

1 ask one final question, which I have telegraphed in advance,  
2 which is: A year from now, if there was one thing that you  
3 would like to see occur, it would be--blank.

4 And, with that, let me invite Dr. Adrian Fugh-  
5 Berman--if I have pronounced your name correctly. If not,  
6 please correct it for me--from the National Woman's Health  
7 Network.

8 **PANEL III - CONSUMERS**

9 DR. FUGH-BERMAN: Good afternoon. Pleasure to be  
10 here.

11 My name is Adrian Fugh-Berman, and I'm Chair of  
12 the National Woman's Health Network, which is a national  
13 consumer advocacy group that takes no money from drug  
14 companies, medical device manufacturers or dietary  
15 supplement companies for that matter. I also integrate  
16 herbal medicine into my practice, and am a consultant to the  
17 Federal Trade Commission on dietary supplement issues, and a  
18 member of the ad hoc panel on botanicals for the U.S.  
19 Pharmacopoeia. And I teach about botanicals all over the  
20 country.

21 It's a women's health issue because more women  
22 than men use alternative therapies. And there is a plethora  
23 of dietary supplements that are specifically marketed to  
24 women. They're very popular with consumers. They're also  
25 very popular with physicians. I've just come from

1 Columbia's Botanical Conference last week, where it's a  
2 whole week-long course--CME course--where we teach  
3 physicians about botanicals.

4           The current available of unregulated products that  
5 are widely divergent in quality, safety and evidence of  
6 efficacy really raises a number of public health concerns.  
7 Consumers have no tools or guidelines with which to assess a  
8 product's quality. Labeling is very vague;  
9 contraindications aren't listed; drug interactions aren't  
10 listed. And there are some dietary supplements that should  
11 just not be on the market at all. I have--comfrey contains  
12 pyralizidine alkaloids with proven hepatotoxicity. There is  
13 no reason for this herb to be on the market. DHEA and  
14 melatonin are very potent hormones that are not part of any  
15 sort of traditional medicine. They shouldn't be considered  
16 dietary supplements. They shouldn't be on the market.

17           I would disagree with the speaker this morning who  
18 would put together herbs or botanical medicines with these  
19 hormones. They're very different things. And the National  
20 Woman's Health Network would definitely support having an  
21 advisory committee on dietary supplements. I would  
22 emphasize, however, that it would be very important to have  
23 at least half of those members be conversant with botanical  
24 medicine. Herbs are quite different from other sorts of  
25 dietary supplements, and really need to be regulated

1 differently. They span the whole spectrum, from foods to  
2 drugs, and it's really important to integrate people who are  
3 familiar with these.

4 I've forgotten to say that this testimony was  
5 prepared by myself and Dr. Varro Tyler, who is one of the  
6 most eminent pharmacognicists in the country. And it's one  
7 of the expertise--it's--FDA needs to integrate  
8 pharmacognicists into this discussion. There are very few  
9 pharmacognicists working in the FDA, and those that are  
10 there are mainly sort of banished to the laboratories, and  
11 they really need to be incorporated into all levels of  
12 these.

13 Even--science supports the use of many  
14 alternative--of many dietary supplements: St. John's wort to  
15 treat depression; garlic to lower cholesterol; folic acid to  
16 reduce the risk of neural tube defects, but even in these  
17 cases, labeling these to reflect caution. Garlic can  
18 inhibit platelets and can cause bleeding; folic acid  
19 shouldn't be used with certain drugs; St. John's wort can  
20 cause photosensitivity. It shouldn't be combined with  
21 certain anti-depressants. So it's really very important  
22 that labels be accurate, be understandable and have adequate  
23 warnings on them.

24 It's really important not to ignore work that's  
25 already been done. There's quite a lot of research on

1 botanicals. There's quite a lot of research on chemical  
2 characterization of botanicals; on quality-setting for  
3 botanicals. Much of this has been done in other countries,  
4 but there's no need for us to reinvent the wheel. And I  
5 think one of the systems that we could use as a model is the  
6 Commission E, which is the body in Germany, an independent  
7 panel, that assessed more than 300 botanicals and determined  
8 whether there was evidence of efficacy and safety. Those  
9 monographs have recently been published in English.

10           So FDA's first priority should be safety, quality  
11 and efficacy of dietary supplements. Unsafe dietary  
12 supplements should be removed from the market. And, really,  
13 the quality issue is the most important one besides--the  
14 next most important thing besides safety. The limitations  
15 of structure and function claims have been extremely  
16 confusing to consumers. It's caused manufacturers of both  
17 worthy and unworthy products to really resort to subliminal  
18 messages and word games. There's no reason that people  
19 should not be able to make a claim when there is adequate  
20 evidence, but there is a lot of misleading labels out there,  
21 and we feel it's really important for FDA to go after labels  
22 that are already out there on the drug store shelf.

23           This is "Brain Gum," which "improves name and face  
24 recognition; helps in recalling telephone numbers, and  
25 improves recalling the locations of misplaced objects."

1 [Laughter.]

2 There is a number of these "breast health"  
3 formulas; this is "Women's Breast Health," "Everywoman's  
4 Breast Basics." These do everything except make a specific  
5 claim for preventing breast cancer. This, for instance, has  
6 a picture of a pink ribbon on it, and says "A portion of  
7 these proceeds goes to support cancer research."--"Breast  
8 health is the number one concern of women. This formula  
9 contains the patented compound glucurate which has been  
10 shown to enhance the major cleansing pathways in the body,  
11 helps the body rid itself of pollutants and foreign elements  
12 not conducive to breast health."

13 This company gives money to the "Breast Health  
14 Project" --

15 [Laughter.]

16 --and says that "Our herbal extracts are potency  
17 assured"--trademark. Potency is one of the many terms that  
18 really needs to be regulated--that these terms on these  
19 labels really need to be regulated. "Standardized" can be  
20 used for anything; "potency" can be used for anything.

21 I'm out of time, but I just wanted to say that you  
22 do have a lot of power on the labeling right now, and  
23 there's a lot to do on products that are currently marketed.  
24 We want to get unsafe products off the market and products  
25 with misleading claims should also be off the market. Thank

1 you.

2 MR. LEVITT: Thank you very much.

3 Mr. Turner?

4 MR. TURNER: My name is James Turner, and I'm  
5 Chair of the Board of Citizens for Health.

6 Citizens for Health was very much involved in  
7 t\passage of DSHEA; generated a significant number of the  
8 million signatures that were sent to Congress, and has been  
9 one of the contributing plaintiffs in the Pearson case; and  
10 also generated 175,000 comments to FDA on its  
11 structure/function proposal.

12 We felt very strongly that changing the definition  
13 of disease was not contemplated by DSHEA, and we also feel  
14 very strongly that that regulation should be withdrawn, and  
15 suggest that any difference between the definition of<sup>2</sup>  
16 disease prior to the passage of DSHEA and now would consider  
17 to be something worthy of further legal action.

18 Citizens for Health is committed to the four basic  
19 rights of consumers that were announced by President Kennedy  
20 in 1962: safety, choice, information and participation or  
21 access. We believe that the construct of the issue for  
22 dietary supplements is that choice and safety are in  
23 tension, and information is the primary tool that can help  
24 us balance those in an effective way.

25 And so in virtually all instances where Citizens

1 for Health has participated in a public debate, it has been  
2 about enhancing the information available on a product--in  
3 this case, the product category of dietary supplements. So  
4 we believe that the number one thing to do is to work  
5 vigorously on information issues.

6 I've been involved in FDA issues since 1968. I've  
7 been involved with the Food Safety Council, which was a  
8 group of consumer and industry people, to work on food  
9 safety questions in the NANDA dietary supplement area, and I  
10 was involved with the nutrition dialogue that was set up  
11 between industry and consumers on nutrition labeling. We  
12 believe strongly that that kind of a process would be  
13 extremely useful here--again, focused on information--to  
14 help us work our way through the choice-safety dichotomy, or  
15 the choice-safety tension.

16 Specifically, we are extremely concerned that FDA-  
17 -we would like FDA to refrain from arguing that it does not  
18 have authority over regulating dietary supplements. It has  
19 a lot of authority that has not yet been used. We are  
20 strongly in support of working on good manufacturing  
21 practices regulation. We believe that's very important. We  
22 think that the adverse reaction report on dietary  
23 supplements needs to be greatly improved. And we would like  
24 very much to see a process like the ones I've mentioned be  
25 used to do that. There is a major role for all of the

1 stakeholders to be involved on an ongoing basis in working  
2 out what we believe are the crucial issues here: information  
3 strategies.

4           Specifically, we feel--and urge--that the FDA not  
5 appeal the Pearson case. We don't see any need to do that.  
6 We believe that you could move forward and do the definition  
7 of "significant scientific agreement"--again, in the kind of  
8 process I'm suggesting, and develop a caveat program;  
9 something that will say the kinds of comments about the use  
10 of information that is not definitive, as the court  
11 suggested. We think it's an important aspect of working out  
12 how information can be used in this field.

13           In the 30 years or so that I've been working on  
14 these issues, I've heard repeatedly, from day one, the  
15 concept that everything is not black and white; that FDA, or  
16 anyone else, can't draw a line and say "all the things on  
17 this side are good for everybody, all the time, and all the  
18 things on this side are bad for everybody all the time. It  
19 can't be done." There's an area where some things fall--  
20 they're always good for everyone. And there's an area where  
21 some things fall, and all things are bad for everyone. But  
22 there's this large area in the middle.

23           In my experience and observation, both in studying  
24 the history of FDA, and being involved with it specifically  
25 since 1968, there has been a tendency on the FDA in dealing

1 with dietary supplements to group all questions that are in  
2 the gray area--and to treat all questions that are in the  
3 gray area as if they were in the black area. That is the  
4 source of almost all of the difficulty that has gone on,  
5 actually, since at least 1962, and perhaps before, in the  
6 FDA's activities. It's been a--it's an enormous, costly,  
7 unpleasant social battle that's been under way.

8           And I'm going to take--I'm going to answer your  
9 last question right now and say what I think I would like to  
10 see as the outcome of the year's worth of work. And that is  
11 that the contentious battle that has been going on between a  
12 segment of the public and the FDA be moved away from the  
13 courts, and away from the Congress, and into processes where  
14 all of the balancing of choice and safety can be worked  
15 through, and a process that will allow all the stakeholders--  
16 -consumers, producers, health groups, individuals--to be  
17 involved in shaping how we are going to talk about this  
18 category. And as Dr. Fugh-Berman has said, the category  
19 contains all kinds of things in it. So we may have to do a  
20 lot of different kinds of modulating and so forth.

21           But we believe very strongly that an information  
22 strategy that preserves choice and preserves safety is the  
23 goal that we should work toward. And the courts and the  
24 Congress are refined enough to make those kinds of subtle  
25 choices without the help of the kind of process that I'm

1 talking about with the participants I've mentioned.

2 Thank you very much.

3 MR. LEVITT: Thank you.

4 Irene Heller, from CSPI.

5 MS. HELLER: The Center for Science in the Public  
6 Interest appreciates this opportunity to present our views  
7 on developing an overall strategy for achieving effective  
8 regulation of dietary supplements under DSHEA.

9 CSPI is a non-profit consumer organization  
10 supported by more than one million members, that has worked  
11 since 1971 to improve national health policies. My  
12 presentation will highlight recommendations which are  
13 explained in more detail in our written statement.

14 First, the FDA should ask Congress to establish a  
15 research program at the National Institutes of Health to  
16 evaluate the safety and efficacy of dietary supplement  
17 ingredients.

18 Second, the results of the research should be used  
19 as the basis for FDA determinations that particular  
20 supplements are safe or pose a significant or unreasonable  
21 risk, and specify appropriate and inappropriate labeling  
22 claims.

23 Third, the research program should be funded by an  
24 industry user-fee.

25 We also urge the FDA to take enforcement action to

1 ensure that foods or drugs are not being marketed as dietary  
2 supplements to avoid regulatory controls that apply to those  
3 products.

4           The recent flurry of consumer warnings on dietary  
5 supplement ingredients, such as GBL, and herbal Fed-phen,  
6 and the proposed rule on ephedra, underscore the need for  
7 FDA to have solid safety and efficacy data prior to the time  
8 a dietary supplement ingredient is marketed. We there urge  
9 the FDA to request that Congress mandate a research program,  
10 paid for by the industry, that would systematically review  
11 the safety and efficacy of dietary supplement ingredients.  
12 Vitamins and minerals known to be generally recognized as  
13 safety and effective, and whose role in maintaining health  
14 is not the subject of controversy within the scientific  
15 community could be exempted from such review.

16           The results of the review will alert both the FDA  
17 and manufacturers to dietary supplements that should not be  
18 marketed, or that should only be marketed subject to certain  
19 regulatory controls. The results of the review could also  
20 be used to support health claim petitions under the NLEA.  
21 The review could be modeled on elements of the over-the-  
22 counter drug review, which determined whether particular  
23 ingredients within a given class of drugs are generally  
24 recognized as safety and efficacy, or the GRAS review of  
25 food additives. While those reviews were slow and far from

1 perfect, they nevertheless demonstrated that comprehensive  
2 reviews of entire product categories are feasible.

3           The NIH would be the best entity to conduct and  
4 supervise this research. It is the premiere research  
5 institution in the United States dedicated to helping  
6 prevent, detect, diagnose and treat disease and disability.  
7 It both conducts research in the laboratories of its 24  
8 separate entities, and supports research of non-Federal  
9 scientists in universities, medical schools, hospitals and  
10 research institutions.

11           The specific NIH institute that has expertise  
12 relating to a particular dietary supplement ingredient  
13 should either test or supervise the testing of that  
14 substance. For example, the National Institute on Aging is  
15 currently working on a research project on the effect of  
16 ginkgo on memory. The National Institute of Arthritis and  
17 Musculoskeletal and Skin Diseases would be the appropriate  
18 agency to test dietary supplement ingredients designed to  
19 promote healthy bones.

20           The Office of Dietary Supplements, which was  
21 established DSHEA, should be given sufficient funding to  
22 coordinate dietary supplement research; at least the five  
23 million that Congress authorized, but which has never been  
24 appropriated. Under DSHEA, ODS has been designated as the  
25 principal advisor to FDA on dietary supplement issues,

1 including safety and claims. Congress specifically directed  
2 ODS to compile a data base of scientific research on dietary  
3 supplements and individual nutrients, and to coordinate NIH  
4 funding concerning dietary supplement research.

5           The research program itself would be funded  
6 through fees assessed on dietary supplement manufacturers.  
7 These fees would be based on an appropriate criterion, such  
8 as market share or annual sales, and waivers and fee  
9 reductions would be available for small businesses. The  
10 funds collected would be distributed in the form of research  
11 grants.

