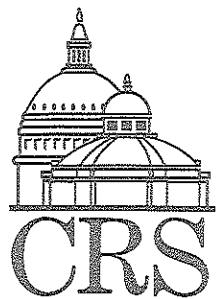


CRS Report for Congress

Dietary Supplements: Consumer Choice Versus Consumer Protection Proceedings of a CRS Seminar June 23, 1993

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**DIETARY SUPPLEMENTS: CONSUMER CHOICE VERSUS
CONSUMER PROTECTION
PROCEEDINGS OF A CRS SEMINAR
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SUMMARY

The current controversy surrounding the regulation of dietary supplements was precipitated by passage of the Nutrition Labeling and Education Act of 1990 (NLEA). The law required that FDA develop and implement regulations on the nutrition labeling of most foods, nutrient content and health claims. Since under the current regulatory scheme dietary supplements are categorized as foods, supplements were to be regulated in the same way as conventional foods.

In the debate of the issues presented in this seminar proceedings, Margaret Visser (historian, York University) discusses why consumers choose to eat certain foods and use certain supplements. Ryan Huxtable (pharmacologist, University of Tucson) outlines his experiences as to why consumers experience health problems with using certain toxic herbal preparations. Michael Taylor (FDA Deputy Commissioner) reviews the FDA's recent proposed regulations for nutrition labeling and claims for supplements, as well as an advanced notice of proposed rulemaking, which raises questions on what course the agency ought to take in the future in regulating these products. Bruce Silverglade (attorney, Center for Science in the Public Interest) outlines the concerns of a number of consumer groups that oppose the dietary supplement legislation in the 103rd Congress. Martie Whittekin (President, National Nutritional Foods Association) reviews industry concerns on safety and product claims. Stephen McNamara (attorney, Utah Natural Products Alliance) discusses the concerns the supplement industry has about product availability, labeling and procedural justice.

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ROWBERG: Welcome to the Library of Congress and the Congressional Research Service. I am Dick Rowberg, Chief of the Science Policy Research Division of the Congressional Research Service. I think that we have a good program on the regulation of dietary supplements prepared for you today. Now I would like to introduce Donna Porter, a Specialist in Life Sciences in the Science Policy Research Division, who will introduce the rest of the program.

PORTER: Thank you, Dick, and welcome to the Library of Congress and the Congressional Research Service. It is gratifying to see that there is so much interest in the issue of dietary supplements: consumer choice versus consumer protection. As you know, we had planned for this seminar to follow a congressional breakfast on the same subject, which was canceled due to the press of congressional business; a victim of timing, not interest. If there is interest in a congressional breakfast for members, please let us know and we will attempt to reschedule it.

As a result of our attempt to try to plan back-to-back events, this room was the only one available on this date. In the planning, I never envisioned that we would have this many staff able to attend a Wednesday morning briefing. However, with so much interest, I determined that there would never be a better time and since everyone was already signed up and the speakers had worked this event into their busy schedules, we decided to proceed. I do apologize for the close quarters. Nevertheless, I believe that we have a very informative program which, while it does not represent every single opinion and view on the degree to which dietary supplements should be regulated in the United States, will provide you with a number of views and certainly the depth of opinion on the subject.

Several administrative items: the left hand side of your packets contains materials selected by CRS, including the agenda; biosketches of the speakers; a listing of citations of the recent bills, laws and FDA Federal Register notices on dietary supplements; and several articles in the lay press on supplements. On the right side you will find materials provided by several of the speakers. There are additional handouts from the speakers on the table for you to pick up. We will allow all the speakers to make their presentations and then take questions at the end. Finally, this seminar is being recorded and will be transcribed for later publication as a CRS report.

Now I would like to introduce my coordinator for this program, Esther Sternberg. Dr. Sternberg is chief of the Unit on Neuroendocrine Immunology, which is part of the Clinical Neuroendocrinology Branch of the National

Institute of Mental Health (NIMH) Intramural Research Program at NIH. I will let her tell you how and why she got interested in this subject.

STERNBERG: Thank you, Donna. A lot of people apparently have asked, "Why NIMH, why me?" The reason that I left my sheltered scientific environment was that I was actually pulled out of it during the EMS epidemic and found myself at the front lines of the public debate on the regulation of dietary supplements. I have received calls from both sides on this issue, from people demanding that L-Tryptophan be returned to the market because they clearly felt a need to have some control over their health through self-medication with dietary supplements. On the other side, people were demanding that L-Tryptophan and other similar food supplements be regulated more tightly to prevent such an epidemic from occurring again.

The striking thing about both sides of this issue is not only the number of calls that I continue to receive and, apparently, you are also continuing to receive, but the great emotionality that is attached to both sides. It has made me realize that it is our responsibility in addressing these issues to understand both the reasons for the desire to use dietary supplements in our society and the reasons that these products may pose risks. We cannot afford to be wrong in the way these products are regulated because if we are, we will jeopardize two fundamental rights in this society: one is freedom of choice and the other is health and safety.

The first two speakers are going to address these two sides of the issue; the reason for the need and reasons these products may pose actual medical risks. Dr. Margaret Visser is a professor of classics at York University in Toronto. She has written extensively and published a highly acclaimed book entitled *Much Depends on Dinner*. There are excerpts in your packet, which get to the core of understanding, from an anthropological and emotional point of view, the reasons for people's needs to self-medicate with food supplements.

VISSER: Good morning. My name is Margaret Visser. I am going to be talking about food and how it expresses social realities. Food isn't just something to eat; food expresses social phenomena. I think it is very important to see this perspective as the background to this whole debate. It is only the background; others are going to address the science.

When people think about food, they normally think first of appetite, desire, and pleasure in the experience of eating. What you eat, what it tastes like, what the food means to you, all matter intensely. Food is outside the body and with every mouthful you choose to let it cross the threshold of your mouth and enter your body. There is not a single, sane human being who is not extremely fussy about their food.

However, pills in a bottle, powders, or capsules are not taken because of appetite, or desire for, or pleasure in the pills themselves. They are taken for various other reasons. One reason is health. Food itself, of course, has always historically been closely related to health. The very first physicians were always

dietitians. The word "recipe" originally meant a medical prescription, which the doctor gave you as advice on what to eat for your health.

The idea that food and drugs are classified to be different categories is a very recent one. As a result, we have forced ourselves to distinguish very clearly between things that really exist in a continuum, or a series of continua. We create two columns--the food and the drugs. Now, in fact, there is a large area in between where they overlap. For example, the natural versus the technological, or general health maintenance versus a specific health problem. These terms are arranged in different columns. People tend to associate the items in column "A". And the items found in column "B" are linked together. "An apple a day keeps the doctor away" versus a doctor's prescription. (Interesting--people have always wanted to keep the doctor away.) Self-help, home remedies, looking after yourself versus the need for expert intervention. And then there are even larger categories, cheap versus expensive, traditional versus modern. Notice that these things, if they are put side by side, wouldn't seem to have anything to do with each other, but they are linked in people's minds because they are all rules of one group, in opposition to another group.

In many ways, we are returning to an older view, that food, insofar as it is responsible for health, is medicinal; that medicines can be foods. The distinction has become blurred again in recent decades. However, there is a whole new dimension, which has been provided by modern chemistry, technology, and concepts about the body. It goes together with the very idea of the body as a machine. The chemical components of food--or anything else--can be thought of as useful not only for health, but for improved performance. You can think of your body as if it were a car. You can speed it up, stretch the body's power in specific ways (as in body building), or think faster by using "smart" drugs. The competitive modern view of life urges us to take boosters for bodily performance. It is each individual for himself or herself out there. So a person thinks, if others are taking "smart" drugs, then I had better take them too, or I will fall behind them in performance when it's important to me to shine, even if it is to shine artificially.

I begin to think food, or the chemicals found in food, are going to help me, or hinder me in the specific goals I have set for myself. So I can use chemicals to make me thin, or clever, or muscular, or whatever it is that I want. Notice in all these areas, food is separated from the pleasure dimension in eating. It is no longer delight, it is fuel for the machine.

Another extremely important aspect we demand of food is always safety. It has always been terrifying, as well as delightful and satisfying, to ingest food. People have always thought of nature as dangerous. It is very recently that we have begun to think that we are dangerous to nature. Nature can be dangerous. Plants are often toxic. Over millennia we have carefully gathered knowledge about what is poisonous and what is not. Many societies, in fact, have set up social structures to maintain supplies of food and ensure that they are not contaminated by enemies, or natural disasters. Now we might have these social and communal structures, but remember, we eat for ourselves. No one else eats

for us. Therefore, we always have a strong natural desire to have personal control over what we eat. We want to know what we are putting into our mouths, and we also want to have a right to choose or refuse what is on our plates.

But, modern cultures, and especially advances in chemistry and technology, have cut us off from the food supply. (We no longer grow our own food, nor do we know the people who grow it for us. Food is brought to us over vast distances, and most of the personal control we have historically had has been taken from us). Food scientists and anonymous commercial networks now decide what we will eat. They give us a range to "choose" from, if they are wise because supermarkets know that we like to browse, choose, and decline to pick what we eat. But they decide what the range of items that are available to choose from. They also manipulate our food, in order to grow it as cheaply as possible--remember, the whole economic system is built on the fact that food must be as cheap as possible--to transport it over vast distances, and make it last as long as possible. They go on to manipulate food so that it looks good in spite of everything it has been through. They make changes in the food, but make it look and taste as though it hasn't been changed.

For the first time in history, human beings can no longer trust their senses to know what they are eating. People have always known that if something tasted a little bit bitter, then it must be poisonous. The human mouth is very good at that, but you are not allowed to do that anymore. We don't know what has been done to our food. We cannot tell. And all of these changes scare the public. People are afraid of being hoodwinked, or tricked into accepting things they never asked for and don't want. People are afraid in the last analysis (and this is a primal fear and nobody is exempt), of being poisoned, of being sickened by what they consume. They are scared by such things as the failures of technology (by pollution, pesticides, and nuclear accidents), even though they are impressed by technology's successes.

Modern people are scared not only that the substances they ingest might not be safe, they are also extremely leery about the ways in which food is produced. People have learned that, "process is product; product is process." That is a quotation from a recent editorial in the periodical *Bio/Technology*.. Now biotechnologists claim that genetically engineered food should not be labeled as genetically engineered because it is only a process. If pig genes are put into pumpkins, they do not have to count even as a food additive because pigs are not novel organisms. The process that forced pigs to merge into pumpkins is entirely new, but no label should be necessary because it is "only a process". Remember, however, when it suits them, they say "product is process". Now this kind of double talk makes the public, or could make the public, very irritable indeed.

Also, people have decided that there are limits to what they are prepared to let scientists do to provide them with cheap food. Civilization has taken a long time about it, but it has succeeded in very recent times in giving people tender consciences about how animals are treated. Remember, ever since we

became homo sapiens, food has always been a way in which we have expressed moral issues. People are frightened about both the safety and the morality (or the lack thereof) that could be implicit in such things as factory farming and genetic engineering. And finally, eons of experience have taught us that it is illogical, as well as naive, to ask the people who sell us products to regulate what they sell.

The people who buy dietary supplements buy them for many reasons and I will identify a few. People are convinced in North America and elsewhere, but mostly North America because it is in the lead, that their diets are inadequate. They feel the food that they ordinarily buy, or that is available to them, has been kept too long, filled with chemicals they don't want, and reduced in nutritive quality. They need to make up for that limitation. That is an economic and political problem.

Next, people are afraid of the medical profession. They don't trust many of the drugs they are given. They are afraid that surgical interventions are often blithely and unnecessarily performed, pills are carelessly prescribed and over-prescribed. They would rather try something else altogether. They think that medical professionals do what they do only for money--that they are, in effect, no longer a profession. True professionals are supposed to work for reasons other than money. People have become convinced that is no longer so. Nothing undermines the trust of people more than the idea that professionals are in it for the money. Professionals have always had to work very hard to maintain the trust of the public. This is why professionals are the way they are, but that's a whole subject in itself. If they are seen to be governed by monetary greed, the trust is withdrawn.

Now if you go a further mile along the road that I have been describing here, you come to the belief that a consumer simply knows better than the medical profession, the wheels of research and regulation grind too slowly, or even miss the really brilliant remedies completely. Consumers feel that they cannot wait and feel they should help themselves now.

Factors like these, and many others, constitute what very large numbers of people perceive as a gigantic, systematic trap. They are not victims entirely. Often, they are themselves part of the problem. Consumers like technology, admire it (with reason), and love the convenience it offers them, but they intensely want to escape the trap, to live in a different reality. And business interests with their customary acumen have perceived this need and stepped in to supply it. In so doing, of course, much of what is offered is more of the same, more of what people want so badly to change, or at least to turn away from.

First, the health food business offers more technology. Dietary supplements proclaim that they are natural, nature's plus, nature's bounty, nature's best. Nature's Way is the name of the largest Australian brand of supplements. Their labels are green, with trees on them, and the phrase "Nature's Way" implies that another way, a different road is being taken from whatever it is that consumers want not to have anymore, are sick of and have

lost trust in. But supplements are often technological artifacts, concentrates and isolates that are not found in nature. Our bodies have not necessarily evolved to confront them. They may not be safe and, therefore, they require research and regulation, independent of the people who sell them.

Like so much else in our culture, many dietary supplements are bottled dreams; commodities promising answers to people's yearnings for success, giftedness, and beauty. People in our culture are accustomed to pushing buttons to obtain what they want on the instant and getting rid of awkward problems by flushing them out of sight. They order what they fancy by speaking into a telephone, they browse through offerings at supermarkets and ready-to-wear clothing stores. It is hard for any of us not to get confused and believe that you can also buy bottled muscle power, capsules that give rise to an improved memory, and beauty in a tube of cream. There are plenty of quacks, big time and small time, all ready to be creative and oblige.

Enormous numbers of people living in the midst not only of plenty, but of excess, in fact, eat very badly. They have no time to eat proper meals, can't cook, and don't concentrate on basic human needs, like nutrition. They recognize this limitation and feel obscurely uneasy about it. But, they cheer themselves up by letting themselves be persuaded, by eager advertising, that they can get away with it. Modern merchandising takes enormous advantage of our longing to have our cake and eat it too, indulge without balancing the indulgence, without paying otherwise than in cash. Some dietary supplements offer opportunities "to get away" with unbalanced living, by cleverly filling in the gaps--by supplementing.

Yet other people take medicinal dietary supplements, feeling that "at least no harm will be done". For example, they know that the medical profession has no cure for arthritis, but offers drugs, which are really only pain killers, with unpleasant and perhaps damaging side effects. They are, therefore, sorely tempted to try concentrated celery instead. It is much cheaper, it sounds harmless, why not try it? Something like concentrated celery sounds not technological, but natural--celery, green. It is, of course, not "natural" at all--but it certainly is not the medical profession, or whatever else such consumers have learned not to trust.

It is essential to note that dietary supplements are not taken because people want choice in preference to safety. I say this because the title of the session is Consumer Choices versus Consumer Protection. Dietary supplement users are, in fact, seeking safety. It may not seem obvious, but that is what they want: safety. They want to choose this alternative, whatever direct benefit is sought because they believe that it is not only better, but safer.

