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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

PUBLIC MEETING ON IMPLEMENTING THE PEARSON COURT DECISION AND OTHER HEALTH CLAIM ISSUES

Tuesday, April 4, 2000

9:04 a.m.

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A G E N D A

AGENDA (Continued)

P R O C E E D I N G S

OPENING REMARKS AND KEY ISSUES

MR. LEVITT: Good morning. I might get people's attention. Since we'll all want to end on time, I think it's important we try to start on time, as well.

Let me begin by welcoming you. My name is Joe Levitt. I'm director of FDA's Center for Food Safety and Applied Nutrition and I will be the host for today's meeting.

What we would like to do is begin with a short overview and background context to put today's discussions in context, and then I'll go through what logistics of the meeting would be.

As I think everybody knows, the subject of today's meeting is to talk about the FDA's implementation of a court decision, the name of it being called Pearson v. Shalala. We also want, at the same time, to deal with claims about mitigation or treatment of disease. Both of these deal with the issue of health claims involving dietary supplements.

While the court case and preceding rule-makings have a long history over the last decade, the recent chronology may simply be summarized as follows. In January of 1998, the District Court ruled in favor of the government's position. The plaintiffs then appealed to the Court of Appeals. About a year later, the Court of Appeals

reversed the District Court's decision and ruled in favor of Pearson. The government asked for a rehearing in the Court of Appeals. The rehearing was granted but the result was to again deny the government's petition. And that takes us to where we are.

There was some ensuing time for consideration of review by the Supreme Court. That was not exercised and so we have this decision to implement.

The decision has five basic elements that we need to understand. Number one, the FDA is instructed by the court to reconsider whether to authorize the four health claims at issue. Second, in the absence of significant scientific agreement, the FDA must determine if the scientific evidence in support of the four claims--and these will be done individually--if the scientific evidence in support of the claim outweighs the scientific evidence against the claim. So there's a threshold scientific question.

If so, number three, the FDA must consider whether the disclaimer or other qualifying language could make the health claim nonmisleading to consumers. And finally, the FDA was also instructed to clarify the significant scientific agreement standard for authorizing health claims.

FDA has set about to implement this decision in an orderly fashion as follows. Number one, we have within our

center our annual program priorities document, which essentially is the center's work plan. We updated that plan in July of last year and among the few updates that we added was the importance of the implementing of the Pearson v. Shalala decision. So that was what we call our A list item, one of our A list items, something we need to devote our highest level of energies to.

Number two, in August with respect to the four particular claims at issue, we issued a contract for a literature review. The claims had last been reviewed in the early part of the 1990s following the passage of NLEA and we wanted to be sure that we had an up-to-date version of what the scientific literature was with respect to each of the four claims.

In September we published a Federal Register notice soliciting scientific data on the four claims for members of the public, to complement what the contractor was doing for us. We also wanted any interested parties again to send us what the updated information is.

In December we published our Federal Register notice on what we said was our strategy for implementing the court's decision, which had been our goal for the previous summer, to arrive at an overall strategy or a blueprint for how we're going to proceed.

That strategy, in and of itself, had five points.

The first was that we would update the significant scientific evidence on the four claims, and you've already seen me speak to that in terms of the contract review and the solicitation of public comments for that. Two, we would issue a guidance clarifying the significant scientific agreement standard. That was a portion from the court decision dealing with clarifying what FDA meant by that.

Third, that we would hold a public meeting to solicit input on changes to the general health claim regulation. So looking beyond the four claims in general, to what extent should FDA be reconsidering the general health claims regulation we have with respect to dietary supplements, in light of the Pearson decision. That's the meeting that we're all at today.

Four, that FDA would be conducting a rule-making to reconsider the general health claim regulations for dietary supplements in light of the Pearson decision. So that will be one of our important next steps following this meeting.

And finally, we know that we need to go individually for each of the four claims involved in the Pearson decision and conduct rulemaking specifically for each of those, as instructed by the court.

So that's what we set out in December as far as our blueprint and how we're going to proceed ahead in an

orderly fashion. We then picked up right from there and later that month we did issue guidance on the significant scientific agreement standard for the review of health claims. That came out just before Christmas and is available on our web page.

In January, at the request of the plaintiffs in the litigation, we extended the comment period on the Federal Register notice soliciting information until April 3, which was yesterday. The reason for that was they wanted to be sure that they could make a submission on the four claims in light of what that significant scientific agreement standard document said. That made perfect sense to us and so we agreed and extended the comment period. As I said, it was just closed yesterday, timely in nature of today's meeting.

We followed through in January and in our various planning documents, both our long-term strategy plan, as well as our 2000 priorities, continued to include implementation of the Pearson decision as a high priority activity.

And today, in April, we have convened a public meeting to solicit public comments on changes to the general health claim regulations for dietary supplements in light of the Pearson decision.

So that is how we have gone about trying to

approach this court decision in the area that an many ways is novel and challenging for all of us.

In the Federal Register notice announcing this meeting, we listed a long series of questions. In order to then take that and try to reframe that in a way that could help us deal more specifically with a large discussion in front of today's group, we have divided the day into three general question areas and we'll have one panel addressing each of those three areas separately.

The first question is, and these questions are on your agenda in your packet today, the yellow piece of paper that I see some of you have in front of you--the first question says: Should health claims be allowed on dietary supplements on a basis other than significant scientific agreement? If so, what should that basis be and what are the appropriate criteria for making decisions about allowing such claims?

That essentially is the standard of evidence question. What does it mean when the court says there is more evidence for than against the claim?

Second is: If such health claims on dietary supplements are to be appropriately qualified so the consumers are not misled, what should be the characteristics of such qualifying language? Should FDA require any other information to assist consumers in evaluating health claims

and prevent them from being misled? So this becomes more of a how-to. If we've met the scientific threshold that the evidence in support of it is more than against, what is the nature of the disclaimer or qualifying language that should be used? And we'll have a separate panel devoted to that question.

And third, while it is not an outgrowth of the Pearson decision itself, it involves many of the same parties and it also involves the issue of dietary supplements and health claims, and that is a question of: Should health claims go beyond claims about reducing the risk of the disease to also 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?

That will be the third panel. That's the result of a health claim petition we got with respect to Saw Palmetto and the treatment of BPH and we'll have a separate intro for that when we get to that panel this afternoon. So for now I will just put that aside and focus back on the first two Pearson questions that I've already gone through.

Now in terms of logistically how we're going to proceed through the day, number one is we will, on each of those three questions, have a panel presentation. These are people that have been invited to the FDA who are known to

have an interest and who are known to represent a spectrum of different views. We want to be sure that all different views are appropriately heard today.

Each of those speakers will be given 10 minutes to make their presentations. When you get here, you'll find logistically if you can possibly do it sitting at the table, it will make it easier than people jumping up and down, and I would encourage the speakers to start thinking now in terms of that. We're kind of crowded up here. It's okay when there's one of me.

Third is that following the three panels--sorry. What will happen with each panel is there will be the five presentations, four or five, depending on how many people there are, and then the FDA panel, which I'll introduce in a moment, will ask questions.

FDA is very much in a listening mode. Our questions will be designed to elicit information from the speakers, elicit potential differences between the different speakers. We'll allow the speakers to respond to each other during that phase. We have done this several other times, I think, pretty successfully in terms of fostering a discussion among the people out here.

I kind of consider this kind of meeting, if you will, to be a discussion between a small group in front of a larger group. But it tends to work if we can get a

discussion among the people and between the FDA folks.

There only are a few instances where the FDA gets to hold a meeting and not have to answer questions itself. This is one of those few times. So we will refrain from responding but we'll try, as I said, to be very much in a listening mode and in a probing mode to try to bring out all the important information.

Following the three speakers, there will be an opportunity for individuals who asked to present and you all will be given, if you've not already in your package, you will have a number, so we'll simply go in order from your numbers and everybody at that point will have five minutes. So to the extent people are already in the audience, I would really urge you to keep your presentations to five minutes. We've done this again on other occasions and it is very capable of happening. And out of respect for your other colleagues who also have to present, we do need to be out of the room on time.

Finally, I believe we're having a transcript made. I want to verify that with somebody in the audience who's going to nod their head. Is there a transcript being made of this proceeding?

Yes, there is a transcript being made of this proceeding. Good, it's up there. So there will be a full record of everything that is said here. In light of that, I

would ask for there not to be any other recording devices in the room. We are making the transcript and that will be available and we'll make that through our web page, and so forth.

Finally, there are some words on logistics I need to get to. Some of these I have probably covered, so just give me a moment.

Outside at the table, for those that did not see it, there are a couple of notebooks that have some of the background materials if anybody wants to refer to them in terms of the guidance on significant scientific agreement, a copy of the court decision in Pearson, our Pearson implementation notice, the structure/function final rule, information on how to access comments to the docket, and statements or testimonies of other speakers and presenters. We don't have copies for everybody but we do have some table copies if people want to refer to that during one of the breaks.

Ah, important information. Bathrooms. The women's bathroom is on the C Street side of the auditorium, which I believe means it's over there, the way you came in, down towards the end by the public doors. The men's room is on the Maryland Avenue side, which means you just have to kind of go and turn left there and it's right by the entrance to the cafeteria, as the plumbing goes, on the

other side of the plumbing. So if you find the ladies room, you'll be able to follow around and find the men's room on the other side.

Security--this is a government facility. People are aware of the security when you come in. Each time you go in and out of the building you will need to go through that again, as all of us do. If you have a visitor's pass, please hold onto that because you'll need that to get back in or you'll have to go through that process again. So please hold onto your visitor's badge and your ticket, especially if you're leaving the building.

Finally, just before lunch I'll try to remind everybody about the facilities that do exist for eating lunch. There is a cafeteria in this building. There are a number of places you can easily walk to outside of the building and we will try and remind you of that just before lunch.

Finally, as a courtesy to everyone if you would please, everyone, if you have cellphones, if you have pages, if you could kindly turn them off. You will be relieved from hearing from everybody and we will be relieved, also. As you know, it is a distraction to hear those things going off through the day.

If you have brought a copy of your comments or speech, please leave a copy at the registration desk so we

have a copy of that.

And finally, I have one correction, which is we issued a Federal Register notice that told everybody there would be provision for written comments. I jumped over that. When we were up there you saw the four things; it said written comments. We do welcome written comments following this meeting. The Federal Register notice states that the time period for that is essentially two weeks, which would close on April 19.

Now I highlight that for two reasons. One is that we sent out an advance letter notifying people of this meeting and in that letter we mistakenly said that the written comment period would be open for a full month. We decided to shorten it for 15 days in light of the fact that this matter is a subject of ongoing litigation and we want to get on with proceeding. However, I also tell people if you just can't get your comments in within that 15 days, FDA has a general policy of accepting comments up until we've actually made decisions. But really we urge people, if at all possible, to try and make it within that two-week period.

Finally, I just want to reiterate that I think everybody here--and look around the room; there's a lot of people that came to this meeting--there's a lot of interest in this meeting. Today you will hear a lot of different

views. You will not hear too many views that agree with each other. You'll hear a lot of views that disagree with other people's views. That is the nature of the subject. That is perfectly permissible.