12           This is an exciting time in the dietary supplement  
13 and food industries, as new discoveries offer the promise of  
14 significant health benefits. But consumers need  
15 scientifically sound information about supplement  
16 ingredients if they are to make informed purchasing  
17 decisions. We therefore recommend the creation of an NIH  
18 research program that will study the safety and efficacy of  
19 dietary supplement ingredients and issue findings on which  
20 the government, industry and the consumer can rely.

21           Thank you.

22           MR. LEVITT: Thank you very much.

23           I wonder if I could pick up on--Irene, your  
24 comment, and ask the other two if they have additional or  
25 different ideas on how we could get the research that's

1 needed on a lot of these products done and evaluated so the  
2 results can be available to consumers.

3 DR. FUGH-BERMAN: Well, I think the first thing is  
4 to be aware of how much research has already been done.  
5 There is a huge amount of research that's already been done  
6 on botanicals, for instance. And people have already noted  
7 that vitamins and minerals, there's also been a huge amount  
8 of research done. So, it's really important to have--to  
9 evaluate, to have access to and to evaluate that data. You  
10 have to know what's out there before you can identify gaps.

11 MR. LEVITT: Mr. Turner?

12 MR. TURNER: I think that an approach such as been  
13 suggested makes a lot of sense. I think there are some  
14 things to think about carefully. Both the examples that  
15 were cited dealt with generally recognized as safe--  
16 generally recognized as safe standard. That standard is a  
17 clear, defined standard to build a program around. It would  
18 be very important if there was going to be a review in the  
19 NIH, that a standard of a similar nature, and what, would  
20 argue, would spell out "significant scientific agreement" as  
21 a standard, and do something of that kind of review might  
22 make sense.

23 The problem is, however, more than just the  
24 research. The context of how the research is evaluated is  
25 equally important. So that--you know, we've strongly argued

1 that "significant scientific agreement" should be made  
2 concrete so that everyone understands what it means.

3           If that were done, and there were such a program,  
4 the second problem is that the outcome of that program  
5 should not be, in my opinion--and part of our argument--  
6 should not be a yes-no program; "if you don't have enough  
7 science, you don't get on the market." That isn't an  
8 appropriate way to do it. The appropriate way to do it is  
9 to evaluate the relationship between the science that  
10 exists, create the risk-benefit ratio dynamic that we're  
11 talking about in all of these issues, and then decide how  
12 you want to proceed.

13           Again, that means--we feel strongly, from  
14 Citizens for Health, that those things which pose a serious  
15 problem should be the most severely restricted, and those  
16 things which don't pose a serious problems should be the  
17 least seriously restricted--even if we don't have firm,  
18 clear evidence of efficacy.

19           MR. LEVITT: Thank you.

20           Margaret?

21           MS. PORTER: Yes. Dr. Fugh-Berman, you, in  
22 addressing the structure/function rule--if I understood you  
23 correctly, I understood you to suggest that the least the  
24 lines that the Agency attempted to draw, and the proposal--  
25 you were concerned that they were not workable and would

1 lead to subterfuge, I think was your word.

2 I'd be interested in the comments of any one of  
3 the panelists on sort of alternative ways of addressing the  
4 variety of claims if the Agency's structure/function  
5 proposal has the concerns that you had identified.

6 DR. FUGH-BERMAN: Well, I think for products for  
7 which there actually is evidence of efficacy, that there  
8 should be an independent expert panel that determines what  
9 level of evidence there is, but that there--you should be  
10 allowed to make a claim if there really is good evidence for  
11 it. But you can't extricate that from determining the  
12 quality of products; that right now, you know, if you put  
13 "ginseng" on the product label, you don't know if it's  
14 ginseng root, ginseng leaf; often Latin names aren't on it,  
15 let alone any other sort of information. And I think  
16 there's a real role for the Agency in spot checking products  
17 that are on the market; that other countries that regulate  
18 botanical medicines, particularly, do check products. IT's  
19 very important to see, you know, what the level of active  
20 ingredients are in them.

21 But--I've had a patient, for example, who was  
22 taking St. John's wort every day, and I asked her why she  
23 was taking it--it's indicated for depression. She wasn't  
24 depressed, but because the label claim says "Supports  
25 emotional well-being," [laughs] she just thought it was a

1 good, sort of general tonic. So it can be very confusing to  
2 consumers.

3 MS. HELLER: I'd like to follow up on some  
4 comments that were made this morning, as well as now. And I  
5 think there's a real need for consumer perception study to  
6 determine how consumers view these claims; whether the  
7 consumer really can distinguish between a structure/function  
8 claim or a health claim, because there are different  
9 consequences and regulatory requirements for each of those.  
10 And if a consumer thinks that the amount of scrutiny that a  
11 product that undergoes a health claim procedure is the same  
12 as something that's a structure/function claim, the consumer  
13 is greatly misled. And I think we really need to do this  
14 survey. I think it would also help in light of the Pearson  
15 decision, if that sticks, because to the extent FDA can  
16 document that disclaimers don't work; that consumers are  
17 very confused, then FDA will have more authority, I think,  
18 to just regulate things so that consumers can understand  
19 them. And that's the point of what FDA should be doing.

20 MR. TURNER: The problem of drawing the line  
21 between structure/function claims and health claims is a  
22 problem of categorization. And I'm not sure that it helps  
23 actually solve any of the regulatory problems that we're  
24 facing--that distinction. It happens to be where the law  
25 settled out in the last round.

1 But what's happening is, in a general societal  
2 way, we're going from very broad, clearly understood  
3 categories--basically, originally, food and drug, and moving  
4 systematically through a differentiation. So that things  
5 that were clearly one or the other of those concepts, are  
6 now confused, or partake of both of those. Some things are  
7 both foods and drugs. And the distinction that first was  
8 used to distinguish those was the claim made. So lots of  
9 energy was brought in on what are the claims.

10 But it seems to me that we're going to go through  
11 a series of categorizations, and I think that the disclaimer  
12 piece is one of the tools that's available. That's why  
13 Citizens for Health supports it. If something is not  
14 harmful, and there is some evidence supporting its efficacy,  
15 we are arguing that there should be a disclaimer that says,  
16 "FDA has not yet established that this is effective"--it  
17 would be safe, but "this is effective for the claim.  
18 However, preliminary data suggests that it might be." And  
19 that's the three-tier label that we've petitioned for, and  
20 we've argued for in Pearson and so on.

21 The idea is that in the societal moving of things,  
22 things are breaking out into sub-categories. Once we get  
23 into the dietary supplement category, really, it makes  
24 relatively little difference about a hormone, whether it's  
25 making a structure/function claim, or a health claim. It

1 poses the same safety problem. So that that distinction  
2 doesn't help us a whole lot.

3 MR. HUBBARD: I'd like to keep going with this.  
4 Dr. Fugh-Berman has suggested that these products, while  
5 they may have efficacy, also have safety issues. And I  
6 assume you're not saying that those safety issues rise to  
7 the level of being a significant or unreasonable risk that  
8 would require FDA to ban them, but rather --

9 DR. FUGH-BERMAN: Some of them absolutely do.  
10 Comfrey should be banned; herbs containing pyralizadine  
11 alkaloids should be banned.

12 MR. HUBBARD: And do you think we at FDA--there's  
13 enough evidence out there that comfrey should be banned?

14 DR. FUGH-BERMAN: [Nodding affirmative].

15 MR. HUBBARD: But you did--I think you said that  
16 St. John's wort and others have some use. And so are you  
17 suggesting that they, in fact, be regulated as drugs, with a  
18 risk-benefit analysis?

19 DR. FUGH-BERMAN: No. Botanicals need to have  
20 their--they need to have a separate kind of regulation.  
21 They span the spectrum from food to drugs, and--well, just  
22 to use an example, for instance--soybeans have  
23 endocrinological effects. There are many soy-based foods.  
24 Then there are soy foods that are enriched with genestein,  
25 which is an isoflavone that's derived from soy. Then you

1 can also go into a health food store now and buy genestein  
2 100 milligram capsules. We have no long-term safety data on  
3 taking purified, isolated isoflavones over long periods of  
4 time.

5 We do have pretty--we have indirect, but pretty  
6 substantial indirect safety data on eating soy food. So  
7 they should be in different categories. Tofu should be in a  
8 different category than purified genestein capsules.

9 With botanical products, they have to be regulated  
10 as botanicals and, you know, I think that we should take  
11 some lessons from other countries that have a lot of  
12 experience doing this. But they're their own animal--or  
13 their own plant, and they really have to be regulated  
14 differently. Because some of them are drugs. You can  
15 isolate drugs from plants. Some of them are ground up  
16 plants. And there's a whole spectrum in between. And right  
17 now there's no regulation of even what the terms are. So  
18 that when a manufacturer puts "standardized" on a product,  
19 it can mean "We say there are 50 capsules in the bottle, and  
20 there are 50 capsules in the bottle." It doesn't really  
21 mean anything.

22 MR. HUBBARD: Well, let me ask Mr. Turner, then--  
23 if some of these products, in fact, have some health use,  
24 and structure/function or other sorts of health use, but are  
25 not universally safe, how does FDA go about--is that a

1 labeling issue?

2 MR. TURNER: The issue--when you say--there's a  
3 serious problem about things which are essential for some  
4 people and unsafe for others. And it's not a problem that  
5 is only in dietary supplements, it's in a lot of areas.

6 Our argument is, first of all--first of all, from  
7 Citizens for Health's point of view, we think FDA should put  
8 substantial amounts of its resources in this area on  
9 figuring out the categories. I think I agree with what Dr.  
10 Fugh-Berman has said: that there's a series of--there's a  
11 whole bunch of things in this category that are different,  
12 and require a different way of being looked at. And I think  
13 that that's an important step that we need to go through.

14 The first step that I think FDA researches are  
15 useful for is safety questions. I think those are the most  
16 important single questions that need to be dealt with. So  
17 that if we look at safety questions, and we find things  
18 where there are safety problems--and they could be small  
19 safety problems to large safety problems, FDA needs to look  
20 at that and figure out, for example, where there is enough  
21 evidence to create an opportunity to take something off the  
22 market that shouldn't be there. That is more important as a  
23 first step in working this all out than figuring out the  
24 efficacy piece.

25 The labeling part of it is: for those things which

1 are not in the category that say we can show that these  
2 things are unsafe--in that category--those things--I don't  
3 think FDA has the authority to take them off the market.  
4 But I do think it has ample authority to guide people toward  
5 the proper use of these substances, again if words that are  
6 there are given some kind of a meaning that everybody can  
7 share as being the meaning of what those words are. And I  
8 agree with the statement, for example, about "standardized."  
9 Those kinds of words need to be useful to help people work  
10 their way through a set of categories that have--that are  
11 safe but we don't know how effective they are.

12           The policy problem is that if you say anything  
13 that doesn't have a full scientific evidence of efficacy  
14 that meets the FDA definition as it currently stands; if you  
15 say anything that doesn't meet that category is going to be  
16 regulated more strictly by either being kept off the market,  
17 or being confined to what it can say, the result is that  
18 many things are dumped into the same category which have all  
19 kinds of different meanings. So that you end up with people  
20 not being able to work their way through the market. And  
21 I'm arguing--we are arguing--that FDA has the ability to  
22 help shape that--taking out those things which are unsafe--  
23 it has the ability to shape the way consumers balance safety  
24 and choice around whatever issue that they particularly are  
25 looking at.

1 MS. HELLER: I'd just like to add one more thing.  
2 I think in the discussion of safety and efficacy we've  
3 forgotten that there are some safety issues under the rubric  
4 of "efficacy." For example, if someone's taking a dietary  
5 supplement to prevent breast cancer and they actually have  
6 breast cancer and should be seeing someone for that, and  
7 they're not seeing someone because they're relying on this  
8 dietary supplement, that's really a safety issue, because  
9 it's preventing people from going to get the treatment that  
10 they need, and it's causing them to make unsafe decisions.

11 So perhaps that, in considering efficacy issues,  
12 there should be a categorization as to products which are  
13 used for very serious diseases--let's say cancer or heart  
14 disease--and products which, if they have no effect, it's  
15 not going to hurt anybody; you know, they're designed to  
16 make you're fingernails grow longer.

17 So I think there needs to be a distinction there.

18 MR. LEVITT: Dr. Yetley?

19 DR. YETLEY: You've all discussed safety as one of  
20 your priorities that you think the Agency should focus on.  
21 Given the range of tools and approaches and resources that  
22 the Agency has available to it, how should the Agency  
23 proceed in terms of dealing with safety issues? We can do  
24 it by regulation. You can do guidance. You can do other  
25 means. Do you have some particular advice for us on how to

1 approach safety issues?

2 DR. FUGH-BERMAN: Well, I think--well, yes, it has  
3 to be--the Agency has to be familiar with the literature so  
4 that it knows what to go after. I think that its--one of  
5 its roles should be to set quality guidelines. I don't know  
6 whether those should be regulations or guidelines--but to  
7 set standards of quality for various dietary supplements.  
8 It's really important, especially in the botanical area.  
9 And there's quite a lot of research in that area.

10 But the main thing is going out into the stores,  
11 buying products and analyzing them, and publicizing the  
12 results. I don't think it should just be up to Consumer  
13 Reports, and CSPI, and some of the other groups that have  
14 done independent analyses to determine that a number of  
15 ginseng products on the market contain no active ingredient,  
16 or some of them actually contain ephedra instead of ginseng-  
17 -that sort of thing. There's a lot of misidentification of  
18 plants; there's a lot of contamination. There's a big  
19 problem with mixing drugs in with herbs, particularly in  
20 preparations that are imported from Asia.

21 There's a lot of different issues out here, and  
22 there are safety issues in products that are on the shelves  
23 now.

24 MR. TURNER: In addition to going out to the  
25 market, the FDA--it seems to me, again, following the basic

1 point that we are pushing from Citizens for Health, which is  
2 a dialogue process, there is a lot of information available  
3 in the dietary supplement community which people, if they  
4 had confidence in FDA would be willing and happy to share.  
5 It's very difficult, however, if the agency is looked upon  
6 as an agency which is constantly going to after whatever it  
7 can put in jail, or some comparable thing. It would be much  
8 better if we could have an open flow of information. It's  
9 not only products that have ginseng that has ephedra, but  
10 there's ephedra that has amphetamines. I mean that's  
11 another issue.

12           It would be useful for the FDA to organize an  
13 ongoing communication system. Two things would help develop  
14 that possibility, I think, very strongly. One would be the  
15 development of good manufacturing practices, and I think  
16 those could be expanded to some extent to include some of  
17 the standard ideas that Dr. Fugh-Berman has been mentioning.  
18 You could create potency and name of source and so forth as  
19 part of that.