People who take dietary supplements have a right to choose among a range of products that do not pose a threat to their health. The L-Tryptophan horror has alerted the public and focused attention on the need to regulate food supplements closely by implementing the laws that are in place--and this is very important. The same is true for all food supplements, and not only for L-

Tryptophan, but other amino acids, imported herbs, and other products. The process by which these supplements are produced also has to be taken into account.

There is a movement to distinguish between food additives, redefined as non-nutritive technological "supports" for foods that must last longer and travel farther, on the one hand, and dietary supplements on the other. The latter would be classified as nutrients and, therefore, as food. The danger is that supplements, being nourishing rather than purely structural non-nutrient additives, might be perceived as not needing all that much regulation, even though they are highly processed and could endanger consumers. It is not that the supplement-buying public is just ignorant and don't care to inform themselves, but many of them--about half the U.S. population--actively seek information. Many of them wind up being very well informed indeed. They are not, after all, some homogeneous and eccentric group, but half the U.S. population. Many are increasingly aware of environmental issues. They are alert to dangers posed by short-sighted technological fixes. Even the most naive of them are people who are trying to change and improve their lives.

There is a deep need that the public should feel they can trust independent, professional regulators to provide them with what they most desire, and everybody desires from anything they ingest, that it be safe. It is sad, as well as frightening, to realize that multitudes of people have learned to suspect those whom they have paid and supported in their studies because they are gifted and brilliant, the people society has designated as its experts. Millions of people suspect their own experts. It is exceedingly dangerous for social cohesion when people start to distrust their political leaders, but distrust of professionals is perhaps more dangerous still. The only way to rebuild trust is to convince the public that their interests are being addressed and safety is being openly, honestly, assured by regulation.

Careful regulation, of course, requires money and facilities provided to agents, and I have to say, like FDA. In fact, the public is generally at fault for not wanting to adequately fund such things as universities, so industry has moved in to provide funding for research. The people who sell the results are the people who fund the research! Therefore, industry often influences research directions. The taxpaying public also doesn't want the expense of giving more funds to agencies, like FDA. (They don't trust FDA either, which is another problem). The result is that industry often ends up regulating itself, which is obviously not in the public's interest. It does not improve trust either. Regulation should not give industry any cause for fear, unless there is something that regulation might expose as dangerous.

Consumers who are afraid of seeing dietary supplements removed from the market are, in fact, afraid of being tricked again. They believe that experts, so-called professionals, are trying for reasons of power and profit to force them to give up the alternative that they believe is safer than the one offered them by distrusted and feared business and professional establishments. On the other hand, the people who sell dietary supplements suspect that there is a plot

essentially by the people who are in it for the money, to use regulation as a trick to get their products off the market. The food supplements market responds to peculiarly modern needs and concerns. It papers over cracks in the social system, such as people lacking the time to eat balanced meals, or people lacking the skill to cook their own food, or people being obsessed by their physical appearance, or a deep-seated hostility to authority of any kind, good, as well as bad.

So it looks for the time being as though the dietary supplement industry will continue to be an exceedingly profitable business. Many people would like, of course, to control this market, to be able to expand it without the hassles and limits of regulation. Others would prefer the public to trust them absolutely, even though they have not always shown reasons why they deserve to be trusted. A lot of the energy in the struggle between regulation and deregulation of the food supplements market, as in many others, is about power, control, and money, not about health or safety. Consumers suspect that this might be the case and it makes them more nervous and distrustful than ever. Consumers, of course, are interested in their health and safety. That is their primary reason for buying food supplements in the first place.

STERNBERG: Thank you very much for a very telling and concise presentation. Dr. Ryan Huxtable, professor of pharmacology at the University of Arizona at Tucson, will be our second speaker. He is an internationally recognized authority on the biological and medical effects of herbs, and the chemicals that are contained within foods. He is going to speak about the medical risks of these products, the problems that could potentially, or have in fact, arisen with a wide variety of herbal supplements.

HUXTABLE: Good morning and thank you. There are about half a million or more species of flowering plants in the world. This is an amazingly successful group of plants, which has evolved in the presence of predation by mammals, bacteria, viruses, insects, and various parasites. The reason this group has been so successful is because flowering plants are excellent chemists. Plants cannot, in the main, run away from their predators; they survive by evolving defensive chemicals.

We recognize the toxicity of plants by relying on only a handful of highly selected, highly cultivated species for food. Of the more than half a million flowering plants, we probably use less than a score as the source of the majority of the calories consumed in the world. Even with these highly selected plants, we have to protect ourselves against their innate toxicity. So, for example, potatoes are sold in brown bags in this country to prevent the light-induced increase in toxic steroids. We have to boil beans vigorously to inactivate the hemoglutinins, which can otherwise cause severe gastrointestinal upsets, including death.

We recognize the toxicity of plants in that one quarter of the prescriptions written in North America still are for plant products, another quarter are for synthetic materials originally obtained from plants, or slightly modified from a

compound present in plants. So I think we should regard the chemical constituents of plants the same way we regard manufactured chemicals and apply the same safety criteria to them.

People get poisoned by plants for very simple reasons. First because the plant is misidentified, which happens not infrequently with commercially sold herbal preparations. For example, one of the largest herb companies in this country a few years ago was selling deadly nightshade labeled as comfrey, which resulted in a poisoning case in Missouri. The same misidentification has occurred in England. A Canadian study showed that about half the samples sold there as comfrey contained a toxic alkaloid, which indicated that, in fact, the preparation was not common comfrey, but another more toxic species in the same family. Second, toxicity of the plant may be ignored. There are many plants sold in various herbal preparations in this country, which are well-known to science to be toxic, but there is no limitation on their sale. And third, for most plants the toxicity is simply unknown. For many of the commonest plants in the garden, few studies have been done on toxicity and even where studies have been done, they are often severely limited to just one constituent of the plant or studies of one duration and not chronic studies. So generally, we still are rather ignorant about the toxicity of many of the plants that are around us daily.

There are a number of factors that contribute to the people getting into problems with herbs (table 1). First, there are the difficulties of plant identification. A plant that is manufactured into an herbal product has often been chopped up or blended; its structure has been destroyed, making identification extremely difficult. Botanically, plants are identified on the basis of their reproductive parts or flowers because these are the parts that undergo the least change. However, in the form that plants are often sold as herb preparations, the reproductive structures are either not present or have been destroyed.

TABLE 1. Factors Contributing to Herbal Problems

- Difficulties of Plant Identification
- Use of Mixtures of Plants
- No Demonstration of Safety or Efficacy
- Persistent Use of a Toxic Plant
- Variability in Chemical Constituents of a Plant
- Difficulties of Showing Chronic Toxic Potential
- Adulteration
- Nomenclature

Source: Ryan Huxtable, University of Arizona, Tucson

Figure 1 shows an herbal tea that was consumed by a woman in Arizona. She drank a gallon a day of it for several days, then lapsed into a coma and died with severe damage to her gastrointestinal tract and liver (heavy consumption

is another reason why people get into trouble with plants). You can see that material in this state is difficult to identify botanically. We did succeed in tentatively identifying it as a Croton species, which was as far as we could go.



Figure 1

Figure 2 [not reproducible] shows three samples of commercially sold herbs from Arizona and Texas. All these samples were sold under the same herbal name. Two of them are prepared from a plant that, I think, is probably innocent and harmless. The third one was prepared from a toxic plant and killed a young child. I will lay a bet there is no one in this room who would be prepared to choose which of these two were safe and drink their choice. This material also illustrates another point in that this toxic plant had been sold commercially for at least 50 years and had probably been responsible for a very large number of poisonings and deaths in young children. However because there is no mechanism for investigating, or even collecting information about such cases, no one realized it until we uncovered this problem some years ago.

Even with plants known to be toxic, examining the product is not enough for you to be able to make any judgement about the relative toxicity of the preparation. One of the big problems in this country is with the use of comfrey, which is a chronic liver toxin, a carcinogen. The sale of this plant is restricted in many other countries, but no restrictions have been placed on it as yet in the United States. Figure 3 [not reproducible] shows a range of comfrey pepsin capsules. The alkaloid content, the concentration of toxins in these preparations vary over a range of 100-fold, from the left to the right. But looking at the material, there is no way you can tell whether you are taking a relatively low-risk preparation or a relatively high-risk preparation. The toxicity of these preparations is exacerbated by the fact that they are sold for chronic consumption. A typical recommendation is to take two or three capsules with each meal on a regular basis.

Another factor contributing to problems with the use of herbs is the fact that quite often complex mixtures of plants are sold. For example, there is one poisoning case from Hong Kong in which four girls were taking a herbal preparation for the heartbreak of psoriasis. All four of the girls became severely

ill and were advised to stop taking the herb. Three of the girls did so and survived, while the fourth continued taking the herb and died. When the herb was examined, it was found to be a complex mixture of leaves, acorns, dates, seeds, sticks, and general debris. The scientist investigating this case was quite a smart fellow, I think. He picked out the seeds, put them into a plant pot, grew them and identified the resulting plant. It turned out to be a toxic species, a Heliotropium species. Of course, this process takes some time to complete. This girl was killed by the same type of toxin that is present in comfrey.

An excerpt from a product information sheet is shown in figure 4. There is nothing toxic about this product: I am just using it as a typical example of material being sold. One point to note is the incredible complexity of the ingredients--Ma Huang, green tea, jujube seed--which are all mixed together. Note the rather typical mixture of terms here: some are mock Latin, not true botanical names, so they are of no help to the scientist, some are English, and some are Chinese, like the Ma Huang. There are some other typical aspects of this preparation. One is the appeal to ancient Chinese herbal wisdom, combined and enhanced by new technology.

FIGURE 4

BioLean is a synergistic fusion of ancient Chinese herbal wisdom enhanced by new technology and adapted to meet Western needs, with the power of a modern amino acid formulation.

INGREDIENTS: Capsules: L-Phenylalanine, L-Tyrosine, L-Carnitine; Tablets: Ma Huang, Green Tea, Schizandrae Berry, Rehmannia Root, Hawthorne Berry, Jujube Seeds, Alisma Root, Angelicae Dahuricae Root, Epemidium, Poria Cocos, Phizoma Rhei, Stephania Root, Angelicae Sinensis Root, Codonopoes Root, Encommium Bark, and Notoginseng Root.

Components in BioLean are 100% pure Chinese herbs and crystalline pure high grade free from amino acids.

This dynamic herbal and amino acid supplement is formulated to help your body burn unwanted fat, increase your energy level, and curb your appetite.

Many preparations combine an appeal to ancient wisdom with an appeal to modern technology. Some other characteristics typical of such preparations is the unspecific and global properties the product is supposed to possess. This material is supposedly used to burn unwanted fat, increase energy levels, and diminish appetite. In fact, it is sold as a weight loss remedy. And a final typical aspect of this preparation is the cost, which is \$95 for a 25-day supply.

A further factor is that, unlike manufactured drugs, there is no requirement for herbs to demonstrate safety or efficacy. I think one good

example of that is Laetrile or Amygdalin, which is touted as a cancer cure. It is a popular "remedy" in this country. Because of consumer pressure, the National Cancer Institute some years ago carried out an extensive and expensive testing of the efficacy of Amygdalin. It was found to be inefficacious in the treatment of cancer and also to present a hazard in that it releases cyanide, which can harm you. So Laetrile was, I believe, banned by FDA. But as a result of public pressure, more than half the States in this country have legalized the use of Laetrile within their borders. Along the Mexican-American border, huge clinics have been set up on the Mexican side for people to go to get their Laetrile. Of course, an additional risk of using such a preparation is that cases of cancer, which might otherwise be treatable by conventional methods, are not treated correctly. In fact, there have been a number of cases of young children dying because their parents insisted on Amygdalin treatment rather than on more conventional treatments.

Another factor in herbal poisonings is the persistent use of a plant known to be toxic. This is distressing to scientists where the scientific knowledge has been available for years, yet it is generally ignored. There are many plants--coltsfoot, comfrey, Petasites (I don't know the common name for it)--which are commonly sold in health food stores, even though there is much scientific evidence regarding their toxicity.

Figure 5

For example, the material shown in figure 5, which I call the "deadly clown" (due to its packaging) was sold as an herbal tea by a pharmacist in Arizona. It killed a young child. It turned out to be a Senecio preparation. This plant is commonly known as a thread-leaf groundsel and it contains similar types of toxins to those present in comfrey. These toxins are the ones that are of most concern to me in my laboratory research, which is why I keep referring back to them.

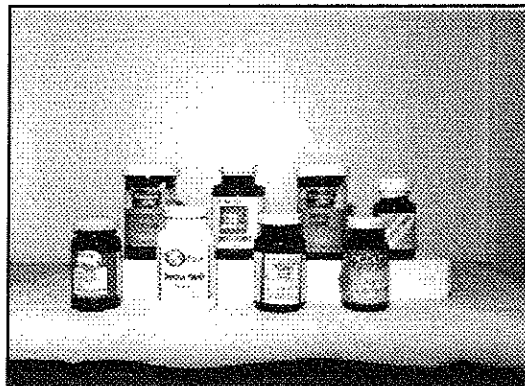


Returning to the comfrey pepsin capsules: these capsules have been implicated in a considerable number of poisonings because the alkaloids present have a cumulative effect. This is not the case with cyanide, for example. I can give you a sublethal dose of cyanide today and it doesn't kill you, then tomorrow you can take the same dose again without too much trouble. With these alkaloids in comfrey, this does not apply; the toxicity is cumulative and once you pass a certain threshold of total exposure, the chances of getting unspecific hepatitis or other problems are greatly increased. The

chances are increased with these kinds of preparations as compared to the use of comfrey tea by the quantities which you are expected to take. If you are using two or three capsules, it can add up to a large amount quickly.

Figure 6 shows a random sample of comfrey-containing capsules purchased in one health food store in Tucson. Considering the "truth in advertising" requirement, I particularly like the one called "Tox-EX". The sale of these materials are banned in Canada and Germany.

Figure 6



Further examples of other plants known to contain toxins include wormwood and coltsfoot. These plants can cause problems, if ingested in large amounts. For small amounts, there is probably not too much risk. These preparations are common in any health food store and you can expand the list of materials very readily.

Another problem with the use of herbs is the variability in chemical constituents of a plant. The botanical identification is not sufficient, unlike with a manufactured drug where you can establish a criterion of purity. Even if you can ensure that the plant is what it is supposed to be, you still have no assurance of its chemical constituents. In the old days, when digitalis leaf was used to treat heart conditions rather than the pure digitalis glycosides, the leaf had to be standardized in pigeon units--how much of the leaf it took to kill a pigeon--and the potency was adjusted to a standard.

The reasons why chemicals vary in concentrations in a plant depends on the time of year the plant is collected, the developmental stage of the plant, the part of the plant that is used, how the plant is collected and stored (such as I already mentioned with potatoes) and a number of other factors. So, with the plant, feverfew, which seems to be efficacious in the treatment of migraine, its effect is due to components called parthenolides. The Canadian government tried to establish a standard for the parthenolide content of feverfew so that the plant could be marketed as a headache remedy. The standard they chose was 0.2 percent. Feverfew samples imported from Europe have an average parthenolide content of 0.4 percent. The same species grown in North America had a parthenolide content of zero. There are obviously some geographic differences, which are not well understood. In both cases the plant was the botanically correct species, but in the one case it contained the chemical, and in the other case it did not.

