

1 a recommendation and actually warn consumers.

2 Three: Require substantiation files.

3 Four: Review and help conduct surveys to  
4 determine more clearly why and how consumers use  
5 dietary supplements and what type of label information  
6 would be most useful.

7 Five: Establish focus groups and working  
8 groups incorporating outside volunteer experts and  
9 others who may be paid, like consumers, scientists,  
10 health professionals, industry representatives to  
11 finalize and help implement regulatory and labeling  
12 strategy.

13 Six: Involve more consumers and non-FDA  
14 experts in the process of proposing criteria for the  
15 eligibility of the OTC drug review systems.

16 Seven: Review the monograph systems of  
17 Germany.

18 Eight: Vigorously enforce the law with  
19 regard to violators regarding GBL, GHP, TMG, and  
20 provide strong consumer education and media campaigns  
21 about the risk.

22 Nine: Require the prominent placement of  
23 warning labels on gray area product such as ephedra  
24 and caution statements for other supplements that are  
25 generally considered safe such as iron, time release

1 niacin and echinacea.

2           10: Establish a more accessible and  
3 scientifically based recording system for dietary  
4 supplements that is user friendly. And again,  
5 scientifically --

6           Eleven --

7           MR. LEVITT: Can I ask how long a list  
8 there is?

9           MR. ONSTOT: I've got two more. Withdraw  
10 the proposal for the word "disease."

11           And finally, define the standard for  
12 significant scientific agreement. Thank you. I'm  
13 sorry I took so much time.

14           MR. LEVITT: Thank you very much. And  
15 don't worry about the extra time. Very clear set of  
16 recommendations. I'll go back and get them from the  
17 transcript too.

18           Our fourth speaker on the Panel is Mr. Ed  
19 Anderson.

20           MR. ANDERSON: Hello. I'm not a health  
21 professional or lecturer, but I'd like to offer my  
22 perspective of my experience with promotions on the  
23 Internet. A lot of this seems very trivial now, my  
24 prepared statement, in light of all the past  
25 panelists.

1                   In 1995 I wrote up charters for a new  
2 global discussion group on skin diseases. In the past  
3 four years I provided information resources for these  
4 support groups, the psoriasis group in particular. We  
5 take the time to answer questions and provide  
6 emotional support. There are about 50,000 messages in  
7 the new user bar code. Much of the open forum code is  
8 about treatment options becoming a main place to  
9 discuss product claims made by advertisers, and those  
10 are mostly advertising on the net. This is on the net  
11 where everybody goes for research. Very little of the  
12 information seems to come from the public to help  
13 answer repeated questions on psoriasis products that  
14 seem too good to be true.

15                   One of the resources at my website lists  
16 some facts about some of the most descriptive claims.  
17 I've tried to get FDA input and attention to some of  
18 these, and there's about four that are dietary  
19 supplements, and probably another eight that are  
20 topical steroids and medical devices and whatnot, but  
21 in the absence of enforcement and response, I'd like  
22 to offer a proposal that could defuse many of these  
23 misleading propositions. These changes could be  
24 applied in dietary supplements.

25                   Listing ingredients on product labels is

1 important for making an informed decision at the point  
2 of sale. I think at the point of sale here is  
3 critical because normally the point of sale is on the  
4 label of the bottle, but before you're -- as Ed Reiss  
5 from the National Psoriasis Foundation said -- when  
6 you click on the order, the point of sale is on the  
7 website. Information is not available. A phone call  
8 to ask about ingredients may lead to a sales pitch by  
9 someone interested in selling the product. And press  
10 releases often addressed consumer concerns by giving a  
11 listing of what isn't in the product rather than some  
12 of the actual ingredients.

13 My take-home message is that product  
14 ingredient information needs to be available online,  
15 and this should be provided by the manufacturer. Any  
16 promotion that describes a specific product prior to  
17 sale should also provide an accurate ingredient list.

18 With the ability of a web site to  
19 accurately list label information, having that as a  
20 requirement can only serve full interest. The  
21 promoters and distributors who don't obtain a web  
22 site, the producer should be required to maintain an  
23 online process. Simple requirement to require -- I'm  
24 sorry. Simply required to provide needed information  
25 to consumers and improve such regulations.

1           Commercial, print publishers and Internet  
2 service providers have the ability to decide which ads  
3 to carry. Service providers have been cooperative in  
4 limiting online fraud by establishing acceptable use  
5 policies, which this usually deals with fraud  
6 according to mail and deceptive advertising, and it is  
7 very effective.

8           That doesn't allow a certain process that  
9 they can basically sign off on, and usually just takes  
10 one complaint, sometimes two. They depend on  
11 enforceable legal guidelines. Deceptive supplement  
12 promotions that lack ingredient information could be  
13 readily addressed by complaints to the publisher  
14 regarding content. Even before this needs  
15 enforcement, this lack of online ingredient lists  
16 could become a red flag for consumers.

17           My second proposal is that every product  
18 label should contain a manufacturer's statement on  
19 cautions and side effects. If the product is known  
20 for a particular ingredient, by comparison shopping,  
21 it should give you a fair warning. It would be clear  
22 when the consumer isn't breathing, the whole story.

23           By putting the accountability on the  
24 manufacturer it takes the burden off the FDA and puts  
25 it back on the producers, where it belongs. An

1 additional listing of manufacturer's suggested safety  
2 age for use by children, this is an easily  
3 recognizable measure of product safety and liability  
4 concerns, should keep it safe. It will get more  
5 useful information, not less.

6 DSHEA shows concern that the FDA might  
7 suppress information on potential benefits by  
8 restricting claims. What seems to be looked over are  
9 the basic sides of the equation, specific warnings  
10 that the FDA shouldn't exclude a requirement that  
11 manufacturers make some statement on their own. There  
12 should be on every label the statement from the  
13 manufacturer, whether or not it's innocuous.

14 One final suggestion: The FDA needs to  
15 implement a complaint tracking database because  
16 complaints, they end up going down -- they get bounced  
17 from division to division and usually end up going  
18 down a dead end, and it's an exercise in frustration.  
19 And if this complaint database were made public so  
20 that people could query it and find out where the  
21 complaints are for a particular company or a product,  
22 that information could be shared in the groups where  
23 people do answer questions and are free to.

24 Thank you for letting me participate here.

25 MR. LEVITT: Thank you very much. Our

1 final speaker on this panel is Marcy Fenton.

2 MS. FENTON: Good day. I am Marcy Fenton,  
3 a registered dietitian and HIV nutrition advocate at  
4 AIDS project in Los Angeles, also the past chair of  
5 the HIV/AIDS Dietetic Practice group of the American  
6 Dietetic Association. I'm here today representing the  
7 AIDS Health Fraud Task Force of California, of which  
8 I've been a member for over the last 3 years.

9 The AIDS Health Fraud Task Force of  
10 California is a collaborative network of individuals,  
11 community-based organizations and government  
12 representatives. It is organized to empower people  
13 affected by HIV to act on their own behalf in matters  
14 of health care and to reduce the harm caused by both  
15 the lack of adequate and accurate information or by  
16 misinformation.

17 We appreciate the FDA for conducting this  
18 meeting and our opportunity to provide input. We  
19 agree with the need to ensure consumer access to safe  
20 dietary supplements that are truthful and not  
21 misleadingly labeled, with the emphasis on "safe,"  
22 "truthful" and not misleadingly labeled.

23 Our constituents are often confused about  
24 what is true and not true. We are subjected to a  
25 bombardment of marketing tactics, promotion of

1 questionable claims or products that may or may not  
2 have the ingredients identified on the label, as well  
3 as ingredients that may be in there that may be  
4 contrary to amounts listed on the label.

5           There is a strong assumption that  
6 supplements on the market are safe, pure and  
7 efficacious and are scrutinized by the FDA, just by  
8 virtue of the fact that they're allowed to be on the  
9 market. Indeed, some products have proprietary  
10 patents used in promotion that increases the confusion  
11 about its legitimate use and efficacy.

12           Increasingly, the boundaries between  
13 dietary supplements, food, drugs and cosmetic products  
14 have become muddled and compromised and need to be  
15 clarified.

16           As we define AIDS fraud as the promotion of  
17 an AIDS-related health product of treatments known to  
18 be false or unproven, we can see that the boundary  
19 between health fraud and the promotion of numerous  
20 dietary supplements has also become dangerously  
21 muddled and compromised.

22           We need a way to identify what is helpful,  
23 what is harmful, what is harmless, and what is harmful  
24 when in combination with other nutrients or drugs or  
25 under certain conditions. As a group, we are

1 challenged to find a straightforward, easy and  
2 reliable way to access product risk and benefits that  
3 is also accessible to our constituents. We need an  
4 impartial evaluator and rating of these products, and  
5 this has to be our top priority.

6 In order to provide that, it will entail  
7 most, if not all the elements of the dietary  
8 supplement program that FDA has already laid out.

9 It would entail a greater commitment to  
10 better soliciting, collecting, analyzing and educating  
11 about adverse effects of dietary supplements.

12 MedWatch, the FDA medical product reporting  
13 program, includes special nutritional products, (e.g.,  
14 medical foods, dietary supplements and infant  
15 formulas), as well as drugs, biologics and medical and  
16 radiation-emitting devices. However most people,  
17 healthcare providers, and even FDA employees are not  
18 aware that MedWatch is supposed to be collecting data  
19 on adverse events of dietary supplements as well as  
20 medicine.

21 Usage of MedWatch is not encouraged, not  
22 easily accessible, nor is it user friendly. One step  
23 toward changing this would be to provide the 800  
24 number and website address on each dietary supplement  
25 label. A way to track, compile and analyze reports

1 with easy access is crucial.

2 Analysis of product would have to employ  
3 evaluation methods that are much better than what is  
4 now in place. FDA will need to outline criteria of  
5 significant scientific agreement. This concern was  
6 well addressed by The American Dietetic Association in  
7 their statement of June 8, 1999.

8 The need in the HIV community for fair,  
9 honest and complete risk-benefit analysis, health and  
10 nutrient content and structured function claims is of  
11 extreme importance. Our constituents are now taking  
12 new, potent, lifesaving medications, some that have  
13 numerous contraindications to other medications, food  
14 components and dietary supplements.

15 The antiretrovirals that are extending  
16 lives also do not work for everyone and we need to  
17 acknowledge and address the concern that dietary  
18 factors, components in food and dietary supplements,  
19 may be interfering factors in absorption and  
20 utilization. We need to have assurances that there  
21 are mechanisms in place to study and report  
22 interactions and the adverse effects between dietary  
23 supplements and these other drugs.

24 Indeed, some supplements may be a factor in  
25 promoting or inhibiting the immune system, and we

1 really need to know and stop being passive about the  
2 situation. We need to know which supplements are  
3 safe, at which doses, and under what conditions.

4           The direct marketing of these products has  
5 been an ongoing serious issue that still needs  
6 attention. I can tell you that in my position, I am  
7 solicited to promote, purchase or recommend products  
8 with some frequency.

9           Recently I received calls that "this  
10 product" has cured AIDS in children in Guatemala,  
11 "that product" is a cure for cancer in Indonesia. We  
12 are concerned that the marketing materials and  
13 promotion are not accurate and in accordance with the  
14 label. To decipher claims in advertising promotions  
15 requires a level of knowledge and information that  
16 most individuals do not possess, mostly because the  
17 advertising is misleading and the substantiation is so  
18 poor to start with.

