unqualified health claim--"This product will do X." The second is a qualified claim based on strong emerging science, and the third, a claim that runs contrary to the weight of the evidence.

For the first category, for unqualified claims, the FTC has recognized that the significant scientific agreement standard, as applied by FDA, is the principal guide that we also use in determining whether the claim is adequately substantiated. An unqualified claim, if it has not been approved for labeling by FDA, is likely to be considered deceptive under FTC law for advertising.

The second category is carefully qualified health claims based on a strong area of emerging science. The FTC law does provide some leeway for qualified claims and I'll quote from the Food Policy Statement. "The commission recognizes that there may be certain limited instances in which carefully qualified claims may be permitted under Section 5, although not yet authorized by the FDA if the claims are expressly qualified to convey clearly and fully the extent of the scientific support."

Finally, if a claim is contrary to the weight of the evidence, it is likely to be deceptive under FTC law and therefore prohibited no matter how carefully it is qualified.

Our experience has been that figuring out how to

effectively qualify that middle category of claims is a real challenge. Without adequate disclosures that clearly convey any significant limitations or any inconsistencies in the literature, consumers can easily be misled.

Generally, consumer evidence on the subject of qualification of claims suggests that it can be very, very difficult to do effectiveness, especially where qualification is necessary to communicate complex scientific information. There are a number of challenges.

The first hurdle is the amount of information consumers can and do assimilate. At least in the advertising context, the data shows that disclosures need to be simple, concise and direct and that consumers don't really absorb more than one or two simple messages. Condensing information about the weight and validity of scientific evidence into a simple, comprehensible disclosure is not going to be easy.

Another hurdle is the consumer's tendency to discount negative information when it's qualifying a primary and positive claim, and there is even some evidence that a subsequent disclosure can have the perverse effect of actually reinforcing rather than limiting the primary claim. And I want to give you a quick example of that from our food copy test.

Part of that copy test, which was commissioned and

released in '98, looked at a hypothetical ad touting the health benefits of a high fiber soup. The question was whether the health claim would create a halo effect that would override any other negative information about the product. We looked at the effect of various disclosures that were designed to convey that the soup was also high in sodium, to the point of perhaps being unhealthful.

What we found, at least in this one example, in this copy test, was that the conflicting positive and negative health messages confused many consumers. Even when the disclosure was worded as a direct health warning about the high sodium content, many consumers tried to interpret that as being somehow a positive commentary on the food.

The FTC has also done some consumer research as part of that same copy test specifically on the issue of what it takes to qualify claims based on emerging science. Consumers in this part of the test were shown one of a series of mock ads with increasingly strong disclosures that described limitations on the science supporting a hypothetical health claim.

As an example, one group of ads described the science linking a fictitious anti-oxidant vitamin supplement with a reduction in cancer risk. The ads ranged from ones that stated science had proven a cancer benefit through four ads, each with increasing decrees of qualification about the

science. Consumers were then asked, for each ad, how sure scientists were about the cancer benefit.

The results of the test suggest that claims based on emerging science require strong, specific and direct disclosures if they're going to succeed in conveying anything about the limitations of the science. For an example, the most effective of the ads that we tested contained the language--I'm quoting from the ad--"It's too early to tell for sure. Some recent studies have failed to show a benefit. Longer-term research is needed." And only when all of those phrases appear together in one ad do consumers' rating about the scientific certainty drop below their rating for the absolute proof claim.

Another very relevant finding, and I think it directly contradicts something that one of the speakers said this morning, was that simply inserting the word "may" into the claim--"Studies are now finding that the product may reduce the risk of cancer"--had no effect on how consumers viewed the state of the science.

It's also important to note that the copy test chose areas where we felt, at least at the time, there was a reasonably strong body of emerging science and it seems reasonable to assume that claims based on more preliminary evidence would likely require even stronger qualification.

Getting the content of the disclosure right

doesn't guarantee that consumers are going to get the right message. The other challenge is to get the format right and to present it in a manner that consumers both notice and understand any disclaimer.

The commission has developed some principles defining what constitutes a clear and conspicuous disclosure and the goal really is don't be subtle.

Placement or proximity to the claim. Obviously a disclosure is most effective when it is placed near the claim it qualifies. Proximity increases the likelihood that consumers will see the disclosure and that they will relate it back to the relevant claim. Is it adjacent to the claim? Is it separated by other text or graphics? Is it on the same panel or is there an asterisk to another part of the label?

Prominence. Type size also matters. The FTC has often rejected disclaimers that were appearing in fine print footnotes. It's important to consider the relative type sizes of the disclosure compared to the claim it's limiting.

Contrasting color. A surrounding border to offset the disclosure can help to make it more noticeable.

Distracting elements. Clutter on the label or in the ad obviously are going to interfere with the disclosure.

So you really have to look at all of the elements of the label to ensure that other text and graphics are not

going to distract consumer attention away from the qualifying message.

And finally clarity--almost done.

MR. LEVITT: Your time is up but you should continue because this is groundwork for the rest of the discussion.

MS. RUSK: I have one minute.

MR. LEVITT: Go ahead.

MS. RUSK: Clarity is closely related to content issues. In the FTC's experience, a disclosure needs to be presented in clear, simple language and syntax with as little technical or medical jargon as possible. And I think there's a real tension there in keeping the message simple and communicating something as complex as varying level of science.

If there's one message I want to stress on this slide, and it's nicely hidden at the bottom here, but fine print footnotes just are not going to be effective.

The last thing I'd like to say is I really want to stress the importance of looking at consumer research in this area, given the inherent difficulties here. Under FTC law, the adequacy of disclosure is measured by its performance. How do consumers actually perceive it? Do they understand it within the context of the entire ad or label?

Our experience has been that it is hard to get it right, that consumer research has often shown us that a disclosure that seems reasonable on its face turns out to be ineffective or have unintended effects. Thank you.

MR. LEVITT: Thank you very much.

Our next speaker is Scott Bass, even though we have asked him to take his name down so we can see the timer in front. Scott is representing the National Nutritional Foods Association.

SCOTT BASS

NATIONAL NUTRITIONAL FOODS ASSOCIATION

MR. BASS: Thank you for requesting the input of NNFA. This is oldest and largest association representing thousands of natural product retailers, distributors and manufacturers. NNFA has been active in governmental proceedings affecting dietary supplements and other products for over 60 years.

I'm a partner in the Washington, D.C. office of Sidley & Austin, general counsel for NNFA.

NNFA has been asked to deal with the question of how to phrase qualifying language for health claims and whether additional information is necessary to assist consumers with health claims. Before answering those questions, we must touch upon the issues posed to panels one and three, starting most logically with the latter.

At bottom, NNFA believes in the integrity of the product category system. That's the system established in the federal Food, Drug and Cosmetic Act. It believes that some products are so severe in effect and carry such high risk in relation to their potential high benefit that they need careful FDA review.

In short, NNFA believes that this country does need a drug approval system. We note that this was reflected in the negotiations that led to DSHEA. Sections 201(f)(f)(3) and 403(r)(6) explicitly separate dietary supplements from drugs.

Pearson, taken to its logical extreme, could be misread to permit any claim to be made with appropriate qualifiers. NNFA strongly opposes any such reading or implementation of that decision.

NNFA does wish to note that there may be other drug categories, such as traditional herbal medicines, for which it would not be appropriate to impose premarket approval regimens. But once again NNFA acknowledges that greater controls are necessary than in the food or dietary supplement area.

Assuming then that there should be health claims and not just one category of therapeutic health claims with endless qualifiers, the question is what is the appropriate standard and what type of disclaimers may be made that are

consistent with that standard?

NNFA believes that the significant scientific agreement standard was too rigidly applied by FDA and is still the subject of too much confusion. In the dietary supplement context we note that the reason that Section 403(r)(5)(d) was drafted in NLEA was precisely to permit FDA to incorporate rapidly advancing science into the health claims approval process and to adapt this new marketplace. FDA's failure to implement that newer standard in proposed regulations in 1991 actually spawned the DSHEA effort.

DSHEA and Pearson alter the FDA claims review standard. NNFA believes that the significant scientific agreement standard should operate in practice more like the manner in which GRAS panels operate. There is give and take, there is consideration of alternatives, and there's very careful consideration of the advancing state of science.

What NNFA believes should not occur is the rigidity with which the old food additive standard was applied as a safety measure to set dietary supplements.

Moving then to disclaimers, Pearson says that disclaimers are preferable to suppression. NNFA agrees. That case also says that FDA can ban claims where the evidence against the claims outweighs the evidence in favor of the claims. NNFA wants to see consumers protected.

A key portion of adequate substantiation is the consideration of safety. The higher the risk, the stronger the disclaimer needs to be. A good example of strong disclaimers are the warnings that responsible companies have adopted on Effedra labels.

NNFA believes that qualifying language should be short, very short. It should be very pointed. The warning should be phrased in a way--or disclaimer--that product liability warnings are phrased, by experts who draft such warnings. Phrases such as "Animal studies only; not tested on humans," "Limited number of human trials; efficacy not fully established," and/or "Not proven in humans" are examples of such strong language.

We do disagree with FTC to the extent that they believe that prefatory language has no role. We believe that precatory language is understandable to consumers.

NNFA believes that disclaimers should be in proximity to the principal claim and they should appear whenever that claim appears on labels, labeling, or in advertising.

On the other hand, NNFA does not believe that FDA should require disclaimers for every type of health claim. It is only where the science falls short of a reasonable significant scientific agreement standard or where safety issues so mandate that a disclaimer should be required.

NNFA does believe that there should be additional information provided by FDA through publicity and through consumer booklets and website information. One area that would be very helpful would be category-specific information in addition to general information on what disclaimers mean. NNFA does not believe that consumers will absorb general rules about health claims and disclaimers but will focus upon the names of the products they intend to purchase.

Needless to say, NNFA believes that the information provided to consumers should not be negative about a product or product category but rather, informative.

NNFA believes that the majority of the dietary natural products industry is responsible and desires proper guidelines. The interests of the consumers are paramount and while there's some inherent risk in promoting the benefits of healthful products, that risk is far lower for dietary supplements than it is for prescription drugs.

Congress made a definitive statement when it created a new dietary supplement category in DSHEA. It also left the drug category intact. NNFA believes that Pearson should be implemented in a fashion that gives full meaning to Judge Silberman's decision while, at the same time, retaining the safety underpinnings of the drug versus nondrug categorization in the federal Food, Drug and Cosmetic Act.

In assessing the viability of disclaimers on health claims, that effort should not extend beyond health claims as such. Assuming that the bright line dividing health claims from structure/function claims is the mention of disease and assuming that health claims are primarily claims for prevention or risk reduction of long-term or chronic disease conditions, disclaimers can be fashioned in simple, strong language that inform the consumer and permit an expanded array of claims. Thank you.

MR. LEVITT: Thank you very much.

Fourth speaker in this panel is James Turner, Citizens for Health. Jim?

JAMES S. TURNER, CITIZENS FOR HEALTH

MR. TURNER: Thank you very much. Citizens for Health also thanks you for inviting us to participate. Citizens for Health was very much involved in the passage of DSHEA, having generated a substantial number of comments to Congress. Also it's been involved in a couple of other campaigns--one getting responses to the USDA's comments or proposals on organic food, and then also to FDA with regard to the definition of disease.

And we also wanted to, as I said I would say last time, thank the agency for having responded in a way that we felt was responsive to our comments. I hope they had some help in shaping that view.

In the current situation, we feel very strongly that the core decision-maker about the relationship between whether--the decision about whether somebody should or should not consume a dietary supplement is an issue that a consumer should make for themselves and we see the agency as being an ally in helping the consumer make that decision, to be able to create data, information, knowledge, guidance that will help consumers make this ultimate decision.

In that framework, I believe that there's somewhat of a historical shift from the FDA being a surrogate decision-maker for the consumer; that is, an agency that defined the things that people should take or could take or be allowed to take. And I believe that that direction, which is, I believe, under way in the consumer community itself, is being reinforced by both Congress and the courts in the kinds of decisions we've been seeing.