To return to my favorite comfrey pepsin capsules, figure 7 shows three brands, like the soap commercials on TV, brands A, B, and C. The dotted areas show the level of total alkaloids, which are toxins. You can see that if you were taking brand C you are at much greater risk than if you were taking brand A,

but there is no indication either on the package labeling or in the material itself to indicate the level of exposure you are getting. Indeed, if a temporal analysis were performed on any one of these brands, there would probably be variation among them.

Part of the reason for the variation in the comfrey pepsin capsules is due to variation in the plant itself (figure 8). The roots contain considerably higher levels than the leaves. The last two bars on the right show the low range and high range levels found in roots. The young leaves contain the least and the mature leaves contain the highest amounts. If a person likes to drink a cup or two a week of comfrey tea and is using a tea prepared from young leaves, the risk is very slight. If a person is using a comfrey capsule or tablet preparation prepared from the root, taking it several times a day, the risk becomes proportionately much greater.

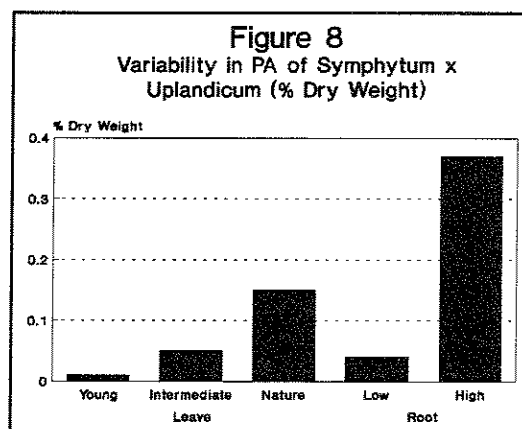
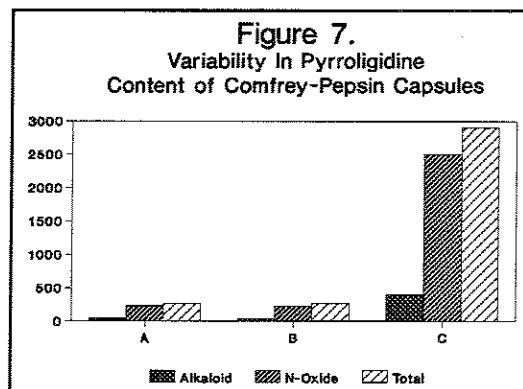


Figure 9 shows the variation in toxic alkaloid content of the leaves of *Senecio longilobus*, the same part of the plant collected from exactly the same site in Arizona over a four year period. This is the plant sold as gordolobo (see figure 5). There is a mean variation in alkaloid content throughout the year, from a low in April to a high in September. More important, the four-year range is enormous. If leaves are collected in April of a "low" year, you are at much lower risk if you make a tea from it than if you collected leaves from September of the "high" year. This enormous variation is typical for plant constituents.

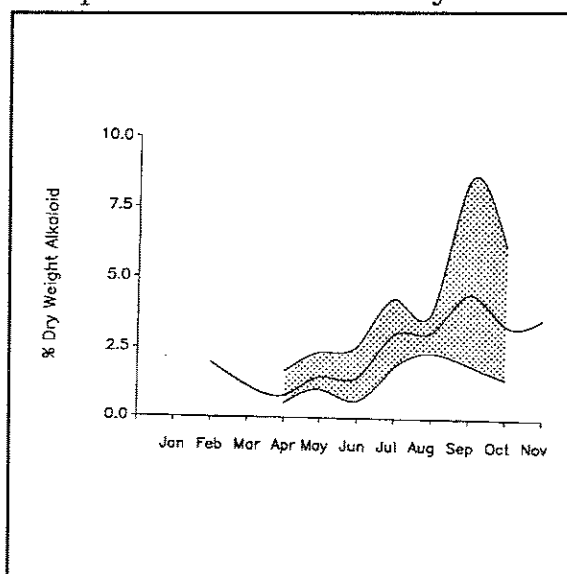


Figure 9

Another factor contributing to herbal problems is the difficulty of showing chronic toxicity. Plants that are acutely toxic and cause consumers to fall dead within a few hours, in general, are not marketed because you lose your customers very quickly. But to me, the plants that are of most concern are the ones that produce chronic toxicity, such as hepatitis, heart disease, or various kinds of neurological problems. The connection between these problems and exposure to herbs can be extremely difficult to establish because of their delayed nature. For example, many herbs contain hepatotoxins, but if an adult person comes down with hepatitis or cirrhosis, the doctor is liable to pass it off as caused by drinking, or not even to investigate the causes, but just treat the condition. So length of time between cause and consequence militates against establishing the mechanism.

Tobacco is a good example of this phenomenon. Tobacco was used heavily for several hundred years before people even began to suspect an association between smoking and lung cancer. It took many years of expensive research to establish that connection to the point where the majority of people believe it and even so there are probably still a considerable number who deny the association.

Another problem with herbs is the difficulties of doing dose calculations to investigate herbal poisonings. Trying to get samples of material that were actually consumed and performing the chemical analyses on those amounts is very difficult.

The public health problems associated with herbal use is indicated by a revealing study done in Sweden. Fifty-three patients with hepatitis of unknown cause were told to stop taking whatever herbs they have been using for a period of 6 weeks. After that 6 weeks period, 52 of the 53 had remitted their disease and had normal liver functions test results. So we can assume that the chronic use of herbs is responsible for a great deal of hepatitis. I think, in general, that herbal poisoning is like sin to a puritan; the more you look for it, the more you are likely to find it.

Another problem is adulteration. For whatever reason, preparations may contain constituents, which are not listed. For example, one preparation, Amborum special F, supposedly an all natural preparation imported into this country and Europe from the Far East, produced a number of cases of Cushing's Syndrome. When it was analyzed, it was found to contain betamethasone as the active ingredient, a manufactured steroid that does not occur in nature.

On the other hand, one survey of ginseng products on the market in North America--ginseng is a popular herb, which commands high prices--found that 60 percent of the samples analyzed contained little or no ginseng. To give you a third example, there was a tea sold in this country prepared from the decocainized leaves of the cocaine plant, Erythroxylon. The tea was sold as an aid in detoxification programs for cocaine addicts. According to addicts, it was successful in stopping the effects of withdrawal. But, when it was analyzed, this tea was found to contain exactly the same cocaine level as the un-decocainized leaves, so it was not surprising that it worked so well!

Figure 10 [not reproducible] shows the label of a preparation that I was contacted about last year. It is a Taiwanese product imported for treatment of numerous conditions, healing liver and kidney, lumbago, neuralgia, feet and knee cramps: the usual very non-specific and wide-ranging list of symptoms. It is sold as being all natural and at the top of the label there is an appeal to traditional preparations, but it is also prepared by "up-to-date modern scientific methods"; the same conjunction of the old and the new. There is a complicated list of ingredients in mock Latin. But, on analysis, this preparation was found to contain pharmacological levels of diazepam [valium], a manufactured chemical, that does not occur in nature. This is an adulterated product.

Another factor which I will skip over quickly is nomenclature. The language used by herbalists does not correspond to the language used by botanists or other scientists. There is not necessarily a one-to-one correspondence in the terms used by the two groups. This lack of common nomenclature can add to confusion in the scientific literature in that people investigating poisoning cases often believe the package information and they turn to a dictionary to translate what is written on the package into scientific terminology; thus, the report goes out with a spurious authenticity. For example, in one important case where a mother in Switzerland was taking a tea containing the same toxins present in comfrey throughout pregnancy, her child was born severely poisoned and died a few weeks later. The people who originally investigated this case translated the package information and called this a case of coltsfoot or Tussilago poisoning. They went on to report that they had found an alkaloid, which is not present in this particular species of plant. It took a great deal of work and supposition to sort out the resulting mess and even now we are not completely sure as to what the material was.

There are certain groups at high risk (table 2). What never ceases to amaze me is the extent to which some people immerse themselves into a kind of a herbal culture. One of the early cases of comfrey poisoning we investigated was a woman who had been taking a handful of the capsules every day for six months. An example of a heavy user is the one I discussed earlier of the woman who died after drinking a gallon of herbal tea daily for several days (see figure 1).

TABLE 2. High Risk Groups of Herb Users

- Chronic Users
- Heavy Users
- Those Using A Great Variety
- Babies
- Fetuses
- The Elderly
- The Sick
- The Malnourished or Undernourished
- Those on Chronic Medications

Source: Ryan Huxtable, University of Arizona, Tucson

Those using a great variety are not atypical. Table 3 shows a range of materials being taken by one young man on a daily basis. We wanted to know if any of them was bad. To my mind, this is a mixture more suited to a gourmet rodent than to a human. There was also a very complicated case reported in the medical literature a few years ago of a young woman who was taking on a daily basis 40 herbs, aspirin, propoxyphene, carisoprodol vitamins, and a bromelain mixture. She suffered abnormal menstrual bleeding. When this very complicated case was investigated, she was found to be taking nine substances that interfere with blood coagulation.

TABLE 3. An Example of Herbs Taken on a Daily Basis by One Individual	
Echinacea	Nettle
Violet Flower	Yellow Dock Root
Comfrey Root	Aloe Capensis
Bayberry Bark	Cortex Cinchonae
Catnip	Bitter Orange
Calendula	Peel
Red Clover	Glentian Root
Dandelion Root	Cola Nut
Burdick Root	Myrrh
Blessed Thistle	Frankincense
Chickweed	Calamus Root

Source: Ryan Huxtable, University of Arizona, Tucson

Babies are more vulnerable because they lack the detoxification systems in the liver that adults develop. Figure 11 [not reproducible] shows one of our cases of a child in Tucson, who was suffering from hepatitis that resulted in chronic cirrhosis as a result of a herbal tea her mother gave her. I think one very good example of the difference between adults and children is given by caffeine, a very common material we are all exposed to. In adults, the half-life of caffeine is about 4.5 hours, which means that 4.5 hours after an individual is exposed to caffeine in the form of a cup of coffee or whatever, half the caffeine has cleared from the body. In newborn babies, the corresponding half-life is 80 hours and in premature babies well over 100 hours. A similar pattern applies to many of the other chemicals to which we expose ourselves.

Let me just finish with the malnourished. Figure 12 [not reproducible] shows a case from the West Indies of a severely malnourished child, who was also often given herbal teas containing similar components to those found in

comfrey¹. I think it is pretty obvious that he is seriously ill. The line marks the margin of the liver indicating that he is suffering from hepatomegaly.

I will stop there. I thank you for your attention.

STERNBERG: Thank you, sir, for a very comprehensive discussion of the risks of herbs. I am sure that there will be questions that can be addressed later. Donna will introduce the rest of the speakers.

PORTER: Next, we will hear from Michael Taylor, who is the Deputy Commissioner for Policy at the Food and Drug Administration. He will talk about some FDA policy activities on dietary supplements, including the Federal Register notices published last week.

TAYLOR: Thank you. I appreciate CRS convening this seminar, Donna, and I am glad to be here to talk for just a few minutes about some of FDA's perspectives on the issue of regulating dietary supplements. I want to talk first about the big picture concerning diet and health and some of the things that FDA has done, the shifts that have occurred in that area. Then I will talk about how the insights about diet and health have been translated into public policy through the Nutrition Labeling and Education Act of 1990 and the things we're doing under the Dietary Supplement Act of 1992 with respect to dietary supplements. Finally I will close by emphasizing FDA's goals and the major issues we view as part of the legislative discussion that is currently going on.

I think we are all well aware of the very major and important insights that scientists gained during the 1970s and 1980s concerning the link between diet and health. Diet is no longer seen by scientists and public health officials as just the source of nutrients that are essential to maintain life, but rather diet is being linked in very major ways to health promotion/disease prevention, providing both opportunities to enhance our health and also opportunities or risks arising from diets that are not properly balanced.

The major threads of this science have to do with macronutrients in the food supply. Fat is a risk factor for cancer and cardiovascular disease, so lower fat diets have been talked about as a way to reduce the risk of those chronic diseases. Other macro-constituents of the diet are also being seen as providing potential benefits in a health promotion/disease prevention sense. Diets high in fiber and low in fat are being recommended as part of the *Dietary Guidelines* related to risk reduction. Because of their fiber and antioxidant vitamin content, fruits and vegetables are being linked to reducing the risk of certain diseases.

This scientific insight has been translated into a major shift in public policy over the last five years. FDA and, I think, the scientific community have shifted

¹ Huxtable, R. Comments on Human embryotoxicity of pyrrolizidine-containing drugs. By Roulet, M. et al. *Hepatology* Elsewhere 9:3, 1989. p. 510-511.

from a skepticism, and some people would call it a bias or a hostility, during the 1970s and early 1980s, with respect to the use of disease-related information on food labels to promote the sale and consumption of various foods. I would certainly say, as an FDA official, that there was at least skepticism and, indeed, imbedded in FDA's understanding of the law through that period, a prohibition on using disease-related information to promote food products.

The science concerning diet and health led to a fundamental shift in public policy and FDA's thinking on this subject. This new thinking is embodied in the Nutrition Labeling and Education Act, which for the first time authorized FDA to evaluate and approve for use on food labels disease-related claims, information whose purpose is to promote the consumption of various foods to achieve a disease-related benefit. This NLEA directive came along with the mandatory nutrition labeling requirements, and the new provisions requiring definitions and consistent meanings for content claims, like low-fat and no cholesterol. The health claims provision was part of a whole package of measures in NLEA that recognized that, if certain scientific rigor is observed, the food label can be a critical source of information for consumers to use to construct healthier diets and improve their health.

Frankly, it was no small thing for this shift to take place and it is something that we ought to recognize and appreciate because we are talking about authorizing companies to use disease-related information to market products for the first time. FDA thinks that this change has enormous potential value for public health.

FDA has implemented the health claims provisions of NLEA with respect to foods in the regulations that we promulgated in final form in January. I'll explain in a moment why we did not include dietary supplements. We have approved a total of seven claims concerning the relationship between diet and health. They involve for the most part these basic claims, the insights of which have developed over the last decade or so concerning fat and cancer, fat and cardiovascular disease, fiber-rich diets reducing the risk of cancer and heart disease, calcium and osteoporosis, and sodium and high blood pressure. We think that authorizing claims have enormous value to improve public health because consumers will be able to rely on these claims to construct healthier diets.

The issue of how this new set of scientific insights should apply to dietary supplements was controversial, to say the least, when NLEA was enacted in 1990. I think those of you who were involved in that debate know how controversial it was. But in that debate, while Congress arrived at a standard for disease-related health claims for foods in conventional form, it was unable to arrive at an agreement regarding the scientific standard that should apply for disease-related health claims regarding dietary supplements. Congress said that for conventional foods, a disease-related claim could be approved if there was significant agreement among scientists based on the totality of the scientific evidence that the claim is valid. Congress also said, however, FDA was to promulgate a regulation determining the standard for disease-related claims on

dietary supplements. It was our rulemaking in carrying out that charge from Congress that, I think, as much as anything has triggered the debate and the controversy that has given rise to the current legislative consideration of possible changes for dietary supplements in the law. When FDA examined the issue of the scientific standard that should be applied to disease-related claims on dietary supplements, the agency was unable then, and as those of you who have read our proposals from last week know, is still unable to discern a scientific or public health rationale for having a different standard for disease-related claims on the nutrients in dietary supplement from the one Congress had established for disease-related claims in conventional foods. A common example is, why should the vitamin C in a capsule be subject to a different scientific standard for disease claims than the vitamin C that is present naturally in orange juice or broccoli or any other conventional food? Again, the agency found no scientific or public health basis for setting a different standard.