19           One last comment. In addition to including  
20 the MedWatch 800 number and website address on each  
21 dietary label, additional information on the label  
22 should also include the maximum dosage, appropriate  
23 use and contraindications. Labels should be large  
24 enough to be read without straining.

25           Thank you for your time today. The AIDS

1 Health Fraud Task Force in California looks forward to  
2 working with you in this important area.

3 MR. LEVITT: Thank you all. I have one  
4 question which is kind of a general question that  
5 anybody can feel it's pertinent to you or your  
6 interest, but it really has to do with striking the  
7 right balance.

8 On the one hand we hear a need for access,  
9 availability and information, and at the same time we  
10 want to have, as the last speaker just said, good,  
11 impartial information. I want the answer. What do  
12 you do when it's unknown? In other words, where  
13 should the balance strike?

14 Should -- when the areas are unknown,  
15 should that be something that is not accessed or  
16 there's clear information that the answers aren't  
17 known? Where would you try to strike that balance?  
18 Whether it's drug interactions, whether it's any of  
19 the number of other things that you said we are not  
20 going to get all that testing done right away from,  
21 even if I had my magic wand.

22 MS. FENTON: One, is it would be wonderful  
23 to have a centralized location where we do have a  
24 database, and along there would just acknowledge that  
25 there is no information, that there's no studies that

1 have been done, and I think the speaker said earlier  
2 today, I think she was kind of kidding, but I think it  
3 is true, the label should indicate that there's been  
4 no test, and so, you know, just by having an  
5 acknowledgment that there's no information is an  
6 acknowledgment, is a step forward.

7 MR. BLONZ: Once you have a standard of  
8 information, once you have a level of information out  
9 there, the absence of information will be noticed.  
10 Now, there's nothing. So, when there's no information  
11 people just hold up their hands, there's nothing on  
12 it, that other product. By letting people know what  
13 we do know, and warning them about what we don't know,  
14 that's a good beginning.

15 MR. ONSTOT: I couldn't agree more with  
16 that statement. Consumers need to know what we know,  
17 and they certainly need to know that we don't know  
18 anything about this particular product.

19 We have proposed a four tiered-system for  
20 informational claims. And, for instance, if you were  
21 going to do it like a movie review system, like one  
22 star would be, forget it, or you're taking -- you're  
23 taking your chances with this thing. We don't -- you  
24 know, they can say anything they want, but it's --  
25 it's probably a lousy choice until we know more. It

1 doesn't say it's a lousy product, it just says we  
2 don't know at all.

3 And, level two would be there's some  
4 traditional use, but we don't have clinical studies  
5 particularly. It has a history of use and so on.

6 Three, would be there's a lot of clinical  
7 studies. There's substantial scientific data, and it  
8 looks not only promising, but it looks like it's going  
9 to be true.

10 And then four would be, the FDA approves,  
11 which the FDA only approves about three and a half  
12 claims for dietary supplements, so that would be  
13 pretty easy.

14 But, then consumers would know that the  
15 level one product is a risk, and in fact it could have  
16 a red light on it or something, or a red dot, like  
17 stop and think about this before you enter into this  
18 particular arena.

19 And, you could have, you know, a pink dot  
20 for level two, and a yellow dot for level three and a  
21 green, go ahead, for level four.

22 MR. MCKEMIE: I have found some useful  
23 information in the statement of Dr. Tracey Fox of the  
24 ADA where he tried to describe what should be a  
25 significant scientific agreement as far as the kind of

1 information that should be provided. They also talk  
2 about the need for substantiation files to be more  
3 readily available to FDA as well as to other health  
4 care professionals. I would refer the FDA back to  
5 this earlier testimony.

6 MS. YETLY: I would like to follow up on  
7 something that Michael Onstot mentioned and ask if  
8 Michael could -- can answer it first, and then anyone  
9 else I would like to hear your input, and that is that  
10 you wanted to, or you suggested that consumers should  
11 have more involvement in the decision-making process.

12 Can you give me more specifics on that,  
13 what type of decision, what stage of the  
14 decision-making process and what kind of mechanism is  
15 needed to make that work.

16 MR. ONSTOT: I don't know all the answers  
17 to all those questions, but I can say that for one  
18 thing, the blue ribbon expert panels need to have some  
19 ordinary consumers as oversight people. You have  
20 really informed people, you know, for instance, the  
21 president -- presidential commission had  
22 Dr. Farnsworth and Mr. Michaela, who is a botanical  
23 expert, and it had industry experts like, I think,  
24 Annette Dickenson. But I -- you know, a lot of those  
25 panels I don't see an ordinary consumer who can ground

1 things and can give you some common sense and say,  
2 wait a minute. You people are suggesting something  
3 that is just really not going to work in the real  
4 world, and so I would include some real consumer  
5 oversight in the process. I mean, the meetings where  
6 your players are highly restricted, that's what I'm  
7 talking about. And what other question did you have?

8 MS. YETLY: What kinds of decisions that  
9 you felt consumers should be more involved in.

10 MR. ONSTOT: Especially the designs of  
11 labels. What kind of claims should be permissible and  
12 what level of validation. This needs to be done with  
13 scientists, and it needs to be done with FDA, and it  
14 needs to be done certainly with academia, but you need  
15 to have the consumers there with you at basically  
16 every step where you've got -- you know, you've got  
17 attorneys and you've got scientists, but sometimes you  
18 separate the consumers in a -- you know, I have to  
19 repeat the word paternalistic way -- that we don't get  
20 it. We are not smart enough. We don't understand.

21 There are a lot of issues that many  
22 consumers do understand, and I think they need to be  
23 at the table. So, I -- I mean, I would make a real  
24 effort, and then we can talk about trust, I mean,  
25 because if you do this and you're really listening,

1 then at least the AIDS community with regard to  
2 dietary supplements, because we have a little more  
3 trust for you with drug development, I will say  
4 because you have done a decent job, and we will  
5 commend you on the development, the expedition of AIDS  
6 drugs, but with regard to dietary supplements you do  
7 not have a good record.

8 MR. ANDERSON: Just to sort of go back to  
9 the last question about too much information. On  
10 previous panels, I'm baffled by the claim that there's  
11 too much information, and one of the best places for  
12 that is from professionals who participated in  
13 consumer uses. Whenever a professional comes online,  
14 he gets listened to, it's usually a very good repore  
15 with professionals. I think the FDA could actually  
16 call private relationships with professional  
17 organizations one way of educating the consumers would  
18 be to educate the professionals and have it spread out  
19 from there, get more professionals participating with  
20 consumer involvement.

21 MR. LEVITT: Thank you. Dr. Bowen.

22 DR. BOWEN: I wanted to get back to the  
23 concern about finding the standard for significant  
24 scientific agreement. I notice that you referred us  
25 back to something that's already been submitted, but

1 do members on the Panel have any suggestions about how  
2 to do that, make that definition?

3 MS. FENTON: To be quite honest with you, I  
4 did read over the American Dietetic Association's  
5 presentation, came out on two pages, I was very  
6 impressed and I said, read it. And because it sounded  
7 to me that it did list, you know, considerations that  
8 should be included and things that shouldn't be  
9 included, like anecdotal information or one case study  
10 or, I mean, as I think Joanne was saying this morning,  
11 if an ER doctor providing this information -- I mean,  
12 we really have to be -- have that level of  
13 information.

14 My hope is that if we can establish some  
15 better system using the MedWatch mechanism because  
16 that's already in place, I think that it's going to  
17 have to be -- I think we have to expect lots of  
18 different types of complaints that are very  
19 complicated, but we will get a greater sense of what  
20 is -- what's really happening currently, and that will  
21 be a factor in creating a component to be considered a  
22 scientific significant agreement.

23 But, you know, I don't think that that's  
24 going to be taking the place of good scientific  
25 studies and evaluation, and even the necessary

1 analysis that have been done are fairly poor because  
2 the variables are so wide. And you spoke earlier  
3 about it too. Do you have anymore information,  
4 Kermit?

5 MR. MCKEMIE: I have no more to say.

6 MR. Onstot: I think one place you have to  
7 start first is ingredient identity and good  
8 manufacturing process and testing. We have to know  
9 what we're testing because that's the problem with  
10 supplements that we see, at least from the AIDS  
11 community's perspective, is that it's -- it's like  
12 what Adele Davis used to say, Which apricot grows  
13 where? It's about what species was tested and what  
14 species is in this product.

15 Is it the inner bark? Is it processed  
16 under certain conditions? We don't know what we're  
17 buying on the shelf compared to studies. So, in that  
18 regard I think good manufacturing practices being  
19 strictly implemented in some way would help in the  
20 process of defining significant scientific agreements,  
21 because then we can agree at least on what we're  
22 talking about.

23 MR. ANDERSON: I think a lot of the claims  
24 that get made, sometimes it seems like there's an  
25 overwhelming number of claims. I know the FDA, I've

1 been told directly, they won't pay any attention to  
2 the Internet or dealing with labeling issues. I think  
3 it actually is possible to deal with some of those new  
4 claims. They're really aren't that many. It's kind  
5 of like a chain letter. The best ones, most  
6 profitable and convincing ones, they propagate. And  
7 you can capsule them, and you could have them in a  
8 complaint database, and somebody makes a misleading  
9 and deceptive claim, that's indicia, and it's clearly  
10 branded whether it's misleading and deceptive.

11 And those complaints can show up in a  
12 database, they can be queried and responded to by  
13 authoritative scientists and professionals. Right now  
14 the information is kind of scattered around. There's  
15 more clearing out for that information. I think the  
16 scientific information will come forth about it.

17 MR. LEVITT: Do you want to make a quick  
18 comment?

19 MR. MCKEMIE: Talking about the Internet,  
20 there is some substantial information there, for  
21 example, the National Council for Reliable Health  
22 Information has a site that can be visited, and there  
23 are web links to many other sites that represent good  
24 information. There's also an Internet news group that  
25 one can join by subscription called "Health Rods,"

1 that has a rather open, sometimes heated debate on the  
2 alternative medical area. And there's a lot of  
3 information there on the Internet if one will seek it  
4 out. Thank you.

5 MR. DORSEY: I understand the proposal to  
6 have four standards of validation of claims, be  
7 associated -- to be for claims about the efficacy of a  
8 product.

9 Do you think that -- are you also  
10 proposing, or do the panelists think that that idea  
11 might also be a good idea with respect to safety  
12 issues? I mean, are warnings thought up -- are  
13 warnings thought of as similarly staggered in terms of  
14 we know a lot about this product, we know very little  
15 about this product, this product is a very big risk?  
16 That would ensure a lot of access to products? Or are  
17 there some products where either the risks are so  
18 severe that no warning will work or where the  
19 knowledge is so sparse that the product just shouldn't  
20 be available?

21 I asked anyone who would care to comment.

22 MR. ONSTOT: I'll answer first then. I  
23 think that there's some merit to that idea because, as  
24 I was suggesting, there's a difference between a  
25 product like ephedra and a product like iron or

1 time-release niacin. Time-release niacin should have  
2 a warning that people with liver damage or people with  
3 HIV, for instance, should not take time-release niacin  
4 to lower cholesterol because it can lead to liver  
5 damage; whereas, non time-release niacin is probably  
6 usually safe but might have some contraindications  
7 too. But those kinds of distinctions need to be --  
8 are very helpful to consumers.

