existence of dietary supplements on the market does not act as a disincentive for drug development”. The Task Force is blatantly promoting drugs over nutrient and botanical therapies at the expense of the public.

Act Up San Francisco, in coalition with other AIDS, Cancer, and Alzheimer’s groups fighting for access to alternative and holistic therapies, opposes all FDA proposals which seek to redefine amino acids, herbs, or other dietary supplements as unapproved drugs or “unapproved food additives”. Further, Act Up San Francisco supports the passage of legislation which protects the right of all citizens to choose their own health care. The Dietary Supplement Health and Education Acts S. 784 (the Hatch bill) and HR 1709 (the Richardson bill) attempt to protect consumer-patient access to anti-oxidants, vitamins, minerals, amino acids, herbs, and other products which FDA has chosen to restrict in ways which can and probably will compromise the health of people with AIDS who seek alternative treatments. We will not give in to bureaucratic or Congressional paternalism in the name of corporate profit or even in the name of “consumer protection”. Nutrient and herbal prohibition is no solution. We will continue the fight for the right of all People With AIDS to choose their own treatments.

Sincerely,

Rebecca Hensler
Women’s Caucus

Michael Onstott
Alternative Treatments Committee

Jim Lewis
Prison Issues Committee

Paul Fertig
People with Immune System Disorders [PISD] Caucus

ACT UP San Francisco
House Appropriations Committee
Subcommittee on Agriculture
2362 Rayburn Bldg.
Washington, D.C.

The following statement concerns the hearings on FDA regulation of dietary supplements, held October 18, 1993. We request that it be included in the record of the proceedings.

A bibliography is included for the documents. The documents themselves are also enclosed for your convenience.

Sincerely,

Michael Onstott
San Francisco Chapter of Citizens for Health
ACT UP San Francisco
CITIZENS FOR HEALTH
San Francisco Natural Health Care Alliance Chapter
1882 35th Ave. San Francisco, California 94122
Telephone: (415) 292-4055

Prepared by Bowen Johnson and Michael Onstott

STATEMENT ON HEARING CONCERNING DIETARY SUPPLEMENT REGULATION
BY THE FDA

CONDUCTED OCTOBER 18, 1993 BEFORE THE HOUSE SUBCOMMITTEE ON
AGRICULTURE, HOUSE APPROPRIATIONS COMMITTEE
We believe that it is the business of the FDA to honestly insure the purity and safety of dietary supplements; it is not the business of the FDA to make our health maintenance decisions for us. The following comment is meant to substantiate this position.

CONCERNING FREE CHOICE AND WHO DICTATES IT

FDA Commissioner David Kessler claims on page 25 of his "Statement before the Subcommittee on Health and the Environment" (Document 1) that he supports the concept of free choice of dietary supplements but that "critical questions exist about how real or free choice actually is when some of the health-related claims on product labels are not scientifically valid". Presumably, a "scientifically valid" claim is a "substantiated" claim. What is FDA's definition of a "substantiated" claim? In the DHHS booklet "Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace" it is asserted (page iv of Document 2) that "These products may be making a wide variety of claims, but they have one thing in common: Not one of the claims has been substantiated by the FDA before their appearance in the marketplace". The FDA's definition of "unsubstantiated" is, therefore, "unsubstantiated by the FDA". Assuming, then, that a "scientifically valid" claim is a "substantiated" claim, the FDA's position is that the consumers' choices are free only when they choose dietary supplements that make claims that are "scientifically valid", that is, claims substantiated by the FDA. Unless the consumers know which choices they must make to achieve the results they are seeking, their choices are not free; and the choices they must make in order to get the results they want are to be decided by the FDA. In other words, choice is not free unless it is dictated by the FDA. This bizarre assertion is the clear implication of FDA's official remarks.