This standard was first embodied in a rulemaking proposal that FDA published in November of 1991, which was the subject of considerable comment and further consideration by FDA. Then it was embodied in the final rule on this issue in regulations that FDA had developed during the summer of 1992 leading up to the anticipated statutory deadline under NLEA for issuing final rules by November of 1992. It was no secret that FDA was going to reaffirm its view that dietary supplements should be subject to the same standard as conventional foods. I think, it was in anticipation of that rule, in part, that a successful effort was made at the end of the last Congress to pass the Dietary Supplement Act of 1992.

Again, just to review for those of you who have not spent as much time on the subject as the rest of us, that Act placed a one-year moratorium on FDA's implementation of NLEA as it applies to dietary supplements for the purpose of allowing FDA, indeed, the Dietary Supplement Act requires FDA, to go through the rulemaking again to establish the scientific standard to be applied to health claims on supplements. Clearly, the proponents of that legislation also anticipated that there would be, and indeed called for, a congressional review of the proper regulatory framework to be established for dietary supplements.

So the proposals that FDA published last week were published as part of the process of completing FDA's implementation of the Nutrition Labeling and Education Act of 1990, but it is being done under a moratorium established by the Dietary Supplements Act of 1992 and deadlines imposed by that Act. We were required to publish those proposals by June 15 and we met that deadline. FDA was also required under the Dietary Supplement Act to issue final rules by December 15, and we are committed to doing that as well. There is an unusual feature of the Dietary Supplement Act, although it is not any longer unprecedented since it was first a feature of NLEA. It is the provision that provides that, if FDA is unable to meet the December 15 deadline for final rules, FDA's proposed rules that were published last week will by operation of the statute become the final rules.

The proposed rules that FDA published on dietary supplements last week cover the gambit of NLEA requirements. They include not only the standard and procedure for establishing additional health claims, but also the rules governing how mandatory nutrition labeling and the nutrient content descriptor rules of NLEA will apply to dietary supplements. It is fair to say, subject to some amplification and perhaps the differing views by others here, that the issues in the proposed rules on nutrition labeling and content claims are not as controversial, and have not been a part of the public debate in the same way that the standard for health claims has been.

Along with these three proposed regulations, FDA published a fourth companion document, that is really in furtherance of the review that the Dietary Supplement Act contemplated and FDA had been undertaking for some time on how the agency regulates dietary supplements overall. It was an Advanced Notice of Proposed Rulemaking (ANPR) so it did not contain any proposed rules per se, but rather raised a number of issues concerning how FDA should be regulating dietary supplements. The ANPR notice, which I would commend to all of your reading, attempts to organize the universe of dietary supplement products into four categories--vitamins and minerals, amino acids, herbal preparations, and then other products that complete the universe of dietary supplements. In that document, FDA tries to provide factual information about the array of products, and outline the public health concerns the agency has, which vary a great deal depending upon the category of the product. Then the document raises specific questions or issues on which FDA would like public comment as we devise a strategy or consider any changes in the way that we might regulate dietary supplements in the future.

I would just like to take a minute to summarize our goals with respect to dietary supplements, which I hope are evident to the reader of the ANPR that I just mentioned. We have said repeatedly and will continue to say, that the agency really has three goals with respect to dietary supplements. I doubt these goals are in dispute at all among anyone at this table or others we talked to about these issues.

The first goal is safety. I think everybody agrees that the products consumers purchase out in the marketplace should be safe. We have tried to keep the issue of safety in a proper perspective, pointing out that the vast majority of the dietary supplements in the marketplace consist of vitamin and mineral products being sold at potencies, including those with potencies well above the recommended daily allowance, that pose no safety concern to FDA. These products are being marketed in ways that make these alternatives, the nutrients in a supplement form available to consumers, and present no public health or safety concern to the agency. The ANPR outlines some areas in which we do have varying kinds of safety concerns with dietary supplements. Unfortunately, I missed Dr. Huxtable's presentation, but I assume he identified some of the circumstances in which herbal products have been associated with toxicity. FDA has an obligation when there are overt hazards in the marketplace to take action to remove those hazards. Again, I don't think

anybody disagrees with that goal, or those kinds of actions by FDA. The agency has taken some action in this area.

The more difficult safety concern that we have about herbal products, and to some extent about products in the amino acid category, is the circumstance in which the agency is not able to prove hazard affirmatively, but knows enough about the materials to indicate that there are safety questions reasonable scientists would ask about the material contained in these products. The question is what body of scientific evidence or information should a company have or know exists before making the decision to market a product for consumers to purchase and ingest? FDA thinks, and indeed it is a principle that we see imbedded in our current law, that when a food ingredient or mixture of ingredients are put into a product for sale to consumers, the company has an obligation to have a scientific basis for knowing that product is safe, under the conditions of use. No substance is absolutely safe under every circumstance. Any product taken to excess, including many that are otherwise regarded as safe, can present safety concerns.

So the question we are trying to address is what body of evidence should be available to support the safety of these products and how can we take into account the realities of the marketplace and the limitations of science to achieve a greater assurance about the safety of these products than we currently have today? The amino acid category is focused on from a safety standpoint in this document. In 1989 we had the L-Tryptophan episode. In 1990, a group of outside scientists operating under the Federation of American Societies for Experimental Biology (FASEB) conducted a scientific review of the safety data available on all currently marketed amino acid supplements for the agency. FASEB reported that while there are some amino acids that do not raise particular concerns about safety, there are others for which there are questions. But FASEB also said that in no case was there an adequate scientific foundation for setting safe upper intake levels for any of the amino acid supplements on the market today.

We think that particularly for products that tend to be promoted in a "more is better" kind of way, most predominantly to athletes and body builders encouraging high intake, we ought to know how much is too much. In the ANPR, FDA invites the industry to provide the agency with scientific data to help us determine how much is too much and the conditions under which these products can be safely marketed. So safety is a primary goal and always will be a primary goal of FDA.

The second goal is that the products are properly labeled. There are a number of issues that can be included under that heading, but primarily we believe that consumers ought to get what the label says they are getting. The product ought to be produced in a way so that if it contains 500 milligrams of calcium, you get 500 milligrams of calcium and indeed the product actually dissolves so that your body can absorb it instead of it just passing through the system, as we have seen happen in some cases. Proper labeling in our mind is also related to safety because often, indeed always, safety is a function of dose.

Products that are safe at one level of intake may not be safe at a higher level, so there ought to be adequate directions for safe use on the package. Some supplements are labeled in a way that instead of saying "take no more than three capsules per day", say rather "take three or more". We need to understand that labeling is related to safety, have a better factual basis for knowing the safe intake levels and have it reflected in labeling.

The third goal is that any disease-related claims that are used to promote products be scientifically supported. That is the basic principle that is built into our current law with respect to drugs and foods. A whole section of the law governs how we evaluate disease treatment claims with respect to pharmaceuticals. The Nutrition Labeling and Education Act governs how the agency is to evaluate disease-related claims for foods. We think it is critical that if a disease-related claim is going to be made, the applicable scientific standard is met. We think that it is appropriate that there be scientific standards so that disease-related claims are substantiated.

Finally, let me just emphasize a couple of points that we think are not properly characterized in this debate because they reflect some misunderstandings about FDA's objectives. This debate is sometimes portrayed as concerning whether consumers will have access to vitamins and minerals. The suggestion is that FDA has plans for, indeed some would argue that it is inherent in the rulemaking proposals that I have just described, an outcome that will deprive consumers of access to vitamins and minerals. Nothing could be further from the truth. There is absolutely nothing about FDA's plans that is going to affect consumer access to that large array of vitamin and mineral products on the market. NLEA has no bearing on access to a product; it bears only on when disease-related claims can be used to market the product. So, the debate should not be conducted in terms of should consumers have access to safe vitamin and mineral products. Of course they should, and nothing FDA is doing will affect their availability.

It is also the case that nothing FDA is doing is intended to affect the marketing of safe products in the herbal category that are being marketed without disease-related claims. For those who come from a culture, a tradition, or decide for their own personal reasons, whatever they might be, that they want access to safe materials from the herbal medicine tradition, they will still be able to use these products for their own purposes based on information available to them. Again, the debate about standards for health claims, or disease-related claims has to do with when the marketer can use that information to promote the product. FDA is not out to take away safe herbal preparations. We do believe that current law applies certain scientific standards, if companies want to use disease-related information to promote those products.

So I guess really what we would hope and are looking forward to having at the heart of the legislative debate in the coming months are these two basic questions. What should be the standards governing a company's use of disease-related information to market products? And what obligation should companies have to establish the safety of their products? These basic questions are the

ones we think need to be grappled with. Obviously, it is up to Congress in the end to establish the basic standards and define the role for government regulatory agencies in answering these questions and assuring that consumers' expectations about the safety of products and the validity of claims are being met.

Again, we just think it is really constructive that CRS and Donna are sponsoring this sort of opportunity to discuss these issues. We think that the public and the legislative debate that we're embarking upon is very constructive to educate the public and I think allow the public policy process, including the legislative process, to either reaffirm the principles imbedded in current law or arrive at some new principles. It is important that it be an informed debate, and FDA obviously will live happily with whatever Congress decides to do. So, again, thank you, Donna. I look forward to the discussion.

PORTER: Now we have Bruce Silverglade who is the Legal Affairs Director of the Center for Science in the Public Interest.

SILVERGLADE: Good morning. Let me tell you a little bit about CSPI for those who may be unfamiliar with our organization. CSPI is an independent, non-profit consumer group. We were founded in 1971 and are now supported by about 600,000 Americans across the country who subscribe to our *Nutrition Action Health Newsletter*. We accept absolutely no money from any segment of American business, or the government. When consumer groups come in to your office--there are consumer groups and there are consumer groups--ask the lobbyist who claims to be representing consumers, when the group was formed? Who is on the board of directors? How are they funded? Do they accept money from the dietary supplement industry? Those questions are very important because there are lots of "consumer groups" on Capitol Hill today.

In the past, CSPI has been involved with several major pieces of health-related legislation, including the Alcohol Warning Label Act, the Organic Standards Act, which was part of the 1990 Farm Bill, and the Nutrition Labeling and Education Act. We have become involved with the dietary supplement issue both as a result of our work with NLEA, which covers dietary supplements, as well as our continuing concern about the relationship between diet and disease, such as heart disease and cancer.

This is a very impressive showing here today with about 15 percent of congressional offices represented. I think that is a very significant number because 15 percent of Congress can influence decisively any floor vote on almost any bill. Although I have never been a courtroom litigator speaking before juries, I feel in a sense I am speaking before a jury today because you will take back information, conclusions and recommendations to your members so that they can cast a decisive vote on this issue.

So, let me get right into the substance of my remarks, which is to describe CSPI's position on dietary supplements, explain the background of the Nutrition Labeling and Education Act of 1990, discuss how the supplement industry is

generating grass-roots mail on this issue, and finally, turn to a brief analysis of the Hatch-Richardson legislation.

First, our position on dietary supplements. CSPI supports the right of consumers to purchase safe, quality-manufactured and appropriately labeled dietary supplements. We recognize that scientific studies point increasingly to the potential benefits of many supplements and CSPI reports on these studies in the pages of *Nutrition Action Health Newsletter*. We certainly believe that consumers should have the right to purchase such products. However, as more and more consumers come to rely on dietary supplements to protect their health, it is certainly more important that health claims on supplement labels be dependable.

The Nutrition Labeling and Education Act sets up a framework for FDA to follow when approving health claims for both foods and dietary supplements. NLEA was enacted by Congress in 1990. It passed by unanimous consent in the Senate and under the Suspension Calendar in the House, which means all of your offices supported NLEA. What you are being asked to decide this year is whether you should repeal a portion of that Act by giving the dietary supplement industry an exemption from the law.

Happily, the food industry is complying with NLEA, so the misleading health claims from cereal boxes and other food labels have basically disappeared from the marketplace. The dietary supplement industry, however, was granted a one-year exemption from NLEA last October and, as a result, misleading claims continue to plague the shelves of health food stores. This situation is very unfortunate because it undermines the credibility of well-supported health claims on dietary supplements.

At this point, I would like to show a few slides. The first slide [not reproducible] is from Quaker Oats, which used to have a health claim on the label that stated it could help reduce cholesterol. This claim has now been taken off the label and the product currently has no health claim. But on January 8th, FDA approved a health claim for products of this sort that are high in soluble fiber. Quaker is in the process of redesigning its labels to comply with the new regulations on health claims. Kelloggs used to make a product called Heartwise with psyllium, a grain that was supposed to reduce the risk of heart disease. FDA had questions about the statement and Kelloggs changed the name of its product from Heartwise to now called Fiberwise (slide-not reproducible). There is no implicit heart disease claim now as a result of FDA action. You will see that all FDA and NLEA are asking is the same treatment for supplement manufacturers.

This next slide [not reproducible] is a good example because the box of Kelloggs Rice Krispies used to say "now with energy releasing B-vitamins" and the back of the box described how B- vitamins provided energy. That claim is now off the box of Kelloggs Rice Krispies. It is still on the box of B-vitamins, though, pictured on the slide here.

CSPI is just asking for the same rules for supplements as for conventional food industry. What other kinds of health claims are being made by the supplement industry? You can walk into the health food store on the corner or in your neighborhood in the suburbs in Virginia or Maryland where we shopped for these products [displayed on the table], and you can find Mental Wisdom, Memory Booster, and Brain Pep. Or Kidney Flush; if you have a problem with your kidneys, we hope you are seeing a doctor and not buying this product. If you have a problem with your eyesight, try Ocu-Care. Slim Tea for dieting. Then we have Virle-actin and Manhood Plus. Guess what that is for? This is an interesting case because this company makes three products: the first is for Jet Stress (figure 13), another called Runner's Edge and a third product called Cell-Guard (figure 14). All three products contain the exact same ingredient--wheat sprouts. And this product, Happy Camper, promises to give you the spirit of the 1990s; it is an "attitude food".

The Nutrition Labeling and Education Act was a landmark consumer protection law, which would require the labels of those products to be changed. Prior to the enactment of NLEA, all health claims for foods and dietary supplements were considered to be illegal as unapproved claims for new drugs. But as a result of the passage of NLEA, dietary supplement producers will for the first time be legally allowed to make health claims on products when they have a substantial degree of support within the scientific community.