I think this offers a significant challenge to FDA in expanding its role as a new kind of regulator. It's not a stop-go regulator as much as it's now an accelerator-brake regulator.

In that setting, I think that the FTC guidelines that have been articulated here provide a very interesting and useful framework. With a couple of comments, the area of using emerging science claims in the FTC--that whole set of guidelines was established before Pearson in the area

that recognized the idea of emerging science claims was in an area that was outside of what FDA had allowed using significant scientific agreement.

What I'm suggesting now is that that category has broadened enormously in the framework of Pearson, and I have a small footnote. The first time I was aware of emerging science as a concept was during the Keystone project on food, nutrition and health, and one of the committees which I served on generated that concept for a very specific reason. That reason was that there is no limitation whatsoever on what can be said by people about dietary supplements and their usefulness by people who do not sell dietary supplements. That is a book can be written and can say anything.

So you have an enormous area of speech that is totally protected, where the consumer is gathering information with no regulatory guidelines of any kind.

Our idea was to create a framework where there could be some help to the consumer to evaluate the kinds of claims that were coming from the general society by allowing claims that could go onto labels that were more robust in their content than the specific, narrow stop-go kinds of claims that were being referenced with significant scientific agreement.

The idea was, in fact, to expand the regulatory

framework to allow FDA to have a participation in more things that the consumer was using to make decisions, all with the idea of helping the consumer make decisions.

I also want to make another point, which is significant scientific agreement still isn't defined, so we're not at all clear what category we're talking about. But if you were to follow the FTC guidelines and create a larger framework from the FDA for emerging science claims, you have a much broader area, even for FTC activities to regulate or to allow is what I'm saying.

When you broaden out the amount of information the consumer is going to receive that is proactive about a substance, then the need for disclaimers becomes more necessary. And I think again a context is needed to think about what the disclaimer-claim relationship is.

We got into the area of proving efficacy in the 1962 amendments when the concept was that efficacy could be established by substantial evidence. That particular standard, according to the legislative history, was a standard that was designed to prevent fraud. The idea was to prevent a claim for which there was no evidence.

That, over time, has evolved into a much more rigid claim in the drug area, so that you now have to establish efficacy. But the purpose when the law was passed was substantial evidence was necessary to support a claim of

efficacy in the drug area. The purpose was to avoid a claim or to make illegal a claim for which there was no evidence, and substantial evidence at that time, the way it was used, meant more than a scintilla of evidence. There was some evidence to support that claim.

The Pearson case and the history of FDA claims, the way that they're unfolding, is moving back in that direction with regard to this category of products, which, by the way, were always foods and still are foods. Dietary supplements are foods. In fact, DSHEA--the complete opposite of what we read in the press--DSHEA did not weaken the regulation of dietary supplements; it strengthened it. It strengthened it in quite dramatic ways, and that's important to understand.

In this claim situation that we're talking about, once you start moving into an area which is required by the First Amendment to allow manufacturers of products or sellers of products to make claims that are comparable to the claims that are made by unregulated speech in books that are people unrelated to a product, as soon as you start moving into that area, the most important single fact is that the information allowed be accurate, that it be clear and accurate.

Interestingly enough, in the first NLEA proposed regulations, this kind of information was contemplated. One

of the sections allowed the statement, "Preliminary data suggest that X may Y." "Preliminary data suggests" is a disclaimer that was actually originally thought to be part of the way that NLEA was proposed, was passed, and FDA proposed regulations including that.

When FDA promulgated the final regulations, it rejected that alternative but never said it didn't have the authority to require that alternative or to allow that alternative. It merely said they felt that it was not appropriate because it was not easy for consumers to understand. It did not, however, say that it could not, under NLEA, permit such a preliminary data statement.

It's our belief that in the context of the notion that what we're attempting to do here is to move information into the hands of consumers through the commerce vector, to make it possible for consumers to have a better standard or better quality of information than they get from totally unregulated information, that in order to do that effectively, using things such as "Preliminary data suggests" helps the consumer make those kinds of choices.

Now I noted in the FTC presentation the notion that there was a halo effect that was identified around the soup example. There is also evidence in FTC studies that disclaimers such as those that can be made about anti-oxidants do affect consumer choice. They do change the way

that consumers buy.

In other words, we need to have more data on how these things actually work and how they are working in the marketplace against the standard of making as much clear information available to the consumer as possible. That's a standard that is a different standard than saying we must be careful to protect the consumer from information that may be harmful. They're two sides of the same coin. I believe the outcome of doing the former would be the same, in the positive sense, with less negative pay-off.

Finally, it's our view from Citizens for Health's point of view that this is a sound category that is part of the consumer taking on--that is, the category of dietary supplements is a sound category that is evidence of the consumer taking on more responsibility for their own health and choices and that the FDA role is to move with that desire and effort on the part of the individual consumer and consumers as a class to help them make those kinds of decisions, rather than to stand in the way and try to make the decisions for them or to guide them into certain kinds of decisions.

In the law, the standard is that the reasonable consumer is the one to be looked at, not the at-risk consumer--in labeling law, we're talking about. The reasonable consumer is the standard to be used, not the at-

risk consumer, for this kind of decision-making.

Thank you very much.

MR. LEVITT: Thank you.

The final speaker in this panel is Brett Kay, National Consumers League.

BRETT KAY, NATIONAL CONSUMERS LEAGUE

MR. KAY: Thank you. Again I want to thank the FDA for inviting me here to present the views of the National Consumers League, America's oldest nonprofit consumer advocacy organization.

I believe I can answer the question that was presented before this panel in one word, which is context. Consumers need information that makes sense to them and it needs to be in a context that they can understand when they're taking these products.

What I mean by that is much of the information in labeling on dietary supplements currently does not fully explain what it's intended to do, how it works, what are the best ways to take it, things such as warnings and contraindications, and without such information, consumers cannot make informed choices. I feel that the health claims will only further serve to confuse consumers if there are no qualifications.

Just as in the direct-to-consumer ads for prescription drugs that are currently out there, there must

be a fair balance, there must be talk about risks and benefits. So, too, must health claims have a fair balance to explain the science and the claims being made.

According to a survey that NCL, the National Consumers League, commissioned last year by Lou Harris and Associates, consumers feel labeling and product information have improved over the last decade and consumers do feel that their shopping skills have improved, as well, and that's the good news. With the passage of important consumer labeling laws, such as the Nutrition Education Labeling Act, the NLEA, consumers have much more information about the food that they're eating and, more importantly, they have a context with which to judge that food.

As Mr. Teisl alluded to earlier, not only is there more information on fat, saturated fat, fiber and cholesterol, for instance; they've also learned why these are important because there have been public education campaigns that have followed up behind that to alert people of the new labeling and to get them to understand not only what is on the label but why what is on the label is important and how it has a significance to their health.

And I feel that the same needs to hold true now for the health claims and for dietary supplements. The bad news, I guess, is sort of that when it comes to dietary supplements, we're still in pre-NLEA days. Consumers do not

have this type of information on the backs of the products in the same way and there's not any type of consumer education, public campaigns to help explain to consumers what these products are for and not only what they're for but why it's important that when they're taking them, how to take them and how it relates directly to their health.

NCL feels that this information is necessary to make educated choices, yet unfortunately, consumers are increasingly using dietary supplements, most times without such information or the supervision of doctors and pharmacists or other health professionals. Without some form of qualifying language, consumers just don't have all the facts.

To give you an example which is sort of off to the side but I think illustrates some of this issue of having qualifying language, it's ginseng. There's three different types of ginseng. There's an Asian, a Siberian and an American, and each has different properties and active ingredients in them but they're often lumped together as just ginseng or all three of them are combined into one product, with similar claims for its effects.

Now according to some of the traditional Chinese medicine and some of the other herbal experts, traditional Chinese medicine treats according to balances in the body--the yin and yang, hot and cold. The Asian ginseng is

regarded as a heating tonic and a yang, which would be inappropriate for those who are already heated up, while American ginseng is a cooling tonic, a yin. So thus they have opposite effects and purposes.

So what happens then if they are combined? Do they cancel each other out? Are there synergistic effects which make one superpotent? What I'm trying to say is what if the consumer is looking for one but gets the other? They don't have a context. There's nothing explained to them why one product is used for one thing or the other and this only serves to confuse consumers.

And I certainly don't expect American consumers to learn the intricacies of traditional Chinese medicine clearly, but what they do need to know, and which disclaimers on labels can help is to explain why they're taking it and what the products are intended to do. That's sort of what I mean by context, what I feel needs to be qualified by health claims so that consumers are not misled. I know that's sort of a jump. I tried to use that as the example.

In the area of dietary supplements, the term is a bit misleading these days. In today's market, whereas the name implied that supplements were products intended to supplement the diet, replace or enhance nutrients that one does not get from their diet and are regulated certainly in

law as foods, this is not how supplements are being used or marketed currently. I think that the paradigm has shifted and supplements are really being treated more like medicines. And I think this is the area where we need to look at them in terms of the claims and the qualifying language.

Consumers are taking supplements to treat diseases and health conditions, such as depression and high cholesterol, prostate problems, arthritis, and the list goes on, whether or not this is what they're ultimately intended to do. I know the disclaimer on them currently says not to treat--you know, the product is not intended to treat, cure or prevent disease. However, that is what consumers are using them for and that's what the implications are when they go to purchase these products.

They see a label claim, whether it be a structure/function claim, a nutrition content claim or health claims, and they don't make the distinction that has been established by Congress or the FDA or lawyers who have written these claims. I think that the legal nuances are often lost on the average consumer. They see a claim and assume that the FDA has approved the product and that it's safe and effective. Without some kind of qualifying language, I think that the consumer might not know that there is some type of science that says that this may be

effective or not proven in animal studies.

I agree with Mr. Bass in the sense that there needs to be strong, clear language that qualifies these health claim statements and it must be easily understood.

In order to ensure that consumers are not misled, I think that there, as I've said, needs to be clear language that's written in lay terms. It can't be in legalistic jargon designed to sort of straddle a regulatory hurdle but it needs to be designed to inform the consumer about the product that they are taking, language similar to the medicine guide requirement language, which was approved by Secretary Shalala in 1996 during the Keystone process that Mr. Turner talked about for prescription drug labeling--not to say that they should be regulated in the same way, but the information that is out there to the consumers needs to be laid out in a similar format, which is medguides are designed to provide context for consumers taking the medicines.

The name of the drug, what it's used for, how it's taken are all laid out in simple, clear format in consumer language. They would use white space. Important is readability on some of these claims, as well. you know, clear fonts in a black type with a white background. A standard format is necessary if consumers are to be able to look up the information and get it and glean what is the

important parts of it from that. I feel that the health claims on the dietary supplements are going to need similar labeling and similar format so that consumers are fully informed and not misled.

There is some precedent with this currently in that the new over-the-counter medicine OTC label language has come out, which has helped to really clear up, I think--they're not implemented yet but they have been passed--to clear up a lot of the formatting and design on OTCs to help consumers, make them much more readable and much clearer, and I think that the qualifying language for health claims needs to have a similar format so that consumers really can get the important information in an easy-to-read format. Thank you.

FDA PANEL DISCUSSION

MR. LEVITT: Thank you very much.

Just looking at the time and looking at what is on the yellow sheets, we started about 15 minutes late from what this sheet said, so we'll try to run this panel about 20 minutes, until quarter after. We'll use the same format as we did before. I'll start.

My question relates to whether we should think of what I would call generic disclaimers or whether we should try to think of what I would call tailored disclaimers more specific to specific cases. And for that, I would focus on

the category of claims where the issue is efficacy, not safety. So I'll take the safety issues aside.

If the issue is efficacy and FDA did determine as a threshold matter that there was more evidence in support of the claim than against, so that was met, but it did not meet significant scientific agreement, should we try and point out very specifically what deficiencies are in the data or should we try to come up with something generic, taking into account the kinds of general points you've already made?