What, then, does "substantiated by the FDA" mean? It means that a group of experts selected by the FDA or by an organization designated by the FDA has reviewed the data originating from primary researchers and ruled on its soundness. The first point to notice here is that the experts who ultimately make the decision are only a small and not necessarily representative selection of the experts available in the relevant field. Why is one relatively tiny group of experts allowed to determine absolutely what is to be regarded as "substantiated" claims? Why rely solely on FDA's bureaucratic approach? As in the cases of vitamin E in the prevention of heart disease and folic acid in the prevention of neural tube defects, people's lives are at stake. The FDA prefers that the ultimate decision on scientific matters rest in the hands of the FDA. Is this an honest way to determine the truth? Under the mandate granted by the NLEA, the FDA disallowed claims for antioxidants as preventives of cancer. Gladys Block and 15 university-affiliated co-signers have disagreed with FDA's judgment that there is no "significant scientific agreement" among primary researchers that antioxidants prevent cancer. (Document 3, the co-signers are listed on page 211). Block and co-signers are not affiliated with the supplement industry. They are epidemiologists, nutritionists and biochemists affiliated with universities. The FDA's group of experts is no better qualified than the Block group of experts. The FDA decided that there is no significant scientific agreement among primary researchers that antioxidants prevent cancer. But within the scientific community there is no significant scientific agreement that this FDA decision concerning primary research on antioxidants is itself correct. It is dishonest to pretend that there is such agreement. The FDA's assertion that a claim has not been substantiated is really an assertion that it has not been substantiated by a tiny officially-appointed selection of the relevant academic community. This is purely a political claim. It cannot be a scientific claim because the judgment of the scientific community may be split. The only reason for preferring the FDA's decision is the belief that somebody has
to tell us once and for all absolutely what to believe. In other words, our choices must be dictated by some authority. This is an odd justification of "freedom of choice" that Kessler endorses. One would think that freedom of choice consists of the consumer's freedom to accept the judgment of one group of equally-qualified experts over that of another. If the scientific experts disagree, who is to choose between them? Obviously, consumers must participate in this decision-making process. It is, after all, consumers who are members of the "expert team" which determines the efficacy of various products. Consumers must be consulted concerning their own physiological reactions to dietary supplements. As non-scientific experts go, the consumer is more honest than the government. The consumer has his or her own interests foremost. The government has the interests of economic pressure groups foremost. Thus, the concept of a sole gatekeeper in the form of a biased government agency is untenable.

SOME GENERAL QUESTIONS CONCERNING THE COMPETENCE AND HONESTY OF THE FDA

Before we can have confidence in the FDA's judgment on the matter of unsubstantiated claims and safety, we need to examine the FDA's record of competence and honesty.

Document 4, a page from the Federal Register detailing FDA's proposed rules under NLEA, states that chromium supplements will not be permitted. Highlighted portions of Document 5 and Document 5A, papers published in The Annals of Internal Medicine and Metabolism respectively, testify to the safety and benefits of chromium supplementation. In addition, Document 6 points out that, according to a US Department of Agriculture study, even a well-balanced diet of 3500-4000 calories would barely provide the minimum recommended intake of chromium. Even if the FDA relents on this point, the fact remains that the Agency was grossly mistaken and had to be corrected. The facts on chromium are quite clear to any literate person, and only gross incompetence can explain the FDA's statement in the Federal Register.

A review of the evidence concerning vitamin E and cardiovascular disease from the medical journal Artery (Document 7) shows just how much data the FDA has chosen to ignore when it speaks of unsubstantiated claims. The evidence, culminating in the Harvard School of Public Health studies (Document 8), is so massive that the conservative bureaucrats of the FDA are now in the awkward position of holding out for conclusive proof before approving a claim for vitamin E. This position is much like that of the tobacco companies which are holding out for conclusive proof that smoking is harmful. After all, no double-blind placebo-controlled studies have been conducted to determine the harmfulness of tobacco smoke to humans. And yet it is scientifically responsible to claim that tobacco smoke is harmful.