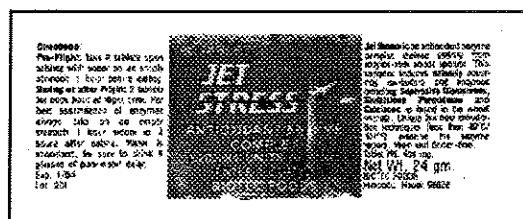


Figure 13

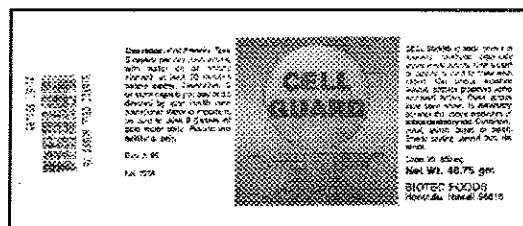


Figure 14

However, many segments of the dietary supplement industry, including the Nutritional Health Alliance, Citizens for Health, the Life Extension Foundation, and others have charged erroneously that the Nutrition Labeling and Education Act allows FDA to ban the sale of many types of supplement products. Congressional offices are getting a tremendous amount of mail because the industry has told the public that FDA is using NLEA to ban the sale of these products. What FDA is doing is saying that these health claims, which are not supported by significant scientific agreement, have to come off the labels.

We have just heard the Deputy Commissioner of FDA say that. *The New York Times* published a story last August that repeated the industry allegations, but the paper issued an unprecedented front page retraction of those allegations. Notwithstanding that the allegations are wrong, groups like NHA and Citizens for Health are still urging consumers to write their elected representatives in Washington in support of legislation that would repeal NLEA.

This next slide [not reproducible] is from the Nutritional Health Alliance's "Health Freedom Guide: Campaign '93". It says "Write to Congress today or kiss your vitamins good-bye." I just hope we will not continue to see false statements like this one, that play a cruel hoax on the American public. There are posters up in health food stores around the country that say basically the same thing--send this model letter about Congressman Richardson's bill or Senator Hatch's bill to your Member of Congress or kiss your vitamins good-bye. FDA is not banning vitamins. What the Richardson-Hatch bills would do is prevent FDA from prohibiting the type of misleading claims we have just seen.

A newsletter published by the Nutritional Health Alliance states "company and store owners should explain to employees the importance of grass-root communications to Congress. Retailers must immediately begin asking customers to call Washington and tell Congress to keep supplements available." And of course, a model letter is provided where this information is distributed.

The executive director of the Nutritional Health Alliance is also the chief executive officer of Nature's Plus, a major supplier of dietary supplements to health food stores. Nature's Plus makes Ultra Hair which is advertised as "containing essential nutrients that can help reduce the risk of hair loss". And complete with Manhood Plus and the Virle-actin, the company completes its product line with Ultra Hair (figure 15) and Ultra Male (figure 16). Ultra Male is made from the freeze-dried prostate glands of bovine, either from bulls or steers, I guess. But there is Ultra Female with freeze-dried ovaries, which come from a cow for the women. And then there is Source of Life, which guarantees an instant boost of energy, and so on, and so on, and so on.

In our view, the industry is playing a cruel hoax on the American public. The same members of the industry that sell products that are supposed to implicitly improve sex drive or prevent hair loss are making deliberate misrepresentations about FDA policy, and the effect of NLEA, simply because they stand to lose hundreds of millions of dollars a year if they are forced to remove shaky and downright dishonest health claims from the labels of their products. After all, who would buy Ultra Male, if it was labelled accurately as prostate glands?



Figure 15

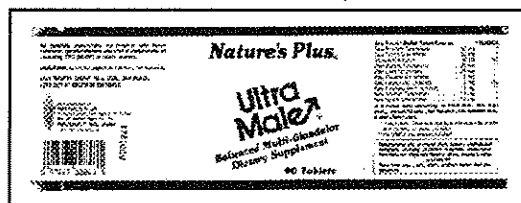


Figure 16

I would now briefly like to turn to the pending legislation and describe more specifically our concerns. More than 17 national public health and consumer organizations have written Representative Richardson and Senator Hatch to express opposition to their bills. The CSPI letter, which is available as one of your handouts, has been signed by the American Association

of Retired Persons, the American Cancer Society, the American Heart Association, the American College of Physicians, the American Home Economics Association, the Association of Schools of Public Health, the Consumer Federation of America, the National Consumers League, the National Council on the Aging, and a number of others. Why are we all so concerned? Well, basically the Hatch-Richardson bills would provide consumers with much less protection against unsafe dietary supplements and misleading labeling claims than is currently provided under NLEA and the existing food safety provisions of the Federal Food, Drug and Cosmetic Act. The bills would also make it extremely difficult for FDA to take prompt enforcement actions against manufacturers of potentially unsafe or improperly labeled products.

With specific regard to safety, the bills would make it more difficult for FDA to take action because it reverses the burden of proof as to who has to show the product is safe or dangerous. On health claims, the bill repeals the NLEA's requirement that claims be supported by significant agreement within the scientific community. The Hatch-Richardson bills substitute a weaker legal standard that would allow supplement manufacturers to make practically any health claims they want, including claims supported by a few inconclusive studies. As a result, these bills are quickly becoming known on the Hill as the "Snake Oil Promotion Act". If they become law, they will frustrate the nutrition education efforts of the Department of Health and Human Services, the Department of Agriculture, and private health and consumer organizations.

The fact is that under the system set up by the Hatch-Richardson bills, FDA could not police the marketplace effectively. That is why NLEA was passed in the first place because products like the ones I showed slides of are still on health food store shelves.

Our biggest concern, however, is that if these bills become law, it will become increasingly difficult for consumers to distinguish between products that make well-supported health claims and others that claim a world of health benefits, but deliver only broken promises. Since some supplements are truly beneficial and important for health, it would be a pity if we end up throwing the baby out with the bath water because the public gets frustrated and confused about who is selling them a bill of goods and who is selling them a product that can really help. The freedom to choose one's own form of health care isn't worth much unless it is an informed choice and a choice that is free of the misleading claims that plague the aisles of health food stores today.

What should Congress do? I think there needs to be some action. I think you have heard some of the concerns raised here. CSPI supports legislation that would ensure the availability of safe, well-manufactured and honestly labeled supplements. We have drafted legislation, which is available as a handout, entitled the Dietary Supplement Consumer Protection Act. It calls for further research on the potential benefits of supplements. It would set up an advisory committee to guide FDA with supplement regulation. It would ensure that FDA has sufficient authority to make sure that supplements are manufactured safely and in accordance with appropriate quality standards. We think passage

of this type of legislation is all the more important as consumers turn in greater numbers to using supplements.

Let me conclude by going back to a point that I mentioned at the beginning. There are so many congressional offices represented here that I feel like this is a jury where you can cast the decisive vote. As a jury, you have to decide who to believe; that is what juries in trials really do, they decide who to believe. Do you believe the people that are selling products, like the ones here on the table, and in the slides we showed? I just noticed also that the National Nutritional Foods Association statement has an appendix attached, which says "there are no deaths from herbs in the last seven years". Dr. Huxtable has cited numerous instances of deaths from herbs. So, who do you believe, the industry that says there are zero deaths or an independent scientist? Thank you.

PORTER: Next, we will hear from Martie Whittekin, who is the President of the National Nutritional Foods Association.

WHITTEKIN: While they are setting up the projector, I want to thank Donna and CRS for convening this seminar and for your diligence in sitting here so long to finally hear the industry's side of the story. I am hoping that as good jurists, you know that you haven't completed your homework yet, if you leave here without hearing the consumer and industry side of the story because so far we have only heard the allegedly grim and scary side of the argument. I would like for you to have time to consider other important factors. Of course, as CSPI stated, letters that were sent to your offices on the Hatch/Richardson bill were letters consumers were encouraged to write. People out in the heartland don't just become inspired out of the blue to write letters, if somebody doesn't give them information about an issue. If your offices received mail on the CSPI bill, it was because CSPI encouraged their readers to write you.

In that we only have limited time and I am going to be followed by Steve McNamara addressing some of the legal issues, I would like for you to please read the speech that I would have liked to have given, if there had been time. It has a lot more substance on some issues. Included is a Yankelovich survey on the American public's opinion about this issue, showing that 89 percent support our position (figure 17). Of course, you are here representing representatives of the public who take care of their constituents hopefully not in a narrow paternalistic way, but by listening to their concerns. They are speaking more clearly than any of the "consumer group" feedback that you get. CSPI does a very nice newsletter, which a lot of NNFA companies, my stores and customers subscribe to because it has a lot of useful information. That does not mean that subscribers to the newsletter endorse every position that CSPI takes, especially if the reader has gotten only half of the story.

The safety information that Mr. Silverglade referred to is taken from the government's own statistics. The poison control centers have not even needed a category for herbs. There may be an isolated unreported case, where somebody uses a product to great excess or does it in a really inappropriate way. For example, if you feed herbs that you don't know anything about to an infant, you obviously are not a rocket scientist. This chart is not to say that somebody somewhere has not died from herbs (figure 18). A lot of the cases Dr. Huxtable presented are pulled from foreign data or from foreign products and noncommercial products. I don't know how they got past FDA's import restrictions, and into the country. There may be an occasional death from some bizarre usage, but I think the safety statistics on supplements speak pretty well for themselves. They have an enviable safety record.

FIGURE 17. Public Opinion Survey: Americans & Dietary Supplements²

Conducted by Yankelovich Clancy Shulman on September 10-13, 1992. Interviews with 502 adult Americans were conducted by telephone. The sampling error is four percent.

1. Do you personally use vitamins, minerals or herbs on a regular basis?

Yes	46%
No	53%
Not sure	1%

2. If scientific evidence shows that vitamins, minerals and herbs are safe and can help prevent diseases, do you think vitamin manufacturers should be able to make truthful health claims for their products, or not?

Yes	85%
No	5%
Not sure	10%

3. If scientific evidence shows that vitamins, minerals and herbs are safe and can help prevent disease, do you think people should have to get a prescription from a doctor to buy these nutritional products, or not?

Yes	13%
No	82%
Not sure	5%

4. As long as vitamins, mierals, and herbs are safe and beneficial, do you think people should be able to choose the strength or potency of these nutritional products?

Yes	63%
No	27%
Not sure	10%

5. Do you agree or disagree with this statement: "Consumers should be able to purchase dietary supplements, and companies should be free to sell these products, so long as the labeling and advertising is truthful and non-misleading and there exists a reasonable scientific basis for product claims?"

Agree	80%
Disagree	8%
Not sure	3%

6. Do you think the Food and Drug Administration should be able to classify vitamins, minerals, and herbs as drugs solely because a truthful health claim is made in the product's advertisement or on its label?

Yes	24%
No	68%
Not sure	8%

7. Where safety is not an issue do you think the FDA should or should not be allowed to classify vitamins, minerals, and herbs as drugs solely because of a nutritional product's strength or potency?

Allowed	22%
Prevented	70%
Not sure	8%

²NHA. Nutritional Health Alliance. Box 267, Farmingdale, NY 11735. The National Health Alliance is a nonprofit coalition of consumers, health care professionals, natural products retailers and dietary supplement manufacturers.

FIGURE 18. Comparative Causes of Death³

Annual Average

Adverse Drug Reactions	60,000-140,000
Heart Attacks Preventable w/Vitamin C	75,000
Automobiles	23,856
Food Contamination	9,100
Boating Accidents	1,064
Birth Defects, Preventable w/Folic Acid	500
Charcoal Briquettes (Carbon Monoxide)	34
Household Cleaners	24
Lawnmowers	15
Auto pesticide poisonings	12
Hair dryer accidents	10
Accidental Iron Poisonings	6
All Plants (house plants, etc.)	1
Vitamins	0
Uncontaminated amino acids	0
Commercial Herbal Products	0

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, March of Dimes, Consumer Product Safety Commission, FDA Reports, National Highway Traffic Safety Commission.

If you look at an average year, the number of casualties from the hazards of everyday life put it in perspective. There are a few unfortunate tragic instances--look at charcoal briquettes. Who would think of charcoal briquettes as a major health hazard? We know that drugs have toxic side effects, but look at the staggering toll. You have to put herbs and other supplements in an overall frame of reference to appreciate the extreme safety problem of supplements.

FDA admits that most of these supplements are safe. CSPI admits that most of them are safe, quoting from their newsletter, and the book entitled *The Right Dose*, written by Patricia Hausman, a nutrition scientist who was formerly an editor of CSPI's *Nutrition Action Newsletter*. I don't want you to leave here feeling afraid of nutritional supplements. On balance, they are very safe products. It is not a problem that really confronts people on a day-to-day basis.

There is a lot of talk about the herb, comfrey, which is a really interesting case as far as I'm concerned. I have been in the business about 11 years and when I first started, comfrey was widely available. After some scientific and anecdotal reports started appearing, indicating that there were problems with

³ Note: items highlighted in bold are food- and drug-related causes.

comfrey in part because a few companies were selling the root, which is stronger than the leaf, all the industry groups (the National Nutritional Foods Association, the American Herbal Products Association, the American Botanical Council, and the Herb Research Foundation) sent out advisories warning members to stop selling comfrey just to be on the safe side. Comfrey is not for sale in my stores, but I think you probably can find it for sale somewhere because to the best of our knowledge, although FDA has studied comfrey for years, it has never sent out an advisory memo. It is not necessary for FDA to sue somebody to get a product off the market. Our industry listens. If there is even a moderate concern based on sketchy evidence, and I think Mike Taylor would have to verify that, we act very fast. There is another herb that FDA is looking into now and while they are, we have already taken it off the shelf and will not be selling it until we hear otherwise.

We are in this business because we want to help people. And 99 percent of the people in this industry are not the ones that sell marginal products that provide the catchy names that make such good news stories. The ones that are fun for show and tell may even be good products, but they are not typical of the products sold in the stores. We sell products to help people; that is the industry's primary interest.

Concerning germander, I have not been able to find anybody in the business who even knows about this product. It is apparently a problem in other countries. Lobelia in excess makes people vomit so it makes no sense to put a lot of it in your product. But it has had OTC approval as a drug to stop smoking, so it is not an illicit product. I am amused when CBS News, CSPI and others report a scare tactic about chamomile tea. It is extremely safe. Chamomile is licensed to be sold in virtually every country on the planet. Critics say that it is related to ragweed. Well, that is a very theoretical concern because there have been exactly five cases in all of recorded history of any kind of allergic reactions to chamomile taken internally.

There are a lot of reactions to some other products. For example, we see reports of food-related complaints to FDA, and 80 percent of them are about aspartame. Maybe we ought to be talking about that artificial sweetener, if we want to be talk about a good use of agency resources (figure 19). The "all other" category here includes food poisoning, which accounts for in excess of 9,000 deaths a year, a very significant number. So if food poisoning that comes in that category along with such problems as MSG, shellfish, dietary supplements, and everything else, supplements can't be a real problem even from a complaint standpoint.

FIGURE 19.
ADVERSE REACTIONS

% Of Complaints to the FDA

Aspartame (NutraSweet ®): 80%

Sulfites: 15%

All other*: 5%

*Includes food poisoning, MSG, shellfish, peanuts and apparently dietary supplements.

I know it is not nice to use somebody's own quotes against them, but I can't resist. From a current magazine, Dr. Huxtable is quoted as saying "In nearly all of the cases I have seen of people injured by herbal teas and that is three or four per year, they were drinking huge amounts, say seven to eight pints a day (about a gallon), the casual user isn't likely to run into trouble." And I would have to say that users of herbal teas tend to be on the very fringe of supplement users because they have to do a lot of reading to know about those products. This quote brings up a point that was mentioned earlier about instructions. The industry could not agree more that we would like to have on every product all of the applicable information. Benefit information should be allowed. Some of these products are herbal remedies that go back a thousand years, and they don't need double-blind cross-over placebo-controlled studies to show the benefit. You don't have to conduct a \$200 million study to prove that prune juice has a laxative effect. Grandma was right, she knew about the effect of this product. Surprisingly, we cannot always put appropriate cautions and usage information on the label.

