labels on it. Not to be used in this way, not to be used in that way. And eventually we get the information overload as consumers where everything is dangerous, and all dangers are perceived equally. And that's the risk we run with warning labels on these products.

Products that have adverse effects and no known usefulness should be removed from the marketplace because there's -- the warning labels, I think, are not going to be an effective deterrent to consumers who are consuming those products because of the information overload and the fact that the suppliers of those products have millions of doctors at their disposal to get the consumer to take that product.

And if I use my own parents and grandparents as examples, they don't even know that the FDA hasn't evaluated the effectiveness of the product. They haven't even read the box that far. They read the front of the box that said this is going to help your memory, and they took it. I think many many consumers are in that same boat. They're not going to read the fine print. It's too boring.

DR. FARNSWORTH: If anybody's wife should know about these things, it's probably mine, but I

went home the other day and there was a bottle of drinking water with ginkgo in it. She knew that ginkgo is good for her because I take it all the time, so she decided to reinforce me with drinking water with ginkgo.

I think everyone knows it's like Coca Cola, you have to put coca leaf extract in it. But they boil it up in hydrochloric acid, one drop in 50,000 gallons, it satisfies the labeling in regards to coca, and this is what happens with these herbal drinks in drinking water. If they put enough of it in, give you a therapeutic effect, you couldn't taste it, it would be terrible tasting. It's just a gimmick. They don't make any claim on the label except by the name of the product, Zoom, or something like that.

I think the way you have to prevent side effects and everything is you -- it has to be the burden on the manufacturer. There has to be a substantiation file. It has to be quality control. I don't think the standardization is a part of GMB, therefore it has to be treated separately. I think, I may be wrong, I'm not a lawyer. That has to be available.

Under appropriate circumstances, if FDA has a good idea that there's something wrong with that

product the public good is better served by having that information available to the FDA.

MR. DORSEY: I found all the responses very helpful. I also meant to ask the following question, that is, when does one -- when does the Agency switch from saying this product requires a warning to this product just shouldn't be out there? And none of you really addressed that. Put a very pertinent example on the table. I probably shouldn't do it.

A panelist earlier in the day said she wished one of the things the Agency would do by the end of the year was to ban ephedrine. Taking that as an example, when is it appropriate to say this product shouldn't be there versus some kind of warning?

MR. OLIVERAS: I'll go out on a limb, if I can, real quick. I think if there's no body of clinical evidence that there is any good effect from the consumption of that particular product, that product should be banned if it has any adverse effects at all.

MR. LEVITT: Other reactions?

MS. PERR: Well, I mean, as in the case of ephedra, you've already had several deaths. I think that's enough. That's an adverse reaction. I mean, I actually don't even see the question there.

DR. FARNSWORTH: I'm not sure that ephedra is what killed the people. It's the people that kill the people. When the label says take two tablets and you take 25 to get a high, I'm not sure you can blame it on the ephedra, especially when you add guarana extract, the highest known concentration of caffeine, added pure ephedrine, then it's a problem, but I don't think you can blame it on the ephedra.

MR. LEVITT: I don't mean to get into a debate about ephedra. Without discussing ephedra, when should the Agency make the choice between a product and the --

MS. PERR: When the product is available in an inappropriate manner to people who can't judge. A 10-year-old died who was taking these ephedra tablets. How could a 10-year-old get their hands on that? It was something that was in one of these boardwalk stores as a fun experience, so he had some. Why is that out there? Who actually needs that? I mean, what's the point of that ready availability?

If you go look at these products as they are currently in stores, if you go to a health food store, that's next to all the other cereals, next to all the other juices, they're in the candy bar section but they appear to be more healthy because of the

environment that they're shown. Maybe these products if they really possess any good ought to be in a separate place, like your pharmacy, where kids don't go in and buy.

DR. FARNSWORTH: But if that's the case, then you should put a warning on prune juice, do not drink a quart or you get diarrhea, or you have to put it on apples. If it's one apple, it's great; two, I get filled up; three, I get diarrhea. But there's no such thing as absolutely safe.

MS. PERR: You're talking about apples versus nicely colored snacks that fit in your mouth, it's a different package.

MR. LEVITT: I am glad to see you're stimulated.

MR. LANGAN: What about the additional illustration of a number of years ago, el-tryptophan, and their documented reports? The supplement 5HTP which contains the same El-tryptophan which was highly controversial and risky and indeed very harmful and deadly.

MR. LEVITT: I'll take that as a statement of some kind. I think just to try to sum up this part of the discussion because both the questions and the comments reflect an issue that FDA needs to deal with

on a case-by-case basis, which is if you have a product that is literally marketed that shows some toxicity, at what level of toxicity or what level of confidence, some combination there, does that lead us to put a clear warning statement on there warning consumers, may cause liver damage, dah, dah, dah, dah as you would with a prescription drug as opposed to saying no, that level of risk is not acceptable, what Dr. Yetly asked earlier to the previous panel about the legal standard is unreasonable or significant risk.

At what point is that toxicity so high that the product should be off the market as opposed to labels? We don't have any clear answers either, but that's one of a long list of challenges we have under DSHEA and have an understanding of what level of information of data triggers what kind of response. In other areas we have it, and in this area we need to develop it. I think that's really the point of what we're trying to get to.

With that, before we let Dr. Perr buy lunch for her colleagues -- I see a whole number of them lining up -- we've asked each panelist again to -- Dr. Perr, you didn't hear this before. Look ahead a year, waive your magic wand and see if FDA could

accomplish one thing a year from now, that would be blank. Why don't we start at the far end of the table.

MR. LANGAN: I think in order to obtain standards of quality and ongoing quality control, the first thing that's needed is true display of leadership on the part of the FDA, and in particular on the part of our new commissioner, Dr. Haney, to really step out in front on this issue.

It takes a lot of political courage, but I think it's really -- it's going to be backed by the scientific and medical communities, by the patient and consumer population as well.

MR. LEVITT: Thank you.

DR. SULLIVAN: I'm not optimistic enough to think that in one year the FDA is going to change its whole strategy and require controlled studies on dietary supplements, as they like to be called, which really do have some pharmacologic action, and that -- those types of controls.

And so in trying to answer this, I really think from a practical standpoint there is one thing that I think they can do in a year's time, and that has to do with the warning label issue. And as part of that I think manufacturers who do promote herbal

medications or herbal preparations as a health aid, I think that the FDA can require labeling that specifically warns them about potential adverse problems in a generic way. I don't think it has to be specific.

I think that one of the things on there should be that anybody taking prescription medications should be advised to discuss with their physician or whatever whether or not taking verbal medications is compatible with their prescription medications. I think that's a simple thing to do.

And if you do create a label mechanism, I think what's on there you have the easy ability to have a 1-800 number, adverse reporting mechanism, and with it, in this day and age, it's so simple to put a web site address on there, I don't know if the FDA has that now, but I think from an educational standpoint, informational standpoint, that we can use web sites, we can use the Internet, because most of this country now is computer savvy enough to punch in and they can learn about these drugs.

The FDA can sponsor a web site that is accessible by the public which provides information on everything you can find on the shelf. They can learn about adverse potential problems and what the real

Point number two is just to reiterate if people were not here this morning we had terrific cooperation from everyone, the speakers, the audience and everyone else. I want to thank you for that. I would remind people to turn off your cellular phones. You're welcome to make telephone calls outside.

There is also a public telephone right outside the door, and there are restrooms both outside and each corner here, and also larger restrooms down by the elevator.

I also -- an actual, this is an herbal supplement, and what -- the way this works is that the actual -- there's a window here, you can turn it and get more information, essentially get twice as much information on the bottle, however much you can fit around, how much you can see through the little window.

One innovative way of getting more information to the consumers. This is the first I learned of this. I thought I would share it and make a general observation about as we try to get information on labels we need to look for innovative ways of communicating that.

I'll pass that down the table. With that, I'm delighted to welcome up to the podium here our by

take the elevator just outside the auditorium to the first floor and use the door to the right. That will get you out of the building quicker.

When you come back in you're going to come back in through the front door and through security again. But again, you can take that elevator outside. With that, I think we will see you at 1:00 o'clock, promptly. Thank you very much.

(Whereupon, the lunch recess was taken. from 12:03 p.m. to 1:08 p.m.)

MR. LEVITT: I would like to welcome everybody back to the afternoon session of our outreach meeting on dietary supplements. Just a couple of quick points before we introduce the first panel.

First point is that there may be individuals who came here today hoping they would have an opportunity to make a presentation but are not on the reserve list. If there are any such individuals we will try to accommodate you at the end of the meeting, time permitting, but I would ask that you sign up outside at the registration table asking to make a short presentation at the end of the meeting and then we'll see how many people we have and how much time we have.

safety of the consumer and ethicacy.

MR. LEVITT: Thank you. Mr. Oliveras.

MR. OLIVERAS: I think one thing the Agency could do is to really work on GMPs, either as guidance or as a final regulatory framework for GMPs because I think it would help the industry decide what they should be doing, what they should be checking, and how they should be checking it and using that information, and that would help give the consumers the dosages that they expect, the purity that they expect in the supplements.

MR. LEVITT: Okay. Thank you very much. Before I let you walk down the stage, I want to keep everyone's attention for about two more minutes.

We will shortly be breaking for lunch. We will take advantage of the time and take a full 60 minutes for lunch, which I think is probably what we need anyway.

You will find in your package a sheet that looks like this that gives you ideas on eating places in the area, including one in this building and one in the adjoining tower.

If you want to get out of the building more quickly than other people -- I am going to have to read this -- to exit the building quickly people can

information we know about the products that they are consuming. I think that's a very simple and reasonable thing that can be done in one year's period.

MR. LEVITT: Thank you. Dr. Perr.

DR. PERR: I agree that the labeling is feasible within one year. As I stated before, the desire to keep the dietary supplements as supplements and separate from a food, such as a cereal, snack, gum, candy bar, soup, that is not appropriate and it's misleading. Even if there are not toxic events, and I'm not sure that they're efficacious ones, and it's misleading to the public.

MR. LEVITT: Thank you. Dr. Farnsworth.

DR. FARNSWORTH: And the FDA should hire some knowledgeable people in this area so that they can sort through all this stuff. But really, I think the substantiation file should not be secret from anybody.

There is nothing that can go in a substantiation file that isn't public knowledge, and if it is proprietory it can be blacked out if someone asks for too much information or facts from the FDA. I think that would make the manufacturers more cognizant that what they're responsible for, the

now fourth panel of speakers: Joanne Ikeda, Mary Mead, Julie Maniord, Ann Coulston and Rita Mitchell.

As we did this morning, we will go right down. We have a new person, but same signs on our timing, and so at the one-minute warning you will see a little sign that looks like this, and after your five minutes are up you'll see a second sign that looks like that. And we would ask people to adhere to that. We had excellent cooperation this morning.