20           And then, secondly, it is very important that the  
21 Agency seriously look at the adverse reporting system,  
22 because it's coming in now in a way that is very  
23 undifferentiated, very unclear; it's being used by  
24 competitors to fight out marketplace battles. And it's  
25 really, frankly--to be very honest with you--it's an

1 embarrassment. And it would be useful if--and we, of  
2 course, and I'm sure these groups and the ones that were  
3 here this morning, would be more than happy to participate  
4 in a dialogue about how to make a system like that work.  
5 So, for example, if we got the adverse reporting system  
6 working effectively, and everyone had confidence in it, we,  
7 and I believe others, would encourage all of the people,  
8 that we are involved with, in terms of practitioners and  
9 sellers and other people in the community, to participate in  
10 that, and to make information available. The way it's  
11 coming in now, however, it's undermining confidence rather  
12 than building confidence.

13 MS. HELLER: I think it might be useful to publish  
14 a Federal Register notice that lists the dietary supplement  
15 ingredients with which FDA has concerns, and to allow the  
16 public to comment on those particular substances, and FDA  
17 can then evaluate the evidence. And it would be helpful if  
18 down the road FDA could publish a book that would be  
19 available in health food stores so at the point of sale,  
20 consumers could see what type of rating a product had; you  
21 know, if it's safe but possibly effective; safe but  
22 definitely effective; unsafe.

23 MR. LEVITT: Thank you.

24 Dr. Bowen.

25 DR. BOWEN: Dr. Fugh-Berman, you mentioned in the

1 context of botanicals that Commission E could be used as a  
2 model. Would you further elaborate on that comment?

3 DR. FUGH-BERMAN: Do you want me to explain what  
4 Commission E is, or --

5 DR. BOWEN: No. I know what Commission E is, but  
6 you could explain it briefly, and then tell us how you think  
7 that could be used as a model.

8 DR. FUGH-BERMAN: This was an independent group  
9 that was set up by part of the German federal health agency  
10 that was composed of physicians, pharmacologists,  
11 pharmacists, members of the industry and consumers to  
12 evaluate information on herbs, about--more than 300 herbs  
13 and herbal mixtures were evaluated and monographs were  
14 written which were used as product labels in Germany.

15 They have--they're sort of like consensus-  
16 conference kinds of documents. They're not referenced, but  
17 they are based on a huge amount of clinical and scientific  
18 data. And I'm not saying that we should adopt them  
19 wholesale, but it's a useful model, putting together a group  
20 that is familiar with botanical research, etcetera, to  
21 evaluate information; they come up with either positive or  
22 negative assessments based on the benefits--known benefits  
23 and known risks of botanicals, and to publish those. I  
24 think it's something that we could, if not exactly  
25 duplicate, but do in a more scientifically referenced way

1 with a group that's familiar with the research. And I think  
2 it could be really useful.

3           Because there's a lot of benefits in dietary  
4 supplements, and there is quite a lot of studies showing  
5 benefits for some of these. But right now there are so many  
6 products on the market that are entirely ineffective because  
7 we have no regulation as to quality. So I really think  
8 it's--you know, there's a dual issue around safety and  
9 around quality, and we need to address it in a pretty  
10 comprehensive way.

11           MR. LEVITT: Okay. Thank you.

12           On my one question of "a year from now," I think  
13 some of this has already been answered, but I'll let  
14 everybody go down one more time and amplify, or say you've  
15 already said it.

16           Ms. HELLER: Okay. Basically, repeating what I  
17 said before, we need to have a systematic review of the  
18 safety and efficacy of the various dietary supplements.

19           MR. TURNER: I think that a substantial amount of  
20 progress could be--you know, I've already said about moving  
21 it out of--moving it into a dialogue and out of a  
22 confrontational forum--but a very substantial amount of  
23 progress could be made if the agency put energy into working  
24 through the quality questions. A lot of the issues would  
25 become much clearer if that were to be done.

1 DR. FUGH-BERMAN: Clear, accurate, comprehensive  
2 labeling of every dietary supplement on the market, and  
3 periodic analyses by FDA.

4 MR. LEVITT: Thank you. What would we do in the  
5 second year?

6 [Laughter.]

7 MR. LEVITT: Okay. Thank you all very much.

8 As we're moving between panels, we have--the next  
9 panel we have Dr. Gary Huber of ANA. We have Dr. Steven  
10 Dentali of Rexall Sundown. And we have Antonio Martinez of  
11 Nutraceutical Initiative.

12 On your agenda you have an additional name of Paul  
13 Simmons. My notes tell me that his views were--he is not  
14 appearing--that he's not here today. Is that right?--but  
15 that some of his views were covered this morning.

16 Thank you. Well, an efficient group. Let's go  
17 right to Dr. Huber.

18 **PANEL IV - NUTRACEUTICALS**

19 DR. HUBER: Thank you for the opportunity to be  
20 here today on behalf of the American Nutraceutical  
21 Association, whose members are health care professionals and  
22 consumers.

23 The American Nutraceutical Association is a non-  
24 profit alliance of individuals with a shared interest in the  
25 science, technology, marketing and production of

1 nutraceutical products. The ANA was established to develop  
2 and provide educational materials and continuing education  
3 programs on nutraceuticals for health care professionals and  
4 for consumers.

5           We want to emphasize that we believe we currently  
6 stand at a most serious confluence of important forces  
7 coming together in the nutraceutical world. This is a  
8 critical crossroad for the consumers of nutraceuticals.  
9 What are these critical factors that we should consider?

10           First, unprecedented numbers of Americans are now  
11 consuming nutraceuticals and other dietary supplements.  
12 There is every reason to believe that they will continue to  
13 do this in the future. For the most part, they are doing so  
14 with a blind trust in those who manufacture and distribute  
15 these products.

16           Second, United States' health care delivery  
17 systems are changing. They are not stable. They remain in  
18 enormous flux as we search for a means of health care that  
19 will work and that is affordable. In this period of change,  
20 increasing numbers of Americans are searching for more  
21 control over their destiny of their own health. They also  
22 want more freedom to control their own health care. One way  
23 that Americans at all levels are fulfilling their quest of  
24 these objectives is to turn to nutraceuticals and dietary  
25 supplements. In doing so they want to achieve as much good

1 health as possible. They want to live as long as possible,  
2 and they want to be free of the rages of chronic illness,  
3 physical disability and mental impairment for as much of  
4 their life as possible. Faced with a medical care system and  
5 a pharmaceutical industry that has focused on disease, not  
6 on prevention, they are turning to nutraceutical products  
7 and dietary supplements in their quest to fulfill these  
8 needs.

9 Third, those who manufacture and distribute  
10 nutraceuticals and dietary supplements can now market their  
11 products without adequate levels of external accountability  
12 for quality or safety.

13 Fourth--and finally--a major force adding momentum  
14 to the potential conflict resulting from the confluence of  
15 these movements is the fact that the unremitting growth of  
16 the nutraceutical industry seen over the past few years  
17 appears to be slowing and in some cases plateauing. As a  
18 consequence, the nutraceutical market is becoming, each and  
19 every day, more competitive. Without control, and without  
20 accountability for quality or safety, the opportunity to  
21 follow the first rule for those who care about the health of  
22 the people they serve--to do no harm--has a potential to be  
23 diminished and lessened under these circumstances. We need  
24 a reliable, independent and intelligent adverse event  
25 reporting system.

1           In the perspective of these considerations, we  
2 need therefore to ask some important questions. Can  
3 nutraceutical products be manufactured under current good  
4 manufacturing practices? Does a nutraceutical product  
5 contain a standardized extract that has been validated by  
6 scientific and clinical studies? How do the consumers know  
7 that the products they take actually contain the required  
8 dosages of ingredients required to produce the desired  
9 results as promised in marketing materials provided by the  
10 manufacturers and distributors? Most importantly, is the  
11 product safe, and does the product have integrity? Without  
12 clear and acceptable answers to these questions, the safety  
13 and integrity of the nutraceutical products and the dietary  
14 supplements will be compromised.

15           What can we do? The pathways of responsibility  
16 leading to a good solution must be shared. The American  
17 Nutraceutical Association recommends attention be given to  
18 the following priority issues concerning the consumer's  
19 safety.

20           One, quality assurance. Manufacturers and  
21 distributors of nutraceuticals and dietary supplements need  
22 guidelines for current good manufacturing practices and  
23 production standards to protect the consumer. The FDA is  
24 the logical source to develop these guidelines and with help  
25 from the manufacturers of supplements and from the trade

1 associations who represent their interests. Ideally, the  
2 nutraceutical industry should be responsible for somehow  
3 regulating itself through a third-party validation  
4 mechanism. If the nutraceutical industry does not  
5 satisfactorily self-regulate, regulation must come from  
6 without.

7           Two, standardization. This is a complex  
8 challenge, but nutraceutical products must be standardized.  
9 Both the consumer and the manufacturer will benefit from  
10 products that are standardized, reliable and dependable.  
11 Nutraceutical products must have a reliable consistency.

12           Three, product stability. Most nutraceuticals are  
13 derived from natural sources that are prone to degradation.  
14 Once active components are standardized, their stability and  
15 shelf-life can be determined. Nutraceuticals of the future  
16 must be labeled with expiration dates and recommended  
17 storage instructions.

18           Four, bioavailability. What are the  
19 pharmacokinetics of nutraceuticals? What are their  
20 interactions with diet and with medications?

21           Five, clinical validation is an essential and  
22 critical priority for nutraceuticals. Safety and clinical  
23 efficacy are definite consumer concerns.

24           People are going to continue to buy and consume  
25 nutraceuticals --

1 MR. LEVITT: Excuse me--if you could try to  
2 summarize, please?

3 DR. HUBER: The consumer needs to be able to trust  
4 health care professionals to whom those nutraceuticals most  
5 want to turn and with reliable knowledge about nutraceutical  
6 products.

7 In summary, the consumer and health care  
8 professionals need to know that nutraceuticals are safe, and  
9 that they are produced and marketed with integrity.

10 Thank you.

11 MR. LEVITT: Thank you very much.

12 Next would be Dr. Dentali:

13 DR. DENTALI: Thank you, and thank you for having  
14 this forum here today.

15 I guess I should say a little bit about my  
16 background; that I was trained as an herbalist, a  
17 pharmaceutical scientists and a pharmacognicist. I've  
18 served on several--a few GRAS committee efforts regarding  
19 botanicals, and I was a member of the special working group  
20 on ephedrine safety in foods.

21 My position at Rexall Sundown is a new one. I've  
22 been there two months. My understanding is that Rexall  
23 Sundown is the largest supplier to the mass market of  
24 dietary supplements and also botanical products.

25 I want to thank Dr. Fugh-Berman and Mr. Turner for

1 making the point that botanicals are different. Because,  
2 really, when you look at dietary supplement categories,  
3 there's basically two: botanicals and all others. That's  
4 because there are special concerns that are brought up when  
5 you're dealing with botanicals, and that's really what I'm  
6 going to speak about today.

7           Although DSHEA will help in providing consumers of  
8 information on and access to safety and efficacy dietary  
9 supplements, it really does not adequately address many, if  
10 not most, when dietary supplements are of botanical origin,  
11 in my opinion. Indeed, the DSHEA Presidentially-appointed  
12 commission on labeling spent a considerable amount of time  
13 and effort attempting to resolve issues surrounding the  
14 labeling of dietary supplement of botanical origin.

15           Many assumptions regarding dietary supplements  
16 really don't fit. It is a--as they are themselves a huge  
17 mixture of components--dietary supplements span many  
18 different categories, you can draw the line pretty much  
19 anywhere. If you want to take different examples, you can  
20 make whatever case you would like as food, dietary  
21 supplement or drug.

22           The World Health Organization recognizes that most  
23 of the world's population relies on botanical products, or  
24 what are known as "traditional remedies" for much of the  
25 health needs of the world. In fact, recognizing this

1 importance, they published a guideline on their assessment,  
2 and this guideline helps to ensure the safe use and  
3 manufacturing of botanical materials used as traditional  
4 remedies. So really what I'm suggesting here is the  
5 category of "traditional remedies," or something such as  
6 that.

7 In the green handout that was out front was a  
8 headline, "FDA is Considering a New Category." I apologize,  
9 I don't have it up here to refer to. It's not within CFSAN,  
10 but that idea is obviously receiving more and more attention  
11 for a good reason.

12 While many developing and developed countries have  
13 an extensive monograph system for traditionally-used  
14 botanicals, we in the U.S. cannot, in conjunction with a  
15 product, educate consumers as to the most basic of western  
16 concepts--honorable action. Indeed, practically all the  
17 modes of action that I was taught regarding traditional uses  
18 of North American herbs cannot be used without the  
19 corresponding product being considered a drug.

20 Although traditional remedies are often understood  
21 to have a broad range of actions appropriate for a myriad of  
22 conditions, the present structure limits what manufacturers  
23 can share regarding what is considered common knowledge  
24 among many peoples. This traditional remedy category--this  
25 establishment--I feel falls into the long-haul category but,

1 however, its implementation brings into focus many of the  
2 issues that you deal with, such as boundaries, safety and  
3 labeling issues--those that are of immediate concern  
4 regarding botanical preparations. In other words, this or a  
5 similar category is needed for a rational and effective  
6 regulatory foundation for dietary supplements of botanical  
7 origin.

8           The solution resides, I believe, in part, to a  
9 well-developed monograph system created by expert  
10 committees, the members of which are uniquely qualified to  
11 assess the botany, historical use, chemistry, pharmacology,  
12 safety and efficacy of herbal materials. The best I've seen  
13 in this regard is the American Herbal Pharmacopoeia, not to  
14 dis the USP. And, by the way, the American Herbal  
15 Pharmacopoeia is a non-governmental pharmacopoeial system,  
16 so there actually must be two.

17           Botanicals are a special case requiring special  
18 botanical expertise and treatment. This issue deserves  
19 expert advice input from botanical experts, both inside and  
20 outside the industry. In fact, I don't think you can do it  
21 well without it. So I think there's an area where it will  
22 continue to appear as something that deserves attention and  
23 I believe that the traditional medicines category is one way  
24 to address that.

25           Thank you.

1 MR. LEVITT: Thank you very much.

2 Mr. Martinez.

3 MR. MARTINEZ: Thank you very much, and good  
4 afternoon.

5 I'm happy to be here on behalf of the  
6 Nutraceutical Initiative, which is an outreach project  
7 that's collaborating with the Foundation for Innovation in  
8 Medicine in Cranford, New Jersey, which is headed by Dr.  
9 Steven DeFelice, the gentleman who actually coined the term  
10 "nutraceutical."

11 I'm also here as someone who was intimately  
12 involved with the development and passage of DSHEA, and I'm  
13 happy to see my colleagues Mr. McNamara and Mr. Turner here  
14 also--individuals who were intimately involved with the  
15 formulation and the development of that legislation.