9 I think that that's a good direction that  
10 there should be cautionary labels and lasting warning  
11 labels on some things, and it could be a tiered system  
12 too.

13 MR. LEVITT: Any other reactions?

14 MS. FENTON: I think my thought was I  
15 appreciate what you said, and it might give us a first  
16 step to evaluating a product. I think it would be.  
17 But, recognizing the different conditions might just  
18 change that. If, you know, for example, the issue of  
19 children, pregnant women, have come up and that should  
20 -- would be a whole different population. Or, if  
21 someone is on renal dialysis, that would be different  
22 from somebody who didn't have any renal complications  
23 or was generally healthy.

24 And then the other aspect is that if  
25 something is truly desirable and very, very popular

1 now I know I, like everybody else, was very struck  
2 with Myrna's story, but when something is extremely  
3 popular in today's society, we people are going to  
4 take it. We have illegal drug use, tobacco and  
5 alcohol use, and people are generally aware of those  
6 problems, but it certainly would be a good first step.

7 And, I think, the question just probably  
8 played around with it, label attendants to have those  
9 labels and then evaluate I think it's worth the  
10 exercise.

11 MR. BLONZ: I think when supplements are  
12 taken out of the context of an intelligently conceived  
13 approach toward health care, the risk goes up  
14 potentially. We now have a bonanza that people are  
15 going to take a risk to use something that might help  
16 them, and they're going outside of any sanctioned  
17 fields and just going and buying the product off the  
18 shelf. And we're just asking for trouble.

19 I think we need to have greater education.  
20 It's unfortunate that most people know more when they  
21 go to buy a major appliance than things that have to  
22 do with their own health and own body. We need to  
23 bring people up to speed.

24 Whether it's with inserts, or bringing the  
25 health care establishment up, health care education

1 for the kids, PSAs were suggested earlier, somehow the  
2 level of knowledge about what those compounds do need  
3 to be integrated so that people don't walk blindly  
4 down that road. Thank you.

5 MR. LEVITT: And now, just before I let you  
6 go back to your seats, in the interest of time if I  
7 could ask people to think in terms of consistently one  
8 thing I'm really focusing on is in terms of  
9 timeliness, some things may take two years, three  
10 years, four years, five years, but something that you  
11 could say at the end, a year from now, the FDA could  
12 accomplish blank, that would be a good thing. Start  
13 at your end.

14 MR. BLONZ: I am sitting with my son at the  
15 start of the next Star Wars movie and a trailer comes  
16 on telling me about what the FDA is doing to protect  
17 us from botanicals and to educate us.

18 MR. MCKEMIE: Very good. I think that FDA  
19 should select out some of the various products,  
20 products such as Ephedra product, the chemical product  
21 that was sold in the health food stores and had such  
22 unfortunate consequences with the son of one of the  
23 earlier speakers.

24 Some of these are very unsafe labeled  
25 products and should be selected out in a very vigorous

1 legal action taken, such as the mass seizure of  
2 warehouse stock would bring to the public the fact  
3 that those products are indeed dangerous. There would  
4 be probably headlines in some papers.

5 The products are indeed very dangerous, can  
6 be very dangerous. These products contain chemicals  
7 or drug ingredients that are very active,  
8 pharmacologically active, and also go far in  
9 engendering the healthy skepticism of the consumer.

10 MR. LEVITT: Thank you. Next.

11 MR. ONSTOT: I would repeat what I  
12 originally said, to fully implement DSHEA,  
13 particularly GMP, and to do an assessment of the most  
14 popular herbaceuticals and nutrients with regards to  
15 adverse effects.

16 MR. ANDERSON: I think I would like to echo  
17 the last panel, enforcement of the worse offenders,  
18 because there are some key promoters out there, I  
19 think they're high profile, they set the example that  
20 all of the other promoters follow, and it's difficult  
21 to find a warning letter from the FDA that's addressed  
22 to any of these. I think some strategic warning  
23 letters, just immediately could take care of a lot of  
24 the problems. More enforcement for worse offenders.

25 MR. LEVITT: Okay. Very good. Marcy. I'm

1 sorry.

2 MS. FENTON: I think that I would ask you  
3 to put in place an easy, straightforward evaluation  
4 system that's accessible to professionals and to  
5 constituents.

6 MR. LEVITT: Thank you. Thank all of you.  
7 As you're moving off the stage and the next group is  
8 going on the stage. We actually have a sixth person  
9 in this next group. We have a chair up there. We'll  
10 try and squeeze that up.

11 We have Michael McGuffin, Kenneth Schwartz,  
12 Ofelia Barretto, Mark Blumenthal, Paul Simmons, and  
13 James Lasiter. Called in that order. Also, we have  
14 two individuals who have asked to make a presentation,  
15 and following this panel they will be allowed to make  
16 a presentation and then we will close the session.

17 MR. MCGUFFIN: Good afternoon. I'm Michael  
18 McGuffin. Thank you for the opportunity to  
19 participate in the forum. I'm here to represent the  
20 American Herbal Product Association, or AHPA. We  
21 represent approximately 300 manufacturers, marketers  
22 and raw material suppliers in the herbal dietary  
23 supplements industry. AHPA will provide full written  
24 comments to the topic at hand at a later date.

25 I came here with a prepared statement, and

1 I wish to include -- that it be included in the  
2 transcript of this meeting. I did bring copies. You  
3 all can read it. But in the context of today's  
4 meeting and the messages delivered here today, I will  
5 only refer to my prepared statement.

6 My purpose is in thus departing from my  
7 rehearsed five-and-a-half, six-minute speech is I  
8 really want to create an understanding among those of  
9 you who have stated very valid concerns here today  
10 that there is a responsible portion of the industry  
11 that shares some of these concerns, that has  
12 recommended and does continue to recommend a solution  
13 to these concerns.

14 So, I'm going to go right to some of the  
15 objectives that we were asked to identify. And the  
16 first one that we would like to make is simply that we  
17 agree that the Agency's stated objectives of safety  
18 and appropriate labeling of truthful and not  
19 misleading labeling must remain as priority, and  
20 that's a two-part equation.

21 Industry has a responsibility to conform to  
22 DSHEA in a meaningful manner and the Agency must be  
23 willing to use the regulatory and enforcement  
24 authority granted by DSHEA to protect consumers from  
25 those that would act otherwise. GBL is not an

1 approved dietary ingredient, nor are any of its  
2 precursors. The FDA needs to remove those illegal  
3 substances which are masquerading in the marketplace  
4 as dietary supplements. They are not dietary  
5 supplements as defined by DSHEA.

6 "Cures cancer" is not a statement of  
7 nutritional support. It is not a structured function  
8 claim. FDA should remove all such labeled products,  
9 they have the authority to do so, they need to use the  
10 authority and enforce DSHEA.

11 We -- my prepared presentation was to make  
12 a -- state as a priority, or rather as an objective,  
13 that the disease definition remain as it was when  
14 DSHEA was passed and recognize that that includes --  
15 that DSHEA clearly allows structure function  
16 statements that address non-disease conditions such as  
17 sleeplessness, constipation, PMS, prostate  
18 enlargement, et cetera, but the most original  
19 objective that I was prepared to offer is cognizance  
20 of the fact that the word "education" in the Dietary  
21 Supplement Health and Education Act is often  
22 overlooked.

23 We believe that the Agency should consider  
24 strategies to fully inform consumers about their  
25 broader health needs as related to the dietary

1 supplements they're consuming. That's what a lot of  
2 the speakers here have been saying today.

3           As an example, saw palmetto might make a  
4 structure function statement regarding the product's  
5 effect on the prostate. The consumer of such a  
6 product would be better informed if the product's  
7 label contained a statement to identify the  
8 prostate-related signals that are generally accepted  
9 to indicate the need to visit a health care  
10 professional.

11           Other work that the trade association has  
12 undertaken. In 1997 we published a botanical safety  
13 handbook that classifies the safety status for 600  
14 herbs. A little over 100 of those we recommended be  
15 labeled not for use in pregnancy or nursing, and the  
16 trade has taken on that recommendation to its members.  
17 A lot of this work has been done. It's unfortunate  
18 that it's not well-known that it's done, but a lot of  
19 cautionary statements that you see on labels, the  
20 removal of Comfrey for internal consumption by the  
21 industry in 1995 was simply not well-communicated.  
22 You know, that's through our own publicity problem.

23           We were asked to address priorities. The  
24 first one is GMPs. We clearly need to, I believe,  
25 suggest that the Agency communicate with industry to

1 determine if any modifications to the industry's  
2 direct GMPs might have become apparent in the past two  
3 and a half years since that was published and  
4 establish a December 2000 vote for a final GMP for  
5 dietary supplements.

6           And we also strongly recommend that the  
7 work that was completed by the GMP working group to  
8 the Food Advisory Committee be taken seriously, that  
9 the guidance that might be established is very direct  
10 to ingredient identity and even specifically to  
11 adulteration with toxic substances to assure that  
12 those products that are subject to that be tested to  
13 assure the absence of these. Other priorities,  
14 adverse event reporting, needs to be revised to allow  
15 manufacturers immediate access to a redacted  
16 statement. And then Ephedra.

17           We absolutely agree as CFSAN has stated in  
18 its 1999 Program Priorities, the resolution of the  
19 issues relating to products containing Ephedra must be  
20 a priority. AHPA does not believe, however, that  
21 those issues can or will be resolved by rulemaking.  
22 Such an approach will only assure that the unfortunate  
23 misappropriation of resources on Ephedra, both by the  
24 Agency and by industry, will continue.

25           AHPA has joined other associations in

1 recommending a specific solution that does assure  
2 consumer safety, and we strongly recommend an open  
3 dialogue among Stakeholders to address this issue.

4 I had a short, prepared statement with  
5 regard to leveraging resources, but it's primary to  
6 believe that we all do continue to work closely  
7 together to resolve these issues. Thank you.

8 MR. LEVITT: Thank you. Thank you very  
9 much.

10 Next speaker is Dr. Kenneth Schwartz,  
11 Genelabs.

12 MR. SCHWARTZ: Good afternoon. My name is  
13 Dr. Kenneth Schwartz, and I'm an endocrinologist and  
14 senior medical director of Genelabs Technologies,  
15 Inc., a Redwood City, California based biotechnology  
16 company that is investigating dihydrotestosterone,  
17 better known as DHEA, as the first new -- successful  
18 first new approved therapy for systemic lupus  
19 erythematosus, a disease primarily in women. Very  
20 timely that this coincides with the Women's Health  
21 Initiative.

22 To date we've had over 571 women who have  
23 participated in our placebo-controlled studies, up to  
24 one year in length, and I would like to share some of  
25 our insights today.

1           The message that I want to leave with you  
2 today is that DHEA and androstenedione and other  
3 androgenic steroids which are currently available  
4 through dietary supplements are in fact potent  
5 steroids and not dietary supplements.

6           Now, this line -- by the way, as I  
7 mentioned, I'm an endocrinologist. I love talking  
8 about my formulas. I hope I can convey some of this  
9 to you.