The one thing I ask is that the deal I always make at these meetings, I say we at the FDA will listen to everybody if, in turn, you'll listen to each other. That, I think, is a fair deal and that everybody be respectful of everybody else's comments and maintain an appropriate decorum in the room through the meeting.

With that, I look forward to what we are about to undertake today. This is, I think, an important area for many interested groups. And with that, I will, I think, begin by welcoming the FDA panel to the stage. In doing that, the others will see, I guess, to get up here you've got to walk up and around the edge. But as we're welcoming the FDA panel up, I'll let them take their seats and I'll introduce them and then I'll move over there, also.

Speakers note the delicacy with which one enters the chairs, since it looks like they touch each other. So a deep breath is also appropriate.

As people are taking their seats, I'll be sitting on the end, so I've already introduced myself. To my immediate right is Christine Lewis, who is the new director of our Office of Nutritional Products, Labeling and Dietary

Supplements in the Center for Food Safety and Applied Nutrition.

Sitting to her right is Michael Landa, who is now the deputy chief counsel in the Office of Chief Counsel. Mike has recently returned to FDA after a long career first in FDA and then out in private practice. We're delighted to have Mike back.

Next is Peggy Dotzel, who is the Acting Associate Commissioner for Policy in the office of the Commissioner. And finally, next to her is Dr. Rachel Behrman, who is from the Center for Drug Evaluation and Research. I think many of you know that in many of these areas, the two centers are working collaboratively. We recently had a meeting just last week dealing with structure/function claims and pregnancy claim issues and at that case, the Center for Drug Evaluation had the lead and we were there in the supporting role, so we are trying to work together on a number of issues.

With that, if you'll just give me one moment to take my seat, I think they're going to do something with the podium and we'll invite the first panel up there. Again thank you very much for your attention and for your participation in this meeting throughout the day.

PANEL I

MR. LEVITT: Okay, if we could welcome the first

panel up? We've tried to make life easy for you by putting your name tag where you sit and by putting them in the order so we'll be able to go right down the table.

First is Jonathan Emord from Emord & Associates. Then Bruce Silverglade, Center for Science in the Public Interest. Bruce Chassy, University of Illinois. John Hathcock, Council for Responsible Nutrition. And Alice Lichtenstein from Tufts University.

I won't make the mistake of asking if everybody's comfortable. I will ask if everybody feels that you're at least situated in a way that you can participate.

All right. What we will do then, if we could ask the microphone to be moved down to Mr. Emord. We have, I guess, two microphones for five people.

The only thing I'll point out to the speakers is the timer is actually sitting right in the middle, in front of Bruce Chassy there. It has a 10-minute timer associated with it. There is maybe a yellow light that goes on with three minutes left. If you see that, that's what it means. If not, the red light will go on after 10 minutes and if you see that, I would ask that you try to summarize, in fairness to the other speakers and getting going today.

With that, Mr. John Emord, if you would begin.

JONATHAN W. EMORD, EMORD & ASSOCIATES

MR. EMORD: Thank you very much.

The questions posed to the panel are, in fact, legal issues that have already been resolved in a final and binding order of an authority higher than this agency, the United States Court of Appeals for the D.C. Circuit, in the case of Pearson versus Shalala. The questions are thus res judicata. They have been judicially acted upon and decided. They're settled by the judgment of the court.

It is thus not the time to ask these questions. It is, rather, long past the time for the agency to comply with the court's order.

In Pearson versus Shalala, the United States Court of Appeals held unconstitutional under the First Amendment the four FDA rules that suppressed four separate health claims my clients wish to make. The court's decision invalidated the agency's rules. As a matter of law, the rules are of no legal force or effect. Yet FDA continues to enforce them.

The court's mandate to implement its decision issued to this agency on April 20, 1999. Upon receipt of the mandate, FDA's duty was clear. It had to discontinue enforcement of the invalidated rules immediately and it had to allow my client's claims to be made with dispatch.

In flagrant defiance of the court's order, this agency, over 11 months later, still enforces all four of the constitutionally invalid rules. Moreover, it has adopted a

cumbersome, extensive and protracted series of regulatory steps that it intends to take before finally addressing the court's constitutional mandate. Those steps appear calculated to postpone FDA compliance with the court's order for years. FDA is thus engaged in a pattern of delay and denial of its constitutional duties.

This past Friday my firm filed an application for preliminary injunction with the United States Court of Appeals to stop the agency from continuing to enforce the four invalid rules. FDA's continued enforcement of those rules is an act of contempt in the face of a final and binding order. It is an act that challenges the supremacy of the Constitution over contrary agency laws. It is an act taken by officers of this agency, who have sworn oaths to support and defend the Constitution. It violates those oaths.

To be sure, FDA is not above the law. It is certainly not above the Constitution. The Constitution is the supreme law and FDA must obey it. FDA should take heed and immediately, this very day, discontinue enforcement of the invalidated rules. It should authorize all four of the plaintiffs' health claims with the disclaimer specified by the court, at least on an interim basis. It may thereafter proceed with its rulemaking to determine precisely how, if at all, it should tailor those disclaimers. But it may not,

consistent with the First Amendment, continue to suppress my clients' protected speech, their health claims, for a moment longer.

The Supreme Court has held violation of a First Amendment right even for a very short period of time an irreparable injury. See Elrod versus Burns, and I quote: "The loss of First Amendment freedoms for even minimal periods of time unquestionably constitutes irreparable injury."

When First Amendment rights are violated, the Supreme Court expects government to eliminate the violation without delay. It considers delay intolerable. See Riley versus National Federation of the Blind and I quote: "Speakers cannot be made to wait for years before being able to speak with a measure of security."

So then what are the Court of Appeals' legally binding answers to the questions you pose? The Pearson court held that FDA may not suppress health claims on the basis that they do not satisfy its significant scientific agreement standard, regardless of how FDA defines that standard. In letters to me of October 5, 1999 and February 17, 2000, Director Levitt accepts this legal requirement.

Thus separate from FDA's health claims review standard by which FDA officially authorizes and approves claims under 21 U.S.C. Section 343(r) is the First

Amendment, by which it must allow even claims it does not authorize and approve if those claims can be rendered nonmisleading through the addition of a disclaimer. FDA may not substitute a new scientific validity test for the First Amendment standard articulated in the court's decision.

The Constitution is supreme law and the agency must ensure protection for all lawful commercial speech, not just a subset of that universe. The FDA must do so in strict accordance with the standards articulated in the Pearson decision itself.

Consistent with rules of statutory construction, FDA may not construe its statutory obligation under 21 U.S.C. Section 343(r) as in conflict with the First Amendment. See generally De Bartolo Corporation versus Florida Gulf Coast Building and Construction Trades Council.

Rather, as the Pearson court explained, under the statute, FDA must define a procedure and standard for authorization and approval of health claims, but under the First Amendment, even if a claim is not authorized and approved by the agency, it must nevertheless be allowed to be made so long as the addition of a disclaimer can render the claim nonmisleading.

The purpose of the disclaimer is to inform consumers of the lack of conclusive evidence for a claim and of such other information as is necessary on a case by case

basis to avoid consumer misperception.

In light of the infinite variety of potential nutrient disease claims, case by case evaluation is unavoidable. The Pearson court held that inconclusive health claims may not be suppressed by FDA unless they convey no scientific information or unless they otherwise cannot be rendered nonmisleading through the addition of a disclaimer. Rather, FDA's remedy for inconclusive claims is the addition of a disclaimer, making the inconclusiveness clear to consumers.

The Pearson court squarely placed the burden upon FDA to favor disclosure over suppression in every instance where a disclaimer can eliminate a misleading connotation. Thus, for example, if a claim accurately conveys a nutrient disease association, FDA must allow it, even if the agency believes the evidence preliminary, unless FDA also reasonably finds no disclaimer capable of eliminating a misleading connotation.

The First Amendment makes FDA, like every other government agency that censors speech, need a high threshold burden of proof to justify claim suppression, proof that a claim cannot be rendered nonmisleading through the use of a disclaimer. The general rule is disclosure of information. That is the constitutionally preferred means for overcoming misperceptions in the market.

Turning to the four claims at issue in Pearson, this agency should note well that the court found all of the claims, at worst, only potentially misleading. The court wrote specific disclaimers for each of the claims, to cure that potential. The court explained that FDA could avoid the erroneous public view that the agency had authorized the claims by including an additional disclaimer; to wit, "FDA does not approve this claim."

Given the Pearson court's constitutional order to this agency, FDA must immediately discontinue enforcement of the four invalidated rules and must, until it ultimately decides the precise language it prefers for the disclaimers, authorize on an interim basis all four Pearson claims with the disclaimers the court has recommended.

Pearson tells this agency that its legacy of suppression must come to an end, that it must henceforth favor disclosure over suppression as the rule, not the exception, that it may not use its health claims review standard as a barrier to the communication of any claim that can be rendered nonmisleading through the addition of a disclaimer, and that the court will view as dubious any agency justification for suppression that is based on the alleged benefits of public ignorance.

Consumers can make choices they perceive in their own best interest if well enough informed. It is the

constitutional duty of this agency to ensure that they are so informed and to favor disclosure over suppression as its standard practice. Thank you.

MR. LEVITT: Thank you very much.

If we could pass the microphone over to Mr. Bruce Silverglade from Center for Science in the Public Interest and if we could reset the timer.

BRUCE SILVERGLADE

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

MR. SILVERGLADE: I'm going to wait till that timer's reset.

Well, as you stated, there is going to be some disagreement on the panel and perhaps not surprisingly, we have a different reading of the court's decision.

The U.S. Court of Appeals held in Pearson versus Shalala that based on the administrative record before it, the Food and Drug Administration must consider whether the use of a disclaimer would eliminate the potential for deception before the agency decides to prohibit health claims not supported by significant scientific agreement. So I think we have a basic disagreement right now because we believe the court's decision should be read as just requiring the FDA to consider whether the use of a disclaimer would eliminate the potential for deception, not require it in all cases.

Moreover, the court created at least three major exceptions to its overall holding and discussed the situations in which disclaimers would not be sufficient to prevent consumer deception and need not be considered by the FDA as a possible course of action. These include situations in which first, permitting a health claim not supported by significant scientific agreement would threaten consumer health; second, where scientific evidence supporting a health claim is outweighed by evidence that is qualitatively or quantitatively superior; and third, where empirical evidence demonstrates that a disclaimer is insufficient to protect consumers from deception.

These exceptions to the court's primary holding significantly limit the number and types of health claims that can be made in the absence of significant scientific agreement. And today I am releasing a letter from 15 national public health medical and consumer organizations to the FDA that urges the agency to fully implement this portion of the court's decision. And since the letter is addressed to Mr. Levitt, I thought I'd pass it down, pass it over at this point.

The organizations urging the FDA to follow the course it has taken in this area include the American Association of Family and Consumer Services, the American Association of Retired Persons, the American Cancer Society,

the American College of Preventive Medicine, the American Dietetic Association, the American Heart Association, the American Institute for Cancer Research, the American Public Health Association, the American Society for Nutritional Sciences, Consumer Federation of America, the National Consumers League, Society for Nutrition Education, and the Association of American Medical Colleges.