We also have four panels to get through this afternoon, three this morning. We need to try to keep on track. After all five people have spoken, we will have a series of questions, and I will conclude with my general question: If you can look ahead a year from now, one thing you'd like the FDA to do, what would that be, as a way of concluding this session and getting on to the next panel.

With that, I'm happy to introduce and welcome Joanne Ikeda. If you can state who you are, where you're from and who you're representing.

MS. IKEDA: I'm Joanne Ikeda, Cooperative Extension Nutrition Education Specialist in the department of Nutritional Sciences at the University of California, Berkeley. I am speaking on behalf of the entire faculty of my department.

The Nutritional Sciences faculty is concerned about the plethora of dietary supplements being marketed to consumers and advertising claims being made for these products. Consumers are treating themselves with doses of compounds in greater amounts than they could possibly get by eating food sources of these compounds.

In addition, supplement manufacturers often use only selected fractions of potentially active compounds of these supplements. This can produce effects that are quite different from those produced by eating the whole food. Almost nothing is known about the long-term metabolic effects of consuming these compounds solely or in combination with others.

Some of these supplements are composed of combinations of substances which are rarely, if ever, found together in nature. And I certainly have seen that a number of times.

The potential for toxic reactions in humans has never been greater. Advertising claims being made for these products are not being substantiated by scientific research. It is our opinion that the situation has gotten out of hand.

In the words of our department chair, "The supplement industry is an embarrassment to the medical

nutritional science and to the honest business community."

Consumers are not being protected against possible harmful effects of long term usage, and consumer fraud appears to be rampant. Obviously what I'm saying is very much in concert with what people have said this morning, so I'm not going to say it all over again. I would just like to point out that Dr. Farnsworth, who spoke, was member of this commission on dietary supplement labels. This commission was appointed by President Clinton.

It produced -- it worked for almost two years under the chairmanship of Dr. Mulden Nesheim, who was chair of the nutrition department at Cornell University. It has more recommendations than you could imagine, and I guess our question to the Food and Drug Administration is if you're looking for a sense of direction, here it is, in volumes. And we don't understand why this document really has not been used to provide guidance.

We reviewed the Center for Food Safety and Applied Nutrition's list of priorities, A-list of priorities on the web site, and we find it appalling that so little will be accomplished in the area of dietary supplements when so much needs to be done.

On a more positive note, we applaud the outreach to stakeholders. We also would like to reiterate what other speakers have said about the need for the availability of information on adverse event reporting, that most medical professionals have no idea how to report an adverse event related to the intake of a supplement.

And the final comment by my department is the very first question posed by the FDA for this hearing asks, in addition to ensuring consumer access to safe dietary supplements that are truthfully and not misleadingly labeled, are there other objectives that an overall dietary supplement strategy should include?

At this point in time it is very apparent that FDA is not ensuring consumer access to safe dietary substances that are truthfully and not misleadingly labeled. We unanimously agree that this should be the very first priority of the FDA and that FDA should focus on achieving this objective before it goes on to others.

On a personal note, I would like to relate something that is unique. I'm probably one of the few individuals who's speaking today who has experience actually asking supplement companies to substantiate

their claims. I have been an expert for Darryl Roberts and David Copenhaver, the California County district attorneys who are in fact pursuing consumer fraud cases against these companies.

They write to the company and ask for substantiation of claims made in advertising. Then they usually get back a stack of documents like this which they forward on to me.

Let me say that what those companies do is they do a literature search. They go to Medline or some other computer search tool, they identify anything ever published on this substance.

For example, I read all about the use of Chitin in the industry. It's just unbelievable. I would say 98% of what I get has nothing to do with the claim made. The other 2% has to do with animal research.

Generally it's -- for example, recently ginseng, I got a study of about how some mice swam faster after they took a ginseng supplement, and other mice in another study, they swam slower, but still the company concluded this supported their claim that this promoted greater endurance.

I would like to require every manufacturer of dietary supplements to take a business ethics

course because there is just a tremendous lack of business ethics here. I'm just appalled -- I would also like all their experts to take ethics courses because believe it or not, I get all kinds of statements from "experts," for example, three emergency room physicians in Las Vegas Nevada who have provided a certain dietary supplement for weight loss in their patients, and all testify that their patients were happy and lost weight.

Now, I don't know how many people rush to the emergency room for treatment of obesity, but in this instance, I guess we can assume it must be happening since they appear to have all of this expert testimony that in fact this substance works for weight loss. It is a jungle out there.

The man who said, this is like the cart with the snake oil guy coming into town was not under-exaggerating. And I, for one, do not understand why there has been a total lack of enforcement in this area. I think my faculty would agree with that.

They have stated that they feel that government has abdicated its responsibility to the public. Thank you.

MR. LEVITT: Thank you very much. Next speaker, please.

MS. MEAD: Good afternoon. My name is Mary Mead. I am a registered dietitian and a certified diabetes educator. Currently, I am employed at the University of California at Berkeley as a lecturer.

I am the president of the Bay Area Dietetic Association, and am speaking today on behalf of the California Dietetic Association. The Dietetic Association is a professional organization with approximately 7,000 members. It is a -- an association whose mission is to serve the public through the promotion of optimal nutrition, health and well-being.

The California Dietetic Association, which I will abbreviate as CDA, appreciates the opportunity to provide testimony at this hearing, and today the CDA acts as an advocate for the public in strongly supporting stricter regulation and oversight of dietary supplements.

CDA feels, and I'm echoing Joanne, that the recommendations made by the Presidential Commission on Dietary Supplement Labels are consistent in advancing issues of nutrition and health and urges the FDA to incorporate them into its overall strategy and action plans.

Specifically, CDA urges that supplements be

consistent, standardized products, that they be accurately and not misleadingly labeled, and that they have proven value based on scientific study. These standards, we feel, are precisely what the FDA requires of the food industry and the pharmaceutical industry, and consequently these are the standards that consumers expect of pharmaceuticals, food and related products. And I'd say that Americans have gotten in the habit of trusting what's on the label.

The existence of lenient standards to accommodate the supplement industry, a multi-billion dollar industry, put a trusting public at health risk and makes them financially vulnerable.

We believe that consumers want to purchase supplements that are free of contaminants and contain what is listed on the label, products whose safety and effectiveness have been proven with credible scientific evidence before being put on the market. We believe it is the responsibility of the supplement manufacturer to provide this proof.

In another strategy that may help to protect the consumer, CDA urges the delineation of those nutrients that occur naturally in commonly eaten foods and those that do not.

Under this approach vitamins and minerals

for which some form of requirement or formulation standards have been established based on considerable scientific evidence would be in one category. The other dietary supplements category would include botanicals and herbogenic aids, for example, which would require heightened attention, such as more specific labeling, including where to find credible information about the product. And most importantly, these products should be labeled with known contraindications to taking those products.

We feel that this approach might help to assist the Center for Food Safety and Applied Nutrition in allocating resources appropriately by focusing on supplements that could present the greatest risk to the consumer.

Finally, one provision of the Dietary Supplement Health Education Act of 1994 is to better inform and educate the consumer. Currently, the consumer has two primary sources of information about supplements, one source, the supplement industry, and it takes just a brief look at alternative -- our botanical and herbal website to see that the information provided is primarily non -- from non-credentialed, non-credible sources, and many of it is anecdotal and unsubstantiated.

The other source of information that consumers turn to when looking for information about safe and effective use of supplements is his or her physician, pharmacist or registered dietitian. The CDA believes that health professionals therefore are reasonably mandated to have reliable references and resources about dietary supplements, including the benefits and adverse effects.

We rely on health-related government branches such as the NIH, Office of Dietary Supplements, to maintain current database of accessible accurate information regarding dietary supplements. We feel that it's imperative that the office of dietary supplements have adequate funding for this purpose.

In summary, the supplement industry is a multi-billion dollar industry, a mainstream industry. Its marketing strategy is one of the most effective in the world, and that is, take this and you will feel better.

The public today is vulnerable to the unfounded claims, and that this -- I say the segment of the population that's vulnerable is really growing by leaps and bounds. As the number of baby boomers increases and we have people nearing retirement age by

the year 2020, California will have 6.3 million retirees who are looking for dietary supplements to help them feel more energetic, protect them against heart disease and prostate cancer, help them fend off acute and chronic disease.

I think that as our -- as supplements have become more mainstream and the vulnerable population seems to be increasing, it's an ideal time for the FDA to put the consumer and not the supplement industry first.

The industry must be required to channel some of its resources into research rather than marketing. CDA urges that the FDA take a stand for the public safety and health in the realm of dietary supplements. Thank you.

MR. LEVITT: Thank you very much. Next we'll hear from Julie Maniord.

MS. MANIORD: I promise you I have not met my fellow panel members in person, but you may find that hard to believe because much of what I have to say is somewhat repetitive.

Good morning. I represent a community-based organization comprised of various members of professional and community associations such as the National Council for Reliable Health

Information, along with consumer advocates dedicated to the promotion of optimal health through consumer education.

The program was initiated in 1986 to address the increasing problem of nutrition-related health fraud at a local level. I want to begin by affirming my commitment to the maintenance of open channels of communication amongst stakeholders of differing objectives and points of view.

If we share a common priority, that of consumer protection and the provision of ethical business practices, then we should naturally be moved to see both sides of an argument presented before establishing a consensus.

Because of time constraints, the questions posed in the federal register will be addressed in our written submission, and I'll use the time today to focus on a specific area that we believe needs attention by the Agency.

Experience drawn from 13 years of direct correspondence with the public provides the background for our concern and apprehension regarding the public's current broad scale grasp of the dietary supplement issue. We concur with statements made at the June 8th meeting in Washington by the ADA and the

Society for Nutrition Education suggesting that consumers' rights to access dietary supplements must be complimented by their ability to make fully informed decisions or choices.

Consumers' belief in the safety and ethicacy of dietary supplements is justified by this Agency's history of strong regulations of these and other similar products. Application of the policy of caveat emptor, or let the buyer beware, with regard to health-oriented items in this country is news to an alarming number of those seeking information from our program.

We see the issue of consumer education strongly associated with the criteria number one of the FDA's four criteria for priority ranking, enhancement of consumer safety and protection. We also support suggestions from the ADA and FNE that research be directed toward obtaining a better understanding of consumers' attitudes and perceptions and details related to their decision-making process. Data of this nature should -- could then adjunct the Agency's decision to expand upon their consumer education efforts.

In order to at least establish a level playing ground with the present atmosphere created by

manufacturers and others looking to stand a financial gain from dietary supplements, consumers also need to be privy to such information as the fact that regulation of these products takes place following the accumulation of ADRs. In other words, essentially the public provides the testing ground, not the laboratory.

A significant margin for error and inconsistency exists between the evidence suggested by scientific investigations and the supposed remedy marketed to reflect for those findings, and far more evidence supports the fact that ultimate health and well-being depends on the consistent intake of nutrient dense foods, especially your darkly pigmented fruits and vegetables, and the long-term adoption of healthy life practices than that which substantiates the use of the majority of the dietary supplements marketed today.