Who wants to start with that one? Scott? Scott, you can put your name up again. We don't need the timer anymore.

MR. BASS: Well, I think I addressed that partially in my initial comments, Joe, but I think the answer is that the repetition of generic disclaimers vitiates their value. Also, I think there would be a tendency to fight overly restrictive language and perhaps generic disclaimers to too many health claims where it may not be appropriate.

Inherent in your question is you've changed the SSA determination methodology and I think the view of NNFA anyway is that you need to be more product category-specific in order to have any effect on informing consumers of the differences because otherwise, you're really running into

your warning language. I stayed away from that in our comments because that's a whole different area. But I think again the more generic you get, the more you get into warnings and then if you have combined structure/function claims and health claims, you run into inherent contradictions with the Section 6 disclaimer, which will wreak not only product liability havoc but a lot of other interpretational problems.

MR. LEVITT: Who wants to go next? Michelle?

MS. RUSK: I guess I have a little bit of a mixed reaction to which would be better but my first instinct is that generic probably would be something that would cause consumers eventually to just tune out, that if they keep seeing the same generic phrase over and over again, it's one of those government things and you just kind of ignore it and look at the claim.

I also think maybe they might not work when you're trying to apply a generic to an industry that involves such a wide variety of products that consumers are using in such a wide variety of ways, that it may be very hard to come up with something that really fits all of the different situations.

On the other hand, if you start tailoring to each specific claim, you've got an infinite variety, you're obviously increasing your burden exponentially and I don't

know whether it becomes a workable system. I also don't know if you have a different and specific disclaimer for every product that's out there whether it's just going to be too much.

MR. LEVITT: Okay, thank you. Other thoughts? Jim?

MR. TURNER: It seems to me that whenever a situation presents itself with an either/or of that kind, that probably there's a place for both.

So in my mind, this statement that FDA first proposed in 1991, "Preliminary data suggests" and "may," that framework might be a useful framework in a broad set of categories, but I also think that the kinds of specifics that the FTC identified as being very useful to consumers would be valuable to add to that. So you could, for example, say, "However, some studies failed to show," if that's a fact.

Again the standard that I think is the best standard to apply is the most accurate presentation of the data that's specifically relevant to that product.

Now, it may well be that a whole bunch of products have a very relevant piece of information that can be put in exactly the same terms--for example, "Preliminary data suggests." It also may be that some of those have studies that were attempted that did not show the connection that

was being referred to, and that should be there. It should not be left out. And there are other things that I suspect exist about specifics that would not be wise to be left out.

MR. LEVITT: Thank you. Mario?

MR. TEISL: I guess I also agree with Michelle, that quite often we have sort of vague or general disclaimers or warning messages and people just tune them right out.

However, there is also another sort of thing to think about. What is it in the disclaimer that you're trying to do? If you're trying to differentiate a certain class of products because you choose a different--let's say you have three different levels of substantiation--low, medium, and high--and you want to indicate that this class of products has low and this one has high. I mean that has some, I think, some benefits to consumers.

However, there's also, within a class of the low, let's say, or the high, there can be differences across products in terms of how much of the effective ingredient is actually in the product and that sort of thing, whereas if you just had sort of a general disclaimer, there is some sort of value in differentiating among classes but not necessarily products within a class. But tied in with the general idea that general vague disclosures are pretty ignored, I'd say try to be as specific as you can.

MR. LEVITT: Thank you. Chris?

MS. LEWIS: The question I have focusses--I guess one way to word it is the general applicability of the kinds of data we have. And maybe the flip side of it is there's something special about dietary supplements as a category, compared to perhaps foods or drugs, that would be an issue in disclaimers.

Then also are there differences in the principles we see for advertising types of disclaimers on those versus labeling that would play into this whole notion of disclaimers on dietary supplements? I guess I'm looking for ideas or comments. Or are there data that would talk about how movable these concepts are for dietary supplements?

MR. TEISL: I'll take a little bit of a stab at this.

With respect to the first part of your question, what's so special about dietary supplements that's different than food, although there are some people today that specifically said that they think that consumers view dietary supplements as food, I'm not convinced of that, quite honestly. I think that it's more likely that--and I'm not talking about vitamins and minerals, where people do understand that they can get Vitamin from a food and this is a way to supplement their diet, but when you're talking about things like black currant or Saw Palmetto, those are

things that people normally do not consume as food, at least in the United States, and because they're being marketed mostly as affecting some sort of bodily function or helping in some sort of long-range risk reduction in terms of disease--I mean people are more likely to think about dietary supplements more like they think about over-the-counter drugs, rather than foods.

So I think that because consumers probably think that way, it's probably not appropriate to think of the labeling regulations of dietary supplements to mimic those of food.

MR. TURNER: I would like to comment the opposite way. What I said was that under the law, dietary supplements are foods. We would argue that the kinds of claims that are being made for dietary supplements should also be allowed for food and presented in exactly the same way. We would support the GMA on that issue, that the distinction between food and dietary supplements is an artificial one.

We have not taken a position on the question of how dietary supplements and over-the-counter drugs might be comparable, but the distinctions between those three categories tend to be rather arbitrary and not necessarily all that significant.

So in some ways, for example, if somebody has

three things that are good to lower cholesterol--a food, a dietary supplement and an over-the-counter drug, all three of those things--I'm not sure that the way that one would put that claim forward and how one would disclaim that claim would be different between those three categories.

So the issues that I've been addressing have been addressed as dietary supplements because that's the title of the program, but we feel strongly that the relationship between claims on food and claims on dietary supplements should be treated comparably. And I suspect if we look closely at it, a similar claim on an over-the-counter drug would be similarly treated, although that's not our position; we've not articulated that.

MR. LEVITT: Scott?

MR. BASS: I guess in the first part of your question, Dr. Lewis, I would say that Congress spoke to this issue twice in four years. In 403(r)(5)(d) in NLEA it said there's something different about supplements and referred specifically to the rapidly advancing science in a floor statement. And then in the preamble to DSHEA there's a good deal of language about why supplements are different in science.

Notwithstanding that, I think we need to default to position under Pearson what the court said, because I guess the hearing today is about the court decision, and the

court decision doesn't distinguish the two, really, but for the nature of the claims at issue.

I think while you have to treat foods and supplements the same way under the health claims rubric under 403(r), in practice, they're not the same and the reason is exposure. The very same reason that you have issues on functional ingredients that are treated differently based on the fact that you will be eating soup every day and your exposure levels may be different and the disclosure, therefore, of safety concerns is different, as opposed to the volitional act of taking a pill or a capsule every day and limiting that based upon some recommended usage.

The categories have to be treated the same, I think, under law, but there is a difference nonetheless that Congress has recognized in supplements and I agree with Michelle that it's going to be harder but I don't see any way around it.

It goes back to Mr. Levitt's question, which is how are you going to do this generically or specifically. I don't think there's any way but to do it specifically related to the science.

As for your second question, as you know, the prescription drug people at FDA have struggled with this question for years and the fair balance issues in

prescription drug advertising have caused a lot of consternation, but there is a solution, at least that's been implemented. Most of the regulated industry doesn't like it and it may have been administered in a rigid way but I think there is a distinction between labeling and advertising that allows for briefer and fewer disclaimers in advertising than they would on labeling. And given perception patterns for consumers, say, through radio or television spots, there would be a difference in how many times you have to repeat it, whether it would have to be proximate to every claim, et cetera, et cetera.

Those theories are well backed-up by research the FDA has already done in the prescription drug area.

MR. TURNER: Let me respond very quickly on Congress's distinction between foods and dietary supplements. It is a fact that Congress did distinguish between--did say there was a difference, but the House said they should be more strictly regulated, dietary supplements, and the Senate said they should be less strictly regulated, and it was sent over to the FDA to figure out how to interpret that.

What I'm suggesting--

MR. LEVITT: For which we're grateful.

MR. TURNER: And what I'm suggesting is that the claim about a food and the claim about a dietary supplement

is a useful place to look to see how one would articulate what's positive and then put in what the disclaimer is, starting with the claim. And I think you would end up with sort of a generic form with specific product statements that would come out on the basis of information about that specific substance.

MR. LEVITT: Any FTC help here?

MS. RUSK: Yes, I want to respond to that.

On the first part of your question about is there a difference that you need to be considering between the different product categories, I guess our approach, because we don't have the same regulatory framework that you have, has been to treat all the categories the same and to focus, rather than on what the product is, on what the claim is that's being made.

And if you look at it that way, if you're going by what the claim is, there probably isn't really a need to differentiate between the categories. I do think that supplements are more often marketed for therapeutic purposes, directly or indirectly marketed that way, and are certainly used more for therapeutic purposes. So in a practical sense, maybe there is a difference.

On the question about differences between how consumers view labels and ads, yes, I think there are a lot of differences and Scott mentioned some of them. You don't

have maybe the same recall problems that you have in advertising. You have physical constraints that we heard a lot about this morning, about what you can put on the label. I think people weren't thinking about labeling in a broader sense than the box or the bottle, but still you have physical constraints.

On the other hand, there's less variability, I think, in the label than in an ad, which, depending on so many other gratuitous elements, can completely change the meaning that consumers are taking away. So in that sense, you maybe have a little more control.

MR. LEVITT: Thank you. Mike?

MR. LANDA: Thank you.

This is for Mario Teisl and anyone else who cares to respond.

With respect to the studies you referred to in framing recommendations for disclaimers, do those studies, those recommendations apply to information about side effects? Do they have anything to tell us about how to convey that information?

MR. TEISL: Most of the consumer research that I looked at focussed on warning and disclaimer messages with respect to tobacco, with respect to alcohol. There was some health claim food research. In all of those cases that I reviewed, because there wasn't a lot with respect to dietary

supplements, you know, per se, I didn't find things that talked about dosages. I didn't look at OTC drug research or prescription drug research, that sort of thing.

There were a few studies that looked at iron supplements, the warning labels on that with respect to children overdosing and in those cases--actually, that's FDA research--the primary focus of that research was that when the dosage limits, if I can remember correctly, the dosage limits, because it was really new information to parents, they were quite important. I can't remember if there were any specific recommendations of how the dosage should be presented, though.

MR. LEVITT: Any other reactions to that question about safety information?

Okay, Peggy?

MS. DOTZEL: My question is directed to Mario and Michelle but others may want to comment, as well.

My question is this. In looking at the type of information that consumers find useful in disclaimers, is it more, have you found or has anyone looked at whether it's more helpful for consumers to hear information evaluating a claim? A claim is made and the disclaimer would somehow evaluate that, as opposed to other information--in other words, balancing information.

I guess the example I would use is you make a

claim that ingredient X decreases the risk of disease Y. Is it more helpful for consumers if the disclaimer were to tell you the quality or somehow evaluate that claim, or would it be more useful if the disclaimer were to say, but there are other studies saying something else about this, something else about the relationship, maybe negative information about the relationship?

MS. RUSK: I don't know if I can point to empirical evidence but I guess in terms of our policy, what the commission has articulated is that you really need to do both. You need to give consumers some sense of where on a continuum the science is and if there's contrary evidence, if there's significant contrary evidence, you need to let them know about that, too.

I'm not sure if this is responsive to the safety question that you raised but I think certainly depending on the claim, the health claim that you're making, there may be a need for disclosures about safety for that claim not to be misleading to consumers, that if the safety concerns are significant enough or if the claim somehow triggers the safety issue by virtue of what it's advocating, then you may need safety information, as well.

MS. DOTZEL: Obviously I guess I agree that probably the more information that we give, the better, but I'm thinking in terms of we have limited labeling space on

these products, and so to the extent that we have to take that into account.

MS. RUSK: Speaking only from my own instincts now, I would suspect that it would be more useful and maybe easier for consumers to have an assessment, a more qualitative assessment of the science than to have them be told only animal studies or only in vitro studies. A lot of people are not going to know what to do with that. You need to kind of rate somehow where the science is.

