FOOD AND DRUG ADMINISTRATION

PUBLIC MEETING ON:

THE CHALLENGE OF LABELING FOOD ALLERGENS

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P R O C E E D I N G S

DR. FALCI: I want to say welcome to you all. I know some of you have come a long way and we're all glad you arrived safely. Let me give a special welcome to our panelists. We're very glad you're here today.

They've given me a few things to say as far as announcements and sort of housekeeping kind of things. Today is the FDA's Public Meeting on Labeling of Food Allergens, and I'd like to go over some of the administrative details.

Everyone should have picked up a packet, a registration packet, at the registration desk. In your packet, you'll see there is a list of restaurants. There is also a cafeteria. There are a lot of restaurants nearby here. There is also a cafeteria in this building downstairs. You have to go down one flight.

At the registration desk or a little bit off to the side, you'll be able to see various consumer and industry handouts. We hope you pick up a few of those. The guards, I believe, are requesting those of you that came through the I think this is the Third Street entrance, if you have your visitor's pass on you, that you keep that

with you when you enter and leave the building. Use that pass to come back in.

If you have any cell phones or beepers, would you just kindly take a look at them now and shut them off.

The bathrooms are located in the main hall of this building. When you leave this room, go to the right and you go to the main hallway and they're either on the right or the left-hand side, and if you think about, if you'll think about it, too, on the second floor, it's the same kind of configuration just in case they get a little crowded here on the first floor.

We have a sign language interpreter available today. If you know of anyone who needs sign language interpretation, please see the staff people. They'll be walking up and down the aisles.

Let's see. One more message for our panelists. The silver microphones are not to be moved. Those are the ones used for recording, and the black microphones are the ones you can move towards you to make any statements you wish.

The press has some area here in the front seats; if the press would like to come down and come up front, you certainly may.

And let's see, oh, yes, telephones. There are telephones in this building. You can walk out of this auditorium again and go to your right and you'll go past the guard station, and you'll see them right there by the guard station.

And I'd like to just do a little summary of where we've come as far as food allergens are concerned. It wasn't very long ago, actually in 1999, that FDA first thought about being and becoming more active with food allergens, and we did have discussions and we did formulate a plan of action as far as food allergens were concerned.

We formed an internal steering committee within the Center for Food Safety and Applied Nutrition, which is a center in FDA. And we also had a general committee on food allergens made up of a number of people within different offices that are in the Center for Food Safety. And at that time, one of the reasons for our action was because recalls of foods placed in the market, foods that contained undeclared food allergens were at high levels in the nation.

And in 2000, we followed that up. We went out with industry, we went out to industry and to consumers. We gathered data at that time. We were

seeking advice. We were trying to raise awareness of people in the industry as well as consumers as far as food allergens were concerned.

At that time, too, we were trying to decide on accomplishable tasks, those tasks that would make a difference as far as food allergens were concerned in the nation.

And in 2001, you see that we have our website established. You can turn to our website and see a variety of different actions that the agency has taken, examples of training as far as our inspectors are concerned, as far as food allergen control measures that are used in processing plants, how the inspector should go into processing plants and look for food allergin processing.

There is also a Compliance Policy Guide on our website as well, and we're actively training our inspectors over the next six months or so.

Today, we seek further information, and the kinds of things we'll talk about today, you will see eventually in our action plan for fiscal year 2002. So that's what we're trying to accomplish here today as well.

On our agenda, there are three subjects.

Dr. Christine Lewis, who is the Director of the Office of Nutritional Products and Labeling and Dietary Supplements, will be our moderator today at today's meeting. Dr. Lewis will give you an overview on the issues that we will be discussing here today and mention the agency's regulatory framework. And as your moderator, I'll turn this meeting over then to Dr. Lewis.

DR. LEWIS: Thank you, Dr. Falci. And I'd like to add my welcome to his welcome. We are looking forward very much to this meeting, and in our listening mode hope to be gathering a great deal of information today. I will be taking a few minutes to orient us by highlighting the challenges of labeling foods relative to allergens, but as Dr. Falci had some housekeeping rules to say, I have some ground rules to share with you.

The purpose of this meeting is to put forward and discuss information to help FDA determine what additional activities we should undertake vis-a-vis the issues surrounding the food label and allergens.

So our focus today is labeling. We're not addressing the technical aspects of food processing. More specifically our meeting will

address only the topics outlined in the Federal Register Notice, again plain English source labeling, advisory labeling, and labeling of ingredients exempted from declaration.

While we recognize there are other issues such as restaurant labeling and even latex glove allergies, these issues are beyond the scope of our discussions today.

In terms of ground rules for members of the press here, FDA staff will not be giving any interviews because we are in a listening mode. There are three FDA press officers here today, and they will stand right now. One is Ruth Welch, one is Kathleen Kolar, and Sebastian Cianci. Please see them if you have any questions or need assistance.

There will be some brief opportunities to ask written questions to panelists at the end of each panel session. A reminder: these are questions, not comments. And as we move through the presentations, please write your questions on the cards and give them to the ushers as soon as possible.