Let me, in my remaining time, more fully elaborate on the exceptions to the court's opinion that I have outlined. First, the FDA is not obligated to consider using the disclaimer approach when a preliminary health claim raises health and safety concerns. It should be emphasized that the court's overall holding was premised on the basis that supplements at issue in the case do not "in any fashion threaten consumers' health and safety." I'm quoting the court.

However, since the court's opinion there's been a steady stream of reports concerning the hazards of dietary supplements. The Washington Post, for example--I'm sure those in the audience who live in the Washington area saw this article a couple of weeks ago--ran a front page story that proclaimed "Herbal products boom take human toll."

So the government apparently did a poor job of bringing this type of information to the court's attention and the court simplistically assumed that supplements in

general pose no health hazard.

In light of this naive assumption, the relevance of the court's primary holding is quite limited. As the court noted, kind of as an afterthought, "The government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the products affect health," and again the mistake of the court and the mistake of the government was not to bring this evidence before the judiciary and the court again naively assumed that all supplements are safe. That was really a very unfortunate mistake.

Health claims for dietary supplements that are not supported by significant scientific agreement can have an adverse impact on health in several ways, so let me talk about this in just slightly more detail.

First, health claims that are preliminary and relate to essential bodily organs or serious health conditions may certainly affect. And under the court's opinion, the FDA need not and should not consider using the disclaimer approach if a proposed claim not based on significant scientific agreement pertains to such situations.

So, for example, claims regarding the heart, lung, brain and liver and claims regarding serious health conditions, such as risk factors for cancer and heart

disease or conditions such as asthma, birth defects, HIV and so forth, these are not the place to make preliminary health claims with disclaimers and the court recognized that in such situations where consumer health or safety is involved, claims supported by preliminary scientific evidence would be inappropriate, even if accompanied by a disclaimer. You simply can't disclaim the core of the problem in that area.

And the court's holding on this point is well grounded. I would note that in the 1990s beta carotene supplements were being touted by the supplement industry as substances that might reduce the risk of cancer. Preliminary studies did demonstrate a promising link between the consumption of beta carotene-rich foods and reduced risk of cancer but later clinical studies showed strong evidence of actually no benefit from beta carotene supplements and indicated that the use of such products by smokers might actually increase their risk of lung cancer.

So that situation we had with beta carotene really shows the health risk involved with allowing preliminary health claims, and this was recognized by the court, although not the focal point of its decision.

Second, health can be affected when a preliminary health claim would cause consumers to forego a proven dietary or other therapy in favor of a supplement that may or may not be beneficial. As the court recognized, the FDA

may choose to suppress claims not supported by significant scientific agreement in situations where supplements affect health and preliminary claims for supplements that may not be beneficial can cause injury to consumers if they lead the public to choose them over proven approaches to medical or nutritional problems.

So thus, under the court's holding the FDA is not obligated to permit preliminary health claims with a disclaimer if the claim would lead consumers to rely on an unproven supplement instead of a proven dietary or other therapy.

Third, the FDA need not consider using the disclaimer approach when consumers, based on their own observations, cannot determine whether a claim is true. Consumers who rely on preliminary health claims and take dietary supplements for conditions that are difficult to self-diagnose have no way of knowing whether the products are really working.

The use of a preliminary health claim not supported by significant scientific agreement is particularly dangerous in such cases because it may lead consumers to rely on treatments that are not effective. And the court's decision in Pearson does not require the FDA to approve preliminary claims with a disclaimer if the health and safety of consumers are threatened, as it would be in

that situation.

Now, the second major exception to the court's holding that I outlined earlier was that FDA is not obligated to consider disclaimers when a claim is outweighed either quantitatively or qualitatively by superior evidence. I think this speaks for itself. It calls on the agency to engage in a weighing of the scientific evidence, and the FDA is certainly equipped to do that and make that determination.

The third major exception to the court's holding that I outlined earlier was that the FDA is not obligated to consider permitting preliminary health claims when empirical evidence shows that the claim disclaimer is insufficient to protect consumers from deception. Let me discuss this in a little detail.

The court, in Pearson, stated that disclaimers would not be required where empirical evidence that disclaimers similar to the one suggested by the court would bewilder consumers or fail to correct for deceptiveness. The Food and Drug Administration should thus conduct research so that it can obtain empirical evidence indicating when and when not disclaimers prevent consumer deception.

The Federal Trade Commission has conducted a study on health claims in advertising and that study did conclude that certain types of disclaimers are insufficient to

protect consumers. Now it's the Food and Drug Administration's turn to conduct its own research on dietary supplement labeling claims.

The examples of the disclaimer suggested by the court in Pearson, in our view, do not provide consumers with any useful additional information to help them evaluate the safety and health benefits of a supplement. The court suggested simply informing consumers that the scientific evidence is inconclusive or that the Food and Drug Administration has not approved a claim. But that type of statement merely constitutes a disclaimer of responsibility. Such statements do not provide consumers with additional useful information to remedy an otherwise misleading claim.

There is a vast difference between merely disclaiming responsibility and disclosing useful information that qualifies an otherwise deceptive statement. While the court expressed confidence in the specific wording of the disclaimers that it suggested the FDA utilize, it did not "rule out the possibility" that its suggested approach would "bewilder consumers and fail to correct for deceptiveness."

So the court itself admitted that its suggested disclaimers in its opinion were not foolproof and it conceded that it wouldn't rule out the possibility that the disclaimers it suggested in its opinion wouldn't work. So it's therefore incumbent upon the Food and Drug

Administration to conduct the necessary research and resolve the court's uncertainty about its primary holding.

In conclusion, the Pearson decision, by its own terms, significantly limits the applicability of its primary holding to the FDA's health claim review process. And each of the factors that I addressed and that are addressed in the letter by the 15 national health and consumer organizations to the FDA need to be considered by the agency before any health claim, including those four at issue in the Pearson case, is permitted in the absence of significant scientific agreement. Thank you.

MR. LEVITT: Thank you very much. I'm always amazed how much good information people can get in in 10 minutes.

Next is Bruce Chassy, University of Illinois.

BRUCE CHASSY, UNIVERSITY OF ILLINOIS

MR. CHASSY: Well, I'm going to take a different tack, Joe. I'm not going to have a great deal of information. I'm not burdened by any knowledge of the law. I can speak maybe as a scientist who's been in this field for a number of years might look at some of these issues and they're somewhat different than the legal issues that we've heard from the first two presenters.

The first thing I'd like to do is talk a little bit about the context in which we have dietary supplements

and health claims and then take a couple of moments to talk about the actual health claim standard as it's applied and what it means to consumers and how they get information related to health and dietary supplements and then see if we can't put it together with answering the two questions posed to this panel.

We have a very heightened interest in diet and health in this country. That is very clear. It's in the media. It's the subject of a court case today. It's something that has perplexed scientists, consumers. Certainly the dietary supplement industry, a very consumer-driven industry, is scrambling to stay ahead of consumer demands in this area and to respond to newly emerging science. So I think we all agree that there's something very important and very compelling here.

I personally find it paradoxical in that we've been trying for about 30 years to get people to eat a proper, balanced diet and follow the dietary guidelines and suggesting to them that that is perhaps an avenue toward better health and, at the same time, we're finding that there are certainly indications that specific compounds, specific dietary supplements, specific foods are health beneficial, health protective, and offer promise to consumers.

So we sort of have this balance between when do we

depart from a recommended dietary pattern and supplement it with something that we believe will enhance or protect our health. That's a tough decision for a consumer to make each day when you can clearly see that it's a difficult decision for scientists to make.

As a result of it being a difficult decision as to when to allow a health claim, I can see that it is very difficult for the courts to decide when to allow a health claim. It seemed to me in the legal arguments we just heard--as a scientist, not as a lawyer--that we're protecting First Amendment rights perhaps, according to the court, but not looking at the scientific facts and publications in the case, which I think are also important.

I like the 1999 guidelines that the FDA has put out on significant scientific agreement and one point in particular that I think is extremely important is that the kinds of recommendations that come with a health claim are recommendations which are based in sound science that is not likely to be reversed. It may be altered or modified--I'm paraphrasing the words--but it's something that a consumer can believe in. That promotes a confidence in science, it promotes a confidence in the agency, and, as the speaker to my right just pointed out, it protects the health of consumers because we have at times found that what looked to be very promising dietary supplements, foods, turned out to

have a down side.

The problem, of course, is that the process of reaching significant scientific agreement is not clear to scientists, let alone consumers, lawyers, regulatory agencies or anyone else, because it's different in each case. As the document points out, you could very quickly reach a significant scientific agreement where the data was clear, the mechanism was clear, the epidemiology was clear and you could, in other cases, have, for example with soy and cancer, have more than 125 or 150 studies with still no clear significant scientific agreement about the relationship between consumption of soy and cancer.

Well, what are we to do? Well, let's think a little bit about what consumers--where they get their information and what health claims mean to them and maybe phrase it in what we learned from the Keystone Dialogue on health claims on food products, wherein the FDA was requested by the food industry as a recommendation, or at least by the Keystone Dialogue, which was government, academic, industry, consumer groups, to create at least a faster approval process for dietary health claims, and I think I'm going to, as I say, apply that to supplements, and to make shorter, simpler health claims available to consumers.

The FDA has worked on both of these and I think

this is a very important feature. And the reason why is the one thing that nobody has mentioned today is where these health claims appear. They appear on a bottle or a package, the label of a food product or a dietary supplement in this case.

It is very clear that you can't put a whole lot on a label. In that regard I find the court's disclaimer almost laughable. Can you imagine print small enough to read those disclaimers on a dietary supplement label?

What data from the FDA and from marketing surveys showed about health claims on food packages is that shorter is actually better and a long, complicated, legal description on a package is not likely to be read by a consumer. In fact, consumers tend to disregard health claim labels. I don't know why the industry is so interested in health claims if it was just to put the health claim on a label because consumers know that what you find is claims on labels and you disregard them and you turn around and look at the ingredients and see what's in there if you're really interested.

It seems to me that a suppression of First Amendment rights in this case on a label may very well be justified if you can't tell the whole story, but I would also suggest that First Amendment rights are in no other way suppressed because most consumers get the information that

they need about dietary supplements or foods from somewhere other than a label. Usually they go into a store with a purchase in mind. They do not shop health claims along all the bottles and packages on the shelves.

There is an education component involved here. People learn from the media. They learn from the press. They learn from magazine articles. They learn from friends. They learn by going into stores that sell these products and asking people what you can do for this or that or what'll help me with whatever it is. There are a whole variety of ways that people learn about health claims and learn about healthy, efficacious products and there's certainly a wide variety of products out there today.

At times, it's almost like a fad. Things go in and out of style. It must drive the industry crazy trying to make high quality, efficacious products and chase consumers around.

Well, why are they chasing consumers around? Because consumers are getting a lot of information and expressing their desires for various kinds of products. We live in a consumer-driven society.

My contention here is just very simply that there are many avenues for First Amendment expression for companies wishing to offer products. In fact, the shoe is really on the other foot. The consumer is driving the

company to offer the product. I don't think the health claim has any particular value. I don't mean to offend the FDA or the law or the industry in this but I think consumers know better than any of those what they want and what to believe in and I do not believe a little bit of geography on the front of a label is going to either educate, inform or persuade a consumer to buy that product.