MR. TEISL: I basically will ditto that. I think that in essence, one of the reasons probably that FDA has not provided a lot of information for a lot of stuff in the past is that I think it's quite reasonable to think that consumers are going to be pretty confused about six of this, four of that, but this one is more valid and this one's in animal and this one's clinical. I would get confused reading all that information.

So in essence, what FDA would end up doing is instead of deciding--well, in a sense, what you already do is decide what level of research is allowable and then you allow the health claim.

Here you basically would have to expand it so that you would make a reasonable determination of what the level is and then you would provide that information to people. So you'd still be doing some filtering here. Most consumers

don't understand probabilities and scientific validity and things like that.

MR. LEVITT: Thank you. Brett?

MR. KAY: I agree with what Mr. Teisl is saying. I think that some of what we have to be careful about is when you're putting--I think this is sort of what's been happening with science in general in the public, when it's published--consumers are getting increasingly sort of confused and frustrated when something comes out and says this works for X, Y and Z and then two days later or a month later, something else says well, actually we've found out that it doesn't work or that it's more dangerous. Then it flips back the other way and it keeps flip-flopping. What happens is that consumers get increasingly frustrated or may start ignoring all of the claims altogether. Hopefully then they sort of adhere to the everything in moderation tenet, but it's not always assured what happens, that they may or may not then really follow the labels at all. They'll just think nobody really knows, nobody's made up their mind, and really discredit all of the information that goes up there.

So I think you need to be careful with what the disclaimer says in terms of six studies say yes but four studies say no, really how to filter that. As Mr. Teisl said, there's got to be a level that FDA sort of determines what the filter is and then allows it to come through at

that level with a clear statement that's concise, that doesn't constantly flip-flop or contradict itself.

MR. LEVITT: Jim?

MR. TURNER: It seems to me that the concept of a disclaimer and a claim doesn't necessarily have to be completely separated. So, for example, the way I read "Preliminary data suggests" is both providing information and containing something of a disclaimer.

Now if you use the principle that I feel is the core principle, which is to be accurate in the statement that's made, then if you do have data that says or you do have studies that fail to make that connection and say that--"Preliminary data suggest that there's a connection but there are also studies that fail to establish that connection"--that provides a lot of useful information that I don't think is going to turn people off.

I mean the consumers that we deal with at Citizens for Health really want information. They're very, very high information people and I think somewhat representative of the dietary supplement world.

So I guess that being very accurate and specific can be very useful in getting information to the consumer.

MR. LEVITT: Mario had one more?

MR. TEISL: As sort of a reaction to that, the consumers that you deal with are probably selective

consumers. The thing is that this labeling requirement has to be for a lot more consumers than those very educated and--

MR. TURNER: We have to be very careful. The consumers we deal with are the ones that consume dietary supplements.

MR. TEISL: I understand that. What I'm saying is I think--

MR. TURNER: Well,that's the ones who'll be reading the claims on the dietary supplement products, I think.

MR. TEISL: No.

MR. TURNER: You don't think so?

MR. TEISL: No, what I'm thinking is--

MR. TURNER: You mean people who don't consume dietary supplements--

MR. TEISL: What I'm saying is that I think it's in the interest of the industry to market beyond just the current users of dietary supplements.

MR. TURNER: Well, it's about 70 percent of the population right now.

MR. TEISL: If you take away all vitamins and minerals, it's a lot smaller than that.

MR. LEVITT: I think both points are made.

One last question. Rachel, please?

MS. BEHRMAN: This is for whoever would like to address it.

An issue that was raised this morning and that we discussed a little bit at the break has to do with what to do when there's no effective therapy. So if it's a condition, for example, that's left untreated or poorly treated, it could lead to serious morbidity and there is no effective therapy, should that be addressed in the disclaimer and if so, how? In other words, there are competing interests.

MS. RUSK: I'm not sure if I understand the question.

MR. TEISL: You're talking about the substitution between--

MS. BEHRMAN: Exactly. It's competing, that the product may be competing--someone may decide either to alter their current therapy, avoid their current therapy, not initiate current therapy. In other words, there's a competing interest in the supplement and the other therapy that they're already getting or should be getting.

MR. LEVITT: In another context somebody would ask if you need to phone a friend at this moment.

[Laughter.]

MR. LEVITT: Again the question you just framed is if this is a claim for prevention or reducing the risk of X

and everybody acknowledges that it's preliminary evidence and there is another product for which there is a clear demonstration of a reduction of risk, should that disclosure be made on the first product to alert the consumer that essentially the evidence here is not as good as another product where evidence exists.

MR. BASS: Let me take a stab at that. We dealt with that question during the drafting of DSHEA, in part, and the first answer is that it's not a drug and therefore we have to eliminate the treatment side of your question. So we limit ourselves then just to the prevention or reduction of risk side.

MR. LEVITT: Directly competing claims.

MR. BASS: Right. And I would say the position of NNFA would be absolutely not, that you would not feel that you were mandated to say that something else works better.

Disclosure means that it may not work well or it may work well or it may not work at all. But then to go a further step and make an affirmative disclosure that there are two other products, one of which is an herb, one of which is a prescription drug, that work better, I think would be A, not a disclaimer but rather a warning, in line with interaction warnings, and the subject, I think, of a different discussion and B, not mandated, I think, within the reasonable rubric of disclaiming an efficacy claim for

prevention or reduction of disease.

MR. LEVITT: What about something that instead of identifying a product, just say "See your physician; you may want to consult your physician. There are effective treatments for this"--treatment is the wrong word--

MR. BASS: I think the NNFA would be in favor of something like that in appropriate situations, just like they've supported that in the EPHEDRA context when Texas has talked about that.

However, it's only when it is appropriate, when there's some demonstrated need, that there's a high risk and there is a therapeutic danger for people ignoring something else. But that's still, I think, a warning question, not a disclaimer question.

MS. RUSK: I'm trying to think about how we deal with that in advertising law and whether, under a deception analysis, you would need to disclose that there was a more effective therapy or treatment and I can't think of a situation where we've done that.

I guess it's a concern that we have in the supplement area that there is real risk of consumer injury if people are taking less proven products and avoiding proven therapies.

I think the way it comes into play at the FTC is it's a reason to make sure that the claim is really well

substantiated and that you do describe the limitations of the science.

MS. BEHRMAN: When you're thinking about it do you calculate that? In other words, if you know that there's an effective therapy, does that change how well substantiated you believe the claim should be?

MS. RUSK: Well, part of our substantiation standard, one of the factors that comes into play is what is the risk of injury to consumers if the claim turns out not to be true? So I guess that's how it comes into play.

MR. TURNER: Using the principle of accurate, clear information, we would say that there should be that kind of information. However, I would put it in the context that Scott did, as a warning.

MR. KAY: We would also support some kind of at least a warning to see a doctor or other health professional. Maybe "This preliminary evidence suggests that this may be effective. However, contact your physician or health professional for further information or treatment options," something along those lines. It's tough.

MR. LEVITT: With that, let me draw this panel to a conclusion. I want to thank each of the speakers. Again audience--

[Applause.]

MR. LEVITT: We're going to let this group exit

before the next group comes on, just because getting on and off has its own logistics here. We will be going to the next panel before our afternoon break.

If I could ask people in the audience to please take your seats, we're going to start the next panel. We will have an official break after this panel but we're trying to do two panels in succession before the break. Again if I could ask people in the audience to sit down? If you need to step out into the hall, that's fine.

PANEL III

MR. LEVITT: We're ready to begin the third of the three panels, the final panel discussion. We're going to shift gears here a little bit and move away from the Pearson case per se and move into a different issue also related to health claims in the context of a dietary supplement that was raised by a petition for Saw Palmetto in the treatment of BPH.

It's a specific question that we've listed on the agenda. It says, "Should health claims go beyond claims about reducing the risk of a disease to include claims about mitigation or treatment of an existing disease, or are such claims drug claims? Where is the boundary, if any, between these claims?"

So here we're talking about a boundary between everybody saying these are disease claims; the question is

whether or not they are claims that may be made under the health claim provisions of NLEA or whether they are inherently drug claims that have to go through the drug process.

As a way to further frame that, Chris Lewis is going to do a short introduction which I referenced this morning, but before I turn to Chris, let me just introduce the afternoon panelists that we have.

First is Claudia Lewis-Eng from Emord & Associates. Second is Dr. Logan Holtgrewe from the American Urological Association. Third is Bill Soller, Consumer Healthcare Products Association. Marsha Cohen, Hastings College of Law. And Regina Hildwine from National Food Processors Association.

We will be following the same procedures we've done already so I won't repeat them. They're now familiar to everybody. But we will ask Chris Lewis to further frame the question and the issue for this panel.

INTRODUCTION BY CHRIS LEWIS

MS. LEWIS: Thank you.

As Mr. Levitt has already mentioned, the topic for the third panel is still within the realm of health claims but the focus is different from that of our two previous panels. We're changing the subject a bit.

The third panel, this panel coming up, has been

asked to address the issue of the scope of health claims under the Nutrition Labeling and Education Act here in the context of dietary supplements. Basically the question is whether health claims may include claims about mitigating or treating a disease.

By their very nature, claims about the effects on an existing disease are aimed at people who are already suffering from the disease and to date, health claims authorized have been targeted either at the general population or at a subgroup who are at risk for the disease but who are not sick. They don't have the disease. In short, health claims have been about reducing the risk of disease.

The wording of the statute is not specific in this area but among other factors, the structure of the statute, which makes a distinction between foods and drugs, has led FDA to provide for health claims about reducing the risk of disease but not about treating or mitigating a disease, which have been viewed as claims belonging in the realm of drug claims.

In establishing the regulations for health claims, FDA tried to strike a balance between one, recognizing that foods, including dietary supplements, can influence disease outcomes without ceasing to be foods and two, honoring a distinction between drugs and foods.

And just by way of some quick background, FDA has taken the position that nutritional effects of food substances are appropriate subjects for health claims but that effects that are therapeutic, medicinal or pharmacological would not be appropriate subjects for health claims.

It's worth mentioning here that there are such things as medical foods. They're defined by the Food, Drug and Cosmetic Act and are formulated for the dietary management of disease and are to be used under a physician's supervision. More specifically, medical foods are for the management of diseases or conditions for which distinctive nutritional requirements are established by medical evaluation.

So already existing in the realm of regulated foods are foods formulated and intended for the purpose of dietary management of diseases. Medical foods were exempted from the NLEA provisions and so have not historically been the subject of health claims.

But if we return to the issue at hand, the scope of health claims under NLEA relative to mitigating or treating disease has become an issue now because, as Mr. Levitt mentioned, in 1999 FDA received a petition for a health claim concerning dietary supplements containing Saw Palmetto and symptoms associated with BPH or benign

prostatic hyperplasia. We did not take action on this petition, indicating we needed time to consider its implications against the existing background relative to NLEA-driven health claims.

So, as part of this effort, we're today asking questions about the issue of mitigation and treatment of disease; that is, are health claims aimed at sick people or persons with diseases appropriate as the topic of health claims?

Earlier, I should remind you, as part of our implementing regulations on health claims, we had indicated that it would be necessary for a health claim petitioner to show that the claimed effect on disease is associated with the normal functioning of the body and that claims to correct an abnormal physiological function caused by a disease would be drug claims, rather than health claims.

In order to revisit these issues, we're asking several questions. We're asking if the language and structure of the act restrict the permissible type of substance-disease relationships that can be described in health claims, and how we should interpret the situation or the milieu created by health claim and drug provisions of the act, as well as by the provisions for medical foods.

We're also asking about the criteria for making determinations between health claims and drug claims and

about the ramifications for over-the-counter drugs, should health claims be expanded to include treatment and/or mitigation.

We do recognize that this is a complicated topic and we are looking forward to the next few moments. Thank you.

MR. LEVITT: Unlike the morning discussion, which was not complicated.

Okay, let's turn--again, same rules as before--10 minutes. If you can see the light in the middle, if not, we'll give Mr. Soller a special reannouncement of his name several times if he'll put his thing down or move it away a little. Thank you.