People need to be repeatedly advised and reminded of these facts in order to offset their inclination to pill-pop to alleviate their health conditions.

Lastly, consumers need to be much more familiar with the evolutionary nature of the scientific process. Repeated reports announcing

conflicting findings and data turn away those who are unfamiliar with the natural patterns associated with science. Armed with such knowledge, an informed public would much more likely see the virtue of allowing ample time and patience for the gathering of concrete evidence, or simply put, let science follow its course before taking action in its name. People need to know these things so that they can truly make informed choices, fully informed choices.

In addressing the Agency's inquiry of suggestions for the proper allocation of limited resources, we propose that the Agency direct some measure of its efforts toward increasing public awareness and recognition of presently developed resources such as the FDA consumer magazine, the CFSAN web site and ADR monitoring system, et cetera. Efforts to broaden the scope of professional consumer reliance on those resources should prove productive.

Delivering a balanced perspective to the American public entails an active response to media campaigns funded by a billion dollar business. This means employing the use of higher dollar mediums, such as billboards, magazine ads, radio and TV.

We would like to acknowledge the complex issue of delineating between structured function

claims and disease claims. It has been our observation that consumers do not follow these distinctions. Common sense leads to their assumption that a product that improves circulation must then play some role in the mitigation of heart disease.

Again, consumer research is needed to determine whether consumers are able to make meaningful distinctions and to assess their appreciation of this provision of DSHEA, which is assumingly done on their behalf.

To conclude, we invite the FDA to join actions taken to heighten consumer awareness and recognize that doing so is an integral part of assuring consumer safety and protection. Thank you.

MR. LEVITT: Thank you very much. Our fourth speaker on this panel is Anne Coulston.

MS. COULSTON: Good afternoon. My name is Anne Coulston.

MR. LEVITT: You need to pull that closer to you.

MS. COULSTON: With that, I'm Ann Coulston, nutritional associate in Palo Alto, California, and immediate past president of the American Dietetic Association. The ADA supports the need for consumers to have access to dietary supplements as long as their

opportunity to choose is made in the context of a fully informed choice and assured public safety measure.

We have entered in the U.S. a new era of acceptance and incorporation of supplements into the fold of traditional health care, so it's probably not premature to set about the task of answering a few basic questions: What is "diet"? What is "supplement"? What is implied in the term "dietary supplement"?

In recent months products have appeared on the market that blurs the line between food and medicine, from calcium fortified orange juice, to Hanes chunky tomato soup with herbal supplements, and alternative cures with the folksy appeal of home remedies.

Combining herbs and supplements with food gives them an implied legitimacy with shoppers. Consumers may consider them safe and effective because they're on the supermarket shelves, despite the fact the evidence supports neither belief.

Take, for example, a recent study from California which found that more than 4 in 10 patients with heart failure reported taking some sort of natural remedy in addition to their prescription

drugs. A significant number also said that they hadn't told their doctors about the additional pills and potions.

Many products, from ginkgo biloba, to hawthorne berry, to co-enzyme Q, are pitched as heart healthy compounds. Yet while patients put their faith in the healing powers of these supplements, many don't believe they're strong enough to conflict with the mainstream medications they're taking. That's a dangerous misconception, despite the fact that little, if any, have scientific evidence.

It's part of an alarming paradox. Consumers clearly believe supplements are powerful. Why else would they buy them? But they frequently behave as if they didn't. Equally disturbing is that some patients obviously believe that they must be clandestine about their supplements and keep their doctors in the dark. Such attitudes seriously undermine the essential trust of the doctor/patient relationship. It can also do greater damage.

The American Society of Anesthesiologists, as we heard this morning, has recommended that dietary supplements be stopped two to three weeks before elective surgery after reports that anesthetics can perform erratically in the presence of supplements.

That's prudent policy, but what should be done about making sure that such accidents don't happen during emergency surgeries? Very little is known about the drug/herb/nutrient interaction. Of course many drugs are derived from plants and share the same source as many of our dietary supplements. Unfortunately, while this common ancestry says nothing about chemical compatibility, it could be luring consumers into a false sense of security, the mistaken belief that mixing so-called natural products can't be harmful.

The FDA needs to chart itself a clear and consistent course in this uncertain territory. Chief here is the insistence on quality control of substances. What is in the bottle? Is what's in the bottle biodegradable? How strong is it? And what could develop from potential interaction with other supplements and medication?

The market doesn't appear willing to regulate itself, at least for the time being, therefore the FDA needs to step in with pre-market approval as well as post-market surveillance of dietary supplements, both in single supplement form and when supplements are added to our food.

I support the recommendations of the ADA

which were delivered at the June 8th hearing. For ADA to establish categories for dietary supplements, this would distinguish vitamins and minerals about which there is considerable research base from botanicals and herbals from which less is known.

I urge the FDA to seriously consider the establishment of review panels and pre-market review panels for dietary supplements before use. Thank you.

MR. LEVITT: Thank you very much. And finally we'll hear from Rita Mitchell.

MS. MITCHELL: Hi. My name is Rita Mitchell, and I'm the president of the California Nutrition Council, a non-profit organization of nutrition professionals and other individuals representing government agencies, universities and colleges, professional associations, private organizations, the food industry, the consumer groups.

This diverse membership allows CNC to present a unique viewpoint to the dietary supplement issue because our members work directly with consumers; with programs to educate consumers; and with scientific, peer-reviewed research evaluating nutritional needs, safety issues and consumer understanding.

CNC applauds FDA for providing this

opportunity to speak out publicly about the inadequate system of assuring consumer safety with respect to dietary supplements. The first of the specific questions you raised asks for objectives that an overall dietary supplement strategy should address, in addition to ensuring consumer access to safe dietary supplements that are truthfully and not misleadingly labeled. We believe that many dietary supplements available continue to be unsafe and misleadingly labeled.

We would be satisfied if consumers did have access to safe dietary supplements that are truthfully and not misleadingly labeled. Under the current laws, as we all know, dietary supplements do not have to be proven safe or effective before they are marketed. Ideally, the law should be changed to correct the situation and we would support any legislative effort to do so. Consumers need assurances that product are safe and that claims are substantiated by valid scientific research.

CNC members in clinical practice have described experiences in which individuals have delayed conventional treatment of serious illnesses in favor of taking dietary supplements. Information on the package label led them to believe that these

product would help them. In fact, the supplements contributed to severe disability or even death in some cases. Consumers must be protected and they should be informed that current law does not guarantee that all dietary supplements offered are safe and effective.

We strongly believe that ensuring public safety should be FDA's top priority. We recommend that FDA mount a massive public education campaign similar to the anti-tobacco campaign, to encourage consumers to learn all they can about the dietary supplements they take.

In preparing this testimony, I've spoken to many consumers and health professionals. Most of them were not aware of the provisions of DSHEA. They were horrified to learn that product can be marketed before they're proven safe and effective; they're not required to meet the rigorous safety and quality standards of food additives and drugs. They were also dismayed to learn that manufactures can sell product claiming to cure all kinds of illnesses and ailments when in fact, there is no proof that these product will cure the illnesses and may even be harmful or deadly. Consumers have a right to know of the potential risks associated with the intake of dietary supplements.

CNC recommends that the FDA establish specific criteria for a voluntary approval process, allowing product to bear a seal of FDA approval for safety and effectiveness. CNC members would be willing to contribute expertise to the development of such criteria.

We recommend strengthening the adverse event recording system. This should be part of the massive consumer education campaign to let consumers know the importance of reporting adverse events, plus information about how to easily report these events. FDA must improve the follow-up process when adverse events are reported. We urge you to enforce the law to stop the rampant proliferation of dietary supplements with unfounded claims.

In addition, as the part of the adverse event reporting system, we recommend that there be mandatory reporting requirements to the Centers for Disease Control by physicians and other health professionals who learn of documented cases of adverse events related to dietary supplements.

CNC recommends that FDA require specific written information be provided with dietary supplements, including botanicals. The information should be standardized so consumers can make

comparisons and informed decisions. Required information should include, but not be limited to: Active ingredients; directions for use including maximum suggested levels per designated period of time; interactions with prescription medications and over-the-counter drugs; toxicity levels; caution statements when appropriate for vulnerable groups such as pregnant and lactating women, children, the elderly, and persons with compromised immune systems; ad shelf life and storage conditions.

There is still much to be learned in the area of dietary supplements. CNC supports scientific research on the safety and effectiveness of dietary supplements, especially those for weight loss and other widely used product.

In summary, CNC members believe that the public has the right to dietary supplements that are safe, effective, and appropriately labeled. They have the right to information they need to make choices based on sound scientific research. CNC members have expertise in nutritional science and consumer education. We stand ready to assist the FDA in any way we can to achieve these goals and objectives. Thank you for your attention.

MR. LEVITT: Thank you all very much. We

have had an enormous amount of nutritional expertise up here on the Panel. My question is, a number of you people -- you folks talked about consumers needing to make an informed choice, and I think everybody agrees with that. In the context of dietary supplements, what would need to occur for consumers to make an informed choice?

MS. IKEDA: I personally don't think that consumers can make an informed choice because accurate information is not available to them. I just picked up this wonderful little tan sheet out in the lobby of the auditorium, and here it tells me that companies have notified the FDA that they're going to make use claims for their products and in quotation, "sense of security, contentment and serenity." "Use it as a tonic, a natural restorative revitalizer and to help soothe and nurture the mind."

Here's another one, "Supports female balance." "To improve mental acuity and energize the mind and body."

I guess I would have to ask the FDA, if someone notified me and I was the FDA that they were going to make these claims, I would say, substantiate them. Where is the proof? I don't understand why nothing is happening. Why they're telling you that

they're going to make these outrageous claims and nothing is happening. You've been able to ask us questions. Why can't we ask you questions?

MS. COULSTON: I think it's an interesting question that's coming up to all these Panels, how much information does the consumer need and how can they get the information? I think that in our society that's not the way people think. In other words, if people go to the grocery store, they have a certain amount of confidence that what's in a package is what's in a package, and that it's safe to eat and that it's -- if it says rice, it is rice, and things like that. And because of that I think that no amount of throwing text information at consumers is going to make any difference.

I know just from my own personal experience of trying to gather as much information about these products as possible, in order to be able to answer questions professionally of people who might ask me knowing that I'm a nutritionist, it hasn't been easy to devote the time and energy it would take to know what all these products are about, and I've seen such an evolution in the last few years. The flavor in which I tried to convey in my remarks, that people are becoming more and more comfortable with these herbal

supplements. And that's not to say that -- certainly all of them aren't bad, and all of them aren't dangerous, but like anything, excessive amounts can be dangerous, even things we consider are perfectly normal.