10           DHEA is converted to potent androgenic and  
11 estrogenic steroids. As you can see, it doesn't take  
12 an M.D. of 10 years of medical training to determine  
13 that the structure between DHEA, designated on the  
14 left and androstenedione and testosterone are very  
15 similar. They all have the four common rings that are  
16 typical of steroids. It's steroid hormones. Those  
17 are steroid hormones.

18           DHEA is converted in the body to  
19 androstenedione, the Mark McGwire hormone, and from  
20 there is converted to testosterone and in turn to  
21 estradiol. Those are potent steroids, and as you can  
22 imagine, they have potent effects on steroid-dependent  
23 tissues.

24           It's ironic that testosterone, as we all  
25 know, is an anabolic steroid. I'd like to see a show

1 of hands. How many people in the audience think it's  
2 not an anabolic steroid? There are no hands.

3 Testosterone is clearly recognized as an  
4 anabolic steroid, and estradiol is available only  
5 under the "prescription-only" FTC Act. It's only  
6 arbitrary that these other two steroids, which are  
7 very similar in structure, have potent biologic  
8 effects are not regulated under the FTC Act. And  
9 there should be major concerns about the health  
10 consequences to consumers who are taking these kinds  
11 of potentially or unintentionally taking it to promote  
12 health. Now, I mentioned that we have -- next slide.

13 This is data that was from a completed  
14 study that our company completed in 1997. And it was  
15 presented at a group of National Women's Health  
16 Professionals, and they show estradiol levels in women  
17 with lupus who are post menopausal and taken DHEA for  
18 up to one year.

19 This was a placebo-controlled study. And,  
20 the left you can see that placebo, there was no  
21 change, Y-axis is estradiol levels before and after  
22 one year therapy. There was no change in estradiols  
23 in the placebo-controlled group. In 100 milligrams  
24 per day of DHEA, there is a substantial rise in  
25 estradiol, and in 200 milligrams per day there's a

1 very substantial rise in estradiol.

2 Now, these levels are very well above what  
3 would be the normal levels in post-menopausal women or  
4 levels that are conventionally now accepted as being  
5 normal for hormone replacement therapy. In fact, we  
6 had levels as high as 376.

7 This raises serious concerns, and in fact  
8 in our discussion with the FDA, with your sister  
9 agency, the CEDR -- Center for Drug Evaluation and  
10 Research -- we had input into our controls that women  
11 who are post-menopausal must have mammograms and must  
12 have transvaginal uterine ultrasound to determine  
13 whether they're at risk for uterine hypoplasia. A  
14 commonly known side effect of sustained estrogen  
15 motivations. Women who are taking these drugs without  
16 medical supervision are at risk.

17 Next slide. The hormone dependent tissues  
18 that we should be concerned about, and as again, DHEA  
19 is a potent steroid. Hormone dependent tissue  
20 including effects on the breast, prostate and uterus  
21 and possible cancers of these.

22 There is a report in the literature of a  
23 man with prostate cancer whose cancer was  
24 significantly worsened during DHEA therapy, and there  
25 recently have appeared reports that women whose

1 elevated levels of DHEA estradiol have increased risks  
2 of breast cancer compared to women who are not.

3           There are also significant changes in HDL  
4 cholesterol during treatment with androstenedione and  
5 DHEA have induced increased risk of cardiovascular  
6 disease. Particularly important, as we heard from  
7 Ms. Parks, there are unknown additional long-term  
8 risks, especially in children, adolescents and  
9 pregnancy. We know that young adolescent teenagers  
10 are under intense peer control, and they are abusing  
11 these drugs, taking a much higher dosage than anybody  
12 ever anticipated.

13           I need to remind you of a PBS story years  
14 ago where daughters and granddaughters suffered the  
15 consequences of their mothers who were exposed to DHEA  
16 during pregnancy.

17           Next slide. We talked this morning about  
18 quality control, and in fact Stanford Research  
19 Institute has published a study in JAMA that --

20           MR. LEVITT: Your time is up.

21           MR. SCHWARTZ: Next slide. I'm going to  
22 finish up.

23           DHEA is an anabolic steroid. On the left  
24 are criteria for anabolic hormones. DHEA meets these  
25 criteria, and there have been published studies that

1 DHEA will increase and promote muscle regrowth in men  
2 and women.

3 Last slide. So, four messages. DHEA and  
4 other anabolic steroids are steroids and not dietary  
5 supplements. It's anabolic steroid. It does not meet  
6 the DSHEA criteria. Neither DHEA or other anabolic  
7 steroids are found in the diet. They don't meet any  
8 of the criteria for DSHEA.

9 Last slide -- next slide. DHEA is a potent  
10 anabolic steroid hormone, it is not part of the diet,  
11 it does not meet any DSHEA criteria for dietary  
12 supplement, DHEA and androstenedione are unsafe when  
13 administered without supervision, and lastly, CFSAN  
14 can act right now to enforce the DSHEA. It does not  
15 need any change in legislation. I ask you to force  
16 DSHEA to remove these anabolic steroids from the  
17 market.

18 The last thing I want to leave with you is  
19 if you don't like what I say, you can throw a tomato  
20 at me. That is a dietary supplement.

21 MR. LEVITT: With the lights back up, we'll  
22 move back up to Ofelia Barretto.

23 MS. BARRETTO: Good afternoon, I'm Ofelia  
24 Barretto. I am president of Compliant Quality  
25 Solutions, a consulting company for the dietary

1 supplement and food processing industry. I have been  
2 the director of quality assurance of Nutrilite  
3 Division and Amway Corporation and was with the  
4 company for 21 years.

5 I serve on an advisory panel of the U.S.  
6 Pharmacopeia, and am on an advisement panel for OTC  
7 and multi-vitamins and have served on various  
8 Pharmaceutical Excipients Council, and I am a national  
9 director of the American Society for Quality.

10 The Dietary Supplements Subcommittee is  
11 part of a larger group called the Los Angeles  
12 Grassroots Regulatory Partnership, a partnership  
13 between FDA's Los Angeles District and a small group  
14 of individuals representing various sectors of  
15 FDA-regulated industries in Southern California and  
16 Arizona. The partnership was formed in response to a  
17 regulatory reinvention initiative launched by  
18 President Clinton in 1995 for the purpose of improving  
19 communication and identifying and resolving regulatory  
20 concerns.

21 On behalf of the LAGRP Dietary Supplement  
22 Subcommittee, I would like to thank CFSAN for fully  
23 implementing the provision of FDA's Modernization Act  
24 - to provide a process of soliciting public input in  
25 developing effective regulation of dietary supplements

1 under DSHEA. We respectfully submit the following  
2 proposals in response to the seven questions posed by  
3 Dr. Levitt on the CFSAN Dietary Supplement Strategies  
4 and Priorities Program.

5           In response to Question 1, we propose that  
6 an active, strong presence of regulatory oversight be  
7 provided to the industry, balancing that with removing  
8 barriers for growth of healthy compliant industries.  
9 We need a regulatory scheme that is non-duplicative of  
10 state's efforts, fair in its application and promotes  
11 less scrutiny of compliant firms and a higher level of  
12 scrutiny for those companies operating in disregard of  
13 existing laws and regulations.

14           While DSHEA tempered regulatory fervor, we  
15 believe that the U.S. Congress did not intend for a  
16 regulatory absence of oversight from the U.S. FDA for  
17 the dietary supplement industry. Consequently, there  
18 are some products in the market that have consumers.

19           Case in point: Mentioned so many times  
20 today is ephedra-containing products that have caused  
21 over hundreds of reported adverse reactions and about  
22 forty deaths among the youthful segment of the  
23 population. Even with those reported adverse  
24 profiles, this area of concern remains unresolved.

25           On questions 2 and 3. We promote a

1 risk-based approach to regulate the industry. We need  
2 a response mechanism of prioritizing risks. For  
3 example, in some states with limited resources, when  
4 documented cases of illness, death or injuries are  
5 reported, and 24-hour urgent response is mandated.  
6 Where there is a potential organ damage or harm, a  
7 30-day significant response is mandated. The rest are  
8 relegated to a lesser priority scheme. If we adopt  
9 such a program in managing the dietary supplement  
10 industry, then those dietary supplements with  
11 documented history of consumers' adverse events would  
12 be addressed and resolved with such expediency. Thus  
13 we propose a riskbased approach be adopted in  
14 regulating our industry.

15 On question number four: The ANPR of  
16 proposed GMPs for Dietary Supplements must be brought  
17 to a close. These proposed standards are brought by  
18 the industry using the food GMPs as guidelines in  
19 accordance with DSHEA providing adequate minimum  
20 standards without the unnecessary burden of validation  
21 and extensive records review as required by drug GMPs.  
22 Such unnecessary requirements increase manufacturing  
23 costs that translate to higher costs to consumers  
24 without much added value.

25 Training: We also believe that the federal

1 government should provide training to industry. Clear  
2 federal guidance to domestic industries increases  
3 their level of compliance and improves their  
4 competitiveness.

5           On the fifth question: In response to  
6 that, to better clarify the boundaries of regulatory  
7 definitions for drugs and dietary supplements, we  
8 propose a regulation similar to California's Health  
9 and Safety Code Section 110403. This Section lists 40  
10 serious diseases and conditions that make advertising  
11 for them a strict liability, such as cancer, prostate  
12 gland disease, tumors and AIDS, heart and vascular  
13 diseases, tuberculosis, and epilepsy.

14           The California State Legislature intended  
15 these serious diseases as conditions for which  
16 self-cure is not permissible and needs intervention of  
17 medical professionals.

18           I have two more: On question 6 we propose  
19 that U.S. FDA, with support from such organizations as  
20 the National Institute of Health, NIH; and the United  
21 States Pharmacopeia, USP; set and enforce allowable  
22 authoritative statements and standards of quality for  
23 dietary supplements.

24           The development of identity testing and  
25 quantitative methods along with pesticide and

1 microbial safety levels for botanicals are critical  
2 for the safety and efficacy of dietary supplements in  
3 the marketplace.

4 In response to Question 7, we would like to  
5 see an enhancement to the partnerships between federal  
6 and state regulatory agencies. Clear definitions of  
7 each agency's role and responsibilities will support  
8 efficient utilization of resources and provide  
9 substantive response coordination for industry  
10 concerns.

11 In conclusion, the LAGRP Dietary Supplement  
12 Subcommittee appreciates this opportunity to present  
13 their input in the CFSAN 1999 Program Priorities on  
14 Dietary Supplements. Our objective is to effect  
15 regulations which level the playing field while  
16 allowing maximum flexibility to make truthful,  
17 non-misleading claims that will allow consumers to  
18 make informed decisions about taking safe and  
19 effective dietary supplements to maintain and improve  
20 their health. Thank you.

21 MR. LEVITT: Thank you. Next speaker is  
22 Mark Blumenthal.

23 MR. BLUMENTHAL: First I'd like to suggest  
24 to the previous two speakers that tomatoes are a  
25 conventional food, not a dietary supplement, which

1 shows some of the confusion that still surrounds this  
2 whole area.

3           Good afternoon and howdy. I'm Mark  
4 Blumenthal, founder and executive director of the  
5 American Botanical Council, a research organization  
6 dealing with scientific information on herbs and  
7 medicinal plants and their products.