Claudia, why don't you go ahead?

CLAUDIA A. LEWIS-ENG, EMORD & ASSOCIATES

MS. LEWIS-ENG: Thank you.

Good afternoon. I welcome this opportunity to comment on the question posed to the third panel. It's a topic that's very important to many of the firm's clients and, in fact, we represented the clients that submitted the Saw Palmetto BPH health claim petition to the agency.

Unfortunately, on December 1, 1999, FDA summarily denied the health claim petition associating the Saw Palmetto, an herbal dietary supplement, with a reduction in the symptoms of mild benign prostatic hyperplasia. It did

so without following the procedure for dietary supplement health claims review specified in the Nutrition Labeling and Education Act and without following the First Amendment requirements of Pearson v. Shalala.

FDA based its refusal to follow the governing law on the view that the claim goes beyond risk reduction to claim an effect on an existing disease, which FDA surmises may only be made if the dietary supplement is granted new drug approval under the act's drug approval provisions.

Based on FDA's refusal to process the health claim under the act's health claim provision and under the Pearson standard, my firm filed a suit against FDA seeking declaratory and injunctive relief.

The question posed to the panel arises out of FDA's summary denial of the Saw Palmetto claim. The question suggests that FDA wants the scope of the NLEA health claims provision to be construed narrowly, reaching not all nutrient-disease relationship claims but only those that concern disease risk reduction.

But the plain language of the NLEA health claims provision and its underlying history make it clear that Congress meant for all dietary supplement claims that associate a nutrient with a disease to be subject to the NLEA health claim provision. FDA's attempt to restrict the scope of the health claims definition causing dietary

supplement health claims to be redefined as drugs is a rather obvious attempt to hinder, rather than foster, the dissemination of dietary supplement nutrient-disease information.

It is also an anti-competitive move designed to protect the drug approval process from competition arising from full implementation of the NLEA health claims provision. That attempt violates the NLEA. It violates Congress's intent. It violates the First Amendment. And it violates the Administrative Procedure Act.

In 1994 Congress reviewed FDA's implementation of the health claims provision of NLEA. Congress concluded that FDA has a long history of bias against dietary supplements. In fact, Congress faulted FDA for hindering, rather than fostering, the dissemination of truthful and nonmisleading information about the nutrient-disease relationship. Congress concluded that FDA has acted to restrict the information that the public may receive about dietary supplements.

The United States Court of Appeals for the D.C. Circuit similarly found in Pearson v. Shalala that in general, the FDA appears quite reluctant to approve health claims on dietary supplements. FDA's current attempt to say that health claims do not include disease treatment and mitigation claims is yet another effort to block full

implementation of the NLEA health claims provision. If FDA redefines health claims to exclude disease mitigation and treatment claims, it would defeat the essential purpose of the NLEA health claims provision.

In 1990 the President signed the NLEA into law. Prior to its adoption, FDA treated as drugs all foods and dietary supplements that included disease treatment claims. NLEA was specifically designed to make it possible for dietary supplements to carry disease claims without having to become approved drugs, without having to satisfy the substantial evidence, near conclusive proof premarket drug approval standard specified in the act.

Congress expressly rejected the drug certainty standard as a legal condition for dietary supplement health claim approval. If FDA redefines health claims to exclude disease mitigation and treatment claims, it will effectively prohibit those claims altogether.

Under 21 U.S.C. Section 379(h)(b)(1), those who wish to file a new drug application must pay the FDA the hefty and anti-competitive sum of almost $260,000 per application. In addition, proof of drug efficacy is required; that is, proof to a near certain degree under the substantial evidence drug standard.

In adopting the NLEA health claims provision, Congress intended to avoid this heavy burden for dietary

supplements. Congress wanted disease claims to be possible on dietary supplements without having to obtain drug approval for them. FDA has no statutory authority to define health claims in a manner contrary to the NLEA.

NLEA defines dietary supplements health claims broadly to include ones which characterize a relationship of any nutrient to a disease or health-related condition. It's important to note that Congress has used the broadest possible language--any relationship between a nutrient and a disease or health-related condition. The term "relationship" in its ordinary sense and meaning refers to a connection of one thing to another, without restriction.

Disease treatment and disease mitigation are plainly within the universe of nutrient-disease relationships. To prove that Congress intended something other than the plain meaning of the statutory language requires proof and legislative history that the plain language was not intended.

You will look in vain, however, to find any basis in the legislative history to support FDA's position. Congress has never stated any intention to define nutrient-disease relationships to exclude statements that associate nutrients with disease treatment or mitigation.

In the 1990 committee report from the House Committee on Energy and Commerce, Congress emphasized that

the NLEA health claims provision applied to any disease claim and never once stated that the provision was meant only to apply to those claims that refer to disease risk reduction, as opposed to disease treatment or mitigation. In respect to NLEA, Congress stated, "Section 403(r)(3) regulates disease claims. It prohibits any disease claim unless the claim meets the requirements of regulations promulgated by the Secretary. The requirement applies to any disease claim that is made with respect to acquired nutrients and other nutrients in foods."

Again in 1994, Congress made clear that Congress intended the NLEA to permit authorization of all manner of nutrient-disease relationship claims, not just disease reduction claims. Moreover, it made clear that dietary supplements were expressly intended to bear health claims without having to be separately approved as drugs.

Congress stated, "One of the salutary purposes of the Nutrition Labeling and Education Act was to allow claims for nutrient-disease relationships to reflect current science without bringing food within the drug definition of the federal Food, Drug and Cosmetic Act." A clear purpose of the NLEA was to assure that the public would be provided with clear information about the relationship of a nutrient to a disease and to ascertain that the information will be accurate and not misleading.

Congress was thus concerned that the nutrient-disease relationship be accurately characterized, not that the relationship be limited to exclude disease treatment and mitigation. Were it concerned that the naturally all-encompassing term "relationship" be interpreted in a less than all-encompassing way, we should expect to find evidence of that intent in the legislative history. There is none.

Contrary to the position FDA tries to maintain, Congress sought to ensure that the claims were accurately stated. If claims were artificially limited to exclude treatment and mitigation and include only risk reduction, the result would necessarily be a mass suppression of accurately stated nutrient-disease claims, ones that accurately reflect the disease treatment or disease mitigation effect of certain nutrients.

Following FDA's position would also produce the unconstitutional result of causing the NLEA health claim provision to conflict with the First Amendment by denying consumers access to scientifically accurate information that dietary supplements treat or mitigate disease symptoms. Consistent with the rules of statutory construction, FDA must not construe the NLEA to conflict with the First Amendment; it must construe the two to be in harmony with one another.

Repeatedly in the legislative history, Congress

has emphasized that the NLEA health claims provision was designed to be flexible and was to embrace all types of disease claims.

In closing, FDA's denial and suppression of the Saw Palmetto BPH claim not only violates the NLEA health claims provision but also the First Amendment. Under Pearson v. Shalala, the health claim is protected commercial speech that may not be suppressed outright but must be authorized with such disclaimer or disclaimers as FDA reasonably deems necessary to avoid a misleading connotation.

Consistent with its commitment to the court, FDA should reverse its position and evaluate the Saw Palmetto claim under the NLEA health claim provision and under the First Amendment standard established in Pearson. It should stop trying to end-run around the NLEA and, once and for all, implement fully and faithfully, consistent with the intent of Congress and with the First Amendment. Thank you.

MR. LEVITT: Thank you.

Next is Dr. Holtgrewe.

H. LOGAN HOLTGREWE, AMERICAN UROLOGICAL ASSOCIATION

DR. HOLTGREWE: Thank you very much. On behalf of 9,500 American urologists who are the members of our association, we thank you for the opportunity to give our view on this very, very important topic.

First of all, and I want to set the record straight on this in the strongest of terms, lower urinary tract symptoms in older men--that is, frequency of urination, urgency of urination, getting up at night to urinate, the feeling of incomplete bladder emptying--these are symptoms that are not--repeat not--a phenomenon of normal aging. They are always due to disease. The question is what disease?

Arteriosclerosis is a common problem in older men but no one would regard arteriosclerosis with coronary artery disease as a normal phenomenon of aging; it's a disease. And lower urinary tract symptoms are in the same category. They're always due to a disease. As I said, the question is what disease?

We have a concern at the AUA and amongst urologists that men who have these symptoms and treat themselves with an over-the-counter product may be doing themselves irreparable harm and indeed enticing death because there are multiple reasons for lower urinary tract symptoms; some of them are benign; some of them are not benign. Cancer of the prostate is the leading cause of cancer death in African-American males in this country today. It's the second leading cause of cancer death in Caucasian males. Bladder cancer is also very common.

The symptoms of prostate cancer and bladder cancer

are the same as those of benign enlargement of the prostate or simple lower urinary tract symptoms and it takes an evaluation to find out.

Furthermore, when bladder cancer or prostate cancer leaves the confines of those organs, there's no effective cure. The only chance we have of curing men plagued with these disease and unfortunate enough to have them is to make a timely, early diagnosis and institute proper therapy. It is our concern that a man with these symptoms might buy a product and take it, not see a physician, and end up losing that golden moment of cure.

Now certainly there must be package inserts, but any such insert has to have clearly stated the risk of taking this product without a proper diagnosis, and I think that insert has to contain the words "cancer," "possible death," and I think these things should be clearly understood by anyone who markets these. Our fear, however, is that package inserts are not always read and, when read, aren't always understood and aren't always taken under proper advisement. So we feel very, very concerned about this.

The other concern we have is that there's a lack of adequate data in the urological literature of the world today sustaining the value of dietary supplements in the treatment of even benign disease. The data is meager, of

short duration. We have an absolute dearth of prospective randomized clinical trials that are the standard, the gold standard, of medical research.

I am not an attorney and I'm not a politician and I don't understand these issues as well as some others in this room. I'm a urologist, I'm a physician, and our mission as physicians is to treat the patient, protect the patient and provide the best possible care.

I think that our concern at the American Urological Association is that by not having the patient fully understand what he may be doing in taking these products, he may be losing his only opportunity to be spared a significant problem or even a cancer death.

We believe at the AUA that these food supplements or dietary supplements are being marketed to treat symptoms, which are always due to disease. Therefore, these drugs are being marketed to treat disease and they should be under the control of the Food and Drug Administration, just as are other pharmacological products advocated and marketed to treat disease. If you're treating disease, it should be a level playing field.

We feel very strongly that the products that we're discussing here today should have Food and Drug Administration control. We would want to have prospective randomized clinical trials of proper character put together

and carried out under the auspices of the FDA. And if these trials show that there is safety and efficacy to these products, then we would certainly want them and welcome them to the armamentarium of the American physician and the American urologist.

We also harbor some concern about the content of these products, which is rather ill-defined. Sometimes they're a mix of products. Are they compatible one with the other? And what of taking these products in possible interaction with other prescription drugs the older man might be taking, such as cardiovascular medicines, hypertensive medicines, antidiabetic medicines and an array of other medications that he might be taking in treatment of other diseases? What are the interactions? We have no data on that in the current literature.

So in conclusion, I would like to say that in the Federal Register of March 16, 2000, there is a statement that I have underlined here that I think says it actually very, very well. "Section 201(g)(1)(b) of the act provides, in part, that articles intended for the mitigation of disease are drugs." And I think that's exactly what we're talking about. These food supplements and dietary supplements are being marketed as drugs.

I think therefore they should be brought under the aegis of the Food and Drug Administration and that we need

prospective randomized trials of these agents. We welcome those and if, as I said, they prove to be efficacious and safe, let's have them in our armamentarium. Thank you very much.

MR. LEVITT: Thank you.

Next is Bill Soller, Consumer Healthcare Products Association.

WILLIAM SOLLER

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

MR. SOLLER: Thank you.

To set the stage for our remarks on this panel, what I'd like to do is to make two brief remarks that harken back to the previous panels, if I may. I think at least one prior contestant here had that opportunity, as well. Mr. Levitt, if that's all right--

MR. LEVITT: It's your 10 minutes.