I don't think it's an issue of getting more print information to the consumer for them to be able to make an informed choice. I think that the pattern that we follow in the U.S. is that there is some assurance that when you purchase something there is guidelines and rigorous regulations behind it that assures some safety and ethicacy.

MS. MITCHELL: I think the one thing that a consumer needs to make an informed decision at this point in time is that they can't believe anything that they read on the label. I think that's a good message to get across.

MS. MEAD: I agree with Anne. I think, as I stated in my testimony, the consumer is trusting, and it's partly because of the good job that the FDA has done in assuring the quality of the food and drugs that are on the shelves in this country.

So, I think those same standards are applicable to supplements, that consumers are not in the position to make sense from 100 studies. I mean,

if we say give them 100 studies to look through to make an informed decision, no, that's not the information they need.

MS. MANIORD: I agree. Many consumers are still working on the distinction between simple and complex carbohydrates, so throwing a lot of literature at least to them is not going to serve a lot of useful purpose. A realistic, let the buyer beware, related to health-oriented items, this is news to them, this is new information to a large part of the people -- population that I speak to.

MS. MEAD: I think that there's been an effort to do that already with the statement that's in the -- that's currently listed on -- I don't have any -- I had an example, on supplements that say let the buyer beware in -- what -- this is not an approved --

MR. LEVITT: Under the law, all structure function claims have to bear the disclaimer that this has not been evaluated by the FDA.

MS. MEAD: So there is a statement?

MR. LEVITT: The statement has not been, an admitted product is not intended to diagnose, treat, cure or prevent any disease.

MS. MANIORD: I don't think that fully represents the scope of the situation.

MR. LEVITT: I'm just saying that's what it says.

MS. MEAD: It's so official that a consumer almost thinks there's something official about this product. It has an official statement, or there's something safe about it, and so I don't think they really know what to do with that statement.

MS. COULSTON: This morning we talked extensively about warning statements. I think that we all know that they're protective in one sense, but they're not useful.

I mean, how many years have the warning statements been on cigarette packages, is probably the best example. And it has made very little difference to the use of cigarettes or the health hazard that it's caused. And this morning the example of Prop 65, which is the water or alcohol, I'm not sure which statement, that we have in California, that is in all places of business. And it's almost as if that statement protects the manufacturer more than it protects the consumer.

MS. MANIORD: I think along those lines that the FDA should actively renounce anti-FDA movements and propaganda to further --

MR. LEVITT : We'll try to -- we'll try to

limit comments from the audience. With that I will --

MS. MANIORD: At least promote the FDA as a consumer interest organization, at least provide a level playing ground and show that the FDA's purpose is to protect the consumer.

DR. YETLY: FDA has to do a balancing act between protecting public health, protecting consumers from economic fraud, implementing the law as the law states and doing all this with limited resources.

Many of your suggestions that you have made, as well as suggestions from earlier panels, have wanted more public availability to substantiation of safety and claims issues, and have wanted more FDA pre-market review and some decision on those products, yet the law does not clearly in many cases give that to the Agency. How does the Agency reconcile this? And how can your organizations help to fill some of these voids?

MS. IKEDA: I read the Act, and it states very clearly that statements should not be misleading or false, and so certainly persons like myself are able to go to the scientific literature to do a literature search to look at the claims made by the products and to see if, for example, there is any human clinical research in support of these claims.

And, I would think that persons like myself would be willing to do that, to help the FDA, to submit reports to the FDA if we knew something like that.

I have done a number of literature searches and have come to conclusions about advertising claims. I would be delighted to share those with the Food and Drug Administration.

Scientific -- the University of California at Berkeley has an excellent Nutritional Sciences department. We -- like the people this morning who advocated becoming involved in the public helping with this problem. We certainly would like to shed some light on it.

MS. MEAD: What was the first part of your comment, Elizabeth?

MS. YETLY: I guess I -- I am not sure what the -- what is the FDA's full potential at this time in terms of enforcing some of the things we're asking?

MS. MEAD: I had in mind specifically the request we've heard multiple times that there be substantiation for safety and claims to the public to make the statements. DSHEA clearly provides the legal authority to require that.

I was looking for some ways for the Agency to effectively provide the information that people

seem to want, not necessarily for manufacturers, but information. And given our legal authority, given our limited resources and asking for any ideas that you might have since you represent organizations as to how those organizations can help with the scientific background.

MS. COULSTON: I think it's actually a problem with the way the law is written that it's -- everything is post-market surveillance and not pre-market approval. And that I think is a big problem with DSHEA. I think probably everyone in the room recognizes that. And I'm not sure what the alternatives are to change that.

I know that one of the things it's considered very costly to have pre-market approval, but surveillance hasn't really worked, except, you know, occasionally in extreme cases, in my opinion. I'm not an expert in that area.

One of this things that I think associations can do, particularly like the American Dietetic Association, I think most of the other associations represented up here as well, is provide guidelines and guidance for consumers through consumer pieces, consumer information.

Now, that obviously isn't going to reach

everybody, and it will be accepted or regarded as good information to the extent that the consumer, you know, believes professional associations and society. Certainly that's one area I think that all of us who belong to health professional organizations have a responsibility to get good information out to our -- the people that we deal with.

MS. MITCHELL. A couple of CNC members recommended that because there can't be required pre-market approval that there be a system of volunteer pre-market approval where manufacturers could prove ahead of time before they market their product that the products are safe and effective and then bear some kind of volunteer FDA seal of approval.

MR. LEVITT: In that -- in that you meant it would be volunteer that FDA would review or volunteer that some independent scientific group would review it? I'm asking what you're saying.

MS. MITCHELL: I don't know that we thought that all through yet, but we would be willing to provide information.

DR. BOWEN: One panelist talked about consumers differentiating and making a distinction between structure function claims and disease claims. I know many of you worked directly with consumer

groups, as you mentioned earlier. You have a lot of experience in answering consumer questions about these products.

So, my question really is, does anyone have any data that shows that consumers can or do make the distinctions between structure function and disease claims? And I'll provide you an example. Maintains good circulation, considering that a structural function claim. Disease claim, preventing heart attack or stroke. What would your answer be if you were counseling somebody?

MS. IKEDA: The first would be structure function, and the second would be a disease claim, but I don't think there's any research showing that consumers can distinguish between the two, and in fact I think many health professionals would have difficulty.

MS. BOWEN: I guess my question is -- that was already something that I heard from the Panel. My question was, does anyone know of any research in this area?

MS. MEAD. No.

MR. LEVITT: Mr. Dorsey.

MR. DORSEY: I guess I wanted to repeat a question I asked to the last panel and elaborate on it

a little bit. And that is, with respect to safety of active ingredients or products not relating to things that shouldn't be in, contaminants or the like, when is it appropriate to provide a warning as opposed to saying a product shouldn't be available to the public? First part of the question.

The second part of the question is a number of you spoke about the need for information, for example, on contraindications when that information was known.

Do you think it's a concern when there is no information on potential contraindications, and so no information would be provided that consumers would then assume there is no concern about contraindications? And if you think that's a concern do you have a suggestion as to how one would deal with that potential problem?

MS. IKEDA: In my opinion, unless there's been some sort of clinical study where this product has in fact been given to human beings and there have been no adverse effects that we really should not -- there should be a warning on the product because someone this morning talked about a great human experimentation.

You cannot assume that you can put eight

ingredients together that come from widely diverse food, herbs and botanical sources, and that's what's happening out there. They are taking different ingredients that would never appear in a food together. They're putting them together. We have no idea how those ingredients are interacting, and it's just basically a human experiment.

And, I think there should be a warning on the label because you cannot -- no one in this audience can assure a person under those circumstances that that product is safe to consume and won't harm them. How would you know? Those ingredients have never appeared together.

I mean, truly maybe if they're inactive, but these are supposed to be active ingredients. All of them have some pharmacological activity.

MS. MEAD: David, I think that the absence of that statement, the absence of a contraindication statement would be interpreted as there are no contraindications. I think that's what we interpret when we look at pharmaceutical products, and so, yeah.

And it sort of makes me think about a labeling plan. We could fill the label with so many disclaimer statements, you know, that the -- there won't be any room on the label to make any misleading

claims. Such as, the absence of a contraindication statement does not mean that there are none. And we could -- sorry.

MS. MANIORD: I think certainly herbal products should come with a warning that they're not intended for long-term use.

MS. COULSTON: And in the vein of warnings, I think that there should be some warning or caution about taking things classified as dietetic supplements at the same time as prescribed medication.

MR. LEVITT: I want to thank this panel very much. Before we let you leave, one quick run down the table and ask you again to answer the question, if you could look ahead a year from now, and the FDA could accomplish one significant thing in this area, what would you have that be? Starting with Joanne Ikeda.

MS. IKEDA: I would like to see dietary supplement companies think that someone is holding them accountable, and hopefully that someone would be the FDA.

MS. MEAD: I echo that, and that I think that all claims should be scientifically substantiated before a product goes on the market.

MS. MANIORD: I echo a comment I heard

earlier with the last panel that the new commissioner, Dr. Haney, I would like to see her take a position of strong leadership, and one with responsiveness and sensitivity to the dietary supplements industry, but also securing the guiding policy be one of protecting consumer interest rather than securing the bottomline.

MS. COULSTON: The law aside, I think that some efforts have to be made at getting some pre-market control on dietary supplements.

MS. MITCHELL: And in the meantime, consumers needs to be informed. The current law does not guarantee that all current products are safe and effective.

MR. LEVITT: I thank you all very much. Our next panel. If we can ask you to come up on stage. We have John Buttolph, Edward Reiss, John James, Myrna Parks, Frederick Mayer. When you get up you can state where you're from and who you represent. Also pronounce your names properly, if I didn't.

Thank you all very much for joining us. You have heard by now myself repeat this several times, but at the front row we have our timer who will give you a one-minute warning and then a time is complete sign that you can see. We're getting a refill on the water. And while waiting for that -- we

have pitchers over here. If we can get that over to the other table. And with that we will go right down the list as I read names off before starting with Mr. Buttolph, Health Products Claims Alert.

MR. BUTTOLPH: Good afternoon, and thank you for your excellent pronunciation of that difficult name.

I'm John Buttolph, and I'm the founder of Health Product Claims Alert, a consumer group whose purpose is to alert the public about health product companies using false, misleading and unsubstantiated claims to sell their product.

Let me start by stating that our organization supports the consumer's informed use of dietary supplements to achieve a more balanced and nutritious diet. But the consumer is not interested merely in the claims made for these products, but expects companies marketing these products to provide truthful information in compliance with existing law, particularly DSHEA. Unfortunately, in the current regulatory environment, many companies are ignoring the law with impunity, and are making unsubstantiated and dangerous claims for their products' curative powers. I'm here today to urge FDA in the strongest terms to place enforcement of DSHEA as its highest

priority.