16 We are at a state where the confusion that exists  
17 in the marketplace really begs a question as to whether the  
18 Agency has the right kind of tools in order to address them.  
19 At its most basic level, we're really talking about safety  
20 and information questions. What we have now in the  
21 marketplace is a condition where price is driving the  
22 marketplace when it comes to dietary supplements,  
23 nutraceuticals, functional foods--whatever you want to call  
24 them--should be research-driven marketplace.

25 Unfortunately, there are not the kinds of

1 incentives that promote the development of good research-  
2 driven marketplace. Also, we have a new aspect to this  
3 whole question--and I can speak to this because I represent-  
4 -in addition, I was an attorney in a managed care  
5 organization that would like to cover these kinds of  
6 products, but have great difficulty due to the fact that  
7 there is not yet any mechanism that critically evaluates  
8 these kinds of products, short of going the drug route,  
9 which is not a practical matter for most of these products.

10 I know we don't have a lot of time, so I'm going  
11 to jump a little bit. One other point I want to get in  
12 before my five minutes is, when it comes to enforcement,  
13 we'd like to see the Agency begin some type of proportional  
14 enforcement, where if there are labeling problems with a  
15 company out there with a product with bad labeling, the  
16 Agency should take action to take care of that; act quickly  
17 to remove unsafe products.

18 What the Nutraceutical Initiative would like to  
19 envision as a solution to this problem is unlike what is  
20 suggested by the Center for Science in the Public Interest,  
21 which is a government-driven, research-based approach, we  
22 would like to see, very similar to an Orphan Drug Act  
23 enacted by Congress, but dealing with functional foods and  
24 dietary supplements. In fact, there is draft of that  
25 legislation that is circulating on Capitol Hill, and while

1 we had hoped that this legislation would have been  
2 introduced this springtime, it is my belief that it should  
3 be introduced in the Congress by the summer. But it will  
4 not be introduced without consulting with the Agency, and we  
5 will be moving along those channels shortly.

6           But ultimately what we want to see is the company  
7 that does the research ought to get a reward, and they ought  
8 to be tell the whole story--the whole truth--about their  
9 products, and they should be able to do that exclusively for  
10 a time--set period under the law. One of the conditions in  
11 return for that would be that the manufacturer would engage,  
12 and be responsible for post-marketing surveillance of its  
13 products, and that way you would have a phenomena going on  
14 in the marketplace where you would have a tested product,  
15 with a--and with its ingredient, and its formulation, and  
16 you will be able to actually get the kind of data that will  
17 answer safety-related questions and at the same time the  
18 marketplace will change because if there is at least one  
19 approved product out there, the competitors--sort of like a  
20 generic situation--will try to come as closely and match the  
21 tested product. Thus we'll have a situation where the bad  
22 products--the junk that's out there--will not be able to  
23 withstand the market forces there, plus you'd be able now to  
24 have a situation where the mainstream health care  
25 professionals will now be able to look to something; and

1 patients and people at risk--there are different types of  
2 sub-groups of consumers. And we need to have the right kind  
3 of public policy that accomplishes that.

4 So we look forward to working with the Agency;  
5 working with the public, working with industry to accomplish  
6 this. It's quite impressive to see how this whole process  
7 has matured, and we certainly expect to be in the middle and  
8 involved with this.

9 Thank you very much for your time. I'll take your  
10 questions.

11 MR. LEVITT: Thank you all very much.

12 Let me begin with just kind of a nomenclature  
13 question. Two of the three speakers, as well as the title  
14 we assigned is called "nutraceuticals." I think if we all  
15 read through the act, we wouldn't find that term.

16 Help me understand, within the legal terms within  
17 the statute of dietary supplement, conventional food, food  
18 additive, drug--within those terms, where does  
19 nutraceuticals fit?

20 DR. HUBER: Unfortunately, I don't think there's  
21 an agreed-upon definition, so one gets a whole series of  
22 definitions, and that really, I think clouds the issue.

23 MR. LEVITT: Okay. But in your mind, when you  
24 stood up and said, "I'm here to speak about nutraceuticals,"  
25 what were you referring to?

1 DR. HUBER: A naturally-occurring product that has  
2 some biological activity that will affect health.

3 MR. LEVITT: Okay.

4 MR. MARTINEZ: As we are looking at  
5 "nutraceutical," I'll work off of Dr. DeFelice's definition,  
6 and also what is being looked at on paper from a legislative  
7 standpoint. It would be anything that--a substance that is  
8 found in food, or food as itself, that can provide a health  
9 benefit that we have further defined as--that can be used  
10 for the prevention of disease, the reduction of risk factors  
11 associated with disease, and for the management, from a  
12 dietary standpoint, of disease.

13 DR. DENTALI: I'm really glad I didn't mention the  
14 word.

15 [Laughter.]

16 MR. LEVITT: And just following up to the first  
17 two speakers--not that that wasn't clear--what--give me some  
18 sense of proportion of the products you're talking about  
19 with the dietary supplements? 50 percent? 20 percent? 100  
20 percent? 90 percent? Versus foods?

21 MR. MARTINEZ: I would argue that both--you could  
22 apply this definition to either.

23 MR. LEVITT: No, no--you're misunderstanding my  
24 question.

25 MR. MARTINEZ: I'm sorry.

1 MR. LEVITT: Of the universe of products you're  
2 talking about --

3 MR. MARTINEZ: Mm-hmm.

4 MR. LEVITT: --how many of them are dietary  
5 supplements?

6 MR. MARTINEZ: Oh--I would say at least more than  
7 half, to two-thirds.

8 MR. LEVITT: Okay.

9 MR. MARTINEZ: The dietary supplements have been  
10 further out there--I mean, functional foods are now just  
11 coming into play.

12 MR. LEVITT: Would you agree with that

13 DR. HUBER: Without a clear definition I don't  
14 think you can have precise numbers.

15 MR. LEVITT: Okay. But what--you would say a  
16 large proportion are dietary supplements?

17 DR. HUBER: [Simultaneous discussion].

18 MR. LEVITT: Yes? Okay.

19 Margaret.

20 MS. PORTER: Yes. This is a question for Dr.  
21 Dentali, but others would be welcome to address it as well.

22 I heard you say very clearly "botanicals are  
23 different," and that under certain circumstances botanicals  
24 could be foods, or dietary supplements, or drugs. But I  
25 think I also heard you to recommend that claims not be used

1 as the basis for deciding whether a botanical is a drug or a  
2 dietary supplement.

3           If I understood you correctly, I'd be interested  
4 in what other criteria you would use to draw those kinds of  
5 distinctions?

6           DR. DENTALI: I don't know if claims itself can  
7 work well enough the way are using them right now, without a  
8 traditional medicines category. I think that's one solution  
9 it provides--it may allow a vehicle to make claims and set  
10 them off so the consumer understands the distinction, if  
11 indeed consumers would.

12           The other answer is it would have to be done on a  
13 case-by-case basis. And I'm not trying to dodge the  
14 question. I've written--I've extensively reviewed the  
15 literature and written on safety on three botanicals; on  
16 Kava, on ephedra and on ginkgo--with a popular book being on  
17 ginkgo. And they're three completely different situations.

18           Kava, in fact, completely defines the cultures  
19 where it is still traditionally used. So I don't know if  
20 you can say if it's food, drug or whatever, but it's--and  
21 ephedra has a discrete traditional uses and not others.  
22 Ginkgo, the product that has been the most--the research has  
23 done on, is a semi-purified extract. So looking at uses--  
24 looking at historical use--intended use is certainly part of  
25 that. But I think you have to take it on a case-by-case

1 basis and look at the totality of the information on what it  
2 is--what the historic use is and how it's being used.

3 MS. PORTER: Would either one of the other  
4 panelists care to comment on that question?

5 Thanks.

6 MR. HUBBARD: Dr. Dentali, your description of the  
7 monograph system sounds very much like the way we regulate  
8 over-the-counter drugs; and, of course the President's  
9 commission a couple of years ago recommended that we  
10 consider regulating botanicals because they are somewhat  
11 different in that way. Are you saying, then, that that  
12 over-the-counter drug model is more appropriate for those  
13 products?

14 DR. DENTALI: It's possible, if it's modified. I  
15 think that there are--I think you have--what we don't want  
16 to do is live in a world we've got to prove everything  
17 scientifically before we can use what we know by common  
18 sense works--unless there is common sense or science that  
19 shows us that we should treat it otherwise. Comfrey's a  
20 good example; comfrey root should probably not be taken  
21 internally in products. We have enough good science there  
22 for internal use of pyralizadine alkaloids that there's a  
23 serious question for safety. However comfrey leaf, the  
24 levels are much less; comfrey externally, I've found very  
25 little that helps for bruises and contusions as a poultice

1 of comfrey.

2           So, if we have an intelligent monograph system  
3 that takes into account all the variety of--all the  
4 different--the word isn't coming that I'm looking for--  
5 something of that nature, but you would have to then expand  
6 it. I think we must not try and shove botanicals into an  
7 existing framework, but design one that is designed for  
8 them.

9           MR. LEVITT: Dr. Yetley.

10           DR. YETLEY: Well, Dr. Dentali just answered the  
11 question I was going to ask, so I'll have to think of  
12 another one quickly.

13           I think all three of you are suggesting that you  
14 want to find a way for many of these products to be marketed  
15 so that they are either useful in disease treatment or  
16 management of diseases. Do you see this as being under  
17 DSHEA? Do you see this as having to need another category,  
18 and why aren't you interested in existing categories? I'm  
19 thinking explicitly of Dr. Martinez's example of wanting  
20 something similar to orphan drug law. Why do you see that  
21 orphan drug law as it exists now would not work?

22           MR. MARTINEZ: Just simply because it's almost  
23 like if you look at the products that are on the market,  
24 they tell half a story. They don't tell the whole story.  
25 And manufacturers--it's a big semantical game with the

1 Agency. I can tell you that as a private attorney, when I  
2 work with supplement companies, we're all--it's all about  
3 semantics, and coming up with a way that tries to stay  
4 within the boundaries which were set within the law when,  
5 really, I know what the--if a company acts, has done the  
6 research and know that its product can have a benefit for a  
7 particular disease risk factor, let's say hypothetically,  
8 they would like to have a functional way to communicate that  
9 information to the public. And that's what's missing. And  
10 we need to have something in place that would give an  
11 incentive for the companies to do that knowing that, hey, if  
12 I spend the money to do the kind of research, then my  
13 competitors aren't coming to come out the next day working  
14 off of my research, and come out with the same kind of  
15 product. There would be some kind of protection.

16 In exchange for that for a period of time there  
17 would be, you know, the kind of post-marketing surveillance  
18 and other things. I think this is something that we will  
19 sit down and further discuss with the Agency. I know  
20 there's interest on this in Congress about this, because I  
21 think we all want to resolve the controversies with dietary  
22 supplements, because they promise so much. You know, we've  
23 just got to come up with the right framework for that. And  
24 certainly the Orphan Drug Act is an example where incentives  
25 work; 5,000 orphan drug conditions. Before the Orphan Drug

1 Act there were very orphan drugs. Since the passage now,  
2 over 15 years, we have over--almost 200 now, new orphan  
3 drugs to help people with orphan diseases. So that system  
4 does work.

5 MR. LEVITT: Excuse me. Just to clarify, if I  
6 may--and I know I'm violating my own rule. There's got to  
7 be some advantage to being the chair--is the Orphan Drug Act  
8 analogy, I clearly understood the idea of if you put the  
9 money and do the testing, you ought to get some exclusivity  
10 in marketing. That part I got. The Orphan Drug Act, of  
11 course, also works within a system of pre-market review for  
12 that. Do you envision that as part of the system you're  
13 thinking of?

14 MR. MARTINEZ: Well, in the draft that is out  
15 there there will be an actual--there will be an actual  
16 commission set up--established--that's overseen by FDA, but  
17 established out of the NIH. This commission would set up--  
18 working off of similar stuff that's been FDAMA--to  
19 basically, if a company does the clinical research, it puts  
20 together its best evidence, presents it to this body, the  
21 body will make a judgment on it, and that judgment would be  
22 reviewed by the agency and the agency can add things to it--  
23 additional information, etcetera--conditions for the claim,  
24 and that claim would be exclusive to that holder for a time  
25 certain. And we believe that this will actually start

1 shifting resources to research, which ultimately is what we  
2 need to resolve the controversies with dietary supplements  
3 and functional foods.

4 MR. LEVITT: Okay. Thank you.

5 Dr. Bowen.

6 DR. DENTALI: Could I follow up on that first?

7 MR. LEVITT: Please. Because we've got lot's of  
8 time.

9 DR. DENTALI: I want to say that I think we need  
10 to use all the existing categories, to whatever extent that  
11 they are useful and that they'll serve the purpose. And I  
12 still think outside of that we may still find--indeed, I  
13 believe we will find cases where it doesn't work. And I  
14 think we need to balance the strength of the substantiation  
15 on the claim that's being made. If someone wants to sell a  
16 product that they're saying cures migraines, and that  
17 product is feverfew, I expect no less than drugs out there  
18 that have that same claim for that to be sold.

19 However, if there's a substantial body of  
20 traditional information--of which there is--to say that  
21 "many people report using feverfew helps prevent their  
22 migraines," and this is how it's used--and that happens to  
23 be true--that may be useful information for a consumer, if  
24 there's no safety issues, you know, of any type being  
25 involved.

1           So, you know, we have to balance the consumer  
2 information with the risk of using the product. Now,  
3 feverfew is a good example because it's the only product in  
4 North America that's used as a raw botanical for a drug  
5 indication--and that's in Canada. Dried feverfew leaf, 90  
6 percent leaf material of a certain percentage perthenolide  
7 is approved for treating migraines. And it's under a  
8 traditional medicines category--excuse me, it's not. But  
9 Canada is another example of also traditional medicines  
10 category which has good and bad parts to it.

11           The unfortunate situation is that you need to look  
12 at what is--if you're going to use those clinicals in Canada  
13 for that indication, then what you're selling needs to be  
14 closely comparable to what was used in the clinical trials.  
15 So that's Canada's situation for that drug identification.

16           We may have a third situation here where maybe  
17 those--we don't think those trials are good enough to  
18 establish it as a drug here; indeed, we may not have that  
19 type of mechanism. But for consumers to be aware that maybe  
20 we want to just allow the Internet--but do manufacturers  
21 play a part in that? Does the FDA play a part in that? Is  
22 there a risk involved? Should this be useful information  
23 for consumers that people have traditionally reported this  
24 as effective, and let people try it.

25           We may find that a traditional category could be a

1 good vehicle for providing information to consumers to  
2 increase access to safe, effective remedies.

3 So that's pretty much--it's the claims that's  
4 important that we balance that. I had another point, but I  
5 don't remember what it was.