Contrast, however, the FDA's incredible haste in approving food irradiation, which actually destroys vitamin E. Document 9, a page from a journalistic piece which favors food irradiation, points out that irradiation may destroy up to 25% of vitamin E in selected foods. But, according to the FDA's spokesman, "vitamin losses from irradiation should be considered in the context of one's total diet." This bureaucratic gobbledygook sounds impressive, but, we should ask, "What does it mean?" It obviously means that if you wish to maintain your present nutritional level eat up to 25% more food. And, since vitamin E is fat-soluble, and food with vitamin E is high in fat content, the implied advice is to eat up to 25% more fat. This is contrary to prevailing medical wisdom. The FDA says nutrient losses from irradiation are "often" less than those from cooking or canning. This overlooks the fact that food irradiation is not an alternative method of food processing, but will be used in addition to cooking. Irradiated food will be cooked. The nutrient losses are therefore additive and will make a bad situation worse. And the food that is eaten raw will have its nutrients reduced to the level or [often] almost the level of cooked food. Once again, the nutrient losses are additive "in the
PAGE 3

context of one’s total diet.” There will be additional nutrient losses from processing in both cooked and raw food, where, before, there were no such losses. The FDA seems to think that, just because previous nutrient reduction by food processing was not devastating, additional reduction will not be devastating either. But at one point or another, further nutrient loss becomes absolutely unacceptable. If the FDA does not even have the common sense to see this, how can it make judgments on the worth of dietary supplements?

The FDA has proposed that USRDA be replaced by RDI (Reference Daily Intake), which will in some cases recommend a lowering of the nutrient levels required by USRDA. For instance, RDI will be 10% lower for vitamin E. In response to criticism, the FDA, in a page from a debate printed in Nutrition Reviews (Document 10) states that there is a margin of safety built in to the RDAs, so that lowering of recommended nutrient levels to RDI values will not be a disastrous alteration. Apparently it has not occurred to the spokesman for the FDA that this margin of safety is there for a reason. Taking it away is risky -- unless, of course, the reason the safety margin was there in the first place was to protect the public from bureaucrats who want to tinker with the USRDAs.

The consumer might be forgiven at this point for saying: "Now let me get this straight. Vitamin E, a substance that is beneficial, is to be destroyed in the food supply. And supplements of vitamin E are not allowed to bear information concerning their reasonably-determined benefits on the label. Furthermore, the amount recommended to be ingested per day is being arbitrarily reduced. And the FDA is supposed to be protecting us!"

Many consumers would like to know what is going on. But it would not be wise to depend on the FDA to enlighten them. Commissioner David Kessler has been demonstrably less than honest in previous statements on this issue. Just one case in point: “Correction: No Plan to Curb High-Potency Vitamins” (Document 11). In this interview, Commissioner David Kessler misleads, not by making incorrect statements, but by leaving out significant portions of the truth. Document 12, the August 9 New York Times quote from Deputy Commissioner Dykstra, on which Kessler comments, is "...anything above these [lowered recommended vitamin-intake, i.e., RDI] levels would be considered unapproved food additives and it [the supplement with that potency] couldn’t be made. You couldn’t get it by prescription or otherwise." Kessler’s clarification is that FDA "does not object to supplements just because they exceed the RDI but would object to megadoses that exceed safe levels." Note that nothing in Kessler’s remarks really contradicts anything that Dykstra said, although Kessler appears to be contradicting the quote. Remember that an unapproved food additive is presumed to be unsafe. Therefore a dietary supplement which exceeds RDI levels could be classified as an unapproved food additive and thus could be presumed to be unsafe; therefore it could be presumed to exceed safe levels.” Dykstra said vitamin supplements which exceed the RDI would be unapproved food additives. This means that they would be presumed to be unsafe, and therefore would fit Kessler’s designation as "megadoses that exceed safe levels". Note also that these megadoses would exceed safe levels without ever having been proved to be unsafe. Therefore the FDA can remove from the market anything it pleases without giving more than an empty formal reason, i.e. hypothetical safety concerns based on the food additive theory. The Federal law Kessler cites in order to prove that FDA is not allowed to limit potencies of vitamin supplements (Document 13) precludes the FDA "from classifying any food substance as a drug based solely on its potency". But note that the law does not preclude the high potency food substance from being classified as a food additive in order to limit its potency. Kessler has moved from discussing food additives to discussing drugs. Is it his intent to deceive? Considering Kessler’s past performance on this issue, we feel that anything he says concerning it should be regarded with suspicion.
WHY THE FDA AND MANY CONSUMER AND SCIENTIFIC ORGANIZATIONS RESIST CLAIMS FOR NUTRIENTS