8           I am also the senior editor of The Complete  
9 German Commission E Monographs, a book of English  
10 translations of the official evaluations of herbs by  
11 an expert panel commissioned by the German government.

12           This book was ranked second of all  
13 publications in medicine and allied health professions  
14 in 1998 - compelling evidence of the need for  
15 accurate, authoritative information on the therapeutic  
16 uses of herbal products. I also, for the last 16  
17 years, have been editing a peer-review journal called  
18 Herbal Grams.

19           ABC has two suggestions for priorities:  
20 One, that FDA establish an independent, external  
21 expert advisory panel to deal with botanicals; and  
22 two, that FDA respond immediately and directly to the  
23 citizens petition submitted to FDA by the  
24 European-American Phytomedicines Coalition in July  
25 1992, which is a group in Europe that requested that

1 well-researched herbs and phytomedicines be deemed old  
2 drugs under the over-the-counter drug review.

3           This week marks the seventh anniversary of  
4 this petition to which the Agency has declined to  
5 respond directly and in any meaningful manner. FDA's  
6 inaction on this issue sends a mixed message about its  
7 sincerity in dealing with herbals as potential OTCs.

8           Consumers have numerous uses for herbal  
9 dietary supplements: To increase energy, stamina and  
10 a sense of well-being; to prevent short or long-term  
11 illnesses; and as substitutes for FDA-approved drugs.  
12 However, except for a handful of herbs approved as  
13 ingredients in OTC drugs, most herbal product sold in  
14 the United States do not, and cannot, carry  
15 information on the actual therapeutic benefits of  
16 their use, regardless of the quantity and quality of  
17 research documenting actions, for example, treatment,  
18 cure, prevention, et cetera.

19           ABC believes that American consumers will  
20 benefit from properly documented therapeutic claims on  
21 herbal product without requiring these product to  
22 submit to the lengthy and expensive new drug  
23 application process.

24           ABC also believes that any such review of  
25 herbs should be undertaken without adversely effecting

1 their legal status of dietary supplements under the  
2 DSHEA.

3 FDA's highest priority, in addition to  
4 publishing final regulations for GMPs for dietary  
5 supplements, should be the formation of an independent  
6 expert advisory committee concerning botanical  
7 supplements. Recognizing the lack of internal  
8 botanical expertise in the Agency, this committee must  
9 be drawn from outside experts. It should consist of  
10 scientists familiar with the vast botanical  
11 literature, as well as qualified health care  
12 practitioners who are familiar with the clinical  
13 application of botanical preparations, including  
14 qualified herbalists.

15 Membership from various industry trade  
16 groups, consumer organizations and professional  
17 societies should be considered possibly on an  
18 non-voting basis.

19 This panel could cover a variety of  
20 regulatory aspects of herbs, especially  
21 recommendations to FDA for claims for herbal product  
22 under regulations currently provided by the Nutrition  
23 Labeling and Education Act of 1990, (NLEA), DSHEA and  
24 to OTC Drug Review.

25 Also, it advises FDA on potential standards

1 that might be required to produce phytoequivalent  
2 preparations, that is, specific chemical parameters  
3 and/or bioassays to ensure that a preparation can  
4 actually deliver benefits similar to those documented  
5 in clinical trials using a particular type of  
6 preparation, particularly when such research is being  
7 used as a basis for a claim, especially a therapeutic  
8 claim.

9           This idea is not new on botanical  
10 ingredient review. BIR is botanical ingredient review  
11 in response to NLEA. Back in 1991 FDA dismissed this  
12 "proposal" despite the fact that GMA had relied  
13 heavily on other expert panels funded by other  
14 industries, namely FEMA, the Cosmetics, Toiletries and  
15 Fragrances Association for the determination of safety  
16 in new cosmetic ingredients, et cetera.

17           In fact, the BIR was almost a carbon copy  
18 of the Cosmetic Ingredient Review developed by CTFA, a  
19 widely-held perception that FDA was employing a double  
20 standard in dismissing the BIR was one of the primary  
21 factors that motivated members of the herb industry to  
22 promote the passage of DSHEA.

23           Recognizing the importance of evaluating  
24 the well-researched drugs for their possible OTC drug  
25 benefits, the President's Commission on Dietary

1 Supplement Labels, (CDSL), recommended that FDA  
2 establish an expert advisory panel to review herbs for  
3 possible OTC drugs claims.

4 In its final report in November 1997, CDSL,  
5 acknowledged that this recommendation fell outside the  
6 domain of the Commission's purview of dietary  
7 supplements. Nevertheless, CDSL, as mentioned  
8 previously today, recognized that in other parts of  
9 the world herbs are often regulated as drugs, and that  
10 the therapeutic action of herbal preparations, even  
11 when well documented by modern research, cannot be  
12 adequately declared on herb product labels or related  
13 promotional literature when these products are sold as  
14 dietary supplements under DSHEA. Almost two years has  
15 passed since that recommendation, and to my knowledge,  
16 FDA has not responded positively to this  
17 recommendation.

18 American consumers and health care  
19 practitioners clearly want products with complete  
20 labeling of uses and benefits. It is time for FDA to  
21 join with industry and academia to produce meaningful  
22 therapeutic information in that area. Thank you for  
23 this opportunity to testify.

24 MR. LEVITT: Next is Mr. Paul Simmons.

25 MR. SIMMONS: Thank you very much, and

1 welcome to the second, semi-annual motivational  
2 seminar for the dietary industry.

3 I would like to talk about a couple of  
4 things that might be where everybody can agree. We've  
5 got a lot of controversial subjects going on and we  
6 need to get our priorities straight. And I think if  
7 we looked at one item, we could say that every product  
8 in the market should have the safety, identity  
9 strength, quality and purity it purports to possess.  
10 Any disagreement there? And I don't think you'd find  
11 a single manufacturer or sale -- retailer for a  
12 product that wouldn't agree with that on the surface.

13 Now, if you're going to have a product that  
14 has the safety, identity, strength, quality and purity  
15 it purports to possess, you should have documented  
16 evidence that your process is under control on a  
17 repeated basis. Everybody agree with that?

18 So we have an agreement that probably could  
19 spread throughout the industry, and there is no  
20 disagreement by manufacturers, or no disagreement by  
21 interstate holders that those things need to be done.

22 If you have documented evidence that every  
23 facet of your process is under control on a repeated  
24 basis, do you know what they call that? GMPs.

25 So, if we look at the DSHEA Act, it does

1 not repeal Sections 201 and 501 of the FD&C Act. Am I  
2 right, David?

3 MR. DORSEY: That's true.

4 MR. SIMMONS: If we look at the court case,  
5 DSHEA versus FDA, there is nothing in that court case  
6 that says that 501 and 201 of the FD&C Act was  
7 repealed. So, FDA today has the authority to define a  
8 drug as any product on the market that claims to  
9 treat, or mitigate, diagnose or cure disease.

10 And 501 goes on to say that if it is a  
11 drug, and that's what it would be under those  
12 circumstances, that to produce that drug not in  
13 accordance with Good Manufacturing Practice regulation  
14 would mean that the drug is adulterated.

15 Does FDA have the authority to take  
16 adulterated drugs off the market? They certainly do.  
17 Where is the starting place? First of all, FDA should  
18 notify industry and put them on notice through the  
19 federal register and actual mailings to the  
20 Stakeholders that the 501 is still there and nothing  
21 has interfered with it and 201 of the FD&C Act and  
22 really repeat it.

23 And second, that the industry has the  
24 ability to submit to FDA a plan for compliance within  
25 120 days to show that they have documented evidence of

1 process control on a repeatable basis. This has a --  
2 this plan has been used before in the drug, device,  
3 diagnostic, and biotech industry and has been very  
4 successful. I'll show you one.

5 This plan, there's been hundreds of them  
6 submitted to FDA. There is a guideline for doing that  
7 published by FDA way back in 1978, and it's still in  
8 effect today, that industry can submit to FDA.

9 Suppose you're not quite up to speed yet.  
10 You can submit your plan to say, we recognize where  
11 we're out of control and it will be corrected by so  
12 and so. How can FDA disagree with that? Next  
13 question would come: Where does FDA get the budget to  
14 look at all these plans? Through an independent  
15 counsel of industry that can look at these plans and  
16 say, yes, those people do have it under control.

17 Once the manufacturer has submitted a plan  
18 like this, the panel has looked at it, the consumer  
19 can then know that there is an FDA submission on this.  
20 Until we have process control on a repeatable basis to  
21 protect the safety, identity, strength and quality of  
22 the drug, there can be no testing, there can be no  
23 clinicals, there can be no information to consumers.

24 In 98% of the product that's on the market  
25 today that's went through clinicals, or supposed

1 clinicals, there is no documentation on how that  
2 product was manufactured, how it was sterilized,  
3 purified, how it was reduced, and so it makes it  
4 worthless when you come to using clinicals.

5           We need cooperation now between industry  
6 and FDA to take immediate steps to notify industry  
7 that they still have the authority and they're going  
8 to use it and allow industry 120 days to submit a plan  
9 and be subject to fines -- and those fines are not  
10 just for the company, by the way. They're fines on  
11 individuals as criminal cases where you produce  
12 adulterated drug and make it available to the  
13 consumer. Thank you very much.

14           MR. LEVITT: Our final speaker is Mr. James  
15 Lasiter.

16           MR. LASITER: I'm here on behalf of the  
17 Nutrilife division of the Amway Corporation. We're a  
18 manufacturer of dietary supplements and dietary  
19 ingredients and have done so over 60 years. We also  
20 participate actively in virtually all associations  
21 involved in this industry, and its with this  
22 perspective that we place behind this commentary. The  
23 commentary we're issuing is excerpted from written  
24 commentary submitted to Agency and expanded upon for  
25 the benefit of panelists today.

1                   Our primary issue we wish to address as  
2 Stakeholders in the industry is a matter of  
3 enforcement. Commissioner Haney has stated in public  
4 forum on more than one occasion that there is  
5 sufficient statute and regulation today to manage the  
6 dietary supplement industrial. The challenge then  
7 becomes obviously one of the enforcement of the  
8 statutes and regulations that already exist.

9                   To this specific narrow topic then we offer  
10 the following input: The challenge FDA faces today  
11 and overall in governing the business industry, how  
12 best to accomplish this appears to be the matter of  
13 debate, and we offer the following points or  
14 definitions:

15                   The industry is regulated currently.  
16 Commissioner Haney's previously cited statements to  
17 further confirm this. There are a host of options in  
18 continuing that governance under DSHEA. We will not  
19 at this point argue the letter and spirit of the laws  
20 and other additional regulations or only guidelines  
21 are authorized, only that they are not necessary.

22                   A fundamental challenge repeatedly offered  
23 by FDA is a lack of resources in complying with  
24 existing regulations and statutes. Today we offer a  
25 perspective that may be of interest. The concept is

1 not new, but the moniker attached is. We suggest that  
2 the Agency and industry benefit from an agreement  
3 described as cooperative enforcement.

4           Specifically we believe that the industry  
5 as a whole can and should play a role in working with  
6 FDA to enforce the law and regulations at hand.