We will get to as many questions as time allows from you folks in the audience. I do need

to emphasize the questions from the public should be addressed to the panelists, not to FDA, as again we're in a listening mode.

We request that the questions only be on the specific subject that the panel has just discussed.

The last part of the meeting will be devoted to public comment. For those of you who wish to make a public comment and have not preregistered, there are sign-up sheets at the registration desk, first come/first served, and these statements should be no longer than three minutes.

There will be a timer set up for the public presentations. We'll let you know if you're going beyond your three minutes and need to stop. In addition to the oral public statements at the end of the day, you and anyone else may also submit written comments. They should be sent to Dockets, and again that information is in the Federal Register notice, and if you picked up your package, there is a copy of the Federal Register in your package.

There will be a transcript of the meeting available approximately one month after the

meeting. The transcript will be available at FDA's website, again in your package, www.cfsan.fda.gov.

Before I turn to highlighting our challenges today, I'd like to introduce our panelists. In no particular order, we have sitting with us today Regina Hildwine, who is Senior Director, Food Labeling and Standards, Regulatory Affairs at the National Food Processors Association.

We have Dr. Michael Jacobson, Co-Founder and Executive Director of the Center for Science in the Public Interest.

With us also is Lisa Katic, Registered Dietician, and Director, Scientific and Nutrition Policy at the Grocery Manufacturers of America.

And also Anne Munoz-Furlong, President and Founder of the Food Allergy and Anaphylaxis Network.

We also will have with us John Hallagan, who is General Counsel of the Flavor and Extract Manufacturers Association, American Spice Trade Association, and also with the International Association of Color Manufacturers, who will participate on Panel III this afternoon.

We also will have with us Kate Winkler,

Legislative Assistant from the office of the Honorable Nita M. Lowey, who will give an update on congressional activities related to the labeling of food allergens. Ms. Lowey's office was invited today because she's initiated draft legislation on the labeling of food allergens.

I appropriately need to inform you at this point that the current administration has not taken a position on such labeling.

And finally, I'd like to introduce the FDA listening panel, which is directly on my left. First there is Dr. Ken Falci, from whom you've already heard.

We also have Felicia Satchell, who is Director of the Division of Standards and Labeling Regulations in the Office of Nutritional Products, Labeling and Dietary Supplements.

We have Kathy Gombas, who is Deputy Director of the Division of HACCP in the Office of Field Programs.

And Thomas Wilcox, who is a Medical Officer within the Office of Scientific Analysis and Support.

And finally, Theresa Dziuk, Consumer Safety Officer, FDA's Minneapolis District Office,

who will discuss the summary of inspectional findings from the FDA/Minnesota and Wisconsin Food Allergen Partnership.

So, at this point, I will take just a few minutes with the slides to highlight the challenges that we're facing relative to labeling of food allergens.

I believe I can do this; correct? There we go. Keep going. Technology will help us some day. We're just not there yet.

As I've already mentioned, the focus of the meeting today is threefold: source or plain English labeling; advisory labeling; and labeling of ingredients exempted from declaration.

And more specifically, our meeting will focus on the eight most common allergens listed here: peanuts, soy, milk, eggs, fish, crustacea, tree nuts and wheat.

Next. As a bit of background, our current regulatory framework is such that the labels of food made from two or more ingredients list each ingredient by its common or usual name in descending order of predominance by weight in the ingredient statement.

Thus, consumers can obtain information

about the foods that they eat by reading the ingredient list. There are, however, two exceptions.

The first is that the act provides that spices, flavorings and colorings may be declared collectively without naming each.

Second, FDA regulations exempt from ingredient declaration incidental additives such as processing aids that are present in a food at insignificant levels and that do not have a technical or functional effect on the finished food.

However, I need to point out that FDA's policy is that an allergenic ingredient is not insignificant and therefore is not exempt from labeling.

In terms of the current state of play, FDA has two petitions in-house regarding food allergens. One is from the Attorneys General from nine states and requests FDA require a variety of activities including allergen information on the label, an insignia, toll free telephone numbers, good manufacturing practices, and labeling of flavors and incidental additives.

The second is a petition from a consumer

addressing very similar issues.

Next. We also are aware of NFPA's Code of Practice on Managing Food Allergens. This code of practice is a voluntary program adopted by NFPA's members.

Most recently, we've received and are aware of guidelines from the Food Allergy Issues Alliance. The Food Allergy Issues Alliance is a private group comprised of industry and trade group representatives and a consumer group as well as a scientific advisor representing academia. In May, they submitted to us a consensus document on guidelines for food allergen labeling.

The questions on which FDA is seeking information are spelled out in detail in the Federal Register. So just very briefly, they are, first, questions on source labeling. We're asking what plain English terms would be understandable. That is terms such as "milk" instead of "whey." And we're asking about what formats would be most informative. The issues are things such as formats in the ingredient statement itself versus below the ingredient statement as one example.