Why do AARP, CSPI, ACS and other groups support many of FDA's incredibly conservative stances on claims for dietary supplements? And why, for that matter, does the FDA have such stances? Without indulging ourselves in conspiracy theories, we should realize that it is the upper hierarchies of these organizations which make policy. It is the steering committees and executive committees of these groups rather than their rank-and-file members who support the FDA line. Upper levels of hierarchies tend to be more conservative than rank and file members of the groups for whom they speak. They are exceedingly cautious because they make policy and thus are in positions of responsibility; they feel that they must not be perceived as having made mistakes. A mistaken endorsement of nutrient claims is a much more visible mistake than a mistaken failure to endorse, even though the latter mistake may be far more serious and cost far more lives than the former mistake. Therefore, the tendency is to avoid backing nutrient claims.

In scientific organizations, such as American Cancer Society, this tendency often leads to inappropriate resistance to new data. If the new data contradict past authoritative pronouncements -- for example, that supplementary vitamin intake above the RDA is useless -- they meet unusually stiff resistance. Authoritative reputations are at stake. If the "authorities" are perceived to have made mistakes in the past, there will be less respect rendered to their current positions. To the "authorities" this would be an intolerable situation. Science is supposed to be an objective search for truth. Yet self-serving caution distorts even science; and it naturally does so more at the official policy-making level than at the primary research level. We must be very careful what we accept from "official spokespersons" of scientific and other organizations. Much of what they say may be self-serving attempts at justification of their past positions.

The only sane approach is to correct for the bias toward extreme conservatism that inevitably creeps into organizations-- even scientific organizations. One good example is Center for Science in the Public Interest. Bruce Silverglade, quoted in Newsweek (Document 14) produces a bizarre piece of reasoning. Concerning health claims on the labels of supplements, he says "If future studies don't prove something to be true, no one is going to get their money back, and in the end the consumer is going to feel ripped off." But Silverglade considers only one possibility -- the possibility that the claim is allowed but will not be borne out by future research. To be fair he should also consider the other possibility -- i.e., that the claim is not allowed but will be justified by future research. Suppose, for example, that future studies do conclusively prove that vitamin E prevents heart disease. (See Document 15). If, because of FDA indecision, consumers have not been allowed to learn of this preventive strategy, those who subsequently develop heart disease are not going to get their health back and in the end are going to feel ripped off by the FDA bureaucrats. Either way the situation turns out, there will be a ripoff. Which is the bigger ripoff: your money or your health (life)?

American Association of Retired Persons is one of the consumer groups supporting FDA's position. This is ironic since a US Department of Agriculture researcher in a recent review of the literature (Document 16) concludes that the number of cataract surgeries -- the most frequently performed surgery among the elderly and the single largest item on the Medicare budget -- could be reduced by half through the use of high doses of antioxidant vitamins (greater than 500 mg vitamin C and 400 IU vitamin E per day). It is a shame that the AARP steering committee's blindness to the medical literature could most likely contribute to the blindness of its members.

Another review of recent research (Document 17) suggests that high doses of vitamin B-2 (riboflavin) can increase the activity of an enzyme which detoxifies oxidized hemoglobin.
Oxidized hemoglobin is one of the primary causes of damage in stroke and heart attack. Again, AARP is unwittingly misleading its membership. The FDA has stated (Document 18) that no health claims can be made for nutrients ingested above ordinary intake levels; according to FDA's "intended use" definition making such claims converts the nutrients into drugs. No manufacturer or supplier is willing to finance the testing of unpatentable products for their efficacy as "drugs".

Kessler would insist on rigorous drug testing of vitamin C and vitamin B-2 before allowing the elderly to attempt to preserve their sight or their lives utilizing these substances. With all due respect to bureaucratic procedure, we feel that people's eyesight and lives deserve some consideration also. Kessler would refer to the above-referenced claims as cases of "snake-oil promotion". But "snake-oil" in its day had no scientific support whatsoever. The above claims do. They do not have the kind of backing that FDA demands. But this is far from saying that they have no validity whatever. On the contrary, the reviews were put together by recognized experts in their fields, reporting on research done by other well-qualified experts. These experts are by no means infallible, but then neither is an FDA review panel. And to act as though the FDA is the final word on these matters is to avoid the complexity of the issues.