Until recent statements by the new Commissioner that FDA has all the authority it needs to regulate dietary supplements, the Agency seemed to be on a mission to convince the public that its hands were tied, and that in passing DSHEA Congress took away its ability to regulate supplements. At times the Agency has appeared more willing to complain about its alleged lack of authority than to use its actual authority to enforce the law.

Consequently, it's no wonder that a handful of companies are taking advantage of this regulatory vacuum to the detriment of those companies working within the framework of the law. Take for example E-Excel, a multi-level operation based in Springville, Utah. This is the first company my organization focused on - there will be others - and we recently completed extensive review of its product, promotional materials, labels and labeling.

It's hard to imagine a company more aggressive in its violation of the law than E-Excel, which appears to operate in a regulatory framework of its own, and raises profound doubts about FDA's commitment to enforcing the law in the nutritional supplements industry.

E-Excel's founder, Jau-fei-Chen professes to have discovered a nutritional immunology in which she asserts that when the cells of the immune system are properly nourished by E-Excel's product, they can mount attacks on cancers and viruses and successfully defend the body against disease. E-Excel claims that since most food are tainted by pesticides and preservatives, only certain pure food can properly nourish the immune system, and these foods are marketed by E-Excel.

These products are sold through a well-developed, multi-level distribution system, supported by the company's extensive promotional materials and publications. Many of these products are not correctly labeled as food. They contain no nutrition facts panel. Although mostly Chinese botanicals, they're not labeled in conformity with dietary supplement laws. They don't contain ingredient information, nutrition information, or any disclaimers of the miraculous curative effects claimed in the promotional materials.

For example, E-Excel promotional materials claim that a Phytocopia, a cookie, a blend of plant food; Enjoi, a lotus based beverage; Herba, an all natural beverage, and Nutria, a soy-based beverage,

can "treat, prevent and fight cancer," or contain "anti-cancer properties." Promotional materials for a cactus drink named Millineum, claim that it can be used as a remedy for insulin dependent diabetes. These claims made for these products violate existing law, apparently with impunity. How many consumers have discarded their more effective medications based upon these unsubstantiated claims?

This company and its founder, Jau-fei Chen, were warned by FDA in 1989 that her label claims for the product True Balance could make the product an illegal, unapproved drug. According to an FDA document, Ms. Chen promised to redesign her labels and submit draft copies to the FDA office in Denver for review. We could find no record of any follow-up on her part, or by FDA. Then, in 1992, she was charged with a federal felony for mislabeling imported gloves, pled guilty and paid more than $184,000 in fines. During a more recent FDA inspection, the company's vice-president denied having any marketing literature, brochures or product catalogs for seven of its products. However, the company's multi-level marketers quote extensively from promotional materials in selling these products.

In the case of E-Excel, enforcement action

is long overdue. Later this week, my organization will file a Citizen Petition requesting the Agency take administrative action to enjoin the company's unlawful labels and the promotion of food product as drugs. We're also asking the consumers who have purchased these products be notified of the Agency's findings and permitted to obtain refunds.

We urge FDA to enforce DSHEA so that consumers may have confidence that FDA is protecting them from unsubstantiated marketing claims and potentially harmful substances. Consumers deserve enforcement of existing law.

We appreciate the opportunity to present our views on supplement regulation. Thank you.

MR. LEVITT: Next is Edward Reiss from the National Psoriasis Foundation.

MR. REISS: I'm the trustee for the NPF. The NPF's mission is to improve the lives of people afflicted with psoriasis through education and advocacy, and to support research to find a cure for psoriasis.

Psoriasis is a chronic inflammatory skin disease which affects an estimated 70 million Americans, who because of its chronic and complex genetic nature, only have access to treatment that

controls the symptoms to a varying degree for each individual.

These symptoms can be painful, socially stigmatizing, and many people with this disorder are desperate to find new treatment. They're willing to try any new remedies, including those offered in health food stores and at web sites on the Internet.

The NPF supports the rights of people with psoriasis to make an informed choice of treatment methods, including conventional treatment and dietary supplements. However, although the consequences of DSHEA resulted in an increase in available supplements, we are very concerned it's diminished the rights of consumers to obtain the type of complete and accurate information necessary to make an informed choice.

We're also concerned that its provisions can be interpreted in such a way as to effectively eliminate the FDA's ability to enforce any type of reasonable standards.

With this in mind we'd like to make the following points: First, the vagueness of the structure and function terminology articulated in the Act is an invitation for abuse by manufacturers. It forces the FDA to create overly complex regulations

that are incomprehensible to ordinary laypersons to distinguish between permissible and impermissible claims.

Secondly, the structure and function claims require substantiation upon the part of the manufacturer. By putting the burden of proof on the FDA, the statute guarantees sufficient resources for effective regulations will not be available. Given the broad statutory definition of dietary supplements, the field is simply too large to litigate every dispute. The same applies to the listing of adverse reactions. Dietary supplements may contain concentrated biologic reactive ingredients, yet there are no requirements for listing of expiration dates, dosage recommendations, toxicity or overdosing information and contraindications.

Third, neither the Act nor proposed regulations address the issue of Internet sales and marketing. The FDA focused on labeling guidelines, but with the advent of the Internet, the effective distinction between labeling and advertising has changed. Traditionally label information is printed material on or accompanying a product. However, the effective definition of a label is a description of a product the consumer views at the point of purchase in

order to make an informed decision.

When a consumer purchases a product by pressing an order button on a website, what is the label for that product? Text on a container or the promotional material at that web site?

Fourth, the Act doesn't address the issue of international sales. The Internet allows a foreign company to offer their products directly to consumers in the U.S. People need to be aware of the origin of the supplements and their rights under the law. As an example, many people are unaware that certain countries do not honor default judgments awarded in a U.S. civil court of law.

If a foreign company that sells tainted goods in this county wants to avoid litigation here, they merely need not show up at the trial. Any litigation against that company would then need to be pursued in the country of origin, where the laws and burden of proof may be different than the U.S., and the expense of litigation higher.

So, in conclusion, by creating a broad definition of dietary supplements and shifting the responsibility of disproving safety and ethicacy onto the FDA, the Act places an impossible burden on enforcement.

Since the creation of the Act, the industry has grown so large it has become impossible to monitor, given comparatively limited government resources. The end result is that manufacturers of supplements are not effectively held responsible for their products.

This environment creates a haven for unscrupulous companies that would sell potentially dangerous or ineffective products without suitable warnings or meaningful substantiation.

The FDA has the power to regulate and require the testing of drugs before allowing them to reach the market. By comparison, the testing of dietary supplements under the current law is performed knowingly or unknowingly by the general public.

We can make a few obvious suggestions for the FDA to work within the boundaries of the current law. Emphasize enforcement, even if it means frequent litigation. Create a clear distinction between permissible and disease claims. Pursue an active and sustained campaign to educate the public, and the adverse reporting database on the Web is a great first step and we applaud it. And manufacturing standards that will allow the consumer to be assured of conformity between similar venued products. But these

suggestions are stop gap measures only. Ultimately the Act would need to be modified. Its real goal is to allow the public to make informed decisions about the purchase of supplements.

MR. LEVITT: Thank you very much. Our third speaker on this panel is Mr. John James, AIDS Treatment News.

MR. JAMES: Hello. I'm John James, and I founded AIDS Treatment News 12 years ago. We've been publishing twice a month ever since. It's located in San Francisco.

And, I came to speak about a few concerns. This has not been my main area of focus, on herbal products, but I'm just hoping to list some of the concerns there are.

One is that the -- on herbal products, for example, the standardization is much better in Europe, and one hears of researchers needing a bit of some substance for certain tests in a laboratory, and they wouldn't think of getting it here, they would get some European products that are produced under some regulations there so you know what is in the - what it is says on the label has something to do with what's in the bottle.

For example, here if you buy St. John's

Wort, there possibly is some St. John's Wort in it, you don't know how much, you don't know much, if anything, about how it was prepared or whether there should be an expiration date on it or not.

So, one way to approach this would be to educate consumers so that they know the difference, and consumers and their doctors and medical professionals to the extent that they, the medical professionals are open to considering herbal type products at all would then recommend that people buy the product. That might be a bit more expensive, but have some testing behind them and something on the label that's enforceable.

Even the FTC could enforce that, against them putting something on the label. That is just not true. The idea of a volunteer seal of approval sounds like a good one, and I haven't thought through this word-for-word, but there are various ways.

One that would -- one thing that would help on this would be some educational sheets on the line of talk papers, and as such FDA, what it puts out to address some of these concerns to tell the medical community and to tell patients, put it on the Internet, that these are some of the things to watch out for.

For example, in combining herbs and drugs, and when there's nothing known that can be put right on the bottle too. This has never been tested in combination with approved drugs.

We're also concerned that access could be seriously restricted in order to guarantee safety or ethicacy. The problem, you know, is there isn't much incentive to do research for products that cannot be effectively patented, and I would say certainly shouldn't be.

What that means is that if you're going to require a lot of research from when it's marketed, that essentially the product is banned. We're concerned about that as well. And of course there's -- it's been said before. We need -- the adverse events reporting is simply not working. We look at it mostly in regard to prescription drugs, but very few of the adverse events actually seem to occur, seem to get into that system. Doctors apparently don't know what to do to make that better, but it does have to be improved. Those are my comments. Thank you very much.

MR. LEVITT: Our next speaker on this panel is Myrna Parks.

MS. PARKS: My name is Myrna Parks, and I'm

not here in any professional capacity. I'm here to tell you about my son, Josh Parks. Please bear with me. It's very difficult.

He was 23-years-old when he passed away on July 4th of this year. His death is under investigation and we don't know the cause of death at this time. Josh came to live with us in April of this year, and he was very sick. His saliva glands had quit working and he was suffering from diarrhea and vomiting. He had lost 10 pounds in four days. His resting pulse was 120, and normal is 71. Josh continued to suffer from insomnia and bouts of sleep apnea. He had had four emergency care visits prior to coming home ill.

I saw how my son suffered, not realizing at first that the supplements he took to body build, which he told me were growth hormone supplements, were actually making him so sick. He said to me, "Mom, how can it be bad for me? I bought them at the nutrition store." On April 26th, I witnessed a severe poisoning from a new growth hormone product, NRG-3, which later we read on the label as containing five milligrams tetra-methylene glycol purchased at the nutrition store. These stores were advised by the FDA not to carry these product as of January 1999, but they

continued to stock and sell them.

I had gone with Josh to his doctor's office where he was to have blood taken to try to determine his illness. His doctor at that time suspicioned he had a thyroid problem. He was released to go back to work, light duty, and he was going to go work out after he dropped me off. What occurred next is a hideous nightmare.