6 [Laughter.]

7 MR. LEVITT: Okay.

8 Dr. Bowen.

9 DR. BOWEN: Well, I think the whole discussion  
10 here in the last little bit has raised a lot of questions  
11 for us, and I guess what I had heard was that you're  
12 thinking of some of the existing systems that we have to  
13 manage some of the issues around botanical drugs--drugs,  
14 food, dietary supplement, whatever part of that continuum  
15 they're on--and that potentially raises the question of is a  
16 separate system needed for that? And then, if so, would  
17 some of the review be pre-market for certain claims? Would  
18 some of the review for those products that are already used  
19 in traditional medicine--wherever--and then what those  
20 products were for those claims. And it's very interesting,  
21 and I don't think I have a question here, but it's  
22 interesting. It raises a lot of those issues.

23 MR. LEVITT: Does anybody want a further comment?

24 MR. MARTINEZ: I just think there's going to be  
25 sort of an amalgam of what you're outlining, where hopefully

1 we'll have policy in place that will allow this kind of  
2 basic information to apply in general, much like what Dr.  
3 Dentali suggests. But for companies go the--you know, the  
4 extra distance here, that they would be--and that's going to  
5 be ultimately to the whole marketplace's benefit. Because  
6 once we have products out there that have been tested, and  
7 have been critically and scientifically evaluated, you will  
8 see the marketplace will change, because you cannot--if you  
9 know that you have something that works, the junk that's  
10 going to be out there will not stay out there, and you will  
11 then see an embracing and a utilization of this by the  
12 mainstream medical community. I mean, the bottom line is,  
13 the public is far ahead of the Agency, of the--you know, the  
14 marketplace is ahead of the regulators here, and we need to  
15 kind of bring this now into some kind of coordinated fashion  
16 from a public policy standpoint.

17           And there was some--there are tools in place, but  
18 of course we've seen the limitations, I think, of--for  
19 example, with DSHEA, with structure/function claims, and  
20 this--obviously we would need to go now to what the next  
21 step is. I mean, bottom line is people want to be able to  
22 tell the story about their products, but the whole truth.  
23 And we would look forward to working with the Agency in that  
24 regard.

25           MR. LEVITT: Very good. You folks are stimulating

1 thinking.

2 Margaret Porter has one follow-up question. I  
3 have one follow-up, and then we'll do the run-down of "one  
4 item." This is following up on Dr. Dentali's point that,  
5 yes, we still have some time.

6 [Laughter.]

7 You were courageous enough to stick your neck out  
8 and suggest that the traditional medicine system in Canada  
9 has--I think you said both good and bad parts to it. And  
10 since, obviously, you're suggesting that we look at those  
11 kinds of alternative systems to try to see whether there's  
12 something that we could learn from them.

13 I'd be curious as to what you would venture to say  
14 you think are the good parts, and what you think are the bad  
15 parts.

16 DR. DENTALI: Well, I think the good part is that  
17 it allows, basically, the familiarity that an herbalist has  
18 with traditionally used materials to be shared with the  
19 public, and to make those available.

20 One of the bad parts, and this--again, it goes  
21 back to how you're implementing things. If someone has a  
22 serious heart condition, they probably shouldn't be running  
23 off to take hawthorn. Now, there's very good--well, you  
24 know, we can talk about what's very good, and what research  
25 is available to show that hawthorn has discrete effects on

1 improving cardiac function over a long period of time. It's  
2 effects are more, indeed, dietary supplement/nutritional in  
3 nature. Many of the compounds now that are falling under  
4 "the active compounds" of dietary supplements fall into very  
5 broad categories--sub-categories of flavanoids. So that  
6 hawthorn cannot be recommended for heart conditions maybe  
7 prevents the population from including it as part of their  
8 diet, which would possibly prevent a lot more heart disease  
9 from arising.

10           So, you know, whatever system we come up with, or  
11 philosophy we come up with--whether it be of medicines or  
12 regulations--there's always going to be outliers. So the  
13 more points of view we can have on a topic, the more likely  
14 we are to come to an enlightened regulations on it.

15           This comes to, also, with the issue of  
16 standardization--we tend to assume that standardization is a  
17 simple thing and beyond that we tend to assume that it's  
18 measuring the amount of constituents. It is not. And the  
19 examples in the industry are a good way of how you can  
20 completely miss the point.

21           Standardization is the complete body of  
22 information and controls that guarantee a consistent  
23 product. And in many cases, not only do we not know what to  
24 measure, we don't even know how to measure it. What you  
25 guarantee is that you had the correct plant, it was grown

1 properly, it was harvested properly, it was dried properly--  
2 which is the single most important part in determining the  
3 quality of the crude botanical material--and it was  
4 manufactured and processed properly. And again, indeed,  
5 these are the issues that the industry is grappling with in  
6 coming up with definitions.

7 Use of the word "potency," is one that's been  
8 raised before, and deserves proper attention.

9 So--but gaining the basic familiarity that's, I  
10 think, the benefit of a Commission E-type approach, that  
11 these things--these assumptions that we have of how to  
12 regulate and apply to botanicals oftentimes don't hold true  
13 when the details start being raised. What are we exactly  
14 talking about when we try to imply a pharmaceutical on to it  
15 that it doesn't fit. Not always, but a lot of the time.

16 So, again, wherever what we have works, we need to  
17 use it. But if there's areas where it doesn't work, we need  
18 to be open for creative endeavors on how to deal with that.

19 MR. LEVITT: I thank you--oh, you want to --

20 MR. MARTINEZ: Yes, one thing--just as a  
21 historical footnote, I find it kind of fascinating and sort  
22 of we've come full circle here is one of the factors that  
23 actually led to DSHEA was the fact that when the botanical  
24 industry requested establishing a botanical ingredients  
25 review panel, the Agency refused to do that. And that was

1 one of the factors that led to the development and passage  
2 of DSHEA. Here we are now--here can see that the Agency is  
3 actually contemplating here, now what are we going to do  
4 have a handle with botanicals. So it's good that we've--  
5 there's sort of a listening now to that. So--just--it was a  
6 comment.

7 MR. LEVITT: Thank you. And I congratulate Dr.  
8 Dentali for not only answering Margaret's question but mine  
9 at the same time.

10 Why don't we then go through our last rapid-fire  
11 wrap-up. Again, looking a year from now, if I could ask  
12 people to try to focus in narrowly on one thing that could  
13 be accomplished a year from now, what would that be?

14 DR. DENTALI: The establishment of a category, and  
15 the expertise to provide us and the populace with a greater  
16 familiarity of botanicals so that we can use them in all  
17 appropriate ways.

18 MR. LEVITT: Mr. Martinez.

19 MR. MARTINEZ: A year from now I'd like to see a  
20 Nutraceutical Act being debated and under full consideration  
21 by the U.S. Congress.

22 MR. LEVITT: I guess that means there's nothing we  
23 have to do in the next year.

24 DR. HUBER: And what's been said all day long--  
25 safety, safety and safety.

1 MR. LEVITT: Yes--Bill Hubbard wants to make one  
2 quick comment.

3 MR. HUBBARD: I'd just like to say that your  
4 comments sound very much like these--you're not talking  
5 about these things as foods. I mean, DSHEA is for foods.  
6 You know comments very much lead one into the--trying to  
7 find a category that's appropriate for these products, that  
8 they have medicinal properties, they have some risks, they  
9 need to be properly used, potency needs to be established.  
10 And I guess I go back to my earlier discussion with you, Dr.  
11 Dentali, about OTC. Maybe the OTC model's not perfect or  
12 not, but somehow, you know, your comments don't lead me in  
13 the direction of saying these are food products that should  
14 be treated that way. These are a particular kind of product  
15 that should have some regulation, but also have benefits and  
16 usefulness and need their niche. And I think that--that's  
17 what's you're saying, right?

18 DR. DENTALI: No.

19 MR. HUBBARD: Okay.

20 DR. DENTALI: Only because there are perfect  
21 examples where they clearly are foods. Chickweed is an  
22 excellent example. I used to--as an undergraduate student I  
23 made salads pretty much where chickweed was half of it on a  
24 regular basis. So clearly that's a food. It's recognized  
25 as a food, it's used as a food. I don't know about claims

1 for it's being used in weight-loss. Certainly any claims  
2 along that nature, they'd have to be evaluated. Dandelion  
3 greens--food. The list goes on and on. If we want to look  
4 at that category, there's a huge amount.

5 So it is a continuum, completely, where we could  
6 find examples and win an argument on either end of the  
7 story, and every place in between.

8 MR. LEVITT: Okay. Well, listen, I thank this  
9 panel very much again. Before you go down, let me just make  
10 a couple of announcements. We are going to take a 15 minute  
11 break and reconvene at three o'clock.

12 Before everybody runs out to do that, I have a  
13 message--or there is a message for Mrs. Joy Joseph. If  
14 you're in the audience, if you could Naomi Kulicob in the  
15 back of the auditorium--she's standing with her hand like  
16 this--she'll be happy to give you that message.

17 And, finally, if there are people who want to make  
18 a statement at the end of the meeting, please register  
19 outside and then afterwards I'll have the next speakers come  
20 to the front of the room over here.

21 Thank you very much. We'll see you at three  
22 o'clock.

23 [Recess.]

24 MR. LEVITT: Well, if I could ask for people's  
25 attention. If people could take their seats.

1 We are in danger of being on time.

2 [Pause.]

3 MR. LEVITT: We're ready to start the final  
4 segment of the day; what we'd like to call the homestretch.

5 We have two panels, and a small number of  
6 individuals who also have asked to speak. I believe that on  
7 our Consumer panel, unless somebody has just walked into the  
8 room in the last couple of moments, that one of the listed  
9 people, Phil Howry, is not here at the moment. If he's able  
10 to get here later in the afternoon we will definitely fit  
11 him in, because I know he's traveling from some distance.

12 But let me welcome up to the podium Fred Bingham  
13 and Richard Johnson, and we'll be happy to hear your  
14 presentations.

15 10:25 As they come up--we'll continue, as we've done  
16 before, with each speaker making a five-minute presentation.  
17 AGain, once you're up here I can focus your attention in the  
18 front row, and you'll see a little sign that will come up  
19 with "one minute left," and a little sign that will come up  
20 when your time has expired.

21 We'll then subject you to hopefully friendly and  
22 constructive questioning.

23 [Laughter.]

24 And as this group is smaller, I hope it does not  
25 look like an unequal distribution of energy. But I'm sure

1 you have very interesting things to contribute. And please  
2 step right up to the podium.

3 **PANEL V - CONSUMERS**

4 MR. BINGHAM: I'd like to thank you for allowing  
5 me to be here today. I'm delighted that this process is  
6 proceeding.

7 My name is Fred Bingham. I'm the Executive  
8 Directive of DAAIR. We're the largest HIV-AIDS Virus club  
9 in the United States. We supply low-cost and sometimes no-  
10 cost nutritional supplements to people with HIV and AIDS and  
11 other chronic illnesses. We have about 5,000 members.

12 This statement has also been co-authored by  
13 Michael Onstott, who is Executive Director of the National  
14 AIDS Nutrient Bank, based on the West Coast. And he'll be  
15 giving testimony out there on July 20th, I believe.

16 All right. All consumers of dietary supplements,  
17 including people with HIV and AIDS, have a right to expect  
18 that the products we use are pure and safe, and that they  
19 contain the substances claimed on the label in the amounts  
20 specified. Guaranteeing the safety of supplements and the  
21 accuracy of labels with regard to contents is the  
22 responsibility of the manufacturers and Food and Drug  
23 Administration.

24 Consumers also have a right to accurate, clear and  
25 non-misleading information about dietary supplements.

1 Currently, however, there are only a handful of informative  
2 claims with which the FDA agrees. Totally unsubstantiated  
3 health-related claims are essentially undifferentiated with  
4 those that are backed by specific, well-designed clinical  
5 studies. The practice of following virtually all  
6 manufacturer-driven label claims with FDA's statement that  
7 these claims have not been evaluated by FDA does not provide  
8 enough information for most consumers--definitely not.  
9 FDA's disclaimer may, in fact, mislead people to believe  
10 that all claims not evaluated by the FDA are more or less  
11 equivalent.

12 With all the above factors in mind, we would like  
13 to address five interrelated areas of concern regarding the  
14 regulation of dietary supplements.

15 Labeling information. As indicated below, dietary  
16 supplements should contain sections, or boxes, that provide  
17 the following information: supplement facts; active  
18 ingredients, etcetera; health claims and FDA disclaimers to  
19 health claims; a safety profile--safety and purity; and GMP-  
20 -good manufacturing practices.

21 Safety profile--and I've gone into some of this--  
22 this statement will be substantially elaborated on by the  
23 20th of July. The system for reporting adverse events  
24 associated with dietary supplements should be enhanced and  
25 made consumer friendly. Outreach and education to those who

1 use supplements must become a high priority. Product safety  
2 should be evaluated using standardized and objective  
3 criteria to determine if adverse effects are likely to  
4 occur, or if they have occurred. If adverse events have  
5 been identified, then it should be further determined if  
6 they rise beyond an objective threshold past which FDA  
7 action is required. Once verified, the current mechanisms  
8 for FDA response are adequate.

9           Dietary supplement labels should indicate if a  
10 product may be associated with historically known or  
11 reported adverse effects and contraindications. This  
12 information should be--would be contained in the "safety  
13 profile" section of the label. Labels for formulas  
14 containing new biochemical ingredients would also indicate  
15 that the product was associated with a very limited history  
16 of use.

17           All dietary supplement labels should be required  
18 to devote a small but prominent section to inform consumers  
19 if a product is manufactured under a credible standard of  
20 GMP. This standard, as proposed by various manufacturers'  
21 associations, should be higher than the standard for food,  
22 but not as onerous as that which is required for  
23 pharmaceutical drugs. The FDA would supervise verification  
24 of a manufacturer's compliance with GMP for a selected  
25 product. The Agency would also periodically check for

1 contaminants in a variety of dietary supplements to assure  
2 their purity.

3 Health claims. If a manufacturer or distributor  
4 of a dietary supplement makes a health or disease related  
5 claim, that claim must be evaluated under an objective  
6 standard to determine the degree to which the claim is  
7 valid. Once evaluated, claims would be rated on a scale of  
8 1 to 4. The lowest rating, level 1, would be associated  
9 with the absence or extreme paucity of scientific evidence,  
10 while the highest rating, level 4, would indicate that there  
11 "significant scientific agreement" and that FDA agrees with  
12 the claim. Levels 2 and 3 claims would require varying  
13 degrees of scientific proof and/or verification of long-term  
14 history of use, and would be accompanied by an FDA  
15 disclaimer. Appropriately, level 2 would require a higher  
16 standard of proof than level 2, while level 3 would  
17 represent a considerable body of scientific studies and  
18 other specific evidence that clearly placed it above level  
19 2.