MR. SOLLER: By law and regulation, a health claim means that any claim made on the label of a food, including a dietary supplement, that expressly or by implication characterizes the relationship of any substance to a disease or health-related condition, and that's the basic definition that we're dealing with. And key words here are "characterizes a relationship," "any substance," and "disease."

A truthful statement, even if qualified, about how

a substance may prevent or treat a disease is a characterization of that substance's relationship to the disease under consideration, so we think that truthfulness of the health claim is the basic boundary.

Second, FDA's definition of significant scientific agreement, we think, is inconsistent with the Pearson decision. It focusses on the validity of the substance-disease relationship as the decision point, when Pearson dictates the focus to be on the claim that characterizes the relationship and its truthfulness.

FDA's creation of the standard of scientific validity as an approach in responding to the Pearson decision to define significant scientific standard indicates that the agency either does not understand the intent of the court or is unwilling to follow its dictate. If the standard for a health claim is so high as to be not reversed by evolving science, as indicated by the guidance, why then would the court permit the use of a qualifier? FDA's definition of the standard of scientific validity to replace the statutory requirement of significant scientific agreement seems no better than wordsmithing of FDA's original position to the court.

In essence, what is needed is an articulation of a truth-in-labeling standard not unlike FTC's truth-in-advertising standard. So we request that FDA retract the

guidance on significant scientific agreement and adopt one that is statutorily based and expresses the intent of the Pearson decision.

In this regard, the Federal Trade Commission has already addressed the issue of the characteristics of disclaimers and qualifiers to address truthfulness of a dietary supplement claim in the guidance to the dietary supplement industry that FTC put out a couple of years ago.

First, per that guidance, the substantiating evidence should provide a reasonable basis for making the claim. A reasonable basis, per the guide, depends greatly on what the claims are being made, how they are presented in the context of the entire ad, how they are qualified, yet it should be flexible to ensure that consumers have access to information about emerging areas of science and sufficiently rigorous to ensure that consumers have confidence in the accuracy of information presented. Then if the qualifier or disclaimer is to be used, and FTC outlines several criteria--clear, simple, prominent, able to be understood in terms of the extent of the scientific support and the existence of any significant contrary evidence--then based on studies and other support, that is a stronger body of evidence than any contrary information. And I think we heard some other criteria that were elaborated that could be incorporated into that.

So we request that FDA adopt FTC's guide as a framework for creating a guidance on significant scientific agreement for the purposes of health claims.

Now as to this particular situation, health claims relating to disease treatment are an issue that potentially have great public health benefits. Importantly, this issue bears a clear relation to the Pearson decision, which concludes that truthful promotion that is related to lawful activities is entitled to the protections of the First Amendment, notwithstanding the fact that Pearson did not address treatment health claims per se.

But to reiterate our foundational position here, a health claim means any claim made on the labeling of a food, including a dietary supplement, that expressly or by implication characterizes the relationship of any substance to a disease or health-related condition. A truthful statement, even if qualified, as I mentioned earlier, about a substance, how a substance may treat or prevent a disease, is a characterization of that substance's relationship to the disease under consideration.

In sum, it is not, we believe, the validity of the relationship but the truthfulness of the claim about the relationship that is at the core of this overall issue.

To date, health claims authorized by FDA had been for reducing the risk of disease in the general population.

An example of such a claim that was published in FDA Consumer was as follows: "Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life."

However, treatment of osteoporosis, while requiring a diagnosis, includes calcium supplementation. Indeed, the efficacies of currently used prescription drugs are based, in the main, on use of concomitant calcium supplementation.

Hence truthful and not misleading information on the label of calcium supplements about the use of calcium in the overall treatment of osteoporosis, in addition to calcium's role in the prevention of osteoporosis, would be an important public health outreach to a vulnerable population. Indeed, such a treatment claim for calcium for osteoporosis could be qualified to recommend a physician visit to determine whether a potential product user was suffering from the disease.

And note in the FTC arena, FDA permits self-care products with labeling recommending physician diagnosis prior to use--bronchodilators for asthma, anti-fungals for vaginal candidiasis--and such labeling was undertaken at the discretion of the agency, entirely within existing law and regulations.

Further, FDA could specify the scope and extent of safety information needed for a disease treatment health claim and even elements of required labeling to ensure that there is not an unreasonable risk.

In sum, diet-disease treatment relationships can be a logical health-based extension of dietary supplement function. FDA's recognition of this issue carries First Amendment implications. We think therefore it would be sound public policy to amend the health claim regulations to permit such preapproved claims. And, in so doing, we think a reconsideration of nutritive value, how it's defined, might be important to undertake, to recognize that the processes by which a dietary constituent promotes health, maintains proper bodily function, protects the body from the development of chronic disease or other health-related conditions and facilitates and/or restores healthy functioning are, in and of themselves, characteristic of nutritive value, thereby creating a more logically flexible approach to health claims.

In conclusion, we think truthfulness should be the boundary for health claims. We think it's important to develop a regulation permitting qualifiers and disclaimers in health claims. We think that the guidance on significant scientific agreement should be retracted.

And the FTC guidance, as a framework, should be

adopted for guidance on health claims. We think that the FTC guidance has criteria that are very helpful in it, how to describe what a disclaimer or qualifier would be. And we think that disease treatment health claims should be permitted in the context of the truthfulness as the boundary for the health claim. Thank you.

MR. LEVITT: Thank you.

The next speaker is Marsha Cohen from Hastings College of Law.

MARSHA COHEN, HASTINGS COLLEGE OF THE LAW

UNIVERSITY OF CALIFORNIA

MS. COHEN: Good afternoon. I spent a lot of time in the past week wondering why I agreed to come to this meeting, especially since my original invitation was to be on Panel II and then I found myself on Panel III, and I've been wondering what I can contribute, since I basically disagree with the premise of the earlier debate, namely that there is a First Amendment barrier to setting minimum standards for claims made on the labels of government-regulated products.

Note that I projected the dictum of Pearson beyond food supplements, as there's a whole host of government-regulated products and disclosures in the marketplace to which its notions could apply.

Consider, for instance, to get away from safety

issues completely, the disclosure requirements of the Truth in Lending Law or RESPA, the Real Estate Settlement Procedures Act. The premise of those whole laws is that only standardized disclosure protects consumers from being confused even by literally true, in those cases, financial information. There are a whole lot of regulated issues that were not even considered by the Pearson court and yet if you read their language broadly, it would apply.

As a law professor, it's part of my job description to deconstruct and criticize judicial decisions. Pearson leaves me much room for both and I decided to do this, even though they're off the declared subject, because we need to consider the exact task that FDA has been presented by the court.

The Pearson holding has been stated, I think, rather overbroadly earlier today. It is a remand to the Food and Drug Administration to respond to its First Amendment--I'm reading from page 11 of the version that was sent out by the agency. "We do not presume to draft precise disclaimers for each of the appellants' four claims. We leave that task to the agency. Nor do we rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright," and so forth.

On significant scientific agreement, that standard wasn't deemed to be incurably reversed by the court. In fact, it ordered FDA to articulate what it means by that, which FDA has done and has met that.

In fact, for two years I was part of the Keystone Dialogue that earlier speakers have mentioned and I never perceived that anyone with a science background was confused by what significant scientific agreement meant, although it might have been unclear to some of the lawyers. But I think FDA has made it unclear no more, given its guidance.

As to the application of that now well articulated standard to the four sets of claims, that is well beyond my competence but I assume that FDA will be revisiting the evidence and providing adequate explanations of its conclusions.

The various First Amendment dicta are troubling for a number of reasons. I'm no expert on the First Amendment--that is not my field--but I'm very troubled that the FDA didn't raise one of its most potent arguments at the appropriate time and thus it was not heard, although that may be different in the litigation after the remand.

It was Congress, after all, that decided there ought to be some circumscribed exceptions to the drug approval provisions of the Food, Drug and Cosmetic act to meet, as it said, "the growing need for emphasis on the

dissemination of information linking nutrition and long-term good health." Congress thus devised a regulatory scheme that allows food supplements to bear health claims that, prior to the legislation, would have caused the products to be regulated as drugs. The significant scientific agreement standard is Congress's creation.

The Pearson court considered drugs to be an entirely different category than food supplements, notwithstanding its recognition of the new law as creating a safe harbor from drug status for supplements bearing approved health claims.

In fact, there's considerable potential for overlap. Food supplements, to the extent that they make certain claims, are legally still drugs.

I'm also troubled by the analysis applying the First Amendment to the issues in this case. The much-cited Central Hudson case, in fact, provides that the government may ban forms of communication more likely to deceive the public than to inform it. It may well be that advertising will rarely fall into this category. The significant cases upon which Pearson relies all involve advertising.

Furthermore, some of the critical cases, like 44 Liquor Mart, involve bans on the advertising--again advertising--of very basic factual information--that was a total ban on liquor price advertising--the objective truth

of which can be fairly easily determined.

But here we're concerned with the food and drug product label, a highly regulated space where there are required disclosures in mandatory format, even with mandatory type size requirements. Consumer expectations about information conveyed in that space are, I am certain, quite different than about advertising. And we're dealing with information, the substance of the claims, the objective truth of which cannot easily be determined by the consumer.

But the shortcomings of Pearson obviously are not our primary focus, especially at this time of the day. The boundary line between drug claims and other claims is our topic.

I should state up front that I wish Congress had never started down this path and I'm quite skeptical that even "reducing the risk of" claims are read in the limited fashion which their language literally states.

If these products could move beyond risk reduction to mitigation of treatment claims, I think the public would be seriously deserved. While some consumers purchase food supplements as preventive medicine, many others are, in fact, turning to supplements as alternative medicine, hoping to obtain drug-like benefits without what they perceive to be far greater side effects--the whole notion of if it's natural, as food supplements are perceived to be, as opposed

to drugs, often similarly natural in their source, that they are safer.

There may well be a lot of legitimate benefits from the world of herbal and other supplement products as alternative medicine, but these products should be subject to a regulatory regime at least similar to that imposed on more traditional drugs, to assure consumers equivalent protections.

There should not only be adequate evidence of their safety and efficacy but also assurance that dosages are properly recommended, that there is product-to-product and sample-to-sample bioequivalence, that good manufacturing practices are followed, and that prescription requirements have been considered.

Congress, in NLEA especially, made a limited exception from drug status, and recall why it did that. It did that because food companies wanted to put labels on their cereal products about things like the benefit of having fiber in your diet and its influence not just on nutrition generally but to state that that might help prevent certain diseases. That was the basis. That was the factual format in which the NLEA came to pass.

They did not intend to eviscerate our drug approval protections. That would have been a very different debate. And there's nothing anti-competitive about

this--simply a level playing field between supplements and all other products if they wish to be drugs.

Oh, and I should also note that in Pearson, in footnote 6, the court said, "Oh, drugs are different." So you have to be careful in drawing your conclusion.

The current regulatory scheme falls far short, it seems to me. It's the worst of all possible worlds. In the Washington Post, which I saw in its national weekly edition, an official of California's Department of Health Services characterized the current supplement scene as like the wild, wild West and I wholeheartedly agree. FDA doesn't even know about many of the products making claims, has insufficient manpower to ensure that they're substantiated and some skepticism that such substantiation exists is surely justified.

Yet some herbal products could be good medicine. I understand, for example, that St. John's Wort is the most frequently prescribed anti-depressant in Germany, with a lower risk profile than its traditional anti-depressant competitors. This fact is hardly lost on American consumers, who read the structure/function claim on St. John's Wort, "May help enhance mood" and draw the obvious and intended conclusion about its medical purposes.

I mean those of us who are sort of always high certainly don't need it, yet a claim that St. John's Wort

mitigates or treats depression should not be allowed in the United States today because that's clearly a drug claim. This supplement is not being regulated as a drug. And Saw Palmetto--I don't know about its efficacy--should be treated similarly.