7           Today there are examples in this industry  
8 of trade associations applying proposed rules without  
9 benefit of government intervention. We suggest that  
10 this model, with extension, is a model that works to  
11 address the issues stated previously. Akin to the  
12 activities of the NAD, the trade associations of this  
13 industry can build and support laws and regulations  
14 already in place.

15           The support takes the form of a  
16 notification process for a body of trade association  
17 representatives formed into a panel across all the  
18 industry. Actions capable of being taken by such a  
19 panel are administrative only and do not carry the  
20 force of law.

21           However, the failure of an organization to  
22 comply with the findings of such a panel would result  
23 in the notification of the appropriate enforcement  
24 agency, typically FDA, for additional action.

25           The Panel thus has the application of the

1 law at its hand in terms of utilizing the agency for  
2 the enforcement and formal activities of the  
3 government. Since the panel cannot enforce the law,  
4 their only recourse is administrative.

5           The office of the cooperative portion of  
6 enforcement is the Panel upon complete review and lack  
7 of remediation would provide such formal notification,  
8 the FDA has the offense, the source of the reporting,  
9 and the actions taken by the Board or the panel to  
10 date.

11           The expectation then is that the Agency  
12 would act swiftly in accordance with the law. The  
13 benefits of this proposal are bountiful. The industry  
14 at large has long been concerned about the members  
15 giving the industry a poor reputation through their  
16 inappropriate actions.

17           The Agency has long maintained that given  
18 -- that it lacks resources necessary to track down  
19 every incident. The public needs the assurance that  
20 the industry and the government are working  
21 cooperatively to work to ensure a safe supply of these  
22 necessary products.

23           Notification of challenge may come from any  
24 source, either public or private. The public needs to  
25 have the ability to alert the industry to any

1 perceived problem, as does any member of industry, to  
2 provide such notification.

3           The industry may then monitor itself in  
4 order to assure the continued maintenance of a vital  
5 franchise in the U.S. This proposal does not yet come  
6 with a stamp of approval of the industry at large, but  
7 the receptivity of the Agency to such a proposal will  
8 go a long way to achieve this.

9           We hope these comments are indeed helpful,  
10 and we recognize it's your requirement to ponder this  
11 brief description. Thank you.

12           MR LEVITT: Thank you very much.

13           I have a general question which you can  
14 each take or pass onto the next one, as you wish.  
15 Most, or all of you, were here for most of the day.  
16 You have heard a lot of really pretty sharp questions,  
17 criticisms, which I think could be interpreted as --  
18 at some level by a number of the speakers as a lack of  
19 confidence in the products that are marketed dietary  
20 supplements for a whole variety of reasons, but it  
21 really goes to the credibility of the products that  
22 interview companies and people who represent banks.

23           What reactions do you have in terms of  
24 things the industry can do to increase the credibility  
25 as well as the quality and safety of the product?

1                   MR. BLUMENTHAL: First of all, I'm not part  
2 of the industry directly, and I don't sell herbal  
3 products, so I'm not sure I can respond as industry,  
4 but as a non-profit organization with 30 years  
5 involved in herbs, I would like to think that there  
6 needs to be more education on the first level of all  
7 the health professionals.

8                   I was astounded by some of the information  
9 that I heard this morning coming from people who are  
10 health professionals who are really not aware of a lot  
11 of the herbal products that they're speaking of.  
12 Speaking from the tangential and ancillary point of  
13 view, seeing them without really having used them  
14 clinically -- or personally perhaps, I'm not sure --  
15 but really not familiar with the vast variety of  
16 literature involved with them.

17                  There's a real problem with education in  
18 the marketplace. Most people who are health  
19 professionals in this country  
20 are not trained from a scientific point of view,  
21 unfortunately.

22                  From a product quality point of view, I'm  
23 an advisor to a new company starting out called  
24 Consumerlab.com, which is going to be doing systematic  
25 testing of consumer products starting off with herbs

1 and other dietary supplements eventually, and posting  
2 the results of their tests on a web site and also  
3 publications in various magazines. They're going to  
4 be issuing a seal of approval if the companies can  
5 adhere to the quality or the requirements in order to  
6 pass the certain kinds of tests that are being  
7 conducted.

8           One of the problems here, of course, is  
9 that there needs to be validated methods for testing,  
10 which is something that the herb industry has really  
11 been taking a lot of responsibility for through the  
12 organization called the Method Validation Program in  
13 order to establish validated methodology so everyone  
14 can test along the same methods and therefore get  
15 consistent, reliable, repeatable results, which is the  
16 baseline that needs to happen before anybody goes out  
17 and does any testing.

18           Those are some -- I think some concrete  
19 movements that are going forward as a former FDA  
20 official involved, and I think it's going to be a very  
21 interesting way to gets consumers and health  
22 professionals and the press to take notice of those  
23 products that do pass the testing of this  
24 organization.

25           MR. LEVITT: What about more scientific

1 testing for the product?

2 MR. MCGUFFIN: I think the answer to your  
3 last question directly. Yes, I believe there is a  
4 requirement to establish clearly the parameters for  
5 testing. First of all, methods do not exist. It's  
6 the same. Many methods do not yet exist. There are  
7 efforts underway.

8 We need as an industry to support that  
9 franchise through support of those additional efforts.  
10 In response to your first question, I think the  
11 critical elements that are necessary are education,  
12 not just of the public at large, but of health care  
13 practitioners, of dietitians, of everybody.

14 And, further, the education must extend  
15 back inward to ourselves. There are countless times  
16 when I've encountered members of this industry that  
17 are unaware of tenants of the DSHEA, who do not read  
18 the CFR, do not know what the requirements are. All  
19 that does is create an open playing field for lack of  
20 enforcement.

21 The last point that is important touches  
22 back on enforcement of issues. As an industry we have  
23 an obligation to support enforcement activities when  
24 they are necessary.

25 Talked about cooperative enforcement. I

1 think in this industry we have an obligation to demand  
2 other agencies enforcement actions occur in instances  
3 where there is public harm.

4 And I use the GBL example as case study  
5 number one. If we as an industry are louder and  
6 longer and strident in our preachings to the Agency, I  
7 suspect we would not have had continued presence of  
8 that product in the marketplace today.

9 MR. LEVITT: Yes.

10 MR. SCHWARTZ: We hear a lot about the  
11 industry itself enforcing and doing laboratory tests  
12 for content, but it's difficult to do a laboratory  
13 test for content when you don't know what the active  
14 ingredient is, and plants have dozens, if not hundreds  
15 of ingredients in them, that can vary from the time of  
16 the year that they're harvested to country, to season.  
17 I think this is really probably optimistic at best.

18 MR. BLUMENTHAL: You don't have to know the  
19 active ingredients to know marker compounds to test  
20 for chemically -- to know if a plant is a certain  
21 genus or species. There are well documented  
22 microscopic tests, as well as chemical tests, to  
23 determine specific -- certain specific genus and  
24 family to know where the activity is. It's usually a  
25 number of compounds, and sometimes it's groups of

1 compounds, and that's the issue about this validation  
2 program, doing these methodology tests.

3           For six years we've been testing -- the  
4 American Botanical Council -- over 500 commercial  
5 ginseng products purchased in the marketplace.  
6 Getting ready to publish the records, have results of  
7 our report. It finally took almost a year to develop  
8 the methodology just to be able to test these ginseng  
9 products in finished product form. Therefore, tests  
10 that have been published, and methods published in the  
11 literature for raw ginseng root product, properties  
12 found in capsules, tablets, which you have to be able  
13 to identify your ginseng outside out of those  
14 carriers.

15           So, there's a lot of sophisticated work  
16 that has to be done in the area of developing  
17 methodology to test finished product in length. It's  
18 lengthy and time consuming, technical and a time  
19 consuming process.

20           MS. BARRETTO: On the question of how we  
21 can help, industry can help, I would propose a couple  
22 of solutions. I would like to give an example of what  
23 had happened in Southern California.

24           They recently got a Hammer Award, and the  
25 reason for that is this group of competitors formed a

1 group effort, and they shared their information, their  
2 challenges, and it went very well. And many of them  
3 didn't even know how to talk to the FDA people, but  
4 because they were called together now they're doing  
5 and working very well. They're still competitors, but  
6 they shared the problems and they shared what they  
7 know. I think that can happen in this industry.

8           The other thing I was going to say is  
9 industry can also help the enforcement of the  
10 regulations if there is -- first FDA has to publish  
11 the guidelines, which then becomes a mandatory  
12 requirement for all factors, and then the industry can  
13 demand that every company they deal with -- and we  
14 deal with each other, you know, supplying supplies to  
15 the other so that suppliers -- if you won't buy from  
16 the supplier that is not in compliance, then pretty  
17 soon that supplier has to come up and meet the  
18 requirements. Those are the solutions I offer.

19           I think the primary responsibilities and  
20 offerings that industry can make is in education --  
21 internally educating itself. Speaking from the herbal  
22 product side, there is a tremendous amount of  
23 knowledge in our industry of manufacturing and selling  
24 or marketing these products.

25           MR. MCGUFFIN: The Botanical Safety

1 Handbook was put together based on experienced  
2 practitioners. We need to revise that and go broader  
3 into our community to get a higher degree of  
4 participation from toxicologists and various others.

5 I think that that's the primary thing that  
6 the industry needs to do is educate ourselves and --  
7 educate ourselves about the GMPs, the nature of the  
8 product that we're selling and any concerns that might  
9 be actually associated with specific herbs.

10 I think the first thing that has to be done  
11 in order to get industry cooperation is for the  
12 industry to realize that.

13 MR. BLUMENTHAL: I've been involved in GMPs  
14 now for 30 years, and I've been in over 100  
15 conferences, conventions and seminars and so forth  
16 involving FDA people, and I haven't found a better  
17 ally anywhere than FDA, but the industry as a whole  
18 today when you mention FDA they draw back and say we  
19 don't want any part of this.

20 If we're going to have industry cooperation  
21 and submit plans and get into compliance we need to in  
22 some way remove the stigma that FDA has sought there  
23 to get them. FDA is there to protect the consumer  
24 health, safety and welfare, strength, quality and  
25 purity of the product.

1           And if you come to FDA with a problem, you  
2 recognize your problem, FDA will help you work it out  
3 and you know what's wrong and you say I'm not ready to  
4 produce, FDA will cooperate. I think the industry  
5 doesn't know this and needs to understand that FDA is  
6 an agency that is there to help, as well as to please.

7           MR. LEVITT: Thank you. Pass the  
8 microphone to Dr. Yetly.

9           DR. YETLY: Several of you suggested plans  
10 for industry regulations, either independent counsel  
11 that could review submission of GMP plans, or industry  
12 mechanisms to do some review of enforcement or review  
13 of compliance with regulations and laws.

14           Given the range of opinions that you heard  
15 today, the obvious -- and obvious criticisms of these  
16 proposals would be that this is the fox guarding the  
17 hen house. How would you suggest that -- or what  
18 response would you suggest be given to that concern,  
19 and what could be done to make these types of tests  
20 credible and effective?

21           MR. SIMMONS: Candidly, I think the  
22 credibility occurs when enforcement action occurs.  
23 Absent that enforcement, there is no carrot, there is  
24 no sticks, there is suspicion of something dangling in  
25 front of the bull trying to get them to move forward

1 toward compliance.