20 Consumer outreach and education. The goal in  
21 implementing the proposed label additions and changes is to  
22 benefit consumers and assist us in making informed choices.  
23 This requires extensive consumer outreach, media campaigns,  
24 as well as educational seminars and public meetings. A  
25 collaborative effort that includes input from a broad range

1 of consumer groups, scientists, FDA officials and  
2 representatives from the dietary supplement industry must be  
3 mounted in order for labeling information to become  
4 genuinely useful for those who use supplements.

5 Assisted by others in the collaboration, consumers  
6 should take the lead in determining how best to approach the  
7 goal of comprehensive, user-friendly labels to avoid  
8 consumer deception and fraud.

9 And funding and resource allocation--I'd just like  
10 to say that we propose that Congress authorize the  
11 allocation of some additional funds to assure that the FDA  
12 can monitor the safety and content of dietary supplements,  
13 but we also further propose that funding for necessary  
14 improvements in labeling and evaluation of label claims, as  
15 well a portion of the consumer outreach efforts be  
16 substantially obtained through a nominal surcharge on each  
17 unit of dietary supplement sold in the United States.

18 Thank you.

19 MR. LEVITT: Thank you very much.

20 Mr. Johnson, please.

21 MR. JOHNSON: Good afternoon. My name is Richard  
22 Johnson, and I am the AARP Delaware State President.

23 AARP is interested in the regulation of dietary  
24 supplement because lots of our members and other older  
25 persons use supplement products. In recent years, we have

1 commented on FDA proposals regarding the regulation of  
2 supplements and claims made on product labels.

3           At the outset, we'd like to commend FDA's work in  
4 standardizing the label supplements. Clear, readable  
5 supplement product labels regarding nutrient content and  
6 ingredients, with uniform standards for claims are essential  
7 to providing consumers the information they need to make  
8 wise choices. Ironically, consumers are not getting  
9 adequate assurance that the products they choose are safe.  
10 Without proof of product safety, the supplements that people  
11 take to improve their health may actually cause harm.

12           We believe that the Agency's number one priority  
13 in the area of supplement regulation should be to ensure the  
14 safety of these products. We understand that the Dietary  
15 Supplement Health and Education Act significantly hampers  
16 FDA's ability to remove dangerous supplements from the  
17 market. We also recognize that the Agency has limited  
18 resources to dedicate to this issue. However, we urge the  
19 Agency to think creatively about what it can do to address  
20 supplement safety. A major obstacle to supplement safety is  
21 a lack of scientifically sound research. There has been  
22 some research on vitamins and minerals, however research is  
23 needed on many other dietary ingredients.

24           Without a requirement for FDA review and approval  
25 before marketing products, manufacturers have no research

1 incentive. The inability of manufacturers to patent many of  
2 their products and recoup safety research costs is another  
3 disincentive to research.

4           Given FDA's limited research funds, it should  
5 consider alternative funding avenues. One possible source  
6 could be a user-fee program. Every supplement manufacturer  
7 could be assessed an annual fee based on some appropriate  
8 criterion. The monies collected would be distributed as  
9 research grants. Under such a program the Agency could  
10 establish an advisory council to develop research  
11 priorities. One issue of concern to our members is the  
12 possibility of serious interaction between certain  
13 supplement products and prescriptive medicines.

14           Implementing a user-fee research program may be  
15 challenging, however. Some interests may believe it more  
16 appropriate to implement such research through the National  
17 Institutes of Health--the NIH. AARP urges the FDA to work  
18 with other Federal agencies like the NIH, and with Congress,  
19 the supplement industry, and interested consumer groups like  
20 AARP to establish a supplement safety research program.

21           A second issue of concern to us is the problem of  
22 product classification. A product labeling standards and  
23 safety requirements depend on whether it is classified as a  
24 drug, a food or a dietary supplement. But classifications  
25 are not always clear, and are less clear when products can

1 cross the lines of definition. For example, Benecol and  
2 Take Charge are two margarine products that contain an added  
3 substance which lowers cholesterol. Calling these products  
4 something other than drugs or foods--functional foods, or  
5 nutraceuticals--is confusing. We urge that product  
6 classifications be structured such that manufacturers cannot  
7 use them to skirt appropriate regulations. FDA must ensure  
8 that the products are appropriately classified and conform  
9 to proper standards.

10 Finally, we'd like to mention our concern about  
11 the efficacy of supplement products. If sufficient funds  
12 were available, we would like both the safety and efficacy  
13 of supplement products to be researched. Some of the  
14 research is already being done. For example, the Office of  
15 Complementary and Alternative Medicine at NIH is currently  
16 funding research in conjunction with the National Institute  
17 on Aging, on the effects of ginkgo on memory. Clearly, more  
18 of this type of research is needed.

19 At the same time, we believe that the agency could  
20 be doing a better job of reviewing the adequacy of  
21 scientific support for the claims on product labels. AARP  
22 members are especially concerned about the claims on  
23 products marketed to older persons, such as those that claim  
24 to improve memory, promote prostate health, and reverse the  
25 aging process. Our concern is not just that these products

1 may be worthless, but also that they may not be harmless.  
2 Such claims may lead a person to forego proven treatments,  
3 and select alternative remedies that are based on  
4 unsubstantiated promises.

5           AARP appreciates the opportunity to present our  
6 views on an FDA approach to supplement regulations. We  
7 would welcome and opportunity to participate in the  
8 development of a sound regulatory system that protects  
9 consumer health and safety in this rapidly expanding area of  
10 health promotion products.

11           Thank you.

12           MR. LEVITT: Thank you very much.

13           Again, what we'll do is we'll go right down the  
14 row here, and try to do one question each, and then at the  
15 end, I'll ask you to just summarize: if there was one thing  
16 that you could have a year from now, what would that be?

17           My question relates to safety. Both of you have  
18 emphasized that as an important area. The law talks about  
19 what's called "unreasonable or significant risk." Without  
20 dwelling too much, from a lawyer's point of view but just  
21 from a consumer's point of view, for this category of  
22 products, what--how should we go about deciding what's a  
23 reasonable risk and what's not a reasonable risk? You know,  
24 what benchmarks, or from a consumer point of view--you know,  
25 would you want to be assured of?

1 MR. BRIGHAM: I think that anything that might  
2 affect your health that you unknowingly might take because  
3 it's not specified or not proven to be safe is unreasonable.

4 MR. LEVITT: Okay. Thank you.

5 Would you like to--

6 MR. JOHNSON: Well, no--that's really a tough  
7 question. I don't know. All I know is that you need to  
8 establish some kind of objective criteria for--

9 MR. LEVITT: Mm-hmm.

10 MR. JOHNSON: --for establishing this definition,  
11 and that there really hasn't been up to this point. I don't  
12 know if it--it would involve industry and obviously health  
13 care professionals and consumers perhaps--

14 MR. LEVITT: Mm-hmm.

15 MR. JOHNSON: --and some kind of working group or  
16 panel. I mean, I--there are so many dietary supplements  
17 sold that in some way can be dangerous. I mean our catalog  
18 is littered with warnings on the things that we sell. We do  
19 quite a lot of research on them. But--and I think that  
20 safety is the number one priority here, for sure.

21 But also I think that the health benefits that are  
22 gained from these supplements is significant and needs to be  
23 recognized and regulated appropriately.

24 MR. LEVITT: Thank you.

25 Margaret?

1 MS. PORTER: My question is about consumer  
2 research. The second panel this morning, I think, really  
3 stimulated us to look at issues about doing more research,  
4 or having more research done on how consumers actually use  
5 supplements, what they really understand or don't understand  
6 from the labels that are there; whether they follow the  
7 dosage restrictions, etcetera, etcetera. And as  
8 representatives of major consumer organizations, I'd be  
9 interested in your perspective on whether that kind of  
10 research is appropriate; whether your organizations ever do  
11 that kind of research into the behavior and attitudes and  
12 preferences of your consumers, or how you think the agency  
13 would go about getting such research done.

14 MR. BRIGHAM: I think that it's a very necessary  
15 thing. I would strongly encourage you to formalize that and  
16 proceed in some way.

17 DAAIR is a relatively small organization, with  
18 limited funding, and we really haven't taken an objective  
19 look at--I mean, intuitively--because I know so much about  
20 my organization, I can kind of answer that on an intuitive  
21 level, but on an objective, measured level, I can't. And  
22 I'm sure AARP might be able to do a little bit better with  
23 some sort of funding.

24 But I think that that may be one of the first  
25 steps that might be taken in order to structure the label.

1 I mean, these different--well, we're proposing these  
2 different boxes on the label, to see just exactly how they  
3 are being used, and what are the limitations and  
4 understandings, and limitations of understanding. I think  
5 that would be one of the first things I would do.

6 MR. JOHNSON: AARP is, as you know, a large  
7 organization, and in addition to having 33 million members,  
8 there are probably about 600,000 volunteers within that  
9 structure, plus the staff members that give guidance. All  
10 of the feeling is that this is very important, to have  
11 consumer education. And in many of the fields, the major  
12 activity of these volunteers with AARP is information and  
13 education. And we have various things that are very  
14 important to AARP, such as Social Security and Medicare  
15 solvency and that type thing. And I'm sure that, as a  
16 function of that, we would really advocate the information  
17 and education as to what is necessary to make consumers more  
18 informed about these items, and what is the proper of these  
19 things, and such as that.

20 Consumers, left to themselves, I think would tend  
21 to go in the direction of if one pill is good, two may be  
22 better. And so there needs to be some information to be  
23 disseminated that would help to counter that.

24 MR. LEVITT: Bill Hubbard?

25 MR. HUBBARD: Do you believe that your

1 constituencies are more vulnerable to unsafe dietary  
2 supplements than the general population, and do you have any  
3 objective data of injuries or adverse events from  
4 supplements in your various members?

5 MR. JOHNSON: What was your first part of your--

6 MR. HUBBARD: Do you believe that your members, or  
7 your constituencies, are more vulnerable to unsafe dietary  
8 supplements than the general population?

9 MR. JOHNSON: Speaking for AARP, we represent,  
10 generally, the older people in our society, and I think that  
11 they are probably more vulnerable because they are the ones  
12 that are taking a lot of prescriptive drugs. And the  
13 problems arise where some of these supplements may actually  
14 interfere or cause difficulty if you're taking a  
15 prescriptive drug.

16 I was surprised, in reading some of the literature  
17 in preparation for this, that garlic is a blood thinner--

18 MR. HUBBARD: Mm-hmm. Right.

19 MR. JOHNSON: --and yet there's a lot of  
20 advertising of garlic to be used. And if you're on, such as  
21 I am, a medication which already thins your blood--and many  
22 adults, or many seniors may be in that category--that would  
23 be an area of a severe problem. So I think--yes, the AARP  
24 members are probably more prone to have this difficulty than  
25 others.

1 MR. BRIGHAM: Interestingly enough, my answer is  
2 very similar. I mean, people with HIV and AIDS are also on  
3 a great deal of pharmaceutical drugs. I mean, speaking  
4 personally for myself, with kava kava, I used it at a--about  
5 a year ago, and then re-challenged myself with it. I  
6 actually ended up in the emergency room. I was on hamilor  
7 and nortriptyline--a tricyclic anti-depressant. And trying  
8 to manage some anxiety before I went on to a prescription  
9 drug, I took kava kava. And then I re-challenged--the first  
10 time, I was admitted to the emergency room. The second  
11 time, I just went to the emergency room because I was taking  
12 a lower dose, and I just wanted to see if it really did it.  
13 But I nearly passed out. I mean, I went through waves of  
14 passing out.

15 And, you know, and then there's--the historical  
16 use of kava kava can't extend past three months anyway. You  
17 develop quite a substantial rash--skin rash--and dermatitis,  
18 it's known, if it's used consecutively. And we have  
19 warnings throughout our catalog on blood thinning agents--  
20 many of the coumarins and stuff, and different herbs and  
21 botanicals.

22 MR. LEVITT: Bill, if I could just follow up with  
23 you briefly on that--so, in your mind, the remedy for that  
24 problem is labeling on products? I mean, everybody--

25 MR. BRIGHAM: Yes.

1 MR. LEVITT: --doesn't necessarily have the  
2 catalog that you're referring to.

3 MR. BRIGHAM: Right. No. I think there needs to  
4 be some labeling on--definitely there needs to be some  
5 labeling, some safety--you know. And even if it means a  
6 label which opens up. You know--I mean, I know we're  
7 getting into OTC and things like that--I mean, that goes  
8 into these contraindications. You know--and, I mean, they  
9 certainly do exist. And to ignore them--it's really, really  
10 needed.

11 MR. JOHNSON: And expanding a little bit on what  
12 the gentleman said, as we talked of these needs for  
13 information on labels, I could envision a label that would  
14 stretch across the table on a small bottle. But I think  
15 it's necessary, and if it can't be done on a label, it has  
16 to be done somehow, that the people are aware. I've heard  
17 garlic advertised many times over television and radio,  
18 without ever hearing any of the adverse or possible adverse  
19 effects. And, again, it surprised me to find that that was  
20 a side effect.

21 MR. LEVITT: Okay. Thank you.

22 Dr. Yetley?

23 DR. YETLEY: You both indicated that you would  
24 like to see FDA get more input from consumers, particularly  
25 your consumer constituencies in designing label information.

1           What mechanisms do you suggest that would  
2 facilitate that process?

3           MR. BRIGHAM: Well, the establishment of maybe a  
4 bi-coastal group--working group or panels or something--to  
5 meet on a regular basis to establish a framework of what to  
6 achieve, and goals to achieve. I mean, and actually having  
7 some, you know, regular timely meetings with consumers  
8 throughout a process, you know, that establishes a process  
9 and objective goals within a period of time, I mean, and on  
10 a regular basis, and is more formalized.

11           DR. YETLEY: Would you see this as separate from  
12 an advisory committee that was discussed earlier, or would  
13 you see that this could be incorporated into that process?

14           MR. BRIGHAM: I wasn't here for the advisory  
15 committee, but I think I might see it separate.

16           MR. JOHNSON: If we're talking about getting input  
17 from consumers, it might be possible with some of the AARP  
18 publications. We have a publication called The Bulletin  
19 which goes to all AARP members, and the Modern Maturity  
20 magazine. And I'm not sure if this could be accomplished in  
21 a very quick fashion, but if there were such a thing as a  
22 questionnaire that would ask what are your inputs that you  
23 might have as to the needs on labeling for the various  
24 consumer issues, that might be something that could be done  
25 through the publications that we have.

1           The other question that you had as to should this  
2 be in addition to an advisory council, I'd say yes, they  
3 should be separate entities; one being from an advisory  
4 council, and then any other input you can get from consumers  
5 directly.