Josh was driving and he said to me, "Mom, I'm hungry as a hippo," and he pulled into McDonalds. I waited in the car. I watched him eat his fries and I thought, something is not right. I said, "Josh, you're not acting right and I'm going to drive." I didn't get two blocks and he started to sweat, his body began to jerk and spasm. He began to wave his arm out the window. His eyes looked wild and dilated. He couldn't speak. Had he been alone he would have had a serious car accident and other innocent people would have possibly been hurt. As it was, I drove him back to the doctor's office and they called 911.

Josh was taken to the hospital where he became progressively worse. There was no mental response, he couldn't be laid down because he would gag on his own saliva. They kept him partially sitting up so he could drool down his chest. His eyes

would roll back in his head, and it seemed to me my son was dying, and if not that I might have a vegetable to take home and care for. But, let me say this, I would have taken a shell home, whatever God would have let me keep, I would have kept.

He continued to lapse in and out of a coma-like sleep. The doctors kept asking me, "What did he take?" All I could tell them was, whatever it was he purchased it at the health food store. He had purchased Renutrient and Firewater for his bodybuilding.

The toxicology reports that were taken that day showed no drugs in his system. As he slowly began to regain consciousness he showed infantile responses. He would giggle and reach out for his IV. I couldn't leave him alone for fear he would harm himself. This entire nightmare lasted four or five hours.

On the way home Josh began to remember what had occurred prior to his poisoning. He thought he had just passed out and he didn't know why he was in the recovery room. He remembered going to the supplement store and told the sales clerk he was going to go work out, and the clerk advised him that the new NRG-3 was new and great stuff, just take an ounce with eight ounces of water or juice. He said it tasted

terrible and made him sick. On the warning label it read, "Do not ingest. This is a cleaning solution."

You would think this is the end of my story, but it's not. Josh was convinced he had just gotten a bad batch. On Memorial weekend we came home Saturday night to find my son difficult to wake. His eyes were again dilated and he began to lapse in and out of a coma-like condition. We again called 911. This time I could tell the doctors and nurses what I thought it was, a "GHB" precursor. Blood tests and urine tests again showed no drugs in his system. We waited for Josh to wake up, and I remember the nurse saying to Josh, Next time, you won't wake up. She was right. Josh was upset and he was embarrassed that I had overreacted and called 911. I know now why. The product says to just sleep it off and not to call 911. Emergency help could be dangerous. Just let the people around you know you will be hard to awaken.

When we had Josh's wake, many of his friends told me how they had fallen asleep while driving. Some had to be resuscitated by emergency help. They told me it took them two weeks to get off of this drug. They had spent thousands of dollars to purchase it. How they wanted to crawl out of their skin with withdrawal symptoms. They know this is a

drug. They asked me, How can this be sold at a nutrition store? Aren't there laws against this? All of them said, We didn't know how bad it was. It's not what the advertising says.

Josh fell asleep and he never woke up. How many more of our children will fall asleep and never wake up while we wait for something to be done?

MR. LEVITT: I want to thank you for coming today. I know how difficult it was for you. I think you can tell from the silence in the room that everybody's hearts and prayers and sympathies are with you. Thank you.

MS. PARKS: If anyone -- if you can do one thing, it is to tell one person because one grain of sand makes a beach. These people are here today to ask for help, and we need to give that to them, and we need to do it immediately. This is nothing about anything that we can't stop. It has to stop now. We don't have a year, we don't have five years. You've got to do something now.

And it isn't about waving a magic wand, it's about making information available to these children. They are not going to read your MedWatch. They are looking on the websites. They are believing what they read on those websites. You cannot let

nutrition stores go out there and sell these kinds of drugs to these kids. Somewhere, someone has to stop this, and it begins right here in this room, right now.

MR. LEVITT: Our final speaker on this panel is Frederick Mayer.

MR. MAYER: I understand there are chemists in the room. When I was in pharmacy school at U.C., ethylene glycol was anti-freeze, if I'm not mistaken. Tetro-methylene glycol is antifreeze. And just off the subject, but 60 Minutes had a big expose about propolyne glycol getting into the children's aspirin in Haiti, 242 kids died because they used ethylene glycol with Tylenol for taking down fever. And again, I saw this.

My name is Fred Mayer. I'm a pharmacist. I am the president of Pharmacists Planning Services, a non-profit public consumer pharmacy and educational organization. I'm also a practicing pharmacist for 45 years. I'm also past president of California Public Health Association, and a member of the Marin County Unit of the Gray Panthers, along with the Northern California Gray Panthers board of directors.

The National Gray Panthers, in conjunction with PPSI, have formed a coalition to educate seniors

on prescription medications, drug interactions, nutritionals, and in general have had eight meetings regarding FDA, prescription drug issues. These meetings have taken place around the country.

Of the many problems seniors have articulated in our meetings, I would like to point out some of the major issues which stand out in all eight meetings.

Number one, there's a failure to properly label alternative medicines, herbs, natural products with side effects, drug interactions, allergy issues, pregnancy warnings for our grandkids, and a basic understanding of the use of these types of medications.

Number two: There are 107,000 Americans dying each year from adverse drug effects because they're mixing their drugs with over-the-counter alternative medicine and prescription drugs, and they don't know what they're doing and there's absolutely no warning. In simple, over-the-counter drugs that you purchase in pharmacies or grocery stores or whatever, we have OTC labeling. Why can't these drugs be labeled? I don't understand it.

FDA says we can't do it because DSHEA. DSHEA says you can't do it. It can, and must be done.

Number three: Failure for health care professionals, including pharmacists and physicians, to even ask about these alternative medicines and to counsel seniors on these side effects.

Number four: In March of 1998, PPSI and other citizens petitioned the Food and Drug Administration regarding the fact that the Agency has not instituted standards for the labeling of botanicals, nutritionals, and natural products that would be similar to the labeling requirements for over-the-counter drugs.

I am enclosing a copy of this document, and I'll give you copies of this information to The Panel of our citizen petition.

I will not go into the various concerns which are listed, including deaths of kids and seniors who have taken ephedrine as a weight reduction product and stimulants along with the Oakland A's former player, Mark McGwire, now with the St. Louis Cardinals, who is taking androstenedione.

Androstenedione is a simple thing you buy in a health food store, and it breaks down to testosterone. And every young kind that wants to build muscles like Mark McGwire is taking androstenedione, and it's a crime, and you can just

buy the stuff. What's wrong with that? What's wrong with that, the precursor of testosterone? To give young kids testosterone before their time is absolutely ludicrous.

I would like to leave you with this March 26th news release from the Canadian government. I just got this the other day, the folks at the food and drug panel here. The Canadian folks have done something about it. They have passed 53 recommendations, which we need from -- which basically says, one, they're going to have labeling on all their nutritionals. Why can't we do it here? Is Canada that much further ahead of us? It's all there in the 53 recommendations.

Number two: Proof of ethicacy. You can't put a drug, or a product, or an alternative, or an herb, or whatever you want to call it, on the market without proof of ethicacy that it works.

Number three: In the back of this material that I hand you, here's an herb chart for health care professionals that the American Pharmaceutical gives out, and in this herb chart the four G's, ginger, ginkgo, garlic...and...I'm getting excited. I'm sorry. I've got five minutes. I'll slow down here. The four G's, ginkgo, garlic, ginseng and ginger.

If you'll call attention to the back page, all four of them have anti-platelet or anticoagulation drug interactions. We're not talking rocket science here, folks. There are 7 million seniors like myself who've stroked out. We're all on anticoagulation therapy, and you don't even bother to tell the seniors about a drug interaction with four of the most popular -- and I say "you," somebody out there. You've got to protect us.

Sone of our other concerns with include the Gray Panthers and consumers' issues are the issue of echinacea. Echinacea shouldn't be used by folks that have arthritis, lupus, leukemia, AIDS, and so forth, anyone with auto-immune suppressant diseases. You've got to label the stuff because people are dying, and it's wrong.

Seniors are very concerned about another dangerous drug which is being sold in nutritional stores which is classified as Ma Huang. Ma Huang is another name for ephedrine, which many of our weight reduction and many seniors are taking, and now we've got young kids, nine deaths in Fresno from Ma Huang, in something called "Ripped energy" or "Ripped" something. Our young kids get ahold of this and use it for energy, and there's no warning on this

whatsoever.

And again, when I say those ephedrine products should be behind the counter or taken off the market entirely, in Canada -- and I can't believe Canadians are that much smarter -- ephedrine is prescription only. I would like to propose the solution.

Let me get the solutions. I think I got three more minutes here. I didn't see that. I'll save it for later. Thank you.

MR. LEVITT: We thank you for your enthusiasm and your package of material.

MR. MAYER: I don't want your enthusiasm. I want you to do something. We've been before this dog-and-pony-show before, and I came before you, I think it was last month. It is time to do something. People are dying. You've heard it here. And if I'm emotional, I intend to be emotional. Propylene glycol? You've heard it here. They're selling this stuff without any warning. It is a crime.

MR. LEVITT: I want to come back to a moment -- and I know everybody here was a combination of affected and horrified by the experience you've gone through, Ms. Parks.

The product, and I would like to take you

off one -- I believe this is sincere offer, what can we do now? The product that you referenced, which I believe is a GBL product, a product that FDA sought to take off the market last winter, and yet as you said it does appear and kids can get it. And the question I have for you and for the others is, what mechanism do we have to get credible information to these kids that they'll listen to? You know, what -- what do you think your son would have listened to as a credible source of information to say you shouldn't be taking this?

MS. PARK: Well, right now on the Internet they're listening to what is being advertised. They're listening to who sells this. And what they're being told with these precursors is it increases muscle mass without exercise, lose weight, high energy, elimination of cellulite, improves sleep and mood elevation, better kidney function, lowered blood pressure, hair re-growth and restoration of color. Stronger bones, faster healing. Younger, tighter thicker skin. Reduction of wrinkles, improved immune systems and greater cardiac output. That's what they're reading, and that's what they believe.

They don't think to look up MedWatch. They are being allowed to advertise false information and

misleading information. That's what they're believing. You have health food stores, they're selling this stuff and they're not even reading their own warning labels, and it's not being enforced.

You have the sheriff's department going into nutrition stores and getting them to get it off the market and getting off the shelves and they're putting it right back on the next day. They're going to the gym and buying it as weight belt cleaner. That's the problem. That's why they don't look up -- I don't know half the kids that read a newspaper. If you're going to reach those children, you've got to stop the gyms, you've got to stop the nutrition centers, and you've got to stop the false advertising.

I thought we had laws, protective laws to protect us too, but obvious we don't, and they're not being enforced either. So, this labeling and being able to sell tetramethylene glycol, we got GHP off the market but all the precursors are left, and they're even more disastrous, even more dangerous, and you're selling it to kids and saying...what else? While one ounce is okay, one and a half ounces might be an overdose. But to a kid, they're like anybody else. They look at that one ounce. One ounce for the hundred pounder. I'm 200 pounds, so I need two

ounces. They're going to be taking more than what they're supposed to be taking. They're young and they're stupid, and they believe everything that they read. We're the only ones at the age to have enough sense to not believe, and we still -- we still -- I'm just as guilty as anyone else. I thought that I was protected.