I would be pleased if Congress were to go back and undo the disaster that it's created and create a statutory means for alternative medical products that meet drug standards of safety and efficacy to obtain drug approval as drugs in a somewhat different way, without each seller, for instance, having to obtain an individual NDA, because that's what makes it very expensive. Yet each seller would have to demonstrate compliance with GMPs, dosages, labelings and similar requirements under some sort of master approval, like the food additive petition-type process.

Some supplement products so approved might need to be covered by prescription requirements, although most would be found probably relevant for over-the-counter sale.

I appreciate FDA's attempt to deal with the semantics of what is a structure/function claim, what is a drug claim. The agency's Federal Register publication of January 6 could legitimately bear the claim "Promotes soothing sleep." I doubt its careful distinctions are appreciated by typical readers of the claim and I would like to see some research, as people said today, about what

exactly is communicated by the various claims. If what is communicated is in the nature of a drug claim, then the public deserves the full panoply of patient protections in our drug laws. Thank you.

MR. LEVITT: Thank you very much.

Final speaker on this panel from National Food Processors Association, Regina Hildwine.

REGINA HILDWINE

NATIONAL FOOD PROCESSORS ASSOCIATION

MS. HILDWINE: Thank you very much.

I'm with the National Food Processors Association or NFPA, which is the voice of the food processing industry and my comments today are going to be framed in the context of conventional food. So you're going to hear something a little different than you've heard from the rest of the day. I'd like to thank FDA for the opportunity to speak on this issue.

NFPA has a very strong interest in the discussion that's going on today, not the least because we were the petitioner in 1994 in a rulemaking that's now pending on health claims and nutrient content claims flexibility. Our 1994 petition argued the same First Amendment points that were central to the Pearson case, but discussion of this issue is not how I plan to spend my 10 minutes today.

One does not have to stray far from the text of

the federal Food, Drug and Cosmetic Act to find the answer to the first question asked of this panel. And here it's going to sound like an echo. The statute authorizes substantiated food claims that characterize the relationship of any nutrient to a disease or health-related condition.

We've come to call this category of food claims health claims, but the authorizing provisions of the act, which were adopted through the 1990 NLEA, were put forward in an effort to counteract FDA's preexisting categorical ban of all disease claims on foods under the drug definition in Section 201(g)(1)(b) of the act. My lawyer had to write that out for me.

That definition notes that the drug is an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. Notably, in elaborating the NLEA provisions, and here I would differ from Marsha Cohen, Congress made no effort to limit the nature of disease claims that were approvable as health claims to claims about prevention or risk reduction.

To the contrary, Congress deliberately adopted broad language which embraces the full spectrum of potential relationships between nutrients and disease, including all those relationships that are named in the drug definition. Claims characterizing the relationship between nutrients and disease plainly could include not only preventive

relationships but mitigation, treatment, cure, and perhaps even diagnosis.

The only question that is relevant is whether the relationship that is claimed is properly substantiated. And if it is, the statute says that FDA shall authorize the claim.

The health claim provisions go on to include conforming amendments to ensure that foods bearing authorized health claims cannot be regulated as drugs under Section 201(g)(1)(b).

So the bottom line, to us, is that FDA lacks any authority to confine health claims to those expressing a specific type of diet-disease relationship. FDA's authority must be directed toward ensuring that claims are properly substantiated and are stated in a truthful and nonmisleading manner, in view of the nature of all available substantiating evidence.

FDA, in asking these questions today, appears to signal that it believes certain types of claims are appropriate for foods. This thinking reflects an arbitrary value judgment, in our view. It appears to be the kind of paternalism that the court in Pearson versus Shalala soundly rejected.

The Pearson court made it clear that the government, and specifically FDA, must not stand as a

gatekeeper restricting the flow of truthful, nonmisleading information. To justify restrictions on label information, the restrictions must relate directly to alleviating real harms that the information itself otherwise would inflict.

Advancing science has shown that many lines that might be drawn between prevention, treatment and mitigation are, at best, fluid if they exist at all. FDA's own regulations for foods for special dietary use make that point and those regulations are, in fact, the orphan regulations in this discussion.

The special dietary use regulations recognize that foods can be an important part of managing disease by addressing particular physiological needs that exist by reason of physical, physiological, pathological or other conditions. Foods and nutrients that help prevent disease frequently also mitigate and even treat disease. If consuming a food is potentially helpful in relationship to a disease, that information could be communicated lawfully to consumers through food labeling.

We believe we must get away from arbitrary line-drawing exercises that have no scientific or legal basis and are destined to failure in the end.

So the short answer to the question--Should health claims go beyond claims about reducing the risk of disease to include claims about mitigation or treatment?--is yes.

There is no basis for doing otherwise.

The question certainly provokes a great deal of thinking about the role of foods and nutrients in preventing and treating diseases and mitigating their symptoms. For example, can a high fiber cereal be included as part of the treatment plan for certain digestive diseases, such as diverticular disease? Is it true that diets with controlled levels of calories, carbohydrates and other nutrients could be useful in managing noninsulin-dependent diabetes mellitus? Can some patients manage their Type 2 diabetes through diet alone? Can eating chicken soup be effective in providing temporary relief from the symptoms of the common cold? Who would ever do that?

Can dietary calcium do more than merely reduce the risk of osteoporosis? I'm sure many of you know what the recent NIH consensus conference had to say on that point. Can dietary calcium be used to treat orthopedic conditions other than reducing risk of osteoporosis?

For the last of these questions, I'm going to tell you a personal anecdote. A few months ago I fractured two bones in my arm, which was the result of a clumsy fall. It was a simple, nondisplaced fracture, but I had two broken bones nonetheless. I had damaged a bodily system such that it no longer worked properly. I had a disease or health-related condition.

The standard and even time-honored treatment for simple fractures is reduction, immobilization, pain alleviation and time, but at my first consultation with my orthopedist, he also asked me if I was a milk drinker and was very pleased when I said yes. He told me to be sure to keep my calcium up. And, of course, this is happening in about five seconds. Keep my calcium up, get 100 percent of the RDA--he used the old terminology--and take a calcium supplement if I have to.

From that moment, I considered dietary calcium to be a part of the treatment plan of my fracture, along with Ibuprofin and Acetametaphin. I did not need to see reams of scientific studies to persuade me to follow a course that, to me, made perfect sense. After all, if it is well accepted that calcium helps build strong bones--it is, after all, the quintessential structure/function claim for foods in all the illustrations--it was logical to me that calcium might provide some beneficial effect to help rebuild bone injured through fracture. If such a claim could be hypothesized for foods, even in concept, it could create an opportunity for some serious scientific research and soon we might even see milk bars on the ski slopes. And, by the way, my arm's fine.

All are orthopedists as aware of dietary factors as the one that first treated me, even about a substance as

elemental to their profession as calcium? I'm not sure about that. The challenge then becomes how to make physicians as aware of the usefulness of dietary factors for treatment as they are about drugs so that they can advise their patients on the potential health benefits of foods in the treatment of their conditions. Fortunately, the First Amendment environment for this is now more amenable to meeting the challenge.

From fiber to chicken soup to dietary calcium, people have been using foods to help treat or mitigate the symptoms of diseases from the beginning of time. Everyone has to eat, so why not eat something that may help with your particular condition? This is an area of vigorous scientific research and the body of evidence is growing that could be used to substantiate such beneficial claims.

But it's another matter entirely for FDA to authorize a health claim on food labeling along these lines, since the agency typically has interpreted the health claim provisions to be limited to risk reduction. Through this approach, FDA has adopted an interpretation that places undue impediments before claims for conventional foods that should require no FDA preapproval.

The history behind the dental caries-sugar-alcohol health claim, which appears at it very foundation to be a nutrient avoidance claim coupled with a structure/function

claim, raises many questions. FDA's recent rulemaking on structure/function claims for dietary supplements--in this rule, the tension between FDA's policy on implied health claims and structure/function claims has grown increasingly obvious. Heart symbols or pictures of electrocardiograms on food labels have been regulated as health claims in need of the safe harbor of prior approval, while FDA says that cardio health is a structure/function claim.

This internal inconsistency and arbitrary line-drawing illustrates the need for a new way of thinking, a paradigm shift. FDA is now, under Pearson's court order, to create that shift by making room for the free flow of truthful, nonmisleading claims and confining restrictions to those that are needed to remedy the concrete harms presented by fraudulent and deceptive claims.

We think the time has come for FDA to embrace the First Amendment. The statutory language on health claims defines the scope of the vessel, saying it's a glass. FDA, in its implementing policies and regulations, has filled the glass only about one-quarter full. There is much more room in the glass than FDA has been prepared to fill.

The Pearson court tells us that the government must not be so restrictive when the people thirst for truth. We urge FDA to open up the flood gates and let truthful, nonmisleading information flow. Thank you.

MR. LEVITT: Thank you very much.

Let's move right into the questions. I will begin.

Dr. Holtgrewe in his presentation emphasized the point of people self-medicating, in this particular case with Saw Palmetto for BPH but you could extrapolate more broadly also in terms of self-medicating and masking a serious disease, in this case cancer, which can be fatal.

In an area like that particularly, what would be the safe circumstances under which that product could be sold as a dietary supplement, for those who think that it should be?

DR. HOLTGREWE: First of all, there is no known medication of any kind that is known to prevent prostate cancer or bladder cancer--none. There's one pharmacological product that we now know can block the progression of benign prostatic hyperplasia; it is not a food or dietary supplement.

The issue here is, I think, very simple. I've heard a lot of talk about legal issues and about court trials and I haven't heard a lot of talk about the patient, the gentleman who has symptoms, who's going to be taking this, who is the market for this product.

Ms. Hildwine said something about paternalism. I

think this is very important. I think that's the role of government, to be paternal, to protect the American public and, in this case, in the case of our patients, the older male who has symptoms. We want to protect him against taking a wrong turn in the road, a wrong action, and losing valuable time or to be treating himself in an ineffectual manner.

What we need is not more legal action, court action or congressional action. What we need are properly controlled prospective randomized clinical trials showing the efficacy and the safety of these food supplement products, which currently do not exist. That's the answer.

It will not be found in a court of law or in the hallowed halls of our Congress. What we need to know is are these effective and are they safe? And we have some data, but it's limited. I don't feel that it's adequate and I don't think we have adequate information.

So rather than court actions or governmental or political actions, what we need are medical treatments. This is a medical issue, not a legal issue and not, in my view, a political issue. Are they effective? Yes/no. Are they safe? Yes/no. Proper prospective, randomized clinical trials and only that can prove the case. That's our position.

MR. LEVITT: Bill?

MR. SOLLER: I think what's important here is just to step back for a moment because the danger of medical paternalism is that it will take the issue in the extreme and cloud all the other issues that might be attendant here.

What Regina and I were trying to convey is that there is broad language as we think about the definition of health claim. There are two questions that Regina identified and the two questions that we, as an industry group, interassociation, in grappling with this issue, agreed to prior to this meeting.

The first is is the relationship substantiated? And second, is it stated in a truthful and not misleading fashion?

Pearson instructs us to favor disclosure, not suppression. So really the question here is not whether but how. And I think on balance, you've heard a couple of examples here. On the one hand, I provided an example of calcium in terms of how, in the treatment of osteoporosis, it's expected. You're not going to look at an Rx drug, new chemical entity unless an individual's on calcium supplementation.

As an aside for the record, when I broke two bones in my ankle in January it was a supplement, Regina, not milk. I worried about my cholesterol and my physician said to take a supplement.

There is an example where on one end of the spectrum, and I don't mean to bring the case examples in but it really speaks to the patient, the consumer. Both of us were instructed. We wanted to know information. We wanted to hedge whatever we could to have the most rapid recovery from our particular condition.

And I think in that particular situation where you have something like calcium, where you know how it's being treated, to be able to put that into the product label makes a whole lot of sense.