6           MR. LEVITT: Thank you.

7           Dr. Bowen?

8           DR. BOWEN: My question is do you have any data  
9 from your groups of consumers who use these drug products,  
10 are they using it in concert with what is actually listed on  
11 the label, or are they using it differently. And, in  
12 specific, could you talk about the disclaimer--the FDA  
13 disclaimer--about the information. What purpose do you  
14 think that serves, or if that helps?

15           MR. JOHNSON: I don't have any information that we  
16 have knowledge of specific instances. Now, the disclaimer  
17 you're mentioning is the one that says the FDA does not  
18 recommend--I think that's very valuable, and I think--and,  
19 again, some of these things I wasn't aware of until I read  
20 this literature on this subject, but in reading that, it  
21 seemed that that would at least give people pause if they  
22 would read something that was making some claims, and then  
23 they would see that this was not something that FDA would  
24 sanction on the basis of the words in that disclaimer.

25           I think it's very valuable.

1 MR. BRIGHAM: I actually--I think the opposite. I  
2 think that there is--it's a wild, wild west show out there  
3 right now, as far as I'm concerned. I mean, I can't believe  
4 I'm sounding as conservative as I am--

5 [Laughter.]

6 --but--since FDA knows which side of the fence--  
7 I've been before you before on a number of occasions, in  
8 Congress and whatever. But it is--it's a wild, wild west  
9 show out there, and I think that the statement is becoming  
10 essentially meaningless at this point. It's just, you know--  
11 --and there is a substantial amount of deception and fraud  
12 going on. I'm not--you're kind of focusing on health and  
13 safety issues, which are certainly there--certainly not as  
14 much as OTC drugs or pharmaceutical drugs. But with the  
15 health--related to health claims and health benefits, I  
16 think that it's pretty--it's a disaster.

17 So--and there needs to be some more formalized  
18 standard of objectivity and--I mean, I know FDA is going  
19 through the process of redefining, or defining what  
20 scientific agreement is or is not or whatever. But, I mean,  
21 even aside from that, just trying to at least tier these  
22 health claims a little bit to try and more inform the  
23 consumer, you know. And then it's amazing how small they  
24 put that disclaimer--the FDA. I have to look for it, and  
25 it's like--when I'm looking at one of the ads, or whatever.

1 It's really--you should at least require it to be in 10  
2 point type.

3 [Laughter.]

4 MR. BRIGHAM: But, again, someone who has been  
5 involved with this for a long time may find that it's  
6 something that you overlook. But for a novice, or someone  
7 that's not that involved in these use of dietary  
8 supplements, I think it would cause me pause at least.

9 MR. LEVITT: Okay.

10 Margaret, did you say you have a quick follow-up?

11 MS. PORTER: Yes--I really did understand you not  
12 to think that the disclaimer was very helpful, Mr. Bingham.

13 I'm interested in your suggestion--and I know you  
14 said your written comments are going to more fully elaborate  
15 this--

16 MR. BRIGHAM: Right.

17 MS. PORTER: --or your comments on the West Coast  
18 next month, but I understand you to be advocating a several-  
19 tier system that evaluates various levels of evidence with  
20 respect to the varying degrees of efficacy of particular  
21 claims. And, as you know, the more levels one has, the  
22 more--shall we say--complex a system can become. And I'd be  
23 curious as to whether you are going to be advocating whether  
24 we would go to a--some sort of a monograph system, or  
25 whether you've got some models that you would have us

1 examine if we were to try to look at that kind of a system?

2 MR. BRIGHAM: I think I need to think about that a  
3 little bit further.

4 MS. PORTER: Sure.

5 MR. BRIGHAM: But, I mean, I don't know about  
6 going to a monograph system. That may ultimately be  
7 necessary. But I think that this--I mean, if the public  
8 can understand the food pyramid I think they can understand  
9 a four-tiered health claim system. And--

10 [Laughter.]

11 --I mean, and other things, including safety  
12 profile and GMP.

13 MR. LEVITT: Thank you.

14 Dr. Yetley, you have a quick follow-up?

15 DR. YETLEY: Yes, I was just going--I think your  
16 comment--I was going to ask you about how well you thought  
17 consumers would understand a tiered system, in terms of the  
18 shades of qualification. I think there are questions as to  
19 how well consumers understand the food pyramid, so I don't  
20 know about the analogy--

21 [Laughter.]

22 --but if either one of you had any comments, in  
23 terms of how consumers understand various shades of  
24 qualification to a message?

25 MR. BRIGHAM: Well, I think it's really a matter

1 of outreach and education, and you should be given the funds  
2 for this, either through congress, or through some kind of  
3 tax--or, well, let's not use that nasty word--user-fee on  
4 dietary supplements--per unit of dietary supplements. And  
5 we obviously want you to dramatically increase your role and  
6 expand it in this area. And it's going to take substantial  
7 funding, and it's going to take a lot of consumer outreach  
8 and education. But I think it can be done. And I think  
9 getting together this working group, or bi-coastal working  
10 group of consumers is a good way to start as well, you know,  
11 in addition to industry and other groups.

12 MR. LEVITT: Mr. Johnson, do you care to comment  
13 how you think your constituents would respond to a four-  
14 tiered--

15 MR. JOHNSON: I don't have any idea.

16 MR. LEVITT: Okay. Thank you.

17 With that, then, we'll give you one last  
18 opportunity to look ahead a year from now and say to us,  
19 FDA, if I could see one clear accomplishment a year from  
20 now, that would be--

21 MR. JOHNSON: Safety. And, again, as I said, if  
22 we had two that we could talk about: safety and efficacy.  
23 But safety is the primary concern.

24 MR. LEVITT: Thank you.

25 Mr. Bingham?

1 MR. BRIGHAM: Make some stop-gap--I hate to use  
2 that work, because I know the process is going to be long  
3 and tedious to work through this enormously complicated  
4 issue of dietary supplements and the functional foods and--  
5 but some stop-gap safety assessment of various  
6 nutraceuticals, vitamins, supplements and herbs that might  
7 pose a potential risk to the public health that are out  
8 there. And have them placed in some way that--on the  
9 bottle, in a box, or whatever. I mean, I don't know, but,  
10 you know--I mean, I can list, you know, about 15 of them off  
11 the top of my head, just, you know, right now.

12 You know, and getting at least that.

13 MR. LEVITT: Okay. Thank you. And if in your  
14 written comments you would identify those 15 or so, we'd be  
15 happy to know specifically which ones you thought needed  
16 attention.

17 MR. BRIGHAM: Right.

18 MR. LEVITT: Listen--I thank both of you very  
19 much.

20 That concludes this panel. We have one final  
21 panel, four lawyers.

22 [Laughter.]

23 And we have Claudia Lewis-Eng, we have Jim  
24 Prochnow, Steve McNamara, Steve Allis. If you could kind of  
25 figure out how to sit in that order, it makes it a little

1 easier. From either end.

2 [Pause.]

3 Okay. Again--although I think you all have been  
4 watching the proceedings--what we'll do is each speaker will  
5 have five minutes. It looks a little different when you're  
6 up here. Right down here we have the one-minute warning,  
7 and the "time as expired" sign. If we could try to adhere  
8 to that. People have been very good--I want to compliment  
9 all the speakers, who have been very good about trying to  
10 stick within that. And then we'll go down and ask some  
11 questions.

12 Please, first speaker, identify yourself and where  
13 you're from. And in the case of the lawyers, please, if you  
14 could talk about who you are representing here today.

15 **PANEL VI - LAWYERS & DIETARY SUPPLEMENT INDUSTRY**

16 MS. LEWIS-ENG: Certainly.

17 Good afternoon. I'm Claudia Lewis-Eng, and I'm an  
18 Associate with Emord and Associates. And today I'm here on  
19 behalf of our clients Pure Encapsulations, American  
20 Preventive Medical Association, Dr. Julian Whitaker,  
21 Mycology Research, and Weider Nutrition International.

22 I would like to thank the FDA for hosting this  
23 public meeting and providing us with an opportunity to have  
24 this oral presentation.

25 In announcing the meeting, CFSAN made references

1 to its 1999 priorities document for regulating dietary  
2 supplements. While I agree with many of the Agency's  
3 priorities, I must say there was a glaring omission. On  
4 January 15th of this year, the U.S. Court of Appeals for the  
5 D.C. Circuit made a decision in Pearson v. Shalala. And  
6 that decision stands for the general proposition that the  
7 government may not suppress outright commercial speech that  
8 is only potentially misleading, as opposed to inherently  
9 misleading.

10 In that case, the petitioners submitted four  
11 health claim petitions to the FDA, together with the  
12 scientific information, and the FDA rejected all four health  
13 claims. Those health claims were: omega-3 fatty acids in  
14 reduction of heart disease; anti-oxidant vitamins in  
15 reduction in the risk of certain kinds of cancer;  
16 consumption of fiber in reduction in the risk of colorectal  
17 cancer; and 8 milligrams of folic acid in dietary supplement  
18 is more effective in reducing neural tube defects than in  
19 common food form.

20 In the Pearson case, the U.S. Court of Appeals  
21 stated that the fact that FDA found the scientific evidence  
22 submitted by the petitioners inconclusive was not good  
23 enough to reject the claims and, instead, that the FDA  
24 should impose the use of disclaimers to balance the  
25 potentially misleading speech. And that's what I am here

1 today to urge the FDA to make as its number one priority: to  
2 authorize those four health claims submitted by the  
3 petitioners, and include the use of disclaimers to balance  
4 the potentially misleading speech if the disclaimers are  
5 necessary.

6 I also urge the Agency to employ the use of  
7 disclaimers in the case of other health claim petitions  
8 presented to the Agency, as opposed to the outright  
9 suppression of speech. In fact, our firm just recently  
10 submitted three health-claims petitions to the Agency.

11 The first health-claim petition was merely seeking  
12 a clarification from a rule that we already feel applies to  
13 dietary supplements, and that is psyllium husk seeds in the  
14 reduction of coronary heart disease. But the second two we  
15 think that the Agency should really take a good look at the  
16 science that we submitted and, if necessary, attach  
17 disclaimers to balance any potentially misleading speech the  
18 Agency might find. And those are folic acid, B-6 and B-12,  
19 and the reduction of cardiovascular disease; and Saw  
20 Palmetto and the reduction of BPH--benign hyperplasia. The  
21 firm at this time also intends to submit one more health-  
22 claims petition, and that would be vitamin E and the  
23 reduction of heart disease.

24 And so I would urge the Agency, upon looking at  
25 those petitions to really look closely and try to develop

1 some disclaimers that could be used, as opposed to rejecting  
2 the health claims, finding that the scientific information  
3 is inconclusive.

4           And just a gentle reminder to the Agency: we  
5 strongly believe that the Pearson case governs every  
6 instance in which the FDA would choose to regulate health  
7 claims. The case and its Constitutional impact should  
8 really be a priority with the Agency, and we look forward to  
9 seeing the use of disclaimers, as opposed to the rejection  
10 of the health claims.

11           And since I still have some time, I would like--  
12 have one other point that I would like to touch on briefly,  
13 and that is the AER system. Currently, FDA has a system of  
14 collecting adverse event reports. And it doesn't seem that  
15 there's much organization or a systematic method of  
16 collecting that data. For example, there are some instances  
17 where people don't really inform the Agency of the products  
18 they were using, how much they were using, what other types  
19 of medications they were taking, what other things that  
20 might have gone into causing the adverse event--yet the  
21 Agency relies on this information for promulgating proposed  
22 rules. And that was the case in ephedrine.

23           So we think that the FDA should take time to  
24 restructure its AR system and perhaps have a separate system  
25 for dietary supplements as opposed to combining with the

1 food information. So we also want the FDA to take time to  
2 confirm that the information put on the Web is accurate, and  
3 do as much background checking as the Agency can in order to  
4 make sure that information that's posted on the Web does not  
5 adversely affect innocent companies.

6 Thank you very much.

7 MR. LEVITT: Thank you.

8 Next speaker--from Patton Boggs, Jim Prochnow.

9 Help me with the name, because I'm not sure--

10 [Pause.]

11 MR. PROCHNOW: Jim Prochnow, from the wild, wild  
12 west--from Denver, Colorado.

13 Our law firm is based in Washington, D.C., but I  
14 am the chairman of the Denver segment of the office, that  
15 deals with dietary supplements, both from the standpoint of  
16 FDA, Federal Trade Commission, state regulators, product  
17 liability suits, and all the other forces that help to  
18 regulate dietary supplements in the marketplace.

19 And, basically, we represent a variety of  
20 manufacturers, distributors--whether by mail order catalog,  
21 by multi-level marketing, by health food stores, mass  
22 merchandisers, things like this. And in preparation for  
23 this meeting, what we did was we sent out an e-mail to  
24 virtually all of our clients asking for their input about  
25 the questions that were raised in the Federal Register about

1 the importance of dietary supplement regulation in the  
2 future.

3           We've gotten, to date, about a third of those  
4 responses back, but we will tabulate them by the time that  
5 the comments are over. And, actually, quite a few of them  
6 are going to--at lengths to describe what they think are--  
7 their opinion of how dietary supplements and dietary  
8 supplement companies should be regulated in the future, and  
9 we'll be making a very intricate matrix of that information  
10 and passing it along to the FDA, and make it available to  
11 others who are interested in that information.

12           Today, with the very restricted time element here,  
13 I'm going to make only three points. One is this: in our  
14 judgment, DSHEA, which was passed--that magic date in  
15 October of 1994--we think already is a very comprehensive  
16 framework for governing the dietary supplement industry. If  
17 there's going to be any tinkering with DSHEA, it should be  
18 with the expansion of benefits to consumers and the  
19 industry, and not with any restriction of DSHEA by  
20 regulation or otherwise. That's the first point.

21           Secondly is this: we think that the way that the  
22 FDA can best give input from the American public is actually  
23 keying off something that one of the last panelist members  
24 said, and that's "go to the people more." It's okay to have  
25 these types of meetings, and it's okay to deal with the

1 major trade associations, who have a very important role to  
2 play. But like the FDA has done in the area of medical  
3 devices, our clients believe, and I believe that what they  
4 should do is hold a series of meetings in Colorado, where  
5 there's a lot of dietary supplement companies of every  
6 nature; in Utah, perhaps the hotbed of dietary supplement  
7 companies; in California, New Mexico, and places like that--  
8 have one representative from the FDA in Washington, if they  
9 have the resources, otherwise have the local district  
10 office; invite the folks in for a three-hour meeting, and  
11 sit down and talk with them. And then you can really find  
12 out, on a local basis what's going on. It's the best way to  
13 get the most information in a cost-effective way.