To me, that is really the important point because significant scientific agreement is a very high standard, a very difficult thing to define. I understand the court's impatience with it. Scientists can't even do it.

But if you're going to put on a label that something is supportive or preventive or protective of health, it ought to be able to endure. And I just think by definition, emerging science is science which we do not know will endure, which has not met the highest standards.

What we could do is try to make the approval process faster. There are a couple of ways to do that. One is to support more research and to try to get answers faster. Another is to try to constitute some sort of board or body or collection of scientists who basically are supported, maybe more support to the FDA so that they can get a panel to do this--there are various ways you can think about it--to review the literature and to review the science more quickly and to reach decisions more quickly without

changing the standards might facilitate both industry and consumer interests, and I'd be very much in favor of that. But I think changing the standard of what significant scientific agreement is or applying a lower standard would be, from a scientist's point of view, at least, terribly misleading, I think, to a consumer.

So rather than compromise standards, at the very worst, maybe we need to create a category called emerging science claims and let people make emerging science claims, of which there will no doubt be hundreds or even thousands, and they will in an almost anarchic way become meaningless to consumers. I see that as the logical end of the court's point of view.

MR. LEVITT: If you could try to summarize, please.

MR. CHASSY: Oh, I didn't see the lights. I think that's probably a good place to stop. Emerging science is just that. It's not proven science. We're interested in protecting and informing consumers. An emerging science that is uncertain does not inform consumers. Nor do I think labels on bottles inform consumers. Thank you.

MR. LEVITT: Thank you very much.

The next speaker is John Hathcock, Council for Responsible Nutrition.

JOHN HATHCOCK

MR. HATHCOCK: Thank you, Mr. Levitt.

In planning my remarks, I note that the second question to this panel refers to the basis for claims that are not to be based on significant scientific agreement. This seems to me to open the door for responses that may also apply to the questions posed to some of the other panels, and I may do so, but believe me, I'm going to be brief and I think I'll be well under 10 minutes, even though I may go outside the--

MR. LEVITT: We'll give you license.

MR. HATHCOCK: Consumers have a right to useful information that is truthful and not misleading and thus is acceptable under the general misbranding provisions of the Food, Drug and Cosmetic Act. Congress imposed a higher standard for health claims under NLEA, however. But the Pearson decision determined that the First Amendment prohibits FDA from restricting label statements that are truthful and not misleading.

NLEA provided FDA with the opportunity to set a different set of requirements for supplements than for conventional foods, but the agency went through the process and opted to set the same standard.

The Pearson decision, however, now prohibits any standard for health claims for supplements other than the

primary one for all label information; that is that the claim must be truthful and not misleading. The FDA has consistently misinterpreted NLEA to mean that there must be "significant scientific agreement" on the totality of the evidence to support the--and I underline the word--relationship between the dietary component and a disease or health-related condition. This interpretation of a relationship though, as the basis for the claim, directly contrasts with the wording of NLEA, which states explicitly that it is the claim that must be the subject of significant scientific agreement.

The Pearson decision seems to have rendered moot the significant scientific agreement standard under NLEA. Whatever definition or guidelines may be worked out by the agency through the rulemaking process, under Pearson, claims that are truthful and not misleading must be permitted for dietary supplements.

Nevertheless, I do not believe that claims based on conflicting or weak evidence must now be permitted. The power to decide whether a claim is misleading, even if it is literally truthful, gives FDA the authority to prohibit claims that are exaggerated beyond the substantiation and to prohibit claims that are based on evidence that is so weak that no amount of qualification could justify them.

Clearly the Pearson decision permits claims if

qualifiers or disclaimers are sufficient to prevent them from being false or misleading. I believe that the word "may" that goes into a lot of claims, however, is not a very significant qualifier except when the evidence is strong enough to meet the significant scientific agreement standard and there, it seems to be the choice word for avoiding the word "will." "May" is used so that we don't say "will."

The Federal Trade Commission has a set of effective regulatory practices that set the quality and quantity of substantiation required in proportion to the strength of the claim. Similarly, a structured hierarchy of claims, properly categorized and each with its corresponding level of required evidence, perhaps this emerging science evidence that we just heard referred to, may be a useful approach to qualified claims that are to be regulated by FDA.

Identification of such a system, of course, would require innovative, assertive and ultimately cooperative rulemaking. The impact of the Pearson decision, however, clearly is to place the burden on FDA if it wants any substantive involvement in the regulation of claims for dietary supplements.

I believe that the Pearson decision will allow FDA to prohibit claims when the evidence is any of these three: equaled or outweighed by contradictory or contrary evidence;

qualitatively weaker than the contradicting evidence; and third, null or negative. In such cases, no amounts of qualifiers would keep the claim from being misleading. If it were mere speculation and there was no evidence whatever, I believe it would be misleading to mention the possibility, untested.

Nothing in the Pearson decision directly addresses safety. The authorized health claim for calcium illustrates a reasonable use of the quantitative limits and cautionary language. Under all current food provisions of the Food, Drug and Cosmetic Act, safety is a separate issue from benefit, as this panel well knows. Although the FDA's language in approval of certain food additives does make some motion toward the type of risk-benefit analysis required under new drug applications, I think there the agency pushed a bit to try to justify approval of certain food additives.

FDA should recognize that the educational aspects of its regulations of products and labels cannot provide all relevant information that the consumer needs. Resources permitting, however, FDA can initiate educational programs that go beyond the mere regulation of a label.

I believe that there are no general all-applicable bright lines between reduce the risk and treat for a disease. The use of dietary calcium to build bone density

or to reduce the loss of calcium may reduce the risk when the intake is early in life and it may be more of a treatment when it is used to slow the losses that occur later. I think that the boundaries between treat and reduce risk are artificial and you'll have a hard time doing rulemaking that'll satisfy everybody on that.

Health claims would have been considered drug claims prior to NLEA. FDA's distinction between the language permitted under NLEA, such as "reduce the risk," and drug claims such as "prevent" may be a useful model for claims about effects on risk factors versus symptoms of disease. That's going to require a lot of thinking through of the various options and implications.

The Council for Responsible Nutrition believes that the appropriate health claims should be authorized without regard to whether they seem to overlap or duplicate the FDA OTC drug provisions. A justified health claim on a topic addressed by an OTC monograph--that is a health claim for a food on a topic addressed by an OTC monograph might trigger reexamination of the basis and scope of the OTC claim and it is high time that food regulations help to set the scope and application of drug regulations, rather than always the other way around.

To conclude, the Pearson decision resulted from a long-standing, de facto, more rigorous standard for claims

on supplements compared with those on conventional foods. The quick approval in the initial review of a health claim for low-fat foods in relation to reduced risk of cancer contrasts starkly with the initial and protracted denial of the now-approved health claim on folic acid in relationship with reduced risk of neural tube defects.

Although much more evidence for the neural tube defect claim has now accumulated, nothing has changed the conclusion from the original Smith et al's nonblinded clinical trial, a clinical trial that was not allowed to be blinded because the evidence was too strong already.

As an FDA employee at the time,1 I recommended two years before NLEA was passed that we develop a national policy to get more folic acid into young women who might get pregnant. It is now time for an evenhanded attitude toward dietary supplements compared with those for conventional foods. Thank you.

MR. LEVITT: Thank you.

Our final speaker is Alice Lichtenstein from Tufts University.

ALICE LICHTENSTEIN, TUFTS UNIVERSITY

MS. LICHTENSTEIN: Well, not only am I not burdened by any of the legal arguments but I also feel that I've just sort of come out of an ivory tower. But having said that, also having been involved with the recent dietary

guidelines that were just submitted from the advisory committee that were just submitted to Health and Human Services and USDA, which was an evidence-based process and now being involved in the macronutrient panel for the new DRIs, which again is an evidence-based panel, so initially I took the questions that were posed for the panel quite literally and said, well, should health claims be allowed on dietary supplements on a basis other than significant scientific agreement and said well, you can't really answer that until you think what would the other basis be for that? That's what I'm going to address. Is there any other good basis that we could use and then feel confident that the information that was given to the consumers would actually be accurate and would be a service to the consumer?

So what would the potential criterion be? Well first, how do we establish the relationship between a nutrient and health? And usually there are two types of information that one gets. One is sort of association and that's more the epidemiological data and then from that, frequently there are interventional trials which then actually test the hypothesis.

Could we not necessarily need the intervention trials but stop at the point of association? There again there are certain questions that need to be posed. Why, prior to this, did we really feel we needed intervention

trials and couldn't just look at associations and assume that we could make conclusion on that basis?

Well, the issues are that when you do have associations, you look at a population and let's say you see that a certain nutrient is associated with a certain disease or a lack of a nutrient is associated with a disease. You have to ask certain questions. Were you adequately able to actually assess nutrient intake, which means was there accurate reporting?

Well, we know that there's not accurate reporting, that people tend to underreport. You can see that for energy and then, by implication, all the other nutrients that come along with it.

Is there no bias in reporting? Well, again we know that if you're doing a study on fat, you're asking people about fat intake and there is going to be a bias in that they think that you want to hear that they're consuming less fat. They're going to tell you that they're consuming less fat.

Now with newer approaches to look at things like energy intake doubly labeled water, we know that from the observational stuff or observational data that actually that isn't the case as far as underreporting.

Also, if you get information, you get data from people on what, let's say, they're consuming. Then you want

to relate that to disease outcome. You also have to assume that the database on which you are assessing the dietary intake or nutrient intake is adequate and we know that the databases are not that accurate and complete, especially for the newer biologically active components of nutrients that there's a lot of current interest in.

In addition to which drawing conclusions just from association data are dangerous because of confounding, that we know, let's say, nutrient X is associated with also the intake of nutrient Y, whether it be something like beta carotene with fruits and vegetables and Vitamin C, so you really don't know if it's one or the other.

Then we also know that there are certain lifestyle behaviors that are associated with certain nutrient intake, so that people that eat more fruits and vegetables tend to be more active and they tend to smoke less. So it becomes very difficult to attribute the observation of either increased or decreased risk of a certain disease to whether it had to do with the nutrient that you can measure more accurately than the other nutrient or you have more discriminatory power, or whether it has to do with other lifestyle behaviors.

I'd like to now give you a couple of examples about why I think there needs to be significant scientific agreement, and that has to do with some of the recent cases

that we've had where there have been some indications that Vitamin E was associated with decreased risk of cardiovascular disease, yet when the intervention studies were done, whether it be the GISSI study that just came out of Italy, whether it's the HOPE study that just came out of Canada, the alpha tocopherol beta carotene study that came out of Finland, really in none of those cases was there a positive association between taking Vitamin E and decreased risk of cardiovascular disease. There was only study, the CHAOS study, and there was some concern regarding control of that study. And similarly with cancer, the effect seems to be null.

As was already brought up, there is the beta carotene issue, which looked very hopeful with respect to cancer and cardiovascular disease because increased fruits and vegetables is associated with decreased risk and also a lot of biochemical data to suggest the positive effect of beta carotene on malignancy. And again we have a number of studies. The first was the alpha tocopherol beta carotene study, again from Finland, showing a null effect on cardiovascular disease, perhaps in smokers a negative effect of the beta carotene; the CARET study in the United States again showing a null effect on cardiovascular disease and cancer.