Stepping back from that, if--I'll pick red rice yeast extract not because I'm advocating this for cholesterol reduction at all but take ingredient X in that category. If it's determined that if an individual not only is at risk for cardiovascular disease but actually has it and is worried about the cholesterol and this can add something else into the overall prescription therapy, it makes sense to get that information on the label.

Now you step back and you move along the continuum and you get into St. John's Wort for frank depression and you may be in a whole different category.

MR. LEVITT: Because?

MR. SOLLER: Well, you may be in a whole different category because you may determine, when CHPA petitions you to approve it for severe depression, in making a

determination, that it represents an unreasonable risk to the particular patient group that's involved. You've made that determination. And in my comments I mention that you could stipulate in guidance the kind of safety information that you might expect along this continuum.

I think it's very helpful that you brought this particular meeting together to help focus these kinds of thoughts. I will tell you we haven't defined in that continuum exactly what that criterion, set of criteria might be that would distinguish, but certainly to take the extreme and throw everything else out is not what the Pearson court is about, it's not what the consumers want and it is not in the best interest of patients that have the kind of broken bones that we had that benefitted from our physician adding something else onto the particular device that he happened to put on my ankle.

MR. LEVITT: Claudia?

MS. LEWIS-ENG: I just want to make a point. I want to address the safety and efficacy concerns that my colleague to my left mentioned.

We submitted a health claims petition pursuant to the health claims provision, as outlined in the NLEA, and we submitted volumes of information that address both the safety and efficacy of Saw Palmetto for the reduction of symptoms associated with BPH.

So I think that in keeping with some concerns that the doctor addressed, that we have addressed those when we submitted the information to the agency. And in the claim itself if you don't want people to forego medical treatment, you could always include a disclaimer at the bottom saying that you should consult your physician if your symptoms worsen or your conditions are not exactly within the confines described on the label.

MR. LEVITT: And do you think those data would meet the drug standard?

MS. LEWIS-ENG: It's not designed to meet the drug standard. It's designed to meet the significant scientific agreement that Congress subscribed for dietary supplements.

DR. HOLTGREWE: May I respond to that?

I'm very conversant with the literature on benign prostatic hyperplasia. In fact, I'm on a panel that's drawing up guidelines that will be sequel to the guidelines put out by the Agency for Healthcare Policy and Research back in 1994.

There is nothing in the peer-reviewed literature of the world that conclusively proves the efficacy or safety of any of the products we're talking about. Yes, there's literature, there's studies, but they are of short duration. I don't think that any of them are really of the type that would convince me or any scientifically thinking individual

that there's efficacy or safety to these products.

We need these studies. We welcome these studies. We want these studies. And if these studies show the efficacy and safety of these products, as I said before, we welcome them to our armamentarium. We're always looking for a way to treat a patient.

But we have this concern that it will mask a significant cancer and we have the concern that we really don't see the efficacy proven in the studies that currently exist.

So there are studies--I would concur with that--but I think they don't have great scientific merit.

MR. LEVITT: Let's quickly try to finish this question because we have some others to move on to.

Marsha?

MS. COHEN: I'm just concerned. If I were currently brewing up some new chemical entity for some disease, which I'm not, and listening to this I would say, aha; I'm going to do a little something different. I'm going to save my many millions of dollars of study and I'm going to, because I've got enough--I can get general stuff as good as supplements have. I'm going to package it as a food supplement, sell it as a food supplement for the relief of the conditions of whatever, disease X which I'm working on, and I'm wondering how you prevent me from doing that if

FDA moves this one step further.

In other words, wouldn't all people who are now drugmakers suddenly become food supplement makers at great savings to themselves?

MR. LEVITT: Next I'll move it on to Chris Lewis for the next question.

MS. LEWIS: Actually, Marsha, thank you. That's a little bit of a lead-in--

MS. COHEN: Was that your question?

MS. LEWIS: No, not quite. But at the risk of getting too legal, I do want to return to the fact that I think the questions the agency listed in the Federal Register notice suggest we're wrestling a great deal with the distinction between foods and drugs.

And I guess Regina and Claudia Lewis-Eng and Marsha, you, as well, the question in my mind is how should we or could we or do we distinguish between foods and drugs? Are we on the right path with this concept of mitigation and treatment being drug claims? Clearly I'm hearing not, at least from some of you.

So the question is what's the difference between a food and a drug? Is it simply the claim itself? Is there something else going on that we need to consider if that is an important goal? And maybe you need to talk about whether that's an important goal. One of the questions we asked is

what happens to OTC drugs? How does this impact on those substances?

MS. HILDWINE: I'm going to start this simply by saying that we in the food industry are kind of struggling with this, too. Initial thinking is that it's not the claim that determines it or should determine it but perhaps we need to look not so much at the definition of drugs again but the definition of food. What is food? What are the conditions of use of food? And as we settle on how that works, perhaps this is all going to filter out.

We found that in the past decade or so, all of the focus has been on drug-related issues and not enough on food-related issues and yet this is an area where in the development of such products as functional foods, we really now need to understand what is a food.

You look at the statute and essentially the statute begins by saying a food is a food, and that may not be good enough. So we need to struggle with that.

But I think that issues that relate to the form of the product, the conditions of use of the product have some merit in terms of advancing the discussion.

DR. HOLTGREWE: I'll say again that in the March 16, 2000 Federal Register there's a sentence on page 3 that says it all. It's quite simple, straight to the point. "The act provides, in part, that articles intended for use

in the mitigation of disease are drugs."

And in the case of lower urinary tract symptoms, medications and food supplements and dietary supplements, they are attempting to treat symptoms that are due to a disease; therefore they are treating a disease. And if you're treating a disease, there's no difference between the food supplement, the dietary supplement, and an ethical pharmacological product, the latter of which, of course, goes through a very rigorous food and drug control course before it gets to the public.

So there is no difference between a product--I don't care whether it comes from a banana tree or a walnut or whether it comes out of the laboratory of a distinguished pharmacological house. If that product is being marketed to treat a disease, and these products are, they should be controlled in a comparable manner.

MR. SOLLER: Just a comment in terms of food and drug and the importance of considering the intended use, conditions of use, but to reiterate also our comment on the truthfulness of the claim, all important but perforce, that will put you at times into grey areas, which we're struggling with today.

We do have a carve-out area for disease risk reduction claims. What we're saying is that in selected circumstances for dietary supplements, recognizing that

there is a range over which these claims might be made, that the agency could quite properly, appropriately and for the benefit of the consumer, place information on the label about the treatment of disease, calcium being one of the examples.

MR. LEVITT: Next question, Mike Landa.

MR. LANDA: I want to pick up on Marsha's question. Thank you.

Let's assume that you go beyond risk reduction. What's the effect on the drug development process?

MR. SOLLER: Keep in mind that we're not dealing with the structure/function claim regulatory process but we're dealing with a preapproved authorization process where the information is brought in to you.

MR. LANDA: But it's not the same as the drug process.

MR. SOLLER: Well, information is provided for you. We're working on a fish oil submission to the agency that is quite extensive and the information we're providing in there provides what we think would be the appropriate type of claim to allow the safe and beneficial use of this particular product and in the context of all the information and a truthful description of what that is.

It is not that sort of high proof standard of drugs because, per Pearson, would allow disclaimer

information that would be applied to that particular claim. But again I think it's in the overall context of how that's being made and a determination that you can make as an agency as to whether that's an unreasonable risk, given what you have to play into there in terms of disclosure and not suppression of information per Pearson.

But I think it's that balance. It's not an easy one. It's case-specific, as will be the disclaimer.

Now on the drug approval process itself, remember that if it's a new concoction, as I'm hearing here, there is a new dietary supplement approval procedure and you can make a determination there, as well, as to the kind of information that you additionally would need before you would allow that product to go to market.

And from the standpoint of new chemical entity in the prescription field, I have a doubt that it's going to significantly dent the PhRMA R&D machinery and the idea for exclusivity and the whole reimbursement scheme and how that plays out in terms of patient care.

MS. LEWIS-ENG: I have a comment. Your question is what happens to the drug approval process? Nothing has to happen. We have two distinct processes--one for drugs and one for dietary supplements. So one doesn't necessarily have to affect the other.

MR. LANDA: The question more directly is why

would one go to the drug approval process?

MS. LEWIS-ENG: Because dietary supplements are regulated differently and there's one definition for dietary supplements and a separate one for drugs.

DR. HOLTGREWE: I can't resist responding. There should be no difference. You're treating disease; you're treating disease. Whether it's with an apple or a banana or with a pharmacological agent, you're treating a disease. Why should there be a different standard?

MS. LEWIS-ENG: Because Congress said--

DR. HOLTGREWE: Well, I think Congress, in its infinite wisdom, was wrong and it's just that simple.

MS. COHEN: I think the question is whether Congress said that and it seems to me that the debate was not about whether you change the drug approval process for food supplements. That is probably, as I mentioned, that is probably a debate that might be worthwhile--what do you do with traditional medicine to enable it where you can't get the exclusivity in the same way you can with the new chemical entities? Is there a way to create a simpler, less expensive means of the same goal, however? Someone's got to prove the stuff is safe and effective if it is being used for treatment.

MR. LEVITT: Peggy?

MS. DOTZEL: I guess one thing I'm not sure I

understand, so I would ask some people to respond to this, is when we're talking about the proponents of expanding what we have traditionally included in the realm of health claims to treatment or mitigation claims, in proposing this, are there any limits of the types of claims? I mean is there any limitation on this or are you advocating opening the door all the way?

And then if the answer to that is yes, my follow-up question would be so then we have a scheme here where, and this follows up a little bit on Mike's question, we have a scheme here that we have drugs that are out there and the claims are approved on the basis of substantial evidence and we have dietary supplements and the claims are approved on the basis of significant scientific agreement or something less with a disclaimer.

How are consumers to know the difference? And where is the distinction? How are they to distinguish these two types of claims?

MR. SOLLER: The two types of dietary--repeat the last part.

MS. DOTZEL: And how are they to distinguish the two types of claims, the drug claim versus the health claim?

DR. HOLTGREWE: Well, in the silence, I hate to monopolize things but the answer is very simple. They cannot, of course. That's the problem. They cannot tell

the difference. The patient is not a graduate of a medical school; nor is he a pharmacologist. He's a patient. He has symptoms and he reads the disclaimer and it depends, of course, on what the disclaimer says.

But, as I said in my earlier testimony, if you're going to have a disclaimer on products marketed to treat lower urinary tract symptoms, there should be in big, bold letters, "You may have cancer and it may kill you." But anything short of that I think is inadequate.

And I think it also should say that there is not a great deal of compelling evidence that what you're taking will help you.

There's another problem. Men with lower urinary tract symptoms have an enormous placebo effect. If you go to the scientific literature and look at studies on prostate disease and the medical treatment of prostate disease, we know for a fact in many, many well controlled prospective randomized clinical trials that men on a sugar pill will get something like a 30 to 40 percent improvement in their symptoms just because they're taking a pill. That's a known placebo effect. It's been all over the literature for decades. We've known this.

So that's another risk. Even if they take something, it's effective--it isn't effective; there's a placebo effect. And what we need are these trials I keep

talking about.

I'm not against food supplements. I'm not against plant extracts. It may sound like it; I'm not. I just want information about them. And until we have that information, I think we must think first of the patient and protect the patient. That is our primary responsibility.

And to answer your question, there's no way the patient can tell the difference. Somebody else may disagree.

MR. SOLLER: You asked if there are any limits in the type of claims and would you open the door all the way. I wasn't trying to convey that in my formal remarks or my follow-up remarks earlier. What I was trying to convey was that a body of evidence would be put at FDA's door and there would be a claim, plus a disclaimer possibly that would be tied to it in the context of health claim, asking for essentially preapproval of that particular claim.

I think those types of claims, just given my experience in the approval process with FDA and what I know about dietary supplements and where the companies may be thinking about it, may range across a spectrum. And there may be somewhere a very simple qualifier or claim or very limited information maybe attendant to that. I happen to think calcium is that example. That's why I brought I up.

I think, and I'm not going to get into BPH but I