I didn't know what to say to my son when he said, I found it at the health food store. It wasn't until we had the wake and those children came up and told me how bad it was that I really got the picture. They know it's a drug. We are the ones that don't know it's a drug. And it shouldn't be on the market at all.

DR. YETLY: Thank you. All of you have raised concerns in terms of safety issues. If you could make -- if you could help FDA prioritize how you were to deal with safety issues, what would be your top priority for a short-term action, and what would be your top priority for a longer term action?

MR. BUTTOLPH: In the short run, FDA needs to act on the violations that come to its attention. I know that there are citizens petitions filed regularly that call the Agency's attention to violators. And yet if there were reasonable

enforcement, there would be an example to the industry that would encourage a higher standard.

I don't see that happening now. As I look at this industry, the dietary supplement industry, you mention FDA enforcement and people shrug, $5,000, $10,000 to a 100 million or multi-billion dollar industry with grosses of hundreds of millions of dollars, there's no threat.

And if you want to get some attention in the short run in the industry, you need to enforce the violations that come to your attention. I mean, the longer run answering your question, Joe, I think -- my kids have -- I have kids 10 and 13, and they watch a lot of TV, too much TV, watch too much MTV. I tell you, one of the things that's really effective when they see those drugs commercials with that girl frying an egg and taking that -- that's not a warning label. That's not some high faulting academic agency language.

You serious about wanting to reach young people? Get some PSAs and take on the issues of dietary supplements and treat them like they should be treated, as the serious drugs that they are.

MR. REISS: I would agree. The short term, the FDA has no choice but to pursue whatever options

or power they have now. I was under the impression though that there were two very high profile cases, one of them was Ma Huang and they were litigated and pursued to the end and the FDA lost, and that motivated me to basically decry the law itself which I felt doesn't give us sufficient power.

In the short run though, really just high profile educational programs, perhaps traditional media on the web, in particular. Perhaps the FDA could address the same demographic groups that are being addressed by the dietary supplement manufacturers. They could have a site for body builders where they would talk about the various supplements and perhaps gives information that young people otherwise wouldn't get.

MR. MAYER: I think if there's one thing that we would like to see, it's FDA get some guts, adopt the 53 recommendations from the Canadian government, and at least study what they did. It took them a couple of years to do it, and it's all in that packet I gave you.

MR. JAMES: One thing both short and long term would be to get information out to journalists in a form that they can use without getting in trouble because they've used it.

Two: On the information being the warning about the particular risks that are most threatening to people. Thank you.

DR. BOWEN: Again, the Panel has really focused on safety issues here, and if there's anything else that you can give us advice about concerning how we can best educate consumers who need to know about it because they tend to take these products and have these adverse events, give us any additional suggestions you might think of.

MR. MAYER: In your pack I gave you -- for 10 years I worked on USP consumer safety standards. In your pack I gave you is a brochure on the information of goals and objectives on a nutritional brochure to educate consumers, better inform consumers on how these products are manufactured, tested and regulated.

Two: Inform consumers how and why those food supplements are regulated differently than medicines.

Three: Make consumers aware how these products should be treated as seriously as medicine.

Four: Encourage discussion. I won't go on, but it's in your pack. The entire outline is there, and now I'm saying, let's do something, gang.

MR. DORSEY: I guess a follow-up question to that. If -- a lot of the Panels spoke -- on this panel and on previous panels -- have spoken about the fact that many consumers, if not all consumers, are most concerned that consumers are not aware of the extent and the way in which dietary supplements are regulated and how that is different from the regulations of other products like food and drugs.

Do you think that if the Agency were to -- or if somehow the public were to become aware of those things when the Agency did issue public notices about concerns about particular products like GBL and take action against those products that that would, I guess, set in consumers' minds a concern of the notion at least some of these products may not be safe and I've got to be careful about them, and there would be an openness to follow the advice about concerns about some of these products like GBL, or ephedrine or whatever?

MS. PARKS: I personally think that -- and I know and have been aware of what these precursors were, and that they were actually what GHB was. I would do whatever I could to help you get it off the market. I think probably just about everyone in this room would be right behind you and enforce whatever it

took.

I know that you can go to stores and if the meat is bad and that store is selling mad cow disease you're not going to purchase it, and we're going to pull it off the market, but yet we're sitting here with these types of drugs in our nutrition stores and we're not doing a thing about it. They can sell it outright, but they cannot sell it to ingest it. And that's what they're selling it, and it's still on the shelves. It's still being sold. It's still selling out of the backroom at gyms right now. Today. What can you do tomorrow to get it off the shelves? I can't tell you what your job is. Only you know what your job is, and you know what your power is. But I can just say, I'll help you as much as I possibly can, and every single one of those kids at that wake would.

MR. REISS: I was going to suggest that certainly informing consumers about the current extent of the focus on the web because that's right now the most you can put up a web site with as much marketing material as they want, and it sits there and gets hit. And other than regulating such sites, which would be obviously the optimal solution, basically put your own information there in a high profile manner, and that's the only short-term solution I can see.

MR. BUTTOLPH: I think if your target audience is younger people, you need to have an effective way of talking to them. I don't know if a public notice in the daily paper or however you promulgate that is going to get it. You need some high profile spokespeople.

The next time one of these athletes gets in trouble with the law and has to do some public service, don't send them to the library to talk about his reading habit, send them out to do some PSAs about danger for these kinds of supplements and the abuse of these supplements. That's what these people listen to. And if you want to get the attention of these companies, take on some high profile expensive litigation. You take a few more shots, you don't win them, that's not necessarily the most important thing. You have to be out there fighting the good fight. We can't do it. That's your job.

MR. LEVITT: Again, I would like to thank this panel. As all of you before, you get one more opportunity. A lot of you, I think, have been very clear and direct already. I will give everybody one more opportunity to say one clear thing for FDA to focus on in the near term would be.

MR. MAYER: I think the worst thing that

ever happened in my 45 years as a pharmacist is the DSHEA Act. I think if you could focus on overturning the DSHEA Act -- I see grimacing. I think right now you're completely -- for me you're completely powerless. Until you can get your hands on these kinds of medications that are causing the harm, I am not sure -- to be honest with you, we're up here, you're spinning a lot of wheels, so I have gone to my legislators, and I have asked about DSHEA, and I've asked for some more hearings. I think DSHEA is so very, very important.

Just a quicky. I'm in the shopping center in Corte Madera and there a guy comes up with a product selling from a little cart. It's got 16 ingredients in it including Ma Huang, 40 milligrams of ephedrine alkaloid, including guarana. I said, what is guarana? I never heard of it as a pharmacist, which is my ignorance.

He said, it's got caffeine in it. Here's a product with caffeine and ephedrine that raises your blood pressure sky high, they're selling it from a cart in the Corte Madera shopping center, and 14 other ingredients listed in this weight reduction product.

They took this combination of caffeine and ephedrine off the market when we used it in our weight

reduction product called Dexatrim, but yet these folks are allowed to sell it. I'm not sure you can do anything.

Even though more and more people die out there and we give you more and more statistics, you've got to get someone that can act on your behalf because I think you've lost it. And the reason I say this is because you -- I like these hearings -- and I've used up my time -- I think what we need to do is overturn DSHEA, and I'm not sure how you do it. I'm not sure.

MS. PARKS: I think that we must have laws to stop these gyms from selling out of the back rooms, and also putting notices up in the gyms, at the nutrition stores, putting up posters, notifying sales clerks. Making people legally responsible for their misinformation and misguided efforts to make the almighty dollar. These kids are spending thousands of dollars, and they're getting away with it, and we're not enforcing any of the laws that would actually have an effect.

MR. JAMES: I would think to look and analyze carefully where the biggest safety problems are and then come out with media material that's based around actual cases that are things that happened to people. And, sometimes celebrities and whatever it

takes to communicate what the basic risks are that people should be aware of things like.

MR. BUTTOLPH: I've heard that we don't like the law we've got, but let's enforce the law we got. And let's enforce it aggressively until we get a better law. But let's not sit and say, let's not enforce this one until we get a better one because more people will be affected badly.

And the worst thing that could happen is that the government agency particularly will lose any credibility with the industry and with the public, and that is a crime.

MR. REISS: Assuming this is the magic wand question, I would have to agree with the last panelist, the effect of pre-market regulations would be the best thing, but that's not going to happen.

I guess I would agree with Paul that you should stretch the limits of the law to the maximum, and if that means litigating a few high profile cases that would illustrate the limitations of the law, then that is what is going to be necessary.

MR. LEVITT: Thank you all very much. At the conclusion of this panel, we have an opportunity for about a 10-minute break. We can get back here at about 3:00 o'clock.

(Recess taken.)

MR. LEVITT: If I could get somebody's attention. We need to get going for the final session of the day, please. We have two remaining panels.

I'd like to thank everybody in the audience for your attention throughout the day. The next panel has five individuals. If I could ask you to come up please as the others have.

Kermit McKemie, Ed Blonz, Michael Onstot, Ed Anderson and Marcy Fenton.

As you have heard me say multiple times, we'll ask each speaker to limit your presentation to five minutes. In the front row we have two signs here. If you could hold them up so you can see what they look like so you won't be surprised when you're speaking and they get pulled up like that. And then afterwards we'll have a round of questions.

Again, when it comes your turn, if you could introduce yourself, say who you are representing and go into your presentation.

Mr. McKemie.

MR. MCKEMIE: Good afternoon. My name is Kermit McKemie. I'm at this public meeting for the consumer, an older retiree. I retired from an FDA field position about five years ago. Since

retirement, I maintain interest in food, safety and health matters and have informed opinions to share today on the matter of consumer choice and also on GMPs relating to this product industry.

As America's population ages, we will see more and more magic from the bottle to maintain physical and mental vigor. Some older consumers will seek certain products on the belief these are totally safe and have no strong or deleterious chemicals. Chemistry is chemistry, whether to Eastern medicine or to Western medicine.

Many older consumers will seek dietary supplements, alternative therapies out of desperation or because they can not afford mainstream, prescription drugs. A number of older consumers will be fooled by the hype, will not understand the labeling claims and disclaims and will gamble part of their retirement health budget on dubious or possibly unsafe drugs.

Basically, it's a crap shoot out there with dietary supplements. On the other hand, consumers have a responsibility to exercise healthy skepticism and to apply the principals of science in deciding if something is true or not, be it UFO, alien abduction or magic in the pill box. The adage, the fool and his

money are soon departed applies to these products with possible health benefits. The adage, if it is -- if it seems to be too good to be believe, it's probably false.

I'd like to say that it seems today to be very difficult for consumers to obtain good information on alternative health remedies. Carl Sagan in his book, "Science as a Candle in the Dark," has a chapter on science, skepticism, entitled the "Fine Arts of Momentum Detection." This book is highly recommended for those who want to know more about anecdotal baloney, paid testimonial and junk science.