Then we have a situation which is a little bit

different and again, how do you come up with an assessment here? This is with folate, that folate has already been mentioned with respect to decreasing the incidence of neural tube defects and good intervention study. There's also a lot of interest with respect to cardiovascular disease. There's now mandatory fortification. The mandatory fortification did have the effect of increasing folate levels in the population, decreasing homocystine levels, population-wide.

However, still we don't know what the outcome is going to be with respect to cardiovascular disease. From a biochemical level you would predict a decreased risk of cardiovascular disease, but we don't know.

And then the last example is Vitamin C and what I'm going to do is cite three news reports that came out, that consumers are actually being exposed to. One was--and these all happened this month. The first one is March 9. It was an Associated Press story and it said Vitamin C supplement intake and progression of carotid atherosclerosis, Vitamin C supplement use associated with progression of arterial thickening. You think, "Oh, no." Would you make a claim there saying that people shouldn't use Vitamin C on the basis of one study? No, unlikely.

Then March 27, doctors warn against big doses of Vitamin C in cancer treatment. Vitamin C might

inadvertently protect tumors from radiation and chemotherapy. Again this is something that the consumer is being exposed to. This was actually just made on the basis of cell culture work.

But then, the next day, Vitamin C and E protect against aging brain. Vitamin E and C supplements may protect against vascular dimension, may improve cognitive function later in life.

Okay, so here the consumer is now, just in one month, being exposed to a lot of different claims. It's sort of a ping-pong thing back and forth with respect to Vitamin C. What would you put on the label? Could you adequately put all that on the label? Would you really want to put all that on the label? I think most scientists would say one study doesn't mean anything.

Would you do a tally sheet--five good studies, four bad studies or five bad studies, four good studies and then you would put a claim on the label on that basis? No, probably not because not all studies are equal and not all the evidence is compelling from the different studies, which is why I think you have to go back to significant scientific agreement from a group of individuals that are familiar with the strengths and limitations of the totality of the body of scientific data.

I think we're very much hampered because we are

limited still, even in the year 2000, we're limited with respect to what we know about essential nutrients. We're not sure we have identified all the essential nutrients. Although we have a list, we know that there are other nonessential biologically active components. We know that the intake of some nutrients will impact on the intake of other nutrients as far as requirements go. So I think we need to be concerned that if a claim is made for a certain supplement and that the intake is increased of that specific nutrient, will it have an effect on the other one? We have well established ones with respect to things like selenium and Vitamin E but there are a lot of others with respect to minerals and altered absorption.

There are also interactions--well, those really are the interactions. There are also issues related to whether an individual is taking what I'd call sort of more in the physiological range of a nutrient versus a pharmacological range. In both cases they can potentially be valid. Physiological ranges of nutrients can also impact on the biological effect of each other. Then you have something like niacin, which can be used in pharmacological levels as a hypocholesteremic agent. Again we certainly have data about that and what the side effects are but with a lot of the other nutrients, we don't really have that data.

So what it comes down to, and unfortunately I can't see the light. Am I on yellow on red?

MR. LEVITT: You're doing okay.

MS. LICHTENSTEIN: Great. So I'm posing essentially now some open questions because I think that it's very difficult to come up with criterion other than scientific agreement. And one is, and I think this was touched on by one of the speakers, that there's a lot we don't know about how this information would be used by consumers. How do consumers use health claims on dietary supplement labels, both the intended use and the actual use?

Do health statements on dietary supplement labels effectively communicate the message? And I mean that in terms both of accurately and understandably. Because if it's not, then what's the use of having it? We're fooling ourselves if we think just by giving the information, that's our responsibility and now it's caveat emptor, buyer beware. I don't think that that's an appropriate burden to put on the consumer.

Were supplement information to be added to nutrient labels, again, how would it be interpreted?

Another open question is would health claims on dietary supplement labels alter food choices and displace conventional treatment? I think it's something sometimes we throw up those red flags as issues of concern. I think it's

something we really don't know that much about.

However, you can now go and get something like a vegetable concentrate and maybe the vegetable concentrate can make the same claim as if you eat fruits and vegetables, has all the nutrients, but what other impact does it have on the diet? Does that mean--is that equivalent to eating a diet that's high in fruits and vegetables and perhaps not eating other things or just taking a concentrate of vegetables and then eating all the other types of foods that may not be associated with the positive effect on that disease? Will the information and the claims alter consumers' choices with respect to other health treatments?

Again I think it's something that we don't know about but we should know a little bit more about.

Should health claims be allowed on dietary supplements on a basis other than scientific agreement? At this point I would say no and I'd say we really have to look at the risk-benefit ratio and we need to first keep in mind, first, do no harm.

FDA PANEL DISCUSSION

MR. LEVITT: Thank you very much. Thanks to all five of the speakers.

We'll now proceed to the more active dialogue section. Again just to remind everybody, the process we'll use is each of us will try to ask one question. My

experience is rarely does only one person want to answer, so we'll give whoever in the group who wants to answer the question an opportunity, beginning with me.

And I think I'll pick up where the last speaker left off, which is I'll say notwithstanding some of the difficulties that you point out, the court has instructed us, as the first speaker said, to look at these claims and as a threshold matter, to look at does the evidence for the claim outweigh the evidence against the claim?

If you were the FDA, how would you do that?

MS. LICHTENSTEIN: The only way I could see doing it is collecting all the evidence because you don't want to just collect all the good evidence and it wouldn't be right just to collect all the bad evidence for the example being just this month in Vitamin C.

I can't see getting around not collecting all the evidence, looking at it, looking at the quality of each individual piece of evidence and then making some decision as to whether the level of evidence is adequate to support the claim.

Now, whether that is called significant scientific agreement or just independent assessment from individuals that are knowledgeable in the field but are not biased, that's semantics.

MR. LEVITT: Yes?

MR. CHASSY: I think when scientists look at conflicting evidence, it's a red flag. We're trying to lower the dissonance to where all the evidence is pointing in the same direction. And I think the concept that the court has written there, that you look at the preponderance of the evidence, may be a sound legal concept but that would drive scientists crazy. We would say no conclusion is justified.

MR. LEVITT: Mr. Emord?

MR. EMORD: The critical question, again there's a distinction between the First Amendment requirement, which is paramount, and any standard that you would set on the validity of science, the First Amendment taking precedence over anything else because of its legal predominance in the law.

So the question becomes you first look at the actual claim before you, not a hypothetical nutrient-disease association but the actual language of the claim before you. You read it according to its literal meaning, not its hypothesized meaning, not according to some esoteric conception of what consumers may view because you can't make that judgment in isolation.

So looking at the language before you, you asked what its literal meaning is. Let me give you an example. Let's say that the claim is nutrient X cures bladder cancer,

but the science before you only shows that nutrient X increases killer cell activity. Let's say there's either no study associating the nutrient with bladder cancer or there is one or two old studies that are no longer viewed as methodologically appropriate, statistically sound, what have you.

In that case, the claim by its very language is inherently misleading. There's no disclaimer you could reasonably use to correct the misleading connotation. However, if the claim instead was nutrient X may increase killer cell activity and the scientific evidence before you was not conclusive on that point but there were studies indicating that nutrient X may increase killer cell activity, the literal meaning of the claim would invite a qualification so as to avoid the misperception in the public that the claim is conclusive.

We cannot presume that the public is too ignorant to comprehend scientific information. We can also not presume that the claim is the end-all and be-all of all scientific wisdom in the universe and that consumers will not be going through the Internet and other sources of information.

Consumer will. The question for you is do you have a mass black market in claims, such as you currently have now, or do you have a functional system where people

find the disadvantages associated with the review not impossible and are willing to file a claim, to trust the agency to ensure its agency.

Few people will file claims for which there is no scientific evidence. Few people will file claims for which there is conclusive evidence because virtually no nutritional claims come with conclusive evidence. It's the nature of the beast.

So the vast majority of science is in the realm of inconclusiveness and the question is how does the government follow the principle of disclosure over suppression? How does it become a vehicle for the communication of truthful information?

Intelligent minds can create disclaimers. Inconclusiveness can convey to a consumer information. The study cited by Bruce, done by the FTC, did show that in the case of qualitative disclaimers, they were effective and dissuaded people from purchasing products if their interest was to avoid cancer and the evidence was inconclusive. But we get this plethora of information from the marketplace about it and you don't have a chance to pass upon that. And quite frequently, as Dr. Lichtenstein pointed out, you get one study out there that says Vitamin C is going to thicken the walls of your arteries and you have 200 that are locked away in the scientific literature showing the contrary, and

the consumer is being fed misinformation.

The study that the court relied upon in a footnote that we presented to them showed that the consumer relies upon information at the point of sale to predicate its judgment about buying. That's an FTC study done a number of years ago and it shows that just like in my case, when I go to look at a dietary supplement in the store, I do look at the able. I don't just look at the nutrition facts panel. I look at what's on there. I try to figure out what it's about. What are they trying to sell this for? I think most people do.

The reason why the industry is interested in claims is because they see this vast quantity of nutrition science in the literature, not necessarily conclusive but indicative, and on a risk-benefit analysis, this is how consumers make purchasing decisions in the dietary supplement marketplace.

So why not trust consumers with the information? And why not become a vehicle for the dissemination of information rather than a barrier to its dissemination? This is the court's emphasis: disclosure over suppression.

MR. LEVITT: Thank you.

Bruce?

MR. SILVERGLADE: Well, I just want to add a couple of different points. I think the hypothetical that

Jonathan spelled out there would be invalid under our interpretation of the court case because it would affect health in an adverse fashion and the court specifically acknowledged that where health is at risk, the FDA can ban claims outright.

I'd also like to make a comment on what was suggested or brought up about weighing the evidence. The word preponderance of the evidence was brought up and it was said that that's a legal concept that drives the scientific community crazy because in scientific terms you can't just say well, 51 percent of the studies say this and 49 say that, so this claim is valid. Scientific validity is much more complicated than mere preponderance.

So I would like to encourage the FDA not to proceed down the route of a preponderance of the evidence standard, that in a sense, that would be misleading in and of itself because it doesn't represent scientific validity. And in the weighing of the evidence, both quantitatively and qualitatively, there has to be clear and convincing evidence that the claim is valid.

MS. LICHTENSTEIN: I'm a little bit concerned with the concept of giving consumer the information versus burdening the consumer with information without the benefit of input from people that are familiar with the different subtleties and innuendoes of a subject.

From my perspective, if it has something to do with, let's say, child safety, I would like the government to have certain standards, hopefully with input from the--I don't know if it's academic that test that or whoever--who adequately has the expertise to rigorously test it, assess the different responses, risks, and gives me, as a consumer, the best information on whether it's something that's safe or not safe.

In the same way with dietary supplements, it's one thing to give people the information; it's something else to try to ferret out whether that information is valid, whether there's enough of the information to actually support the claim. And I think without having scientific input and some kind of consensus, in a sense, there's an abdication of responsibility, and that's what I'm concerned about.

MR. LEVITT: One quick comment and then we'll move to the next question.