2 I firmly believe that actual, legitimate,  
3 strong and public enforcement when rightfully applied  
4 is the vehicle by which you will get this bull's  
5 attention. And I'm speaking on behalf, I think, of  
6 the broadest section of the members of this panel.

7 MR. BLUMENTHAL: I think the things that we  
8 need to remember is that industry response when  
9 guidelines are given, and if there are no guidelines,  
10 for example, for a plan for compliance everybody says,  
11 how did I do this? And you're going to turn it over  
12 to people who are my competitors and they're going to  
13 be examining and all that? I think once guidelines  
14 are developed in the biotech industry in LVP and SBP  
15 product, that those panels, once the guidelines were  
16 developed, were very effective and won the respect of  
17 industry as a whole.

18 MR. MCGUFFIN: To address your question, in  
19 order to build credibility in that kind of industry  
20 importance, it needs to be structured in a manner  
21 that's quite broad and includes our critics. Some of  
22 these critics are good friends of ours.

23 Dr. Tyler, Dr. Farnsworth are perfectly  
24 willing to tell us when they believe that any  
25 statement that's made is out of line or

1 unsubstantiated. Some of those critics we've met in  
2 building good relationships with FDA and other  
3 organizations that have been represented here.

4 I think that that would be tough, primarily  
5 -- would just be the way that we structure would have  
6 to be prepared to answer those criticisms, and then  
7 we'll move it by showing we do have some activities  
8 that we have taken.

9 When we became aware of the problems  
10 associated with paralyzing alkaloids and Comfrey,  
11 which was then quite a large volume herb in the  
12 industry, we had it off the market by voluntary action  
13 within 18 months.

14 We did the studies that we needed to to  
15 assure that evidence was significant. We made a  
16 recommendation, and the recommendation was quite well  
17 accepted by the industry. We need to continue to put  
18 together a body of such actions so that we can show  
19 that we actually do stand for a safe and properly  
20 labeled product.

21 MR. BLUMENTHAL: I would like to point out  
22 in the, again, response to Dr. Yetly's questions, you  
23 don't have to rely on the taxpayer's dollars to burden  
24 the FDA. Through the American Herbal Product  
25 Association, the herb industry in general has done a

1 remarkable job on a number of levels. The problem I  
2 think is partly that we tend to use the word  
3 "industry" to be a homogenous or monolithic concept,  
4 and it's not.

5           The herb industry, the facts stated it's  
6 pluralistic, it's comprised of all kinds of different  
7 groups and companies from research-based companies  
8 that are very clinically oriented to all kinds of  
9 manufacturing that may be making the product in  
10 bathtubs and selling it at truck stops. Who knows  
11 where? Hearing some of the products today painted  
12 with one broadbrush, all of the people in this  
13 industry, and expect it all to stick, and a lot of  
14 levels that they work with in general.

15           MR. MCGUFFIN: The groups, I think, have  
16 done a very commendable job in taking self-regulatory  
17 initiatives in areas where there's been a void in any  
18 activity whatsoever, and if there's more that can be  
19 done, and there are people that are not members of his  
20 organization that are not necessarily going to comply  
21 or anything, that Mr. Lasiter is proposing that  
22 regulations are going to be needed to be enforced  
23 through some form of governmental agency because  
24 that's the last resort, and they're the people that  
25 are going to take full advantage of the less fair

1 situation until they have to.

2 DR. BOWEN: This morning we heard from  
3 several different panels, health care professionals  
4 and also consumers about the information gap, and then  
5 this afternoon you have come to us and told us that  
6 industry can help with more education, not only to  
7 health care professional and consumers, but to  
8 yourselves. Can you give us some examples of how you  
9 would better educate the public and health care  
10 professionals?

11 MR. BLUMENTHAL: I'll take a shot at that  
12 since I'm involved in education, and in many cases  
13 regulators and state boards informally, et cetera,  
14 would be able to evaluate some of the benefits of  
15 these products and clearly indicate what these  
16 products are.

17 And that's one of the -- it's always been a  
18 question today, if you look at the examples of the  
19 toxicology issue, the safety, the risk and issue of  
20 what are the potential benefits of these products, and  
21 lacking any federally approved, officially approved  
22 products like conventional drugs, any adverse  
23 reactions, any case reports of any folks running to  
24 the hospital emergency rooms shows up against a  
25 backdrop of no benefits, and the safety issue gets

1 exaggerated out of this relationship as opposed to if  
2 it were a conventional drug where it would be listed  
3 as part of the 106,000 people that died or whatever.

4 One of the primary things that needs to be  
5 done is to focus on the benefits of these herbs as  
6 well as the risks of evaluating their benefits  
7 according to literature reviews and then letting the  
8 results of this expert panel, this information, go out  
9 to the public and hopefully have the FDA be part of  
10 that.

11 FDA has been criticized. FDA -- consumer,  
12 you have a list of herbs to avoid. You never had a  
13 list of herbs you might want to take because FDA can't  
14 possibly -- seems like it has its hands tied because  
15 it would be tantamount to a drug approval.

16 It's not an equal playing field, and it's  
17 difficult. I think that one of the ways for education  
18 to really get on track is to set up an expert panel,  
19 have them evaluate the benefits and the risks and have  
20 it all come out and put it out there and have  
21 industry, academia and education working together to  
22 educate.

23 MR. MCGUFFIN: I think we've heard some  
24 really good ideas here today. Mark's discussion of  
25 the botanical ingredient review or some independent

1 body that would look at the data that exists, taking a  
2 copy of the literature review and coming up with a  
3 statement for saw palmetto that is clearly  
4 substantiated in this dosage and this form,  
5 manufactured by this means and then put a public  
6 relations element in them, make sure that that message  
7 is well delivered to consumers at large.

8 Jim's idea to establish a cooperative  
9 enforcement. I mean, it's a fresh idea. I'm not  
10 really prepared to comment on it for you today, but  
11 I'm intrigued by it. And if it is put in place, put a  
12 public relations element to it.

13 Someone earlier mentioned the idea of a  
14 database where we could include -- I know how to get  
15 to FDA's web page, but does the consumer for the GBL?  
16 And if not, how do we make sure that's FDA's plan?  
17 And when you search for GBL, you don't just hear all  
18 of the outrageous claims, you also see that FDA  
19 warning.

20 I think it all has to do with finding a way  
21 to put a public relations spin on a lot of the good  
22 work that we're already doing or talking about  
23 designing. Not a simple project.

24 MR. SIMMONS: Just a quick tag to Mark's  
25 presentation. We have a three-tiered approach to

1 claims. Any claim regarding -- to Mark's comment --  
2 regardless of product or incorporation, the claim has  
3 to be accurate, appropriate and simple. The accuracy  
4 is the scientific rigors, literature qualification.  
5 Accuracy is paramount, and then we get to the  
6 stumbling block, is the appropriateness.

7           What did we see? Gee, makes you feel  
8 better. Supports good health. And those claims have  
9 come about because we have this absolute thought of  
10 what is an appropriate claim, structure function, life  
11 of health claims. I think the endeavor you've  
12 embarked on is indication of that. It's a clear  
13 indication of how you think this information is.

14           Until we can understand and better  
15 communicate concisely accurate information, we're  
16 going to run into this appropriate barrier, and until  
17 we can find appropriate and convey meaningful  
18 information to the consumer, we're going to be stuck  
19 with frivolous claims and inferences, which is not  
20 where you want to be for many of these products.

21           MR. SCHWARTZ: I feel like I'm almost on  
22 the wrong panel. There's a non-sequitur. To  
23 accurately display the claims and to avoid, one would  
24 have to acknowledge that these are very potent and  
25 potentially dangerous drugs, and how can one reconcile

1 that and still market them without complying with the  
2 FDC Act? You have to advertise them as legitimate  
3 drugs.

4 MS. BARRETTO: I will -- there's a  
5 difference there because we don't -- in the industry  
6 we don't really believe that some of those items that  
7 are there are really -- that they're supplements, but  
8 they're being claimed that they're supplements, so we  
9 don't agree.

10 And I just want to say that having been  
11 here the whole day today and listening to the  
12 complaints that were given this morning, you get an  
13 idea that this industry is out of control, that we're  
14 all snake oil salespeople, and that's really what the  
15 impression is, and that's not the truth because there  
16 are very responsible industry people here that are  
17 doing their best to make sure that there are safe and  
18 they are efficacious supplements.

19 However, what we want to do is also to make  
20 sure that those -- I want to go on and say  
21 fly-by-night folks, maybe they don't fly by night,  
22 they get rich, but those companies that are not like  
23 us, responsible, you, the FDA, have to help us  
24 regulate them.

25 You need to set the guidelines, and we will

1 help you make sure that they follow the guidelines so  
2 that you really need to help the industry to  
3 straighten up those that do not behave. And, training  
4 -- training is very important.

5 We had the training program -- we had a  
6 training workshop in Los Angeles last October, and  
7 that was very good, and there were very many small  
8 industry players that were there. It was amazing to  
9 realize that they didn't really know what GMP was.

10 That outreach that FDA did -- Dr. Yetly, we  
11 thank you again. That was very important for this  
12 industry because they're big players, but there are  
13 very, very, very many small players, and we need to  
14 support them. So, we need to have that outreach, that  
15 training that's like the one we did last October.

16 MR. SCHWARTZ: At the recent national  
17 meeting of the Endocrine Society last month it was  
18 discussed that androstenedione is being promoted at  
19 doses up to two milligrams a day. We know that young  
20 children abuse these. There is no excuse for them  
21 being available on the market. And there is no such  
22 thing as a remarkable company that would market them.

23 MR. BLUMENTHAL: Once again, I would  
24 participate with FDA in about 23 or 24 seminars on  
25 GMPs for drug, disease and diagnostic industries.

1 Those were attended by about 3,000 industry  
2 participants, and based upon those seminars those  
3 people went back and today are in compliance with FDA  
4 to make themselves available on districts on a  
5 reasonable basis to participate in those articles so  
6 that there's legitimacy to the interpretation of GMPs  
7 for this industry.

8 MR. LEVITT: Thank you all very much.

9 David Dorsey leaned back and asked me if he  
10 had to have a question, and I said no, he didn't have  
11 to. So, I think that means it's turned back to me  
12 with the one last question. I think we'll start at  
13 this end and work down that way.

14 Again, in terms of timeliness, looking  
15 ahead a year from today, if there was one thing FDA  
16 could do that would advance the regulation of dietary  
17 supplements, it would be in -- again, I would ask you  
18 to please succinctly say what it is. Thank you.

19 MR. SIMMONS: Waving the magic wand one  
20 year, recognizing one year is one year, the FDA should  
21 withdraw its proposed rule on structured function  
22 claims and instead put forth an effort to close the  
23 gaps from the regulatory continuums that run from  
24 conventional food and drugs, functional food,  
25 traditional medicine, herbal alternatives, et cetera.

1           In support of that they also need to devote  
2 efforts to claims structures and assist in the  
3 defining of those additional subcategories for  
4 products. Thank you.

5           MR. BLUMENTHAL: I would like to see the  
6 fact that FDA had made it very clear to industry that  
7 no testing means anything -- that's until they're  
8 producing products under GMPs is done first, and only  
9 after they're in compliance and are producing products  
10 that the safety, identity, strength, quality and  
11 purity has been clearly defined.