After having worked for FDA for a good many years in both the food and the pharmaceutical area and field inspections, I've see reviews of that. I'd like to make a few comments on GMPs. GMP regulations and inspectional coverage should be equivalent. From past personal experience a completely volunteer system will not work. A few companies, the bad apples in the barrel, will cut corners out of ignorance or greed for possibly terrible consequences.

Recently this month some of you may have watched 60 Minutes where antifreeze material was substituted apparently deliberately with glycerine USP

and killed some 80 Haitian children. This could well happen in this industry. The product is herbal, and the herbal ingredients include noxious weeds. Standardized on the part of the plant having identified in activity processed to retain activity and be free from dirt, vermin contamination, pesticides or both. Products should be compatible with a master formula procedure in a sanitary facility.

FDA should have full authority, including criteria established in the bioactivity of the ingredients and the potency particularly as related to long term storage on the shelves.

If this information is declined and this review is unsatisfactory, such as a lack of acceptance testing, or filthy manufacturing conditions, then the product should be considered adulterated under the Act under Sections 4283084, and expeditiously removed from the marketplace. I'd also believe, and this is my opinion, that FDA should charge inspection fees to implement such inspection systems.

FDA seems unable to prevent the marketing of a fair amount to remove unproven or dangerous products. This has a definite impact on the overall credibility of FDA as an effective consumer protection

agency.

This is a multi-billion dollar business. The products are found in health clubs, they're pushed by coaches in high schools, colleges. They're found in shopping malls, gas stations, sales counters, almost everywhere. They're pitched day and night, on the Internet, on TV, print media and other venues. In consideration of this multi-billion dollar business, FDA should take a much more proactive stance to regulate and to provide informed choices for the consumer. Thank you.

MR. LEVITT: Thank you very much.

Just before we move onto the next speaker, I had a note that I forgot to read before, although you already knew about it already, and apparently the court reporter has asked, not withstanding the five minute rule, we try to speak a little more slowly. You did beautifully. The next speaker is Ed Blonz.

MR. BLONZ: Good afternoon. My name is Ed Blonz. I'm a university-trained scientist and former academic. I'm now self-employed. I have a number of publications in peer-review journals and have written seven popular books on food and nutrition. My efforts during the past 10 years have been specifically focused on bridging the wide gap between scientific

research and public understanding. And in addition to responding to consumer questions online, I have a weekly newspaper column that goes to more than 600 newspapers around the U.S. And I deal with a wide range of issues on nutrition, food, food science, health and now alternative medicine. I receive more questions than I could ever hope to answer, and I'm grateful for being given an opportunity to share some of my experiences.

First, I applaud the efforts to enhance FDA effectiveness in the regulation of dietary supplements. In my experience, one of the greatest dilemmas is the uneasy balance between the regulatory imperative to establish safety and reliability and people who want their cures now.

Our treasured societal freedoms open the door for a never-ending variety of scientific shenanigans. Those grounded in rational thinking would agree that there has to be a mechanism to control unsubstantiated claims. Science should and must be the final arbiter of what gets told to the consumer under the aegis of authority, but I've observed that many so-called "experts" find a great deal of flex with the facts -- especially when commercial interests are concerned. Indeed, companies

that take the high road where research and verification are concerned, may find themselves at a competitive disadvantage to other companies that play fast-and-loose with their science. This must stop.

Typical strategies involve a reliance on anecdotal evidence coupled with a pitch that "it worked for them, so why not for you." We have heard this all throughout the day. Factor in the support of a good salesperson with pseudo credentials, and you could end up with a very impressive marketing clout.

There's also an incessant parade of infommercials bleating their endless tirades of testimonials, each offering framed with the trite sounding statement, "finally a product that really works."

Another conduit for questionable products is the burgeoning field of multi-level marketing. This marketing technique has neighbor selling to neighbor, oftentimes trying to recruit them into their sales force. I found that when health-related products are being offered, the facts tend to take a backseat. In many cases, the dealer has no real training in any health-related field.

As the average age in this country continues to rise, we have the reality that more and

more people suffer from, or are at high risk for chronic ailments. They're often told to grin and bear it by a managed health establishment made ever more impersonal by a myopic focus on the bottomline.

These are the realities, and they don't lend themselves to simplistic solutions. As food for thought, I'd like to suggest the following:

One, testing for safety and effectiveness continues to be a thorny issue. Manufacturers complain that there's little economic incentive for them to fund the research needed to prove their health claims. Besides, once done, the results could be used by anyone. Despite this argument, though, the burden of testing must fall on the industry that stands to profit from supplement sales, not on the FDA. Tax incentives might be made available in order to coax the industry into action.

Two: Congress should consider giving the supplement industry a defined period to get its house in order. During this period, a self-policing policy would be established, safety testing could be started, and a non-partisan panel could be empowered to decide the type and amount of proof needed to affirm product potency and purity and establish health claims. A triage approach would be utilized to assure that the

most critical issues are handled in an expeditious manner.

Three: The FDA, in cooperation with other government agencies, perhaps making use of the Cooperative Extension Service, would be charged with providing a series of warning labels or inserts to inform consumers about side effects, minimum toxic doses and potentially dangerous interactions with other nutrients or herbs. Similar information would be made available to health professionals. This would have the added benefit of helping to open the doors of communication between patient and health professionals regarding the use of alternative health modalities.

Advertising campaigns would be instituted to alert the consumer to look for products that carry the product inserts. In tandem with this, an industry or government sponsored "seal of approval" might be instituted to help consumers identify and patronize the companies that take part in the process.

We all can recall how a massive effort was instituted to develop tamper-proof seals as a consumer protection measure. We can do it again. We need to do it again.

In conclusion, we must be ever cognizant that what is speculative and unproven is not

necessarily false. It simply means that the requisite tests have yet to be done. Much of what is now mainstream science was once considered irrational at one time. If regulations end up overly conservative, it would lead to an inevitable consumer backlash and a black market, with proponents elevated to the standard of martyrdom. Not only would this tarnish the image of the FDA, the enforcement implications of such a development would be staggering, both politically and in terms of funding realities.

The onus must be put on the industry, with the industry put together with the regulatory agencies charged with enforcement. The bottomline is to strike a common ground where the consumer is the ultimate beneficiary. Thank you.

MR. LEVITT: Thank you very much.

Our third speaker on this panel is Michael Onstot.

MR. ONSTOT: Thank you. I am executive director of the national AIDS Nutrient Bank, a nonprofit organization that's in Northern California that provides free nutritional supplements to people with HIV, AIDS.

I would like to agree particularly with the last two speakers, and particularly the last speaker,

because I found that the morning to be a little scary with the toxicology emphasis and the threat to the first amendment.

And I particularly found Dr. Farnsworth's comments to be refreshing because I think we need to strike a balance here, but I only have five minutes, so.... We -- that is, Fred Bingham and I, Fred Bingham being from an AIDS buyer's club in New York have given previous comments at the June 8th meeting at the FDA regarding a system of labeling that would enable consumers to know the difference between claims that were well substantiated and those that were not.

Today I would like to address some of the concerns and priorities within the AIDS community regarding the regulation of dietary supplements, also I would like to briefly cover a few of the problems with the current situation followed by some recommendations. And given the previous testimony I don't think I'm preaching to the choir here. I think I have different opinions, but in the AIDS community I realize that we have a sense of urgency that possibly other people do not have.

And also, I think that we have to look at the reality of consumers and include them, and that's going to be one of the themes. And the number one

concern for consumers of dietary supplements, including hundreds of thousands of people with HIV, AIDS is access. Access in the broadest since. Access to affordably priced, quality products and to accurate none misleading information about safety and ethicacy.

Just briefly, our priorities are the following:

Number one: Unrestricted access to safe dietary supplements.

Two: Useful and accurate information about safety, such as adverse effects, contradictions and particularly interactions with drugs. I take 17 pills twice a day, and some of those pills definitely interact with herbs that I also take, such as sulmarin, but I really don't know to what degree those interactions are taking place. I am not about to stop taking the sulmarin because it is helping keep my liver enzymes down.

I would rather risk the interaction of lowering the doses of the HIV drugs because liver damage is going to kill me faster than HIV in this particular case.

Three: Quality assurance and label integrity based on good manufacturing practices, or GMPs.

Four: A label system for structure function in health-related claims that are located to the degree to which a claim has been scientifically validated.

Five: Availability of low cost quality supplements, especially for lower income people.

Six: Substantial continuing consumer input and involvement in the entire process of developing and implementing strategies for regulating and researching dietary supplements.

We want to be at the table, but in the past we have not been at the table in the way we should. We have been in -- at least not in the AIDS community at least -- we've been at the drug table. We have not been at the dietary supplements table to the degree that we should have been. And in fact, DSHEA was basically written by industry lawyers, and we actually worked with the industries to get it passed because we were concerned about access.

But, now we have this process and we commend you for opening up the process but if we're not heard we're going to have to look elsewhere for regulations and we're going to have to look elsewhere for products if they are taken off the market.

So, we are very concerned about the threat

to viable products and we would -- we would ask you to give us the kind of information, and I mean, at least facilitate the kind of information that we really need. There are real problems with the current situation.

On the one hand we are frustrated by the virtual deluge of totally unsubstantiated and sometimes misleading and even harmful claims. The profit-driven industry has made some efforts but has never really solved the problem, and may be incapable of regulating itself.

I think it is, as per the Internet, for instance, but on the other hand, an enforcement-oriented FDA has failed to develop the kind of unbiased expertise within its ranks that is absolutely necessary to properly regulate the dietary supplements against the economic encroachment of effectively lowercase incompatible nutrients and botanical remedies.

A relatively paternalistic FDA, although it has made some strides -- and I do want to commend you on that, has also failed to take on a reliably constructive leadership role that empowers consumers to make informed choices.

With respect to dietary supplements, many

of us in the AIDS community do not trust the Agency to consistently act in our best interest. In the past the FDA has overreacted to situations of anecdotal evidence involving theoretical safety concerns by assembling or actually removing products from the market and thus severely restricting access.

FDA must focus on products that are genuinely harmful. Currently, the Agency is involved in a type of distraction in that it's trying to define the word "disease" in a way that would eliminate many valid structure functions and health-related claims.

We are opposed to censorship, but consumers in the AIDS community are caught in the middle between the Wild West Show of ridiculous and misleading health claims and the FDA, who we believe has acted in ways that may restrict our access. To the recommendations -- and I know I'm out of time, but I got to give you something -- I've got to tell you something positive.

Number one: Fully implement DSHEA as Congress and consumers have intended, especially regarding GMPs.

Two: Utilizing current data, make a preliminary assessment of some of the most popular vitamins, herbs and nutritionals and appropriate adverse effects and/or particular risks, and then make