MR. CHASSY: I'm a little concerned about the reliance on that 1989 FTC study. I didn't mean to insult the FTC but it's an old study and I think there's more of that kind of work that needs to be done because I don't think any of us can really say for certain what consumers interpret when they read these labels and what would be or would not be useful to them.

I don't think, though, that it's the FDA's job, as

I see it, to be validating sort of soft claims. The consumer, as Jonathan just pointed out, is seeing all these claims in literature and is making their own decision, so it seems to me we have full disclosure. You read it, you make your decision, and it's the FDA's job to allow a health claim when there is a significant scientific agreement.

MR. LEVITT: I'm going to pass the microphone over to Chris Lewis.

MS. LEWIS: Thank you. I'd like to pick up on a few of the themes that I've heard and I'm not quite sure I can phrase the question correctly, but relative to the scientific standard for something less than significant scientific agreement, and particularly perhaps for Dr. Chassy and Mr. Hathcock, the issue was brought up of the idea of claims being reversed by science. And Dr. Lichtenstein talked about the ping-pong nature of daily data that hit the consumer.

I guess I did hear some introduction of the idea of a place for emerging science and I'm not quite sure I'm hearing that there's a standard for that other than the standard of significant scientific agreement and maybe you could talk about is there one or is there not. I think I've heard several different points at different times. That would be helpful.

Dr. Chassy, in particular I think I'd like to hear

from you.

MR. CHASSY: If I were the agency, I wouldn't want to be administering that. I think it's difficult.

I think in this particular case, for example, the health claims that were not allowed by the FDA are very good examples of those that would fully meet the emerging science kind of requirement. I think what you would want to have is basically--I don't want to use the word preponderance of evidence--maybe all of the evidence pointing in a direction but perhaps the definitive or corroborative studies haven't been done.

You know, we always say that if you're going to do an intervention trial, somebody else should do it somewhere else and it should come out the same way if it had the same design, and that makes you feel good. But what about when you know the mechanism, you've seen the epidemiological data, they're all pointing in one direction and somebody does a clinical trial and it's very supportive of what you were thinking going into it. Maybe that's emerging science that people have a right to know about.

If the intervention, as is the case in beta carotene studies, doesn't bear out the epidemiology and the mechanistic hypothesis, then you wouldn't do that. You wouldn't say that this is a promising piece of science.

So again I think you need consistency. It's maybe

the amount of evidence you have and the length of time that it's been available. We also say that science needs to stand the test of time.

So I would look at it as something with a shorter time frame and less than a complete set of evidence but all pointing in the same direction. And I do think these four claims clearly fall into that.

MR. HATHCOCK: Dr. Lewis, as you know, science never provides certainty. That's true whether we're talking about clinical trials or epidemiological evidence or a mixture of the two.

A preponderance of the evidence could actually change with time. We can increase the evidence for something; we can increase the evidence against something. So the proportionality in the preponderance can easily change. And it's not only epidemiology but also clinical trial. It is not just nutrition, but we don't have certainty in the drug area, as well.

The way that preponderance can change can sometimes, I believe, change the decision that ought to be enforced regarding whether or not a particular claim is permitted, assuming that FDA has the authority that is granted under NLEA for authorization for a claim before it can be made.

With the Pearson decision relating to dietary

supplements, I'm not sure--and, as you know, I'm not an attorney; I'm simply trying to look at this in a logical way--I'm not sure that FDA has this kind of premarket authorization authority for the claim. It's simply if it's truthful and not misleading, it can be made and most labeling is not authorized by FDA.

The primary standard under the misbranding provisions of the Food, Drug and Cosmetic Act does not require premarket authorization of the claim. And if FDA finds that something is not truthful or it is misleading, then it has the authority to take an action to declare the product misbranded. But having said that, it's not an issue perhaps of authorization.

So the preponderance would apply in either way but the preponderance does need to be read in these ways that rely on interpretation of the quality, as well as the quantity of the evidence. Simply counting studies doesn't work.

MR. SILVERGLADE: I'd like to add a few points. On preauthorization, I think the court's opinion is very clear that FDA does have the authority, both under the statute and the Constitution, to require premarket approval of claims. That was not criticized by the court.

Second, we object to the term "emerging science," which has been mentioned several times this morning.

Emerging science is somewhat of a marketing term, I think, that the industry has come up with. It sounds to me like it's new and improved. It implies that that science will emerge when, in fact, it may or it may not emerge. It implies a presumption that the science will pan out when we, in fact, don't know.

So what we're really talking about is not emerging science but uncertain science, uncertain science.

The court really kind of got it mixed up when it talked about disclaimers and disclosures. The classic Supreme Court case on disclosures in consumer advertising is where the lawyer advertised that he would take your case for free, on contingency, and even if you lost, he wouldn't charge you anything; there would be no cost to you. And, in fact, the lawyer made the consumer pay court costs, which can be quite substantial, if the case was lost.

So that was deceptive and the Supreme Court said that the answer is to require disclosure, not to ban the advertising but to require disclosure that the consumer would still be liable for court costs if the case was lost. And that type of disclosure does present useful information because after the consumer reads it, the consumer can say, "Aha, now I know the truth. This is the missing link. With this disclosure, now I see what they're advertising. Now I know the truth."

And the problem with the disclaimers suggested by the court is that it doesn't give the consumer the missing information to close the loop, to say "Now I know the truth" because, in fact, all the consumer knows is that the FDA may not have approved the claim or that the scientific community is disputing it, but they don't know if it's safe; they don't know if it's effective, and that's really what the consumer wants to know.

MR. LEVITT: Mike?

MR. LANDA: This question is for, initially, at least, Jonathan Emord and Bruce Chassy.

How, assuming you would take safety into account in the context of a health claim or the acceptability of a health claim, how would you do that?

MR. EMORD: I think here, as well as many other instances but here particularly, I think Bruce got it wrong. The issue on safety that the court addressed was whether or not these particular ingredients were unsafe when consumed, not the question of whether the claim would render them unsafe in some hypothetical sense--long-term risk-benefit sense. The court looked specifically at the question: Are these things unsafe? The substances, not with regard to the claim.

Then, finding the substances to be safe, and safe is a relative term and here the agency has a spotted

history. In the Kessler administration the attempt was to take virtually unlimited dose levels and say that if at some dose level it's unsafe, it's unsafe.

But the point is we have to look at it in perspective. If the dose recommended is one that would not result in harm to consumers, it's safe.

Is there an instance where a claim could render a dietary supplement unsafe? I'm sure there is such an instance. For example, if the claim were "Discontinue chemotherapy; rely on Vitamin C as your exclusive remedy" and that was submitted to the FDA, I think you could easily deny that claim. And if the claim is inherently misleading, you can suppress it outright.

The question becomes one, I think, of recognizing that with emerging science, and here again I disagree with Bruce's definition. I think emerging science, if we understand it correctly and we can even define it, is that which is part of an evolutionary process which has not yet reached a degree of conclusiveness that is generally accepted in the scientific community. Virtually nothing reaches that level of conclusiveness. A few things do, and even that level of conclusiveness is subject to change in the case of drugs and supplements. And we have to look at the question of the claim's terms within the current environment. We can do nothing more than that. We can't

hypothesize about whether science will ultimately be conclusive in one direction or another. If it ultimately is conclusive against the claim, you could then deny the claim.

I think we have to be--this is a static--this is not a stationary process. It's evolutionary.

Safety is the same point. What we believe to be safe today may, in 20 years, be regarded as wholly unsafe, but we should look at the substance and determine safety, not look at the claim and say that the claim--hypothesize and say because we associate a reduction in the risk of cancer with the consumption of anti-oxidants that there may be a reduction, that that means that people will discontinue chemotherapy. That is not the claim before you.

Otherwise, if we hypothesize endlessly and assume, presume the consumers will act in one way or another, you can never fulfill the First Amendment duty, which is necessarily language-based. It's necessarily focussed on the meaning of the terms before you.

MR. LEVITT: Anyone--

MR. CHASSY: With two Bruces, I didn't know which one you meant. But since I used the term "emerging science," I want to return to it.

I actually agree with the other Bruce here; it's uncertain science. And I agree with Jonathan; it's emerging science. It is both at the same time, whether it's an

industry term or not.

Jonathan used a word in talking about what he considered a reasonable disclaimer that I think is found in health claims and in emerging science claims, and that's the word "may." The word "may" is itself a disclaimer. It seems to me that consumers understand or ought to understand what the word "may" means, and that's why I was somewhat put off by the lengthy court disclaimer. I think you can, with a very few fudge words, make a health claim considerably softer because you are, in fact, not promising someone that something will do something. I think it is understood that even a health claim is the best available knowledge.

That said, I can give you an example of safety in a food product and make a comment about that. There is a body of evidence that says consumption of phytoestrogens may have health-beneficial effects, particularly related to cancer, particularly in post-menopausal women, whatever. There's also a body of evidence that says that consumption of phytoestrogens can promote estrogen-dependent mammary tumors.

So if you had a health claim saying phytoestrogen consumption is going to protect you against cancer, you would certainly want to quality that by saying unless you happen to have an undetected estrogen-dependent mammary tumor.

Secondly, we're talking about an area where these aren't drugs that have immediate effects or necessarily acute toxicity. We're talking about dietary remedies, supplements, that are going to be used over 20 or 30 or 40 years before their full impact is felt. And I take issue a little bit with Jonathan in the sense that yes, you want to look at the immediate acute toxicity and the immediate safety, but you would also want to know that over 20 or 30 or 40 years, consumption of novel amounts of novel ingredients would, in fact, have long-term safety for the consumer. Hence the reluctance to approve a health claim without having it stood the test of time, in addition to having a body of scientific evidence that was pretty consistent.

MR. HATHCOCK: I beginning that the safety issue can devolve into an unanswerable set of questions if we aren't very careful. If the product is safe under the law and is in the marketplace legally, even if nothing is said, then that safety should not be an issue with regard to the health claim that's made, unless the health claim recommends dosages that are considered unsafe and are prohibited by law.

If a high dose that would be needed in order to achieve a health benefit carries significant risk that causes it to be adulterated at that dosage, then you don't

need to consider the safety as part of the health claim issue; you should have those dosages out of the marketplace by declaring them adulterated and removed from the market on that basis, rather than weighing into how it would impact on the claim.

MR. SILVERGLADE: The other Bruce.

The court's discussion of the use of disclaimer situations where a supplement affects health was quite broad. Those were the words of the court--"affects health," and that could, of course, mean acute toxicity. It could also mean encouraging a consumer to use an unproven remedy when there's a proven remedy available. That consumer, whatever their symptoms were, they're not going to get better, they're going to get worse, and that's going to affect their health.

Even in a worst case scenario, the consumer's not going to know whether or not this supplement that's promoted on the basis of a preliminary claim is actually working or not. They may think it's working but they may be suffering from a condition that's difficult or impossible to self-diagnose and again their condition could worsen quite a bit and they won't even know it.

So there's any ways for supplements promoted on the basis of preliminary health claims to affect health and we certainly believe the court, who certainly cares about

consumer welfare, would take all of these into account.

MR. EMORD: One additional point to qualify Bruce's point. The court expressly stated to the agency that similarly they say--well, we can just abbreviate it. If the court says, and I quote, "The government's interest in preventing the use of labels that are true but do not mention adverse effects would seem to be satisfied, at least ordinarily, by inclusion of a prominent disclaimer setting forth those adverse effects."