I don't pretend to be able to tell you why it happens, but when a company puts the proper labeling on a product saying "not to consume over this amount per day", "don't take this product if you are on MAO inhibitors", "don't take this product if you are pregnant or lactating", that product gets removed from the shelf by the government. The manufacturer is told to remove the statements from the label and only then can they put it back on the shelf. It doesn't make a lot of sense, but it has something to do with the technicalities of the law that if that type of statement is made, then the product becomes a drug. That is part of the problem we're talking about here. There is an unreasonableness in the regulations--I would like to think it is in the regulations because Mike Taylor is a nice person and I think he is trying hard to do a good job at FDA; maybe the agency is just dealing with rules that don't make any sense. I hope it is not that the prejudice the agency has exhibited for many years is contagious. But there is something in the rules that just does not make any sense.

I know some consumer groups are very anti-industry, but industry is what America is about. The natural foods industry employs 340,000 people; we are a very labor-intensive business. It is referred to as being a huge industry, but it is about half the size of Coca Cola. It is implied by critics that we do not provide value for what we charge for our products, which is ridiculous. We have consistently led the country to improve nutrition and prevention. If you want to talk about profit for something that doesn't help people, why don't we ever look at industries that are selling unsubstantiated dreams on TV for things that have no nutritional benefit such as carbonated beverages and chips? You can't be anti-industry. You have to look at the products people are using, how they are using them and the benefits that they receive.

This bottle [displayed] represents a product you have to hope FDA likes because the way regulations are currently set up, this product could be banned. The rules are too broad because under the current regulations this product, if added to food, becomes a "food additive" and, therefore, it is subject to the food additive provisions of the law. It is not on the GRAS [Generally Recognized as

Safe] list. In fact, there haven't been double-blind cross-over placebo-controlled studies to show that it is safe. You can get a toxic level of it. So it would be very easy for FDA to say in court that this product has not been shown to be safe, and their experts are not in total agreement on it. Therefore, the manufacturer automatically loses. As a manufacturer, there is just no way you can win that argument. There is even another way that FDA could get it off the market. If somebody says this product will prevent dehydration, which is considered a drug claim, that claim makes it is an unapproved drug, which cannot be sold. The product we've been discussing is water, which shows that FDA has enormous power.

I think the agency has done a very good job of managing its public relations. So I don't think they would go after water, but they have done something almost as extreme with Evening Primrose Oil and Black Currant Oil. FDA has repeatedly tried to ban these safe products using the food additives regulation. These products are not high profile consumer products and only a small percentage of the country would know if they were no longer available, but they are very important to those people who use them.

FDA's slowing the dissemination of crucial prevention information is another problem. I presume that they are going to have to arrest the State of Florida because of this ad. The ad refers to a study that has just recently been published showing that higher than RDA levels of vitamin C will extend the average life about six years (figure 20). The statement is accurate, truthful and nonmisleading. It is information that people need, but this is not a legal ad. I could not provide this information in my store. I cannot take the government's own studies and distribute them to my customers, if they relate to products that I sell.

Where this problem gets to be a really critical factor is for a product like folic acid. In the State of Texas we have an abnormally large problem with spinal birth defects compared to the rest of the country. Nationally about 2,500 babies a year are born with spinal defects, about 500 of which are fatal (figure 21). Supplements of folic acid or adequate folic acid in the diet would prevent this problem. However, I cannot give the research findings on this connection or even the CDC report on the issue to a woman of child-bearing age that comes into my store. There is certainly something very wrong with that as a public policy.

FIGURE 21.

Most dependent on government assistance for health care:

The Poor
The Elderly

Most at risk to poor nutrition: **The Poor**
The Elderly

% of
Low Income Women*
With Intake Below
70 of the RDA

Vitamin A	52
Vitamin E	66
Vitamin C	37
Vitamin B-6	78
Folic Acid	89
Calcium	60
Iron	85
Zinc	76

* Less than 131% of Poverty Line

I know that soon FDA is going to figure out a way to balance the pressure between the need to control the safety of the food supply and will approve the health claim for folic acid. But at what cost in the waiting? We have known of this connection for more than 20 years. At what point is it okay for consumers to start learning about this relationship? How many babies have to die? In England, there was an 84-year gap between the time that they discovered that limes would prevent scurvy and when the government finally started putting limes on the ships. Hundreds of sailors died in the meantime. This is the same kind of thing. Out of all of the hundreds of legitimate health claims that should be approved, FDA has only approved one that applies to supplements. FDA has not even approved claims for supplements that they have approved for food. We must allow a free flow of truthful information. If claims are false, FDA has the power to stop their use. The industry does not want fraudulent products on the market because it is bad for the public and bad for business.

The supplement industry recently started putting into written form standards that we have been developing for several years. We will have guidelines on good manufacturing practices, safety and truthful health claims published shortly in final form that can then become a requirement for all of our industry members. We have prepared this document and enforcement plans so that we can root out the fringe element. Of course, there are fraudulent claims out there. Name a business, including public service, where there aren't people who take advantage of the system. But the bulk of the information that people need to know is like that on folic acid and we cannot wait until there is consensus to pass it along to consumers. Unfortunately, FDA's interpretation of "significant scientific agreement" becomes too much like "consensus". You rarely get consensus and even when you do, it isn't always right. Back in the late 1800s, the experts were pretty well agreed that the automobile would never be popular because people were too attached to their horses.

One of the things that is very sad about this situation is that according to FTC consumers actually learn best from advertising and marketing promotion.

I guess it won't surprise you that the average American does not subscribe to the *Journal of the American Medical Association*. A lot of the nutrition information has finally gotten prominence in popular media, which a great number of Americans do read. But the people who need it the most, the ones in the lower education and income brackets who depend most on government support of health care, don't read *Time* magazine. Unfortunately, Geraldo doesn't do programs on the disease prevention benefits of foods and supplements.

There are a great many products that are well researched. Garlic is an example. The stack of garlic studies I have is almost two feet high, which is only half of the literature available. There are 1200 studies showing the benefits of garlic. But that is not enough for FDA. The requirements that they have set up have to be changed because there is no harm in the public knowing that garlic will lower their blood pressure. To deprive consumers of that information forces them to take a more toxic prescription at much higher cost.

One of the biggest factors overall is the amount of money that could be saved in the long run by providing this information. Dietary supplements can have an enormously positive impact on the health care crisis that we are facing. We cannot afford any longer to have a disease-based health care system. We have to be looking at prevention and non-toxic, low-tech remedies to use in conjunction with our high-tech wonders. If we wait for people to get sick enough that they need a really heroic effort, it is very expensive. A lot of diseases can be stopped very early.

Figure 22 gives you an idea of some of the potential savings. The Kellogg report estimated results from improved nutrition, but we are also talking about how people eat. As Dr. Visser pointed out, people eat for a lot of reasons unrelated to nutrition. A lot of what people eat now is based on whether the food is available at a drive-up window with a very high percentage of meals eaten in cars. And improving the diet is difficult, especially with all the advertising on television that appeals to the taste and the social aspects of food, but we could get people to take a multivitamin for some insurance, if we could tell them why it is important.

**FIGURE 22. Potential Savings
in Disease Care Costs**

*From Improved Nutrition &
Dissemination Prevention Information*

Kellogg Report Estimates:

Respiratory	1.4
Arthritis	0.9
Mental illness	1.4
Alcoholism	14.5
Digestive Disease	1.0
Kidney & Urinary	1.3
	— \$20.5 Billion

Health Studies Collegium:

Cancer	7.0
Stroke	23.0
Cardiovascular	15.0
Adult Diabetes	29.0
Gingival & Dental	43.0
Neural Tube Defects	45.0
Hip Fracture	4.0
	— \$166 Billion

*With Use of Natural Therapies including
Supplemental Nutrients & Herbal Remedies*

Townsend Letter for Doctors:

Prostate	2.8
Asthma	3.0
Heart Attack	1.0
Osteoarthritis	1.0
Ear Infections	.5
Ulcer	1.3
	— \$9.6 Billion

**TOTAL, SELECTED CONDITIONS =
\$196.1 BILLION**

The bottom line is that we are looking at very significant potential savings. In fact, we are talking about hundreds of billions of dollars in health care costs and enormous suffering that could be prevented, if the public was encouraged to be educated. We must figure out some way that the industry and FDA can work together under more rational laws to tell the story of nutrition.

So far, FDA has been very polite, but we have never been able to get them to help us with our industry self-regulation. Let's face it: you could quadruple the size of FDA's staff and you still wouldn't have enough people to have an agent standing in each manufacturing plant watching each bottle come off the line. In every industry, you have to start with self-regulation. FDA is then the safety net when self-regulation fails. We want to be able to call on FDA to get rid of fraudulent and unsafe products. Steve will tell you the tools that they have for doing that already. In fact, a careful reading of the proposed legislation will show you that we are really enhancing the ability of FDA to be able to identify a class of products that are unsafe and present a reasonable hazard to the population, and take them off the market, without using tricks in the law like the food additive provisions.

A careful reading will also show that we are promoting a balanced bill, that is in the public interest, as well as the industry's interest. We are not trying to repeal NLEA. NLEA was passed with a provision that there could be a separate standard for dietary supplements. FDA chose not to write those regulations. I have enclosed a list of ways in which foods and supplements are different (figure 23). As Dr. Visser pointed out, they are used quite differently. We are

FIGURE 23. Supplements Compared to Foods

There is a major difference in the way nutrients from supplements are consumed as contrasted to foods.

Supplements:

- * **Controlled amount**
- * **Optional/intentional**
- * **Targeted** to unique needs
- * Concentrated
- * Usually no calories
- * No taste
- * Convenient
- * Often less expensive
- * With retailer assistance
- * With label instructions
- * Can avoid restricted foods

Food:

- * **Random**
- * **Mandatory, we must eat**
- * **Indiscriminate**
- * Small amounts
- * Calorie consideration
- * May dislike taste
- * Often more expensive
- * Self-serve
- * Usually no instructions
- * May have to eat more of a food they wish to avoid, e.g., fat

not trying to repeal NLEA because we favor the concept. We are only asking that the regulations written support it, taking into account that people use products like peppermint tea for an upset stomach or garlic for lowering blood pressure. These uses are facts that the public needs to know. If more useful information is taken off the labels, and no hint can be made about the product's use, how are consumers going to find it out? We cannot give out scientific studies, which means consumers have to go to the library and read reference books--that just doesn't happen.

I want to make a parting comment because CSPI has maligned some good products and mixed them with the questionable. I wanted to take exception to this product [Ultra Male] for a personal reason. Eleven years ago when I bought my first store, this product was on the shelf. There were no products on the market then that were considered stimulants for male potency and this product was never promoted the way CSPI suggests. This product is a nourishment for the male glandular system. It is part of a whole line that includes Ultra Female, Ultra Nails, Ultra Minerals, Ultra Vitamins and more. Ultra was just a term to indicate it was the best male formula. Men and women do have different nutrient needs. Naturopathic physicians know about glandulars; it is organ-specific nutrition. This product has vitamin E and zinc, nutrients shown with good research to help the male glandular system and overall health.

I picked this product in particular because I have had a number of customers, including my brother, who had fertility problems, which were corrected with proper nutrition. These reports are anecdotal, but backed by research. Other products CSPI has shown bear nutrition statements, not health claims. I just want you to know that not everything is what it at first appears to be from the way it is presented by CSPI. Even the wheat sprout products shown by Mr. Silverglade do have multiple effects. Niche marketing (more than one label style) is not a new concept. Don't let somebody put all these various products in the same category and assume that they are all a problem. If there are real problems, FDA should go after them. I do not know why they haven't. I wish they would; they are an annoyance to all of us.

Now I want to turn the program over to Steve. Thank you very much for being an attentive audience. You are probably hot, tired, and hungry.

PORTER: And finally, we will hear from Stephen McNamara, who is an attorney in Washington, D.C. with the law firm of Hyman, Phelps and McNamara. Today he is representing the Utah Natural Products Alliance (UNPA).

MCNAMARA: Let me make a couple of suggestions. I have provided a written presentation, which I had planned on making but, given the lateness of the hour, I don't think anybody would want to listen to it right now. The written presentation is available for you to pick up. What I would like to do is talk about three items just briefly in a responsive way, just to get some other thoughts in your mind. I am hoping that this is round one in what will be a

series of opportunities for you, whether in meetings like this one or visits with people who come to your individual offices, to examine the facts, and to do some reading and reflecting on what is the truth here. I am going to talk about product availability, labeling, and a third item that the government has avoided mentioning, but which is very important and is part of the legislation that has been introduced.

First of all, let's talk about product availability. Deputy Commissioner Taylor told you product availability is not part of NLEA and that he does not know why the industry is worried about it. And the Center for Science in the Public Interest said basically that product availability is not an issue. Product availability may not directly be part of NLEA, but it is very much an issue to this industry because FDA has been taking away products that are important, products that are popular from the perspective both of people who market them and consumers who have wanted to purchase them. I am no scientist, but let's discuss one or two examples quickly.

One is chromium. As recently as two years ago, which you can verify by a footnote in my paper, FDA announced that "dietary supplements of chromium are not permitted". What is chromium? According to the National Academy of Sciences (NAS), chromium is an essential mineral that NAS has recognized. Among other things, it is required for a number of nutritional functions, including maintaining normal glucose metabolism. Observations on chromium supplementation studies in the United States, as reported in the NAS' *Recommended Dietary Allowances* indicate that at least half of the subjects with impaired glucose tolerance improved with chromium supplementation, suggesting that many people in this country may not be getting enough. There is also a comment that trivalent chromium, which is the form used in dietary supplements, is extremely safe. In this kind of situation you might expect to see people getting awards for providing trivalent chromium. Most of the major companies in this industry are doing so--manufacturers who sell products like Centrum and One-a-Day. (In passing I note that FDA has avoided mention today of the large number of responsible products. Instead, FDA goes out and finds the small volume items with the allegedly inappropriate claims that make good stories). The point is that major products have added chromium over FDA's threatening objections. Chromium is essential, useful, and makes sense, but FDA is threatening.

There are reasons why companies are concerned. One of the most striking experiences that I ever had at FDA concerned a dietary supplement product. Our firm had been retained by a British pharmaceutical, dietary supplement and nutrient manufacturer that sells its products worldwide. The company had an interest in a substance called Evening Primrose Oil, which was being sold in the United States as a dietary supplement of gamma linolenic acid. I am not a scientist, so I cannot tell you the scientific merits of this product, but I can tell you what FDA people said and how they behaved.

One of the advisers of the company was a gentleman named Sir James Black. Sir James has received the Nobel Prize for Medicine, clearly a person of

great intellectual capability and knowledge in this area. I was in England with the company and I advised the company that FDA had issued an Import Alert saying that dietary supplements of Evening Primrose Oil would be illegal because the agency regarded the substance as an unapproved food additive. (By the way, that is also the theory on which FDA asserted that dietary supplements of chromium were improper.) Company personnel including Dr. Black expressed disbelief and wanted an opportunity to speak with FDA about why the company's scientific personnel believed that the substance is clearly safe, generally recognized as safe and useful--and not a food additive.