The long list of products with "unsubstantiated" claims (i.e., claims unsubstantiated by the FDA) found in the DHHS booklet "Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace", presents no argument at all that these claims are "snake oil" claims. We have included a review article (Document 19 from the journal of Clinical Pharmacology) concerning the extensive research on CoEnzyme Q10 and heart disease. We must emphasize here that the original "snake oil" was not supported at all by any medical research; but CoEnzyme Q10 has considerable backing. To equate CoEnzyme Q10 with "snake oil" is a symptom of bureaucratic myopia which sees no further than its rules and regulations. It is not the business of the FDA to see further than its rules and regulations, but FDA should refrain from using such exaggerated rhetoric as "snake oil" when referring to claims backed by legitimate medical research.

One can see, just by employing common sense, that the FDA's approach to claims is distorted. Kessler's testimony (Document 20, page 25) indicates that the FDA saw no need to subject supplements of vitamin C to a different standard of proof than vitamin C in broccoli. If that is true, why does the FDA insist that high-dose dietary supplements of vitamin C must be subjected to a more stringent (drug) standard of proof than vitamin C in broccoli? (Document 18) The FDA, in considering vitamin C intake and its relevance to cancer prevention, points out that US average vitamin C intake is well above the RDA. (Document 21). In the context of proposed claims for vitamin C as a preventive of cancer, this point about average intake could only be meant to imply that Americans get quite enough vitamin C, therefore it probably is not relevant to the issue of cancer prevention. But this implied FDA point is doubly irrelevant. The RDAs explicitly do not take into account the causal relationship between vitamin intake and chronic and/or degenerative disease (Document 22). Second, the average intake is uninformative without data, which the FDA does not give, about the actual distribution of vitamin C intake — i.e., what percentage of the population consumes C above the RDA and what percentage consumes below the RDA. The average intake does not distinguish between, on the one hand, a situation in which relatively few consume far above the RDA and relatively many consume below the RDA; and, on the other hand, a situation in which most consume slightly above the RDA. FDA does mention median intake but only while including supplement use in the calculation. What about the median intake of those not taking supplements? This would be the significant point to consider in evaluating the adequacy of a normal diet in cancer prevention. It is interesting that the FDA manipulates its approach in such a way that it avoids this issue and thus the question of the value of supplement use will not arise. Even without being an expert,
one can tell that the FDA’s approach to claims lacks common sense.

FDA VS. THE DIETARY SUPPLEMENT INDUSTRY: A CASE OF INSTITUTIONAL BIAS

FDA’s deep institutional bias leads the agency to form policy and make decisions based on a distorted perspective. According to the Dietary Supplement Task Force Report (the Dykstra Report) the task force considered various issues in its deliberations, including "...what steps are necessary to insure that the existence of dietary supplements on the market does not act as a disincentive for drug development." We would like to know under what authority the FDA is charged with pursuing these steps. Cannot the existence of drugs on the market act as a disincentive for the use and development of dietary supplements? For instance, pharmaceutical drugs can be used to treat symptoms as a sort of quick fix for a chronic, long-term problem, whereas in some cases supplements may have the potential to prevent certain conditions or promote a kind of biochemical balance which may address the root cause of the symptoms and re-establish well-being. We as consumers have concerns about the public policy ramifications of pursuing steps to insure that the existence of dietary supplements do not act as a disincentive for drug development. By framing the issue in only one perspective the Dykstra Report favors one industry over another. Allopathic and holistic approaches to health care may remain somewhat independent as industries but must be complementary in terms of therapies and strategies for improving the health of the individual. A Federal agency should not be in a position to decide that one approach be promoted over another.