14           The other comment that I wanted to make today--and  
15 my biggest comment--is this: the FDA has good folks that are  
16 sitting here, but they probably aren't going to get much  
17 funding than they have now to carry out their duties. So I  
18 hear all of these people saying a lot of good things about  
19 what these good folks should do, but the fact of the matter  
20 is they're going to be able to do very little more than  
21 they're doing now without a lot of increased Federal  
22 funding, and that's unlikely to happen in today's political  
23 atmosphere--and in the atmosphere of the dietary supplement  
24 industry.

25           So what I'm proposing today is that everybody here

1 should think about something that actually was raised by one  
2 of the last people to speak, but I'm going to raise a more  
3 specific thing, and that's this: and that's an industry-  
4 funded check-off program. For those of you that know what  
5 check-off programs are all about, basically it's where the  
6 industry itself has Federal legislation that enables monies-  
7 -not a tax--but monies to be collected on a per-unit basis,  
8 whether it's a half-cent per bottle, or whatever's agreed  
9 upon--the money is not spent by the Federal government. The  
10 money is--it's a check-off program that's spent by the  
11 industry. The industry itself elects members to a council.  
12 It's a very intricate thing. It's been done very  
13 successfully in the cotton industry, in the beef industry,  
14 in the propane industry, now the heating oil industry. It's  
15 a very effective thing. People can disagree with different  
16 aspects of it. But the important thing is, it would be  
17 industry-controlled as opposed to the FDA controlled.

18           When DSHEA was passed, I remember the fighting  
19 that went on beforehand, and the fight was to have less FDA  
20 regulation, not more. And the reason for that is this: it  
21 was thought that historically the FDA was at odds with the  
22 industry and with the American public over health. I think  
23 that attitude is shifting somewhat. Still, the regulators  
24 are never going to know as much about your industry as you  
25 know about the industry. And unless you want more

1 regulation, the industry itself, either through a check-off  
2 program, or through some other mechanism, is going to have  
3 to develop an effective means to regulate itself.

4           Personally, I'm not in favor of any more  
5 regulation. The marketplace is a powerful regulator itself.  
6 Product liability suits, claims, insurance--things like  
7 that. But if there's going to be more regulation, let's let  
8 the industry do it, and not the FDA and the government.

9           Thank you.

10           MR. LEVITT: Thank you very much.

11           Next is Steve McNamara:

12           MR. McNAMARA: Good afternoon. I'm Steve  
13 McNamara. I'm with a law firm that generally limits its  
14 practice to matters of food, drug, medical device and  
15 cosmetic regulation. And I'm here today specifically<sup>n</sup> on  
16 behalf of one of our clients--Starlight International,  
17 headquartered in the lovely location of Monterrey,  
18 California, where some of us would like to be more often.  
19 Starlight is a manufacturer and distributor of dietary  
20 supplement products.

21           I've been asked to address today and issue that,  
22 interestingly, does not appear to have been raised at all at  
23 this meeting up until now. It's an issue that goes to the  
24 heart of FDA's authority in certain respects; for example, I  
25 heard Mr. Levitt earlier ask one of the prior speakers,

1 "Would you recommend that we use regulations or guidelines  
2 or what?" It's also an issue that could save FDA a lot of  
3 resources if approached appropriately, I believe.

4 And basically, this is the point. And I should  
5 say here, we have a detailed paper that discusses the  
6 citations and quotes the supporting authority for all of  
7 this. I'm just going to try and hit the high points in an  
8 oral summary.

9 The basic point is this: I've spent about 50 hours  
10 going through the legislative history of the Dietary  
11 Supplement Health and Education Act over the last two weeks,  
12 at the request of the client, to look at this particular  
13 issue. It brought back a lot of memories. As some of the  
14 FDAers will recollect, I testified both in the House and the  
15 Senate for the coalition of Utah companies that asked  
16 Senator Hatch to introduce and sponsor the Dietary  
17 Supplement Health and Education Act. So I've been rather  
18 thoroughly involved with this for the past five years.

19 Having refreshed my memory, and having looked at  
20 the facts, it seems to me that--it would be pretty clear  
21 that because of certain unique provisions in the Dietary  
22 Supplement Health and Education Act--provisions that were  
23 specifically considered during the legislative process--and  
24 because of provisions that do not apply to any other parts  
25 of the Food, Drug and Cosmetic Act, it appears to us to be

1 the case that FDA does not have the authority to issue a  
2 regulation that has binding effect with respect to the  
3 adulteration or safety provisions of the law that have been  
4 discussed earlier today.

5 Let me just, for purposes of oral summary, and  
6 recognizing that many of you are not lawyers, go to the  
7 essence of some of the key points.

8 First of all, on the face of the law itself,  
9 Section 402(f)(1) of the Food, Drug and Cosmetic Act, as  
10 amended by the Dietary Supplement Health and Education Act,  
11 there are a series of provisions to the effect that a  
12 dietary supplement will be deemed to be adulterated "if"--  
13 and these have been referred to by FDA representatives  
14 today, including Mr. Levitt, and summarized at one point  
15 accurately as, a dietary supplement's adulterated if it  
16 presents a "significant or unreasonable risk of illness or  
17 injury" etcetera.

18 At the close of this section, however, after all  
19 of these adulteration provisions are provided, there is the  
20 following unusual provision: "In any proceeding under this  
21 subparagraph, the United States shall bear the burden of  
22 proof on each element to show that a dietary supplement is  
23 adulterated. The Court shall decide any issue--" any issue--  
24 "--under this paragraph on a de novo basis--" i.e., all  
25 over again, from scratch, not relying on a conclusion that

1 has already been reached in the past by the FDA.

2 I believe on the face of the law that says that if  
3 FDA goes to all of the work to publish a regulation, and  
4 then marches into court with a regulation that says a  
5 particular section--particular dietary supplement is  
6 adulterated because it contains a certain amount, for  
7 example, of ephedra that exceeds the level that the  
8 regulation allows, and that therefore the supplement is  
9 adulterated, the Agency will not be able to rely on the  
10 regulation but will instead need to prove its case from  
11 scratch that that particular supplement is adulterated under  
12 the statutory standard, and that the company would be free  
13 to offer data to show that its product, as evaluated by it,  
14 with its own marketing history is, in fact, safe for use and  
15 not adulterated. And the regulation would not establish the  
16 outcome.

17 I am reassured in my conclusion about this by  
18 looking at the legislative proceedings. It happens that  
19 this very section of the law originally had a provision in  
20 it for FDA to issue regulations, but that that provision--  
21 that authorization for regulations--was explicitly deleted  
22 before the final section of the law was passed.  
23 Furthermore, the earlier provision did not have the section  
24 that said that a court shall decide any issue on a de novo  
25 basis. And, in fact, that was added when this section was

1 put in and when the explicitly provision for a regulation  
2 was deleted.

3           There's more in the legislative history. It's  
4 discussed in some detailed in the paper. We will welcome  
5 other dietary supplement companies focusing on this issue in  
6 taking a good hard look at it, because we believe it  
7 establishes a point that many in the industry will have a  
8 common point of view about: that FDA itself, when it moves  
9 to articulate what it believes the law requires with respect  
10 to safety or efficacy under Section 402(f)(1) should be  
11 relying on guidelines, not regulations. And if it spends  
12 all the money--time, money and effort that are necessary to  
13 issue a regulation, the regulation won't have any more  
14 effect in court than a guideline anyway. So why not  
15 creatively shift to guidelines, rely upon guidelines, and  
16 the agency can get a lot more guideline work done in a  
17 shorter amount of time and with less resources than would be  
18 taken by regulation.

19           Thank you, Steve.

20           Steven Allis--last speaker on this panel.

21           MR. ALLIS: Thank you.

22           As the last speaker, I'm sure I'm--everyone's got  
23 the same thought right now. So I'll try to just hit a few  
24 key points and then move on to the next phase.

25           My name is Steven Allis, and I'm an associate at

1 the Firm of Emord and Associates. I represent a company  
2 called Biogenics, which does business as Eola International.  
3 They manufacture a variety of dietary supplements, including  
4 dietary supplements containing ephedra.

5           When I first saw the notice for this meeting it,  
6 to me, summarized that FDA was looking for comment on how to  
7 identify where to proceed; how to prioritize its tasks and  
8 to put those tasks into effect, or to accomplish those  
9 tasks. I'm not asking in the comments to really do much of  
10 a change. I'm not really focusing so much on that, I'm  
11 focusing more on how to go about that change; not exactly  
12 what should be changed, but the processed involved with  
13 that.

14           There are three points I'd like to focus on.

15           The first is that in the decision that the agency  
16 is going to make, it should rely on sound science, which is  
17 a very obvious statement. And I'm sure your scientific  
18 staff would agree with that, because that's their bread and  
19 butter. The sound science standard, the standards used to  
20 evaluate that have been recently affected by the Pearson  
21 decision, recently mentioned by Ms. Lewis-Eng. And in that  
22 decision, the court, as part of it, said that the FDA needs  
23 to define a scientific standard that would be applied to  
24 dietary supplements. And the language, of course, involved  
25 "significant scientific agreement."

1           And what I want to point out is, as far as the  
2 procedure used for defining the scientific standard here--  
3 the point that what I want to refer to--a duality I've  
4 noticed with the agency, not only working as an attorney but  
5 as a former scientific reviewer in the Office of Device  
6 Evaluation--I have seen that when a company wants to  
7 petition the FDA, as with the recent health-claims petitions  
8 that my firm submitted, the standard, of course, there is  
9 scientific evidence that demonstrates significant scientific  
10 agreement. And in that, it's not really clear where that  
11 lies, especially after the Pearson decision.

12           Some science like well controlled randomized  
13 studies, of course, fall under the category of good science.  
14 Things such as anecdotal evidence are usually--are almost  
15 totally rejected, and they should be, because they're not  
16 really good science. They're little cases here--someone had  
17 this affect, and someone had this other effect. So in that  
18 situation a company is asking FDA to do something and the  
19 reaction is, well you have to reach a certain level of  
20 science. Some science is bad, some science is good--we're  
21 going to draw the line somewhere in the middle.

22           Now, when the opposite happens--when FDA is  
23 seeking to take action, as in the case with ephedra, these  
24 anecdotal reports all of sudden become valuable. They're  
25 used as a basis for saying, "Okay, we have something--some

1 information, scientific or not, that is going to be used to  
2 base our regulations on--to base our regulatory decisions  
3 on." And as in the case of ephedra, a number of adverse  
4 event reports--AERs--were used as a primary basis for  
5 prompting the regulation which is currently pending of  
6 ephedra.

7           The problem, of course, with AERs is that they are  
8 just cites--or one moment in time where someone had an  
9 effect from a product, and that's just kind of floating out  
10 there. There's no real reference to put that in. It's not  
11 a study where you had a certain population, or we can derive  
12 a percentage from: how many people had a bad result. And  
13 not only that, but the AERs also are flawed because they--  
14 sometimes you don't know what product they took, how much  
15 they took of it, what other conditions they had. And I just  
16 bring up these--this duality. We have a situation where  
17 FDA--where someone's asking FDA to do something and the  
18 standard is a strong scientific standard. And when FDA is  
19 trying to do something that involves an industry or a  
20 company, that standard gets kind of ignored. It's kind of  
21 made a little bit over inclusive. And I'm just asking that  
22 whatever the Agency decides, to stick with sound science in  
23 its procedures.

24           The second theme is to ask the agency not to  
25 overregulate. Now, that's another overstatement, but what

1 I'm getting at with that is--again, I can use ephedra as a  
2 good example. That's a product where there are some bad  
3 actors out there. The product has been tied to a possible  
4 illicit use for some manufacturers. There's also problems  
5 that might be attributed to the labeling claims, or over--  
6 too high of a concentration of ephedra.

7 Now, what I would hate to see is where a few bad  
8 actors ruin it for the whole industry. And that's  
9 particularly alarming when you consider that the existing  
10 statute and regulations could allow effective regulation to  
11 get these bad actors from ruining it for the rest of the  
12 industry.

13 There are already regulations in place to prevent  
14 claims that aren't supported by science. There are various  
15 other tools already in place that could be used to stop  
16 these bad actors. There's no reason to put another layer of  
17 regulation to restrict ephedra, particularly when that  
18 regulation is based on, like I said before, the faulty  
19 science of the AERs.

20 And as a last point, I want to refer to--whatever  
21 the Agency does, to be fair. And that's another overbroad  
22 statement. Here, I have to refer to what Texas has recently  
23 done, or is trying to do with ephedra, and that would be  
24 passing regulations saying that "we're going to regulate  
25 botanical ephedra a certain way, and synthetic ephedra

1 another way." There's no real justification for treating  
2 the two differently if it comes from a plant source or a  
3 chemical source. There is no science that I could find out  
4 there, or that anyone I relied on could find out there,  
5 saying that there is--the body recognizes the difference  
6 between the two.

7 I'm just using Texas as an example of an agency  
8 that is saying, "We're going to treat these two versions of  
9 the product differently" with no apparent rationale.

10 So I just ask for the Agency to keep fairness in  
11 mind when they're applying any of the regulations of  
12 industry.

13 Thank you for your time.

14 MR. LEVITT: Thank you very much.

15 For my first question I'd like, if I may, take  
16 advantage of the fact that we have four very knowledgeable  
17 lawyers up here, and while not picking up necessarily on the  
18 particular points you made, you're all familiar with DSHEA.

19 One of the things that has struck me in learning  
20 more about it is there is a long litany of issues that might  
21 benefit from definition, clarification, throughout that  
22 statute. In your experience, could you each list, just in  
23 your mind, one or two legal definitional kinds of issues  
24 that would really us paying attention to, giving  
25 clarification to?

1 MR. PROCHNOW: This is Jim Prochnow. The question  
2 that I get asked the most frequently by clients is what does  
3 "substantiation" mean? Usually I say, the FDA has refused  
4 to define substantiation in its comments to various rules,  
5 and said it's kind of like pornography; we recognize it when  
6 see it.

7 But substantiation is a huge issue, because people  
8 do want to comply with the law. And, as you know, as a quid  
9 pro quo for making structure/function statements, you have  
10 to have substantiation for what you say is true. So I would  
11 say in the clarification arena, more clarification about  
12 what's "substantiation" would be helpful.

13 And I want to say I agree with Steve. And I say  
14 use of guidance documents is the way to get this done, as  
15 opposed to regulation. It will take too long for  
16 regulations, and you need the industry to buy in on it from  
17 a voluntary basis anyway. So I'm all in favor of  
18 substantiation, and the use of guidance documents to  
19 accomplish what the FDA needs to accomplish in this area.

20 MR. LEVITT: Thank you.

21 Who else would like to comment?

22 Steve?

23 MR. McNAMARA: Well, I do think there's a  
24 fundamental problem over the so-called "disease" definition,  
25 but that goes even broader. I mean, part of it goes to the