I advised that FDA had already expressed the agency's view, but as requested I arranged a meeting for Dr. Black that included the head of the FDA food center and senior FDA nutrition and compliance personnel. We came in for the meeting and Sir James started to explain why he felt Evening Primrose Oil was indeed generally recognized as safe. The FDA representative in charge of the meeting would not allow Dr. Black to proceed. The FDA representative said that he did not want to let, and would not let, Sir James explain for the FDA personnel in attendance why he believed that FDA was wrong and why he believed that dietary supplements of Evening Primrose Oil were rational, useful, made more sense than dietary supplements of B-vitamins, ought to be available, and were clearly safe at rational potencies.

What FDA didn't know was that Sir James met with Senator Hatch afterwards, and when he was asked what had happened in the morning meeting with FDA, he told in detail what had happened and how surprised he was that FDA was not open even to letting him explain his views about why this material was GRAS.

You can go up to Canada and get a dietary supplement of Evening Primrose Oil. You can also fly to England, to Paris, to Bonn, to Oslo, to Stockholm, to Athens, to Israel and buy Evening Primrose Oil. But it is FDA's view that this material is not generally recognized as safe. If you want some sense about FDA's crusade to prevent the American public from having access to this material, which is so widely available elsewhere in the world, I would call your attention to the program from the FDA's most recent annual awards ceremony. The Commissioner gave an award to the Evening Primrose Oil team, listing more than 60 FDA personnel who were thanked by the agency for their aggressive action to prevent the American public from getting Evening Primrose Oil.

Part of the question you have got to ask when you deal with public policy is, where should our scarce public resources be spent in this society that we live in, and how safe do you want to be and what is the trade-off for the powers that FDA is asking for and wants to exercise? Should FDA be able autocratically to assert that it does not believe a food substance is GRAS because it doesn't think so and thereby deprive people who want to consume the substance access to the material? As my paper shows FDA has ample authority in the existing Federal Food, Drug, and Cosmetic Act (FDCA) for the agency to take action against a product that contains any poisonous or deleterious substances that "may be

harmful to health". FDA does not need the additional food additive authority, which UNPA believes FDA has abused in the case of dietary supplements. One of the goals of the health food and the dietary supplement industry is to circumscribe FDA's ability to autocratically assert food additive status for dietary supplements of safe food substances that human beings in this country want to obtain and companies want to provide.

Let me turn to the second issue, i.e. labeling. The types of claims that have been talked about here today probably reflect a very small percentage of the actual volume of sales out in the marketplace.

It is remarkable that neither FDA nor any of the other speakers noted that if these products are promoted with false or misleading labeling claims, FDCA already gives FDA authority to bring civil seizure actions, injunction actions, and criminal prosecutions. FDA has also issued regulations that provide for recalls. If a product bears a false or misleading claim (which can be deemed to have occurred under the Act simply for the failure to reveal material information) there is ample authority for the agency to act if and when it wants to, and there have been periods of time in the past when the agency has acted.

I would suggest that the fact that the agency has not exercised its existing authority is not necessarily a justification for giving it more authority and creating a larger bureaucracy. Let's talk about what FDA regards as the cure for the alleged problem, and you tell me whether in your hearts it is the kind of society you want to be moving our country toward.

The health food industry will agree that FDA has the right to act aggressively against any product that bears false or misleading labeling. That is not the issue. The issue is what, procedurally, do you do about it? FDA's concept here is to move away from policing the marketplace and taking action against products that are false or misleading. Instead, FDA wants a new rule that a company cannot make a claim until FDA first approves the claim in a new regulation that will take years to issue. Under FDA's approach, nobody gets to make a statement about any disease-related information until FDA has decided first that it is okay to do so. Do you know how expensive and time-consuming that "deadhand on innovation and information" kind of approach is? It typically takes FDA several years to issue a new regulation in the real world.

I have had a conversation with FDA personnel about applying FDA's proposed new approach for supplements. I asked whether--and I would be happy if Mr. Taylor or anyone else at FDA would deny this--if a dietary supplement company wants to publish a monthly newsletter that truthfully describes the recent scientific literature about nutrients and their health and disease-related benefits or whatever else has been reported in the literature, the company can go ahead and do so on its own responsibility? Well, the answer from FDA comes back no, and there is a whole series of levels about no.

First, FDA's view is that a newsletter, insofar as it carries the company's name on it, and addresses research about any of the nutrients that the company

has in its products, becomes "labeling" for the company's products. Second, FDA says that under NLEA policies, nobody is supposed to provide health-related information in labeling without first getting the information cleared in advance by an FDA regulation. That means a petition to the agency, then a rulemaking proceeding and then a final regulation, which will take at least three years altogether. It will take you at least three years to get each issue of your newsletter approved. But it is more complicated than that because FDA says that furthermore it might never approve any of those newsletters because the latest scientific literature may not constitute "significant scientific agreement", so that it is very doubtful that any of those new studies, even if truthfully reported, would be allowed to be described in a product's labeling, including a newsletter. This policy is what is at hand--a prior restraint on speech, which puts you at the mercy of a hostile regulatory authority.

Let me give you an example quoted in my paper. It concerns the Zapata Haynie Company, which is not in the dietary supplements business. (It is actually George Bush's former company, for those of you who follow that kind of trivia, which owns, among other things, one of the largest fishing fleets in the United States. They fish for Menhaden--you are not likely to have eaten a Menhaden because it is an oily, bony little fish. But the Menhaden fishery is, I believe, the largest commercial fishery in the United States.) Because of its interest in fish, the Zapata Haynie Company filed comments in the proceedings that FDA has conducted on omega-3 fatty acid health claims.

The company consulted with some eminent scientists and proposed a model labeling statement to FDA. Listen to this proposed statement. "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 definitely have such an effect, but a number of researchers believe that such information may exist and research is underway to obtain further information." Now, according to the scientists consulted by the company, that is a short, balanced, statement about the current state of the knowledge. Yet, FDA has not allowed that statement to appear on the label of any food or dietary supplement.

Among the reasons FDA has asserted on behalf of its position is that the agency cannot under NLEA allow statements about controversies, even if they are truthfully presented because a controversy is not "significant scientific agreement". FDA's concept is one of not authorizing a statement about a health-related condition until there is significant scientific agreement that a substance actually prevents a particular disease. FDA does not intend to allow truthful statements describing the state of the recent literature, or truthfully summarizing a controversy. Is that the kind of society you want to live in?

FDA has ample authority right now insofar as going after false or misleading labeling or unauthorized "drug" claims. FDA has brought civil seizure actions and injunction actions and even criminal prosecutions against companies and individuals for selling falsely or misleadingly promoted food

products including dietary supplements, or for making unauthorized drug claims. FDA has brought such actions unsuccessfully in the past, and they could do it again. There is even a Supreme Court case, *Kordell* in 1948, which upholds FDA's authority to regulate as drugs dietary supplements and other food products that are promoted with unauthorized health claims that amount to drug claims. The agency already has that power. They don't need the additional power, especially when the agency seeks to impose a prior restraint on truthful and non-misleading speech.

I would like you to reflect on some of the labeling that FDA has been willing to suppress in the past. One of the letters I have attached to my statement shows what FDA has told some companies. For example, if you are selling a supplement of vitamin C and rutin, FDA does not want you to say on the label how much rutin is in the product because FDA does not think that is authorized. Earlier today, there was some complaint by another speaker that one could not tell by looking at the label which or how much of certain herbs were in a particular product. And yet FDA has been writing letters to companies that sell dietary supplements, trying to suppress quantitative labeling. See the FDA letter attached to my paper. The issues are a great deal more complex than FDA's presentation here today would suggest.

I have spoken about product availability and labeling. The third thing I would like to talk about is procedural justice.

A provision included in both Senator Hatch's and Congressman Richardson's bills would allow a company that receives a warning letter from FDA to obtain judicial review of that letter. What is this about? Today, if you are the president of a dietary supplement company and FDA does not like what you are doing, the first way the agency can go about laying a regulatory burden upon you is to send you a formal warning letter. This letter typically is addressed to the president of the company, it typically tells the company that one or more of its products are in serious violation of the law, it typically threatens a court case, and then it typically provides the company 15 working days to tell FDA what the company will do to stop the action that FDA has stated is illegal.

Well, assuming FDA is right, the letter can be an efficient enforcement mechanism. It can be an effective way to resolve a situation. But suppose you disagree with FDA? Suppose you would like to get independent judicial reviews of whether FDA's allegation that your company is violating the law is correct. Do you know that it is FDA's position that you cannot have judicial review?

FDA's position is that its warning letters constitute final agency action. Of course, the letters never say that the agency might change its mind. They are written as absolute conclusions, and they are released to the press and put on public display at FDA headquarters. A warning letter can have a devastating impact on a company's stock value, investors' opinions of the company, the willingness of banks to lend to the company, competitors' statements about a company out in the marketplace, or indeed what your children think about you

when you come home at night and they have read about the letter in the newspaper. But FDA says you can't even get judicial review of the merits of FDA's public statement to you that you are in serious violation of laws--and that, I believe, is fundamentally wrong.

So, I would suggest to you, as I conclude my remarks, that, I believe we have some real problems here. We have FDA overreaching in the enforcement of its food additive authority with respect to components of dietary supplements. We have FDA asking for more power than it needs over labeling. Indeed, what ought to be anathema to any American who cares about our historical interest in free speech, FDA is asking for prior restraints on truthful and non-misleading speech in the context of labeling. Finally, the agency does not even want to let a company obtain judicial review after FDA disparages the company and its product line in a public warning letter. I think these are real problems that need to be addressed. Thank you.

PORTER: As you can see, we do not have significant scientific agreement among our panelists. Okay. Let's take a few questions.

QUESTIONER: Commissioner Taylor, our constituents are, as you can imagine, very concerned about losing their vitamins and that is consistently what they express concerns about. This is, I think, primarily in response to some well-published FDA regulations to remove vitamin supplements from the market, or at least that is the impression that people have. I don't know how correct that is, but they really dominate the public perception about FDA's intention, even though Commissioner Kessler has said that FDA is not interested in taking vitamins off the market. Do you think that FDA would be willing to reassure consumers that it will not ban the sale of selected products by listing vitamins and their potencies on the GRAS list, or some comparable list that would permit the sale of these products? It would assure consumers and the manufacturers of these products to be sold. And the flip side is that FDA would identify product categories targeted for enforcement action so that there will be some sort of safe harbor where people will know that they are likely to get targeted, by contrast, if they entered that area.

TAYLOR: Let me just say a few things. First, it is terribly unfortunate that the perception has been conveyed to consumers in general, and your constituents in particular, that FDA is about to take their vitamins away. Indeed, it is unfortunate that events that have nothing to do with the vitamin and mineral products have your constituents concerned. Events completely unrelated have been used misleadingly to portray FDA as out conducting raids to take vitamins and minerals away. Nothing could be further from the truth. We have looked for ways to be as categorical and unequivocal as we can. I have said it here today and invite your suggestions about ways we can get this message out so that your constituents will hear it: nothing FDA is doing, intends to do, has ever thought about doing would take away those vitamin and mineral supplements that so many millions of Americans purchase for whatever reasons.

You mentioned raids to take away vitamins and minerals. One event that has been portrayed in those terms concerned an operation out in Takoma, Washington involving a Dr. Jonathan Wright. In the execution of warrants there were found, as there was probable cause to believe would be found, the manufacture of various products, including injectable forms of various vitamin preparations imported from Europe, but being prepared under conditions that resulted in contamination of these injectable products. FDA action to address issues such as these has nothing to do with taking away vitamin and mineral supplements available in grocery stores, drug stores or health food stores.

MCNAMARA: Mike, what did FDA mean when it said that dietary supplements of chromium could not be sold?

TAYLOR: I am glad you asked because that is not what it said.

MCNAMARA: I have a quotation. We can all go look up our Federal Registers.

TAYLOR: Let me tell you what the document that you quoted said, the uncertainty it generated, and the statement in the subsequent Federal Register document. Chromium is a substance that has not been formally listed as generally recognized as safe by FDA. The agency has, therefore, not taken an affirmative position permitting chromium in dietary supplement form. The statement of the agency's position in that Federal Register notice invited comments and in response to those comments, the agency in a subsequent Federal Register Notice, has clarified that just as companies are free with respect to any food ingredient to make their own determination that a product, or a substance, is GRAS and market it on that basis, so too are they free with respect to chromium. FDA is not out taking chromium-containing dietary supplements off the market. We would do so only if we encountered a form of a chromium-containing dietary supplement product that raised an affirmative safety concern. So chromium supplements are not threatened. FDA is not removing chromium supplements from the market.

MCNAMARA: What about the Evening Primrose Oil?

TAYLOR: Again, Evening Primrose Oil raises an excellent case study of the difficulties FDA encounters in enforcing the law with respect to dietary supplements...

MCNAMARA: Well, let me just be clear that Mr. Taylor's answer is about vitamins and minerals. We can provide a long list of products that have been sold in dietary supplement form that FDA has taken action against. If you are not intending to take them away, you need to know that there are--

STERNBERG: I would like to interrupt before we get into a shouting match between the two sides. It is clear that this debate points out one of the biggest problems of this issue. We are talking about a lot of different products, some of which may either have clear risks, some no risks, or some unknown

risks. We could spend the entire day singling out and debating specific products, while the issue that is really the concern here is how do we decide what is safe, what is not and how do we guarantee safety. The bottom line here is the consumer. I think we all agree that we want to provide consumers with products that are safe and at the same time not take away their fundamental freedom of choice. But there shouldn't be a trade-off between these two rights--safety and freedom of choice. How do we guarantee both?

MCNAMARA: But an important question also is whether FDA has been depriving people of substances that they have wanted to obtain. The way I have heard FDA respond has been along the lines that they are not taking away vitamins and minerals.

TAYLOR: Why are you citing old Federal Register notices that have been superseded by new Federal Register notices? As a lawyer, the first thing you learn is that ...

MCNAMARA: Because FDA has published several notices in its series of food labeling proceedings, some of which have suggested that dietary supplements of certain substances--including the essential mineral chromium--were not proper. I don't know which way they are coming out lately. If Mr. Taylor is going to assure us today that chromium is safe, that's fine. But I can certainly tell you that there have been recent FDA actions against such products as Evening Primrose Oil, Black Currant Oil, Borage Oil, CoEnzyme Q10, Chlorella, Orotic Acid, and Orotate compounds. There are numerous products in the health food market against which FDA has taken action. I just don't want it to appear that the agency is not taking away products.

QUESTIONER: I would like to return to Ms. Whittekin's anecdote implying that her brother and sister-in-law were finally able to conceive a much awaited child after her brother availed himself of the benefits of a course of Ultra Male therapy. However, as an NIH endocrinologist who abides by the scientific method that requires a more rigorous standard of truth than personal testimonial, I should like to note that the putative ingredients in the prostate extracts that confer Ultra Male's implied effects on male potency are the male sex hormones testosterone and dihydrotestosterone. The latter is a derivative of testosterone that is more potent than testosterone itself. One of the problems with the administration of testosterone and androgens with respect to reproductive function is that they are not fertility agents at all; in fact, their administration inhibits the production of brain neuropeptides that drive the pituitary-gonadal axis to promote endogenous testosterone and sperm production. In this regard, it would have been a misnomer to name your niece after the product.