We as consumers have some deep concerns with regard to the dietary supplement industry, but we have greater distrust for the regulatory direction of the FDA. One problem that we face is that the issue is framed in such a simplified way that industry appears to be the villain and the FDA is promoted as the savior; from this perspective, consumers are disempowered. Occasionally industry promotions misleadingly manipulate consumer choices. Sometimes, consumers are genuinely exploited. Because of FDA’s entrenched bias, the agency often tends to over-react to these cases. And although FDA actions are in some cases justified, there are many instances where FDA is reacting to hypothetical, exaggerated, or non-existent violations. Some examples are recent FDA actions against blackcurrant oil and evening primrose oil (so-called “safety violations”) and the list of “snake oil” claims in the DHHS booklet “Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace”. After reviewing the data, a reasonable person would conclude that many of the claims listed in this booklet are true and many are unproven or false. The problem is that the FDA has not developed a mechanism to determine the difference between what is true, what is unproven, and what is false. In its rigidity, the FDA can see only in terms of “substantiated” and “unsubstantiated” within its own insular regulatory framework. Thus, “unsubstantiated” claims such as chromium as a regulator of blood glucose levels are all inaccurately equalized to become false claims as far as the FDA is concerned.

Within the framework of its distorted perspective and well-documented biases FDA is calling for more policing powers. Organizations such as CSPI are in agreement only because they mistrust the FDA less than they mistrust the dietary supplement industry. This is poor justification for empowerment legislation which would give FDA more power to regulate that which it does not understand. Congress must begin to take responsibility for understanding the complexity of these issues. Complete deference to FDA is not a viable option. Congress must also listen to its constituents. Real consumers of dietary supplements are not calling for more policing powers for FDA. They are demanding more of a voice in the decision-making process. After all, it is our health and well-being which is at stake.
SAFETY OF DIETARY SUPPLEMENTS

The DHHS booklet "Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace" lists a number of safety concerns. FDA has concerning dietary supplements. Kessler, in his testimony, (Document 23, page 20-21) says "...ingredients that are naturally occurring in conventional foods often are concentrated in supplements, making it easy to greatly exceed the normal intakes from conventional foods..." and thus raising safety concerns. People tend to forget that such products as butter, lard, and sugar fit the description Kessler gives above of "supplements". Butter, lard, and sugar are concentrated ingredients which naturally occur in much less concentrated form in conventional foods. In the case of butter and lard, we have an example of concentrated ingredients that are known to be harmful. These are concentrated sources of saturated fatty acids which raise blood cholesterol levels and lead to cardiovascular disease. By Kessler's own logic, these concentrated food supplements of saturated fatty acids that are known to be harmful should be removed from the market. They are by implication harmful drugs. A drug is defined as a substance which alters the physiological functioning of the body. Concentrated sources of saturated fatty acids alter the functioning of the liver, causing it to increase production of blood cholesterol. Is FDA demanding that butter and lard be removed from the over the counter market? If not, why not?

The Federal Government in general does not seem to care much about toxic substances in the marketplace. Cigarettes kill 500,000 people annually, and they remain an over-the-counter drug. The hypocrisy of the Federal Government is too easy a target to belabor; yet it should be mentioned. The cynicism of consumers concerning the motives of the Federal Government is not going to go away until these inequities are corrected.

One area of concern has been l-tryptophan. The FDA still claims that the cause of eosinophilia-myalgia syndrome is related to high doses of l-tryptophan. However a use patent has recently been granted (Document 24) for high doses of pure uncontaminated l-tryptophan as a treatment for EMS. Evidence therefore exists for the claim that uncontaminated l-tryptophan reverses the problems caused by contaminated l-tryptophan. Therefore pure l-tryptophan could hardly be the cause of EMS. The FDA has presented some rat studies to implicate l-tryptophan, but the study used to back up the use patent is a human study, and a human study is always more relevant than a rat study.

With regard to the alleged dangers of germanium supplements of Ge-132, we have enclosed a letter from Parris Kidd, Ph.D. (Document 25) which demonstrates that the problems with germanium are parallel to the problems with l-tryptophan: a contaminant was responsible for the toxicity. Ge-132, pure germanium sesquioxide, has never been associated with kidney damage. (Contact Parris Kidd for references). A product should not be condemned because it was contaminated. Only the contaminant should be condemned. The FDA makes the error of confusing the pure sesquioxide form of germanium with the germanium dioxide contaminant.