So again the notion is full disclosure and disclosure of the adverse effects.

MR. SILVERGLADE: The only problem is that sometimes we don't know the adverse effects. Like on beta carotene, we didn't know that the studies would actually show that it might increase the risk of cancer in the smokers. No one knew that so it's impossible to make an effective disclosure in that situation.

MR. EMORD: I think you can. The disclosure is simple. If you smoke, you might do well by not taking a supplement with beta carotene in it.

The point is, and the scientific evidence there is subject to dispute; it's not a conclusive point. One point that needs to be pointed out here, I think, is that if you wish to qualify something, the evidence had better be of high quality to do that because you are necessarily

informing consumers of something that is negative, that will dissuade them from doing something. And if the evidence is inconclusive and you say it's inconclusive, that's fine. But if the evidence is inconclusive and you suggest strongly that it ought to be followed, then that, too, is misleading.

So Bruce's position that if there's inconclusive evidence it ought to be stated categorically in a negative sense is misleading to consumers.

MR. LEVITT: Dr. Lichtenstein, you'll have to close up this question.

MS. LICHTENSTEIN: Two quick points. One is I'm getting a little bit concerned about hearing about putting claims on the label and also about putting disclaimers on the label and how big the label actually is. From a very practical point of view, I don't know if any studies have been done on how likely it is that consumers are going to read something dependent on font size but I think it's actually an issue that can't be underestimated.

MR. LEVITT: Our second panel will get to address that.

MS. LICHTENSTEIN: Okay. The other issue has to do with safety and it has to do with dosages. If the recommended dosage is assumed to be safe or if there's no evidence that there's an adverse effect, I think one also needs to take into consideration that if I get a bottle of

something and it says that it may reduce my risk of breast cancer, I may decide well, you know, if one pill's may reduce my risk of breast cancer, maybe two definitely will. And one can't assume that people are just going to be taking what is in the actual dosage.

MR. LEVITT: Just before I pass the microphone down to Peggy, we actually have reached the end of our allotted time. Because I think this panel is so central to what we're doing throughout the day, we'll go a little while longer but we'll try to end by 12.

MS. DOTZEL: My question is directed at no one in particular. I'd actually like to hear from as many members of the panel who would like to address it.

What we're talking about today is providing information to consumers and providing good information to consumers. And my question is that if we're talking about a standard, whether it be the emerging science standard or some other standard other than significant scientific agreement, it seems to me, and correct me if I'm wrong, that we're getting into an area where it's probably more likely that at some point in time we will learn new information about certain claims, so the information that we put on the label would have to change.

And my question is to the extent that we want to give consumers good information on the label, how do we

address the issue of changing labels? If we have to change these labels every year or two years or whenever new emerging science comes out, how are we going to continue to supply good information and how do we address any kind of confusion that might create in the marketplace?

MR. EMORD: The question is a good one, obviously, and science, because it is evolutionary, will result in changes in information. We all recall the Surgeon General's report on a package of cigarettes, something I know that's rather sensitive to discuss with the agency today after the Supreme Court's decision.

But to notice that the Surgeon General's language evolved over time and that the recommendations on a cigarette package evolved to mention other disease effects that were a consequence of it, the point is that if scientific evidence does establish that there is an adverse effect that previously was unknown--anaphylactic shock and peanut butter--a disclaimer alerting those individuals who are in that subcategory that would be affected is appropriate and the agency, as part of its duties to protect the public interest and health, should be active in that regard.

So I don't think it's appropriate--and the same is true with regard to the drug regime. You update labels on drugs periodically based on new scientific information; the

same should be true for supplements.

MR. SILVERGLADE: I think that's a very good question. And as Dr. Lichtenstein illustrated with her prepared statement, there's really new studies every couple of months or every week really on some of these products. And at a minimum, it would seem like the FDA would have to require the industry to reprint labels twice a year or something of that sort, which would just--I know from my experience with nutrition labeling, the food and supplement industries consider that to be a impossible burden, so I really don't see how it's workable.

MR. CHASSY: I'm going to pick up on what Bruce just said, even though it's not the question. I think that industry would consider it an impossible burden to be printing all the disclaimers that we're talking about.

I think you would need to set up a mechanism for review. I think it's unrealistic to think that you could do it on a rolling basis or every six months, but there should be some ongoing review, which would mean a lot more agency resources devoted to this category because there are a lot of products out there. But unless you do that, you're going to have to rely on manufacturers to be scanning the literature and voluntarily updating however they qualified their statement.

MR. HATHCOCK: I would just address two points

very briefly. The first is the idea that a claim should be unlikely to change with new additional scientific information that will accumulate in the future.

Let's suppose that you have a situation in which a body of scientific evidence is judged barely to make the significant scientific agreement standard or barely judged to miss it. It's a close call either way, that boundary under current practice. Those two bodies of evidence are not significantly different other than they happen to be with a very fine line drawn between.

So I think this concern about it being unlikely to change can be exaggerated and perhaps it's been done already.

With regard to the controversy and the uncertainty and the evidence that comes out even in a short period, as Dr. Lichtenstein mentioned, that's not only true for supplements but look at hormone replacement therapy. It's one of the fixed features of health news, that somebody has a new study on hormone replacement therapy and they've found a benefit, but then they've found a new risk or have repeated the same risk that we already knew as a point of comparison.

So I think it's not just the supplements; it applies to practically all consumer products, including drugs.

MS. LICHTENSTEIN: Even if there was a mechanism for updating labels, even if it was technically possible to do it every six months, I think it's not necessarily going to be possible to reprogram the way people think about the claim that they have read because it's unlikely that people are going to keep rereading the labels on their supplement bottles, assuming that they've made a decision six months ago, a year ago.

And that's why I think that one needs to have a very, very significant body of evidence that most likely--knowing that everything may change and that all science is continually being reassessed, caution, as opposed to assuming that you can just keep updating every one is probably a more reasonable tack.

MR. EMORD: This is the precise reason why the court's disclaimer is so good, because the term is used, inconclusive. The claim is inconclusive and as long as the claim is inconclusive, and that's the vast majority of scientific information, there will be this bandying about in the scientific community.

One way of serving the public and aiding in this regard is for FDA to take an affirmative role, such as we've suggested in our litigation, posting on your web site and requiring in the label a reference to the web site, where the agency's analysis of the varying conflicting scientific

evidence is presented there, and you can update this information.

If the evidence--so we have a weighing of the evidence. You have the disclaimer that the evidence is inconclusive. That carries along a rather good period of time, I would suggest, because in most instances that's the given play of science and there isn't a conclusive answer.

If there does come a day when there's a conclusive answer that the claim is false, then it's inherently misleading and the agency can say it's inherently misleading.

If there comes a day where there's information about an adverse effect not previously a part of the claim, then the agency can inform a party of that. And Bruce and others will petition the agency. The agency will be informed.

So I think that you could have an evolutionary role and serve the public by posting on a web site this information, as you do in so many other instances, as when there is actual adulteration in the market, you use that. You don't require all companies to put on their label that some product imported was adulterated; be careful to examine this product in detail to determine that it does not have that in it.

So you can be fully disclosing information without

always changing the label.

MR. LEVITT: One final point here.

MS. LICHTENSTEIN: I'm very concerned about relying on updating people on the basis of what happens to be on a web site because I think it cuts out a lot of people with respect to getting that information and it's perhaps some of the people that it's most important to get it. There's got to be another kind of mechanism. The literacy rate in the United States is extremely high. Access and utilization of the web is not, at this point.

MR. EMORD: One other point. We also recommended an 800 number where the company would sponsor the 800 number and you could call and get the information in print.

MR. LEVITT: We have time for one last question but I'm going to ask the panelists to try to be brief with this answer.

MS. BEHRMAN: Okay, and it's somewhat targeted. It's for the panel members who believe that we should adopt a standard less than significant scientific agreement. And if we do adopt that standard or if that's how claims were to be evaluated, I'm a little confused as to what would, in fact, be full disclosure because we all agree there's going to be conflicting evidence. And in drugs we have a slightly different view of that and how we handle that but we also have a whole lot more space on our label, and we have a

learned intermediary, so it's really different.

What should we be obligated to do with the conflicting evidence? How do we fully inform and do so in a way that actually will achieve some sort of consumer recognition?

MR. EMORD: First I think it's an important point to note that as a matter of law, it's a fait accompli that significant scientific agreement is not legally the barrier to the dissemination of information.

Your standard is the First Amendment. The court supplies you with the definition of the standard in the decision. That's the standard you must apply. If you constrict the universe in any way by substituting some validity test for the First Amendment test, you necessarily violate the First Amendment again.

So on the question of conflicting information, you accurately characterize it for the consumer.

MS. BEHRMAN: Well, can I press you on that further?

MR. EMORD: Sure.

MS. BEHRMAN: Let's go back to not being misleading, then. We have 11 studies, six of which are favorable, five of which are not. So very vague. And I believe by your standard you would believe that a claim could be supported by that. How does one convey that degree

of uncertainty to the consumer?

MR. EMORD: Well regrettably, you have not supplied sufficient information for anyone to knowledgeably write a claim because the question is the qualitative value of the study, what is being conveyed, the actual language of the claim. We look at this very literally and it's the only way you can do it. From an English language perspective, what is the plain meaning of these terms? When we look at the scientific evidence, is it conclusive? Is it inconclusive? Is it so preliminary that there is--and it's irrelevant. Is it relevant and preliminary? Is the claim merely preliminary? Is the claim--let me give you an example.

Is the claim that there's little--this is the claim. There is little scientific evidence to associate X nutrient with Y disease. Nevertheless, we've included that nutrient in here in the hopes that you may find it useful. That's the claim that the person submits to you, okay?

MS. BEHRMAN: That's unlikely.

MR. EMORD: You see, the question is accuracy. The question is accuracy and you can turn this agency into a vehicle for disseminating information accurately to consumers or you can reject that and create an iron wall or even a semi-porous wall that robs consumers of health information.

What the court's telling you to do is to favor disclosure over suppression. It's not easy in every case. It's going to require, just as evaluating every drug application is a different experience every time, the same is going to be true here. You can't create a standard that is invariable. You have to use the court's definition. It is at a higher level of actualization.

MS. LICHTENSTEIN: I think we may actually be agreeing for the first time. I think your example is very good, that you've got six studies that say one thing and five studies that say the opposite and you're right; we don't have enough information. And I think that's where it comes in to having to evaluate--one needs to evaluate each individual study and then come to some kind of consensus, whether it be scientific consensus or whatever, on whether it's sufficient to actually make a claim.

MR. HATHCOCK: I concur with that. It will require judgment. You must weigh the quality, as well as the quantity, of the evidence and come to any decision. Whether you use predominance of evidence or whether you use preponderance of evidence or whether you use significant scientific agreement or any other term, there's still a judgment about what it all adds up to, and I don't think you or we can avoid that.

MR. SILVERGLADE: I would just add again the

threshold question, though, for the agency is would the preliminary claim adversely affect health? And there's a very broad interpretation of that that can be surmised from the court's opinion. And the agency shouldn't be in the business of getting into weighing preliminary evidence if it turns out that the preliminary claim could adversely affect health.