WHITTEKIN: The critical factor might have been the zinc, and maybe they should have called the product something else.

QUESTIONER: Well, it may have been zinc, but it certainly was not the prostate extract, which would have been counter-productive because its effect

would have been to lower rather than raise the sperm count. I should add that the sperm count in American males is 50 percent lower now than it was a generation ago for reasons that are not entirely clear, but may relate to our exposure to various sex steroids.

Since I have raised the issue of the scientific method, I should also like to address Mr. McNamara's lament that if FDA persists in its current course, natural food and drug firms won't be able to get out their monthly newsletters chocked full of interesting tidbits. My laboratory has published several papers in the *New England Journal of Medicine* in the past few years of which we are very proud. It takes years, not weeks or months of wishful thinking, to verify the truth of this work and before it can pass muster of a group of our scientific peers. I cannot publish a monthly newsletter because I have to validate the truth of my statements utilizing the scientific method. I don't know your threshold for disseminating information, but the scientific method should also be the basis for your standard of truth.

WHITTEKIN: I would like to clarify just one thing. Glandulars are not a significant source of the hormones you described. Also a lot of these letters that you get when people express concern about losing their vitamins: "vitamins" has become a generic term to the population. They don't talk about dietary supplements, which is our term for these products. When they say vitamins they may well mean their chlorella, the protein supplement they take as an athlete or whatever. This terminology problem may be where part of the confusion comes in because FDA is always very careful to say they are not taking vitamins off the market because if products contain reasonable potencies and don't make a health claim, they aren't going after them. So technically they are correct. But people are concerned where they see in these new proposed regulations and the Advanced Notice of Proposed Rulemaking indications that all herbal supplements--the garlic, camomile, ginseng, and peppermint tea all in the same bag with the comfrey, which is not really being sold--will be taken off the market. They also see all of their amino acids, which would include some that maybe ought to have more instructions for use, are going to be taken away right along with the extremely harmless ones. Like L-Lysine used to help people with their canker sores.

HUXTABLE: As a point of fact, comfrey is still being sold. I purchased a kilogram of comfrey root in a health food store just a few weeks ago.

WHITTEKIN: As I say, here and there it is sold because FDA has not sent out an official notice. Sellers are beginning to think that the association does not know what it is talking about. When we tell them not to sell it, they say, if it was a problem, the government would tell them. (Bulk comfrey is used mostly for external applications.)

MCNAMARA: But existing law already enables FDA to take a poisonous or deleterious product off the market at any time.

SILVERGLADE: Steve, can I respond to your comments on existing law because existing laws may be on the books, but they may not be practical for the agency to enforce. Congress gave FDA a better law, NLEA, which provides an efficient enforcement mechanism requiring pre-clearance so that the agency, with its limited resources, can finally get a handle on this problem. That is what this is all about.

MCNAMARA: I think that addresses a fundamental policy issue on which we would strongly disagree with you. Giving the government unnecessary, and I believe it is unnecessary, pre-clearance authority over speech is always a dangerous precedent. The Italian government regulated efficiently under Mussolini, and it may have been the only time the Italian government ever did, but it wasn't necessarily an accomplishment. I don't think that giving FDA pre-clearance authority over truthful and non-misleading speech about health and disease-related benefits of dietary supplements is the way to go.

SILVERGLADE: Someday you may be able to argue pre-clearance authority before the Supreme Court, but under current constitutional law you are stating kind of a wish list.

MCNAMARA: I am not talking about whether it is constitutional at this point. I am talking about the question of how the law should be amended, if at all.

TAYLOR: I just want to clarify one point about FDA's approach to availability of products. Steve asserted that we have taken actions to remove from the market products that companies want to sell and consumers want to purchase. We plead absolutely guilty to that. Our obligation under the statute as written today is to take action with respect to products that do not meet the statutory safety standards, the requirements concerning the making of disease-related claims, and raise the consumer protection concerns embodied in the statute. We could and would be happy to have a briefing that goes through the number of enforcement actions we have taken to remove products from the market when violating the statute. Please, if I was misunderstood to say we never take an action to remove a supplement product from the market, that is not what I meant. What I will come back to and say over and over because it is the rhetorical point that has been raised to undermine FDA's credibility in this area, is that we are not out to take vitamins and minerals off the market. Vitamins and minerals are not threatened. Access to vitamins and minerals is not going to be affected by anything we are doing. It is critical that as the public evaluates this issue they understand what the issue really is, and again, it is not about access to vitamin and mineral supplements. It is about how we assure the safety and validity of claims for a host of other products out there that are far less familiar to FDA scientifically and far less familiar to most consumers.

If I could just make one other point about Evening Primrose Oil (EPO), and I cannot possibly debate Steve on this issue because he has been involved in it very substantially longer and knows a lot more about it than I do. It is a classic

case of the difficulty we confront in enforcing current law and illustrates some of the points we have been making about limits on our current practical authority to enforce the law. I think the Ultra Male product illustrates this point as well. EPO originally came into the U.S. market promoted for a host of disease-related purposes. From FDA's vantage point, it was a classic case of health fraud, and the agency pursued it in a regulatory enforcement way on that basis.

The industry then removed the explicit claims from the labeling, which is the standard procedure when approached by FDA for those kinds of illegal claims and labeling. Then the question is, while the product is still being sold in a market that has been conditioned with respect to these disease-related claims, what does FDA do when the industry simply takes the information off the label making it difficult for the agency to prove that these illegal drug claims have been made? One of the options has been to consider whether the product is being marketed in compliance with the food additive provisions of the law because the substance is not generally recognized as safe.

There is a disagreement between FDA and other scientists about the question of whether there are safety concerns regarding the particular fatty acids and their profile in some vegetable oils. There has been extensive litigation on that issue, which consumed a lot of FDA resources. But it illustrates how difficult it is for the agency to hold companies responsible under the current regime, which has strong standards in the statute, but it is not always that easy to enforce.

As just presented, Ultra Male is a great example because I think many consumers would see this product as one that has an implied claim to improve male sexual performance. Martie has just explained it as really being simply a dietary supplement for men. I guarantee you that if we attempted to make a case based, in our judgment, on this very clearly implied drug claim of improving sexual potency in males, we would have to litigate extensively over whether this product, in fact, was merely a dietary supplement product for men.

That is why we set priorities in how we use our current enforcement resources and quite frankly, it is why there are a lot of products out there that the agency has not yet acted against. FDA has fairly scarce resources, using 15 to 20 FTEs a year in the field out of the 2,500 or so total to investigate and consider actions regarding dietary supplement products. So we focus on products that affirmatively present a safety hazard or make extreme drug claims, such as for cancer, AIDS and other serious disease claims, that amount to health fraud and pose indirect health hazards by taking people away from established therapies. There are a lot of products out there that do not meet the current standards and reflect some real practical constraints on our ability to hold products to those standards.

QUESTIONER: You mentioned that FDA currently has powers in the law to go after these products. You described the industry as paranoid that FDA has some kind of weird aggressive agenda against the health food industry. Why

do you think they are not using these laws to fulfill whatever that agenda is? The only one we hear is the public health concern, but you suggest that there is something behind FDA's motives that we have not heard yet that is aggressively going after these products. If these laws are effective enough, why don't you think they are using them?

MCNAMARA: I can't put my mind in FDA's mind. But let's be clear on the facts. Among the facts are that the law currently provides that an article shall be deemed adulterated if it bears or contains any poisonous or deleterious substance, which may render it injurious to health. The court cases have said that the "may" means that it may possibly, and you don't have to show that it actually was harmful to the weak, the young, the old, the sick, the infirm, et cetera. It is a very good, strong standard for FDA. If you took away their food additive authority, they would still have plenty of authority any time they focused on anything they wanted to remove. It is a very generous authority.

The problem with the food additive authority is that it imposes this general recognition of safety concept. When that law was enacted, the legislative history shows that the burden would be on FDA to prove an absence of general recognition of safety. FDA testified in Congress that it would be the standard, which you can find in my written statement. In the courts now, however, FDA argues instead that GRAS status is an exception, and the burden is on a company to prove that a substance is in fact generally recognized as safe. So FDA shifts the burden onto the company, and then FDA's argument in court is that as long as FDA has some witnesses who say that a substance is not generally recognized as safe, then as a matter of law it cannot be "generally recognized" and the court ought to hold no trial at all and there should be summary judgment for the government. The agency has a fine record of winning those cases.

The way it has turned out is that essentially the assertion by FDA of absence of GRAS status becomes almost a necessarily self-fulfilling prophecy. FDA lost a case about an animal feed once, when a jury ruled that a substance for use in chicken feed was not GRAS. FDA also lost an argument in a situation where there was no other ingredient in the product, and the courts said you can't have an additive if it is not added to anything. But what FDA has now is a standard that is so biased for the agency, when they choose to apply it, that industry has almost no hope of winning no matter what the evidence of actual safety.

QUESTIONER: This whole argument and controversy has not come up in any of the information I read about the additive law, but against the labeling of products. Do you recognize the concern consumers may have as to labeling being misleading and what would be the proper thing? And I am not looking for a response about additives, but I am talking about happy campers.

MCNAMARA: Sure, we do not want to build additional layers of permanent government bureaucracy, to be reviewing each new label, every time it is revised, before it can be used. Instead, FDA should police the industry and

take action against products that bear false or misleading claims. Take enforcement actions against those products like it can and used to do.

QUESTIONER: Under what standard must that claim be made?

MCNAMARA: The Federal Food, Drug, and Cosmetic Act already says that a dietary supplement of vitamins and minerals or any other food shall be deemed to be misbranded if its labeling is false or misleading in any particular. The case law says that even if all the rest of a label is truthful, all that is required for FDA to act is one false or misleading statement. FDCA also says that failure to reveal a material fact is sufficient to show that a label is misleading. So, FDA has very broad authority in the statute that it can exercise.

QUESTIONER: Under what standard can health claims be made, what scientific method applies and under what kind of standard procedure? As consumers, we have seen a couple of examples and I do not have any way of judging whether or not these examples are on the far side, but evidently there are enough to make us wonder who to believe and under what standard we can believe the claims.

MCNAMARA: I doubt Mr. Taylor would tell you he could not win court cases against the kinds of products that have been discussed. Would you really say your lawyers couldn't go out and win those cases, Mr. Taylor? I don't think they really believe that, in any event. What they want is a more convenient standard for themselves, where the burden is not on the agency. Maybe I grew up in an old fashioned era 25 years ago, when people thought that the government ought to have to prove there is something wrong with a product before the government goes after it, and you had a right to make a statement without government pre-clearance, if you were prepared to defend your statements as being truthful and not misleading. We should not give the government pre-clearance on labeling statements that a company is prepared to defend as truthful and non-misleading statements.

WHITTEKIN: I think you have to have a bit of faith in the free enterprise system. If people spend \$5, or \$10 or \$20, which is typically the cost of these products, and experiment with a product that promises a dream that doesn't come true, we're not talking about curing AIDS and cancer. Nobody is asking for the right to make claims that are so extreme. If they don't get the satisfaction that they wanted from that product, or it doesn't work for them, (for, example, there are people who don't respond to valarian for relaxation like 95 percent of the population would) they can return the product and get their money back. As long as we're starting from a basis of safe products, there is no physical or economic harm.

STERNBERG: I think you might get a different response if you asked an L-Tryptophan patient who was either dead or permanently crippled. It would be hard to give their life back.

WHITTEKIN: I'm glad you brought that up because we're talking about contamination and I said starting from a basis of safe products.

STERNBERG: I don't want to take one side or the other, but I do want to make sure that both sides are brought up when each point is discussed. I think we should recognize that there is a need for safety.

WHITTEKIN: I said start with safety. Contaminated L-Tryptophan was not a safe product.

STERNBERG: I think everybody agrees with that.

QUESTIONER: I have just one comment quickly. I walked into a GNC store recently and saw a lot of claims in the names of the products and the literature that is sold in stores, but didn't accompany the products per se. One question I had was if I was to use a blender and take the bark from a Pacific Yew tree, or I made it in a tea or a capsule and sold it and I had some basis for believing that it had some kind of basis for a health claim, why should I be held to any different standard than Taxol or Quaker Oats?

WHITTEKIN: Dietary supplements should not be allowed to make cancer-cure claims, like Taxol can. That is not what we want. That is not the kind of thing you use a home remedy for.

QUESTIONER: No, not a home remedy, but let's say I put it in a capsule and I wanted to make implied claims that there are some indications that there was clinical promise in its use. If I did some studies and one study showed that it had an effect, would that be an adequate basis for a claim?

WHITTEKIN: No, we really think there should be more structure. The industry is working on a structure itself for identifying the cut-off point. We have asked FDA to work on this issue with us, but they are much more interested in the convenience of having just two slots--foods and drugs. A lot of things do not fit in that structure because supplements have more distinct benefits than foods, but they are not as toxic, or as dramatic in their actions as drugs are. The industry would not make a product like you are talking about and make an implied claim for cancer on it because they would get prosecuted for doing so. That is proper because that would be a very irresponsible claim to make.

QUESTIONER: I have a book that is sold in a health food store and under cancer it lists 20 products, a variety of herbs to use. But when I got to the herbs, the actual bottles in the store don't contain any claims.

WHITTEKIN: So we should burn the books, too?

QUESTIONER: No, no. I was just wondering, about this situation where there is a lot of information in the marketplace, some of it may be reliable, some of it may not be. But with that information out there being constantly sold, I

think under current proposals it would be a different standard for drug firms, why should the standard be any different for supplements?

WHITTEKIN: Because there is a difference in the way that supplement products are delivered and used by people. Folic acid is a really good example. You do not want to do something capricious with the food supply by authorizing a health claim that is going to apply to everything people ingest. If everything from Twinkies and pork rinds to orange juice contains folic acid, then you run the risk of masking a pernicious anemia problem that is particularly prevalent in the elderly. On the other hand, with a supplement, which consumers take deliberately, you have control of the intake level, and can target it to individuals who really need it, like the women of child-bearing age, and you avoid the other problems. There are quite a number of differences between the way people take supplements and the way they take the food. Food is very much random and you cannot target it, so fortification needs to be monitored more closely than supplements (see figure 7).

QUESTIONER: But there are specific prescription vitamins that should be available for women, called Madelaine Springs, and as they do contain folic acid that are specifically targeted to women who are pregnant.

WHITTEKIN: If they are fortunate enough to go to a gynecologist before they get pregnant to get that information. Women need to learn of the connection before conception.

QUESTIONER: Then you should have a label on these folic acid supplements in health food stores that they should be taken only by pregnant women and not by people in their 50s and 60s...

WHITTEKIN: We would love to be able to target the information, but we cannot do that now.

PORTER: I think we have to stop here. This debate could go on all afternoon, which I would love to do with you, but I don't think that is possible since we have speakers who have planes to catch. I would like you to join me in thanking the speakers for their presentations. And thank you all for attending.