We understand that there are genuine cases of potentially unsafe products, such as ma huang, but the FDA's approach in this matter has not been evenhanded. The FDA allows thousands of deaths from aspirin but when the agency becomes aware of six cases of liver damage among chapparal consumers, the product disappears from the market. In the case of such "problematic" herbs as ma huang, lobelia, yohimbe, comfrey, chapparal, etc., warning labels and not prohibition seem to be the solution to the problem. The same is true for vitamins and amino acids. What consumers really need is more information to make educated choices.
Safe products are illegitimately being removed from the market so that the FDA can establish its parameters of power through the court system and then act quickly against products which are genuinely unsafe. The fact is that FDA already has sufficient authority to remove products which endanger consumers. Hypothetical or irrational safety concerns should not rule public policy. Every food, every substance we ingest is toxic at some level of intake. When FDA cannot identify an "upper level" for safety, the agency asserts that this unknown quantity is a safety problem in and of itself and a justification for removing a substance from the market. We should be looking at reasonable standards of risk vs. benefit. Consumers should not have to wonder where we will be able to obtain amino acids or herbs in the underground. Over-regulation of dietary supplements (i.e., prohibition of certain dietary supplements, even restriction to prescription status) is, in a sense, the equivalent of total deregulation of these supplements, because it necessitates a completely unregulated black market. The black market will provide potentially dangerous products with completely unchecked claims. People with life-threatening illnesses and other highly motivated consumers will risk their health and sometimes their lives to acquire the over-regulated or otherwise unavailable supplements through underground sources.

**RECOMMENDATIONS**

The main problems in the area of dietary supplements are claims and safety. We want reasonable claims and we want safe products. But relying on one tiny, suspect group of experts to provide these determinations is hardly satisfactory. We need some assurance that the Federal Government is dealing fairly with these issues. Since all experts are biased and experts disagree, we cannot afford to rely on one unrepresentative selection of experts. It makes no sense to leave the decision-making process in the hands of only one biased group; this skews the resulting judgments. If a broad spectrum of groups is included, the biases should counteract each other and something closer to an unbiased position will emerge from the deliberations. Genuine consumers, non-FDA scientists, industry representatives, medical practitioners, herbalists and holistic care providers, as well as FDA scientists, should be included in the decision-making process. The consumers should be allowed some voice in choosing who makes the decisions that affect their health and lives, because experts disagree.

Specifically, we would recommend the following:

1. Clarify Congressional oversight concerning FDA drug bias which leads to their abuse of power to reclassify vitamins, minerals, amino acids, herbs and other nutrients as unapproved drugs or unapproved food additives.

2. Prohibit FDA from imposing any limit, for any reason, on dosages of dietary supplements without independent scientific proof.

3. Require FDA to consult with cultural and ethnic groups, and practitioners within those communities before removing any item of cultural significance from their market for any reason other than imminent danger.

4. Override FDA's June 18, 1993 proposed labeling regulations that would prohibit all but pre-approved claims on dietary supplements.
(5) Require that FDA follow due process, including advanced notice and public comment before regulatory action to remove products from store shelves is taken.

(6) Create a regulatory review board to assist in the regulation of dietary supplements. We need reasonable standards of purity, safety and quality. We need a model for health care choice and the right to privacy. The function of the review board would be to guarantee consumer access to accurate, objective information, as well as safe, pure and properly labelled products. FDA would still have the right to restrict access if it could prove significant risk. As part of a certification process for evaluating dietary supplement standards, a review board would be formed. As previously mentioned, this review board would be composed of consumers, FDA scientists, non-FDA scientists, wholistic M.D.’s and other practitioners, as well as industry specialists. The review board would certify products according to safety and efficacy. Products not meeting FDA standards would be sold and labelled accordingly. The consumer would retain the right to choose products for which health claims were not proven. Further, the consumer would know via an FDA disclaimer on the label which products were not certified to be effective. Warning labels would be required for such products as chapparal and ma huang, higher doses of vitamin A and vitamin B6, etc., but access to them would not be otherwise restricted.

NOTE: The national Citizens for Health organization has not endorsed the specific recommendations in this section. These issue only from the San Francisco Chapter of Citizens for Health.
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