MR. LEVITT: In this case, the other Bruce.

MR. CHASSY: Let me pick up on that to say--

MR. LEVITT: And we'll have this be the last word.

MR. CHASSY: Include in "adversely affect health" things that people might not now be consuming because of a change that they made in their choice of either supplements or foods. I think that's important.

My last word ius this. I don't understand how the consumer is going to be robbed of precious information if we put down an assertion and a disclaimer. We already say "may" on even the validated health claims. If we soften it more and we make it very long on the label, I just don't see how that violates First Amendment rights. I understand the legal issues here but to me, people are getting their information other places.

As FDA's own studies show, a content claim on a package is just as compelling to a consumer as a health claim because the consumer already knows that Vitamin C is

good for them or beta carotene is good for them.

I would not lower the standard.

MR. LEVITT: Thank you and let me thank all the panel members. I think it's worth a round of applause.

[Applause.]

MR. LEVITT: This concludes our first panel.

Look in your sheet. The most important thing you have is a green sheet which shows you places to eat. We will try to reconvene at about 1:00. It's a little less than an hour but I think there's time to get in and out. 1:00 we'll reconvene. Thank you.

[Whereupon, at 12:05 p.m., the meeting recessed for lunch, to reconvene at 1:00 p.m., the same day.]

AFTERNOON SESSION

[1:03 p.m.]

MR. LEVITT: If I could get people's attention, please, it's time to start the afternoon session. Thank you very much.

PANEL II

MR. LEVITT: Let me begin by welcoming the members of our second panel, who are still in the course of adjusting how to fit on very small chairs in a relatively small space. So from this side of the table, we understand.

Our panelists this afternoon for the second panel are Mario Teisl from the University of Maine, Michelle Rusk from the Federal Trade Commission, Scott Bass, a lawyer representing the National Nutritional Foods Association, James Turner representing Citizens for Health, and Brett Kay representing the National Consumers League.

We will follow the same procedure that we did this morning. Each panelist will have 10 minutes and we'll go right down the order. There is a little clock. Actually we learned from this morning that you have to put your name down so that people can see the clock. The way it was set up, I could see it fine but the speakers couldn't.

The yellow light goes on when you've got about three minutes left and the red light goes on when your time is up. If the red light does go on--not to put any pressure

on you but in the last panel only one red light went on--and I will remind you that the time is up and if you could try to summarize, please.

We'll then go through a question and answer format, going down the panel and having a discussion back and forth.

To remind people, this is a continuation of our discussion from the Pearson case. We've kind of shifted to should you and what are the criteria for qualified claims to a much more practical discussion of how do you make qualified claims--what kinds of disclaimers, and so forth. The actual question we wrote was: If such claims on dietary supplements are to be appropriately qualified so that consumers are not misled, what should be the characteristics of such qualifying language? Should FDA require any other information to assist consumers in evaluating health claims and prevent them from being misled?

And with that, we'll start with Mario Teisl from the University of Maine.

MARIO TEISL, UNIVERSITY OF MAINE

MR. TEISL: Good afternoon. Before continuing, I want to thank the Food and Drug Administration for inviting me to this important forum.

Today I'm going to answer the main question with some specific recommendations based upon results from a wide

variety of consumer research. Although many of these studies do not focus on dietary supplements, the recommendations I make are based on findings that are relatively consistent across studies. However, one should note that consumer reactions to labeling programs often differ based upon product-specific factors, and I would recommend that more research be performed to gauge consumer reactions to specific examples of dietary supplement labeling.

Finally, I would like to add that some of my recommendations are contingent on the assumption that there will be multiple levels of health claim substantiation allowed.

Now for the first recommendation. Disclaimers should be simple, direct and strongly worded. The wording of disclaimer messages can greatly influence their effectiveness. Disclaimers that provide background or general information are often ineffective. In fact, consumers often view general disclaimers as simply a tool the manufacturer uses to protect themselves legally.

In addition, the effectiveness of the disclaimer is greater if it is intensely worded. Weakly worded messages, even from highly credible sources, are ineffective in changing consumer perceptions.

Recommendation two. Disclaimers will have to be

claim-specific to indicate to the consumer that the substantiation of different health claims will vary. Previous to Pearson, FDA had one uniform standard for all health claims. However, after Pearson it seems that this will no longer be true. Consumers will need to be informed about this for several reasons.

First, consumers need to understand the particulars of each product's level of substantiation to more correctly evaluate the credibility of the claim. A second reason for clearly delineating across claims is to maintain the credibility of more highly substantiated claims. Meagerly supported claims that may change repeatedly across time as new health-related research is performed are likely to generate higher levels of skepticism for all health-related claims.

In addition, the reputation of agencies like the FDA seen as regulating the health claims is also likely to diminish.

Number three, disclaimers should focus on providing information that is new to the consumer. Telling the consumer what they already know is not particularly useful.

Number four, disclaimer items should be physical separated from other nondisclosure items. There are two reasons to separate disclaimer from the other information.

First, reducing the amount of informational clutter around the disclaimer increases the readability and ease of use. Second, the disclaimer should be understood by consumers as a regulatory mechanism, not as part of the marketing information provided by firms. Consumers see regulated information mechanisms as much more credible than firm-provided information.

Number five, the actual disclaimer should be placed on the back of a product container. In general, consumers view the front of the container as the area that the manufacturer uses to sell the product, whereas the back of the container is the area where regulated information is placed.

Number six, a reference to the disclaimer should be located close to the claim and clearly refer to the presence of a disclaimer. In general, the presence of a disclaimer tends to reduce the likelihood that consumers will continue their information search onto the back of the container. Thus as asterisk or simple footnote-type reference may not be enough because consumers may mistakenly think that the footnote refers to material that supports the claim.

Number seven, to enhance readability and increase effectiveness, the font size for the disclaimer and for the reference to the disclaimer should be comparable to the font

used in the health claim.

Number eight, definitions of all terms should be consistent with common understanding and usage. Consumers must be able to understand before they can use the information provided. Research should ensure that consumers' perceptions of any important information are the same as those that the agency intends.

Number nine, the disclaimer label should provide references to disclosures of supporting documentation available at off-label locations. Informed consumers should have access to detailed information about a health claim's level of substantiation. The label does not have the room needed to provide this detail, thus necessitating an off-label disclosure.

Number 10, if the disclaimer is to have supporting documentation, then this documentation should be placed prominently at the point of purchase and be made available on a secure FDA website to permit consumers to examine and easily compare different products. Each product's disclaimer should refer to the availability of the supporting information.

Number 11, all disclaimer and disclosure information should be presented in a standardized format to decrease consumer confusion and increase credibility. Where possible, this includes standardizing the size and location

of displays, font type and size, terms and definitions and any graphical elements. If different products exhibit different disclosure structures, then making comparisons among products will be difficult. Consumers want product information standardized so that they can make apples-to-apples comparisons.

Number 12, research should be performed to determine the feasibility of developing methods to summarize or score the level of substantiation for a claim. Even with the availability of more detailed supporting documentation, time and cognitive constraints will probably not allow many consumers the ability to assimilate the detailed information. One simplifying strategy would be to create some sort of ranking or rating scale that could be used as a signal for the level of support made for a claim. Of course, a major difficulty here is that developing such a scheme will be highly difficult and probably highly controversial.

Thirteen, if a scoring mechanism can be developed, then providing some sort of benchmark information may provide clarity and increased understanding. An example would be the inclusion of a minimal acceptable score or some descriptive text highlighting whether the level of substantiation was low or high.

Number 14, disclaimers and other disclosure

information should be product-specific. Consumers want to know about the attributes of the product. For example, dietary supplement users want to know about recommended dosages, possible interactions between the supplement and other medications, the overall safety of the product, any side effects associated with the product, any special considerations for specific population groups--for example, children. General information will not allow consumers to differentiate products in the manner they most desire.

Finally number 15, dietary supplement labeling should be part of a more general information strategy. There are two parts to this information strategy, each having its own aim. One part of the information strategy should focus on heightening consumer awareness of the new labeling program. Successful labeling programs are often linked to either a public education campaign or to a heightened exposure of the problem within the media. It is a combination of labeling and off-label education that seems to be most effective in altering consumer perceptions and behavior.

The aim of the second part of the information strategy is to have consumers question the prior assumptions. One incorrectly held assumption is that some consumers think that after they use a particular product, they can independently assess whether the product was

effective, which in most cases the consumer cannot do.

Another incorrectly held assumption is that consumers seem to view health claim disclaimers solely as a comment about the reliability of the supporting research. However, the disclaimer is often meant as a commentary on both the reliability and the validity of the supporting research.

These two assumptions taken together lead many consumers to believe that the only way to determine the effectiveness of a product is to try it and see. This try-it-and-see attitude complicates matters in the long run because positive perceptions of one product experience can influence how consumers view similar products.

Further, as consumers develop increased experience with products, they're more likely to reduce the level of information search prior to purchasing similar products.

The summation of all these effects is that the impact of any disclaimer information will be greatly reduced with more experienced consumers. Labeling by itself will probably not affect these individuals unless an information campaign successfully makes these consumers question their assumptions.

To finish I'd like to reiterate that the actual implementation of these recommendations will require additional research. Given the low level of scientific and

statistical literacy in the U.S. and the complex nature of determining health effects, an expanded health claim labeling program for dietary supplements will have to be carefully designed. Poorly designed labeling is likely to generate confusion, which will lead to incorrect product choices and to an overall reduction in societal welfare. Thanks.

MR. LEVITT: Thank you very much.

Our next speaker is Michelle Rusk for the Federal Trade Commission. And as people have heard already, their research has been cited several times today.

MS. RUSK: For all kinds of propositions.

MR. LEVITT: So we're glad you came.

MICHELLE RUSK, FEDERAL TRADE COMMISSION

MS. RUSK: Thank you for allowing me to take part in this meeting this morning and to describe the FTC's experience with qualified health claims in advertising. I hope it will be helpful as you develop your labeling policies.

Before I begin I need to make a qualified claim myself and that is that while I can describe the commission's policy and our experience with qualified health claims, any opinions I give today are my own and not the official opinions of the commission.

My comments this morning will cover four aspects

of this issue. First, I'm going to outline the FTC's policy on health claims in advertising. Second, I will talk about what the FTC has learned from consumer data and cases about the content of disclosures; that is, what it takes to effectively qualify claims to reflect the state of the science. Third, some facts about format and you'll hear a lot of what you've already heard from Mario this morning--how disclosures should be presented, what are the elements of a clear and prominent disclosure?

And finally, I'd like to stress the importance of gathering consumer research to confirm that the right message is really getting across.

Under Section 5 of the FTC Act, claims are permitted in advertising as long as they can be qualified to prevent the misleading interpretations. The commission will only prohibit or ban a claim outright if the potential for deception cannot be cured by disclosure. And that's the starting premise for the FTC's approach to health claims, which we described in our '94 Food Enforcement Policy Statement. That policy statement dealt with food health claims but the same principles apply equally to supplements and we reiterated those in our Dietary Supplement Advertising Guide.

Very simply, the FTC views health claims as falling into sort of three basic categories. One is the

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