12           MR. LEVITT: Thank you, Mark.

13           MR. LASITER: I would like to think that a  
14 year from now the FDA would develop a relationship of  
15 starting an expert advisory panel to deal with this  
16 very difficult issue of how to regulate herbs for  
17 their claims of safety, and through knowing that there  
18 is a strong sentiment among the academic community of  
19 various means to form an ad hoc community of this.  
20 The movement is starting to happen. ABC is involved  
21 with it, and hopefully the Agency can work with this  
22 movement and make it part of a regulatory review  
23 process and not something that's ad hoc and defacto.

24           MR. LEVITT: Thank you. Ofelia.

25           MS. BARRETTO: I agree that the safety is

1 number one; however, everyone has already asked that,  
2 and given you all kinds of advice on that  
3 recommendation.

4 I would like to say that it's also part of  
5 safety. I would like to see the exposure of the GMP  
6 requirement. It's very necessary.

7 MR. SCHWARTZ: I have one very simple  
8 request, and that is simply enforce DSHEA. You can  
9 remove steroids under the DSHEA Act.

10 MR. MCGUFFIN: GMPs.

11 MR. LEVITT: I can count that as one  
12 thought though. I want to thank you all very much. I  
13 want to remind you, we have two individuals who have  
14 asked to give brief presentations, and so as this  
15 group is going off the stage, maybe in that direction  
16 over here, we can invite up Mr. Paul Bullard and  
17 Christopher Groh.

18 I think at this juncture we will dispense  
19 with the questions and answers, but we will be happy  
20 to hear your presentation. Paul Bullard. Identify  
21 who you're from and so forth.

22 MR. BULLARD: Thank you for squeezing me  
23 in. My name is Paul Bullard. I am vice-president of  
24 regulatory and legal affairs for Pharmacist's  
25 Corporation. We're a major manufacturer of vitamin,

1 minerals and herbal supplements in the Los Angeles  
2 area, and we market primarily to the mass market.

3 My comments will be very brief. I'd simply  
4 like to say that there is a responsible contingent of  
5 dietary supplement manufacturers, and it includes the  
6 makers of the majority of supplements sold today.

7 Responsible members of this industry  
8 welcome and encourage greater enforcement efforts by  
9 FDA to forcibly address industry abuse, help establish  
10 a positive reputation for this industry and provide a  
11 level playing field for all responsible companies.

12 We have heard repeatedly today that  
13 consumers need to be protected, but I would like to  
14 add that industry also needs to be protected from the  
15 bad actors and fringe companies that taint the  
16 reputation of the industry as a whole and jeopardize  
17 the applicability of useful appropriately labeled  
18 products for millions of consumers.

19 The Agency should no longer delay in  
20 instituting the strong enforcement. Enforce GMPs.  
21 Step up inspection and challenges to unsafe products  
22 and unsubstantiated claims.

23 We constantly hear that DSHEA is to blame  
24 for the current circumstances, but FDA still has  
25 multiple and ample authority under DSHEA and the Food

1 and Drug Cosmetic Act to require safe products and  
2 truthful, non-misleading claims.

3 Much of the current problem is that FDA  
4 simply hasn't been assertive enough to leverage the  
5 tools at its disposal. The sad truth is, industry  
6 learns to play the endorsement game. Manufacturers  
7 and marketers quickly learn what's likely to be  
8 targeted and where extra attention needs to be paid.

9 If FDA will take action, industry will  
10 respond. If you will finalize GMPs and find the  
11 resources to inspect manufacturers, industry will  
12 clean up its sloppiness.

13 If you will challenge and require  
14 substantiation for label claims, the claims will  
15 subside. If you will take decisive action against  
16 unsafe products, manufacturers will take greater care  
17 to research and assure the safety of new products.

18 Therefore, again, my message is simply that  
19 FDA has the tools but needs to characterize its  
20 authority to enforce DSHEA and regulate the supplement  
21 industry, to weed out the unethical, careless and  
22 reckless practices and operators that detract from the  
23 responsible majority of supplement manufacturers.

24 Thank you.

25 MR. GROH: Thank you. Thank you for

1 letting me speak. My claim is Christopher Groh. I'm  
2 an attorney, and I'm also a consumer advocate. My  
3 interest in this area stems from my wife's death,  
4 which is her anniversary eight years ago today. I've  
5 listened to a lot of people here today, and I share  
6 the sentiments of most of you.

7           For many years I've been struggling to get  
8 people to become aware of many of the dangers and  
9 risks involved with herbal products, dietary  
10 supplements. One of the things I did want to point  
11 out is that in 1993 FDA, then deputy commissioner of  
12 policy, Michael Taylor, wrote in a speech the FDA's  
13 goal -- excuse me -- the FDA's goal of regulating the  
14 entire spectrum of products referred to as dietary  
15 supplements are as straightforward as they are simple.

16           They are to assure that the products are  
17 safe and properly labeled and that any disease or  
18 health-related claims for scientifically support, and  
19 he goes on to say, let me talk a little bit more about  
20 what these goals mean.

21           First, safety. No one questions the goal  
22 of safety. It is FDA's top priority, and the first  
23 thing consumers have the right to expect of any FDA  
24 regulated product promoted directly to consumers and  
25 sold over-the-counter. In fact, we find that

1 consumers commonly assume that if a health-related  
2 product is readily available in the marketplace, it  
3 must have been evaluated and approved for safety by  
4 the FDA.

5 First suggestion, I don't have just one,  
6 but I have several, is that the FDA in addition to  
7 what the industry has referred to as the nasty little  
8 label on the bottle, an additional label that would be  
9 set in bold print contrasted against the background of  
10 the packaging that clearly states, this product has  
11 not been tested or approved by the FDA.

12 All too often people go into health food  
13 stores, they're given advice, oftentimes it's wrong.  
14 This eliminates, at least minimizes the chance for  
15 that to occur. I think that's an important element so  
16 that consumers can make informed, intelligent  
17 decisions about what product to take.

18 Second point is the FDA has asked a number  
19 of people what the guidelines should be. I think the  
20 FDA should establish the burden of proof. What is it?  
21 Was it necessary to show that a product is unsafe or  
22 unreasonably dangerous?

23 Based on my experience with herbal diet  
24 teas, I would say it's something, a little bit more  
25 than 100%. And I can point out that the FDA and panel

1 special advisory commission who concluded that those  
2 products were dangerous and needed labels has come out  
3 with a potential statement that again advises against  
4 prolonged use, which was the recommendation of the  
5 advisory committee to the FDA.

6 The herbal research counsel has also  
7 suggested that these products be limited. German  
8 Commission Monographs talks about it, defense experts  
9 in the cases I've been involved with all agree that  
10 these products should not be used for long term.

11 What kind of proof do you need in order to  
12 require such a labeling requirement, at least on these  
13 products, not even sold as dietary supplements but  
14 sold as food?

15 So, my first suggestion was establish some  
16 guidelines so that people like myself can know exactly  
17 what it is that is necessary to get the FDA to take  
18 some kind of formal action to protect the public.

19 The third point, and I know it's late and I  
20 appreciate everyone who stuck around, is that people  
21 need to be educated. Not just people, consumers,  
22 medical professionals. It's important because as a  
23 result of the publicity that has been generated from  
24 the teas and certain things that have taken place, I  
25 have received calls from a number of people, including

1 pregnant women that were taking the teas with the  
2 approval of their pediatricians. I've seen other  
3 doctors throw away products that people had taken in  
4 because of their concern.

5 I think it's important that the FDA engage  
6 in some kind of real public effort to notify the  
7 public, the medical profession and include schools.

8 The ABC in California issued an alert about  
9 alcohol and ginseng. You see these little bottles of  
10 Dr. Chen's ginseng with 40 to 60% proof alcohol in it.  
11 I think it's critical that parents, you know, people  
12 like myself who assume this tea was safe, realize  
13 these products were untested and not approved.

14 The other point is that to mandate the  
15 company's reports are adverse reactions. As it now  
16 stands under DSHEA, there is no such requirement, and  
17 if I had more time I would present the deposition  
18 testimony that I have submitted to the FDA from one  
19 company official who I deposed when I asked the  
20 question how many complaints of adverse reactions have  
21 you received from this not natural ephedra, but which  
22 was containing a synthesized HDL, he had received 3500  
23 consumer complaints of adverse reactions that were  
24 never reported to the FDA. Why? Because there was no  
25 such requirement.

1                   Other depositions showed that some  
2 companies who received complaints throw them away,  
3 keep no receipts. I think it's essential that these  
4 complaints be required to be reported, that the FDA  
5 look at them, that they be included in the adverse  
6 monitoring system so that the consumer, the other  
7 people, people like myself, can find them.

8                   Finally, I would suggest that the FDA  
9 improve their web site. It's known as the Food and  
10 Drug Act, but -- Food and Drug Administration Act, but  
11 we know from the testimony here that almost half the  
12 American population takes some form of vitamin or  
13 dietary supplements or herbal products.

14                  I think you need to put more information on  
15 the site so that it's readily available. I think you  
16 need to have some kind of special advisory panel, as  
17 Mr. Blumenthal had suggested, which will allow people  
18 to know what they're talking about, to evaluate some  
19 of these websites so that you can bring them to it so  
20 that people don't have to be Internet experts in order  
21 to find the reliable information about both the good  
22 and the bad.

23                  I'm not anti-herb. I know there's a lot of  
24 good herbs. I know a lot of modern medicine has its  
25 genesis in herbal medicine. It's the products that

1 are being promoted as weight loss, thermogenic  
2 boosters, muscles builders, diet teas, those are the  
3 products that need the attention of the FDA.

4           And the companies that are responsible, and  
5 I submit it's not just a handful. I submit it's the  
6 big guys. The GNCs, the Twinlabs who are out there  
7 putting these products on the market with no tests, no  
8 science behind any of the products that they sell  
9 regardless of whether or not they manufacture them.  
10 And if there are violations, the last point is go out  
11 and enforce it.

12           I brought to the FDA's attention a number  
13 of violations and nothing has happened, including the  
14 one where this company had written in sworn testimony  
15 admitting to spiking their products with Ephedrine  
16 HDL. Thank you.

17           MR. LEVITT: Thank you both. That  
18 concludes our meeting for the day. Again, I want to  
19 thank everyone who came today, when you spoke, when  
20 you listened. Hopefully many of you did both.

21           I think that we had a lot of very important  
22 presentations. As I said at the beginning of the day,  
23 we should not expect that everyone is going to agree,  
24 but we need to begin by sharing truths, by listening  
25 and by foraging ahead.



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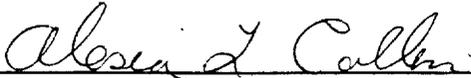
I, ALESIA L. COLLINS, a Certified Shorthand Reporter of the State of California, do hereby certify:

That the foregoing proceedings were taken before me at the time and place herein set forth; that any witnesses in the foregoing proceedings, prior to testifying, were placed under oath; that a verbatim record of the proceedings was made by me using machine shorthand which was thereafter transcribed under my direction; further, that the foregoing is an accurate transcription thereof.

I further certify that I am neither financially interested in the action nor a relative or employee of any attorney of any of the parties.

IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: August 19, 1999

  
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