Also, in terms of source labeling--next slide--we're asking about whether or not multiple

formats would be confusing and should source labeling be voluntary or mandatory?

Second, we have a set of questions on so-called advisory labeling, advisory labeling falling into the category of such things about "may contain" and its impact on consumers.

And, in the next slide, questions about the appropriateness of advisory labeling including questions should the recommendations in the State Attorneys General petition be adopted and what about the criteria in the Food Allergy Issues Alliance?

Next slide. In terms of advisory labeling, we're also asking are there better alternatives to advisory label statements and do advisory statements adequately inform consumers? I should add that examples of current advisory labels in practice include, for instance, "may contain peanuts" or "manufactured in a facility that also processes peanuts."

Next slide. We are also asking should these advisory statements be prescriptive and what should be the location and prominence of these statements?

The third set of questions focuses on

flavorings, spices and colors. We're asking if FDA should continue to address the labeling of individual allergenic flavors, spices and colors on a case by case basis. We also raise the question of label location and the issue of mandatory versus voluntary labeling.

And in the next slide, we've also asked for comments on the labeling of incidental additives. What minor ingredients or processes would manufacturers be unlikely to recognize? And also when products are to be further processed or repacked, is better labeling on intermediate products necessary?

The questions on the labeling of incidental additives in terms of lastly, we're asking whether FDA should codify its policy that allergens cannot qualify as incidental additives that are exempt from labeling?

That basically highlights the purpose and issues we'd like addressed today during our meeting, and at this point, I think we will actually begin our program.

More or less without further ado, we'd like to turn to some remarks from Ms. Kate Winkler, who as we've mentioned before is from the Office of

Congressman Lowey. Ms. Winkler.

MS. WINKLER: Good morning. I'm delighted to be here today. It's also a pleasure to see so many people here that the Lowey office has worked so closely with. I too have to do a little good housekeeping before we start and say that I am Mrs. Lowey's legislative assistant. I handle her food safety and agricultural work. However, I'm not an official spokesperson for the congresswoman. If the press has any questions for the Lowey office, you can feel free to give us a call afterwards and speak with our press person. I'm just not at liberty to do so.

I'm here in my legislative capacity to talk about the work that my boss has been doing over the last year and a half on the food allergin issue and let you know where our piece of legislation stands at this point. Mrs. Lowey has a long record of achievement on food safety issues. She wishes she could be here today. She's actually up in New York catching up on a little district time, but Mrs. Lowey was formerly on the Agriculture Appropriations Subcommittee.

On that subcommittee, she took a strong interest in food safety issues. She's introduced

legislation that would require manufacturers to put a "best if used by" date on all perishable foods. She's also authored legislation that would require all fresh meat and poultry products to come with a nutrition label just as prepackaged food does, but her interest in the food allergy issue has taken her pro-consumer work to a new level.

I'd say about two years ago, we started to receive a number of mail and, you know, when she'd be in the grocery store making shopping visits--you know she's been a member of Congress now for more than ten years--people would come up to her and let her know their frustration with reading labels, and that's when she turned to me and said what can we do about those that have a food allergy and can't get the information that they need off of a food label?

So, you know, unfortunately, misleading and insufficient labels are not only a burden for some of us who look for expiration dates, but it's a serious health hazard for the millions of Americans with a food allergy. Food allergic consumers and the parents of food allergic children do not have a choice. Their health and lives depend on reading labels.

That's why Mrs. Lowey moved to introduce the Food Allergen Consumer Protection Act. An estimated 30,000 Americans suffer severe and even life-threatening reaction to foods each year and about 150 of them die. While we can't prevent allergic reactions, we can enact common sense food labeling requirements that will help consumers avoid allergen laced foods.

Currently, even those with a food allergy, even if they read labels for every food product they purchase every time they shop, they still cannot be assured that a product is safe.

For example, under current regulations, food manufacturers do not have to identify the products used in certain flavorings or additives. This exemption leaves critical health and safety information off our food labels. Although flavorings and additives are present in small quantities, for the millions with a food allergy no amount is irrelevant.

Furthermore, ingredient statements are written for scientists, not consumers. For example, how many people know that surimi is another term for egg. Food allergic children should not be expected to decipher terms like

"casein, albumin, or muso."

The bill that my boss has sponsored would require that food statements list in plain language what if any of the eight food allergens are contained in a product.

Beyond improving the readability of labels, it's time for manufacturers to clean up their acts. Too many manufacturers are preparing multiple products with the same cooking utensils or on the same production lines without properly cleaning the equipment. These practices must stop. A recent FDA study found that one-quarter of all manufacturers did not list ingredients that can cause potentially fatal allergic reactions and 47 percent of manufacturers did not check their products to ensure that all ingredients were accurately portrayed on the label.

There is no excuse when it comes to health and well-being of our children. Manufacturers should be taking every step possible to ensure their product safety. And as mentioned, the industry did recently propose voluntary guidelines, and my boss has worked very, very well with organizations like Grocery Manufacturers and National Food Processors Association, and she was

incredibly pleased that these guidelines were issued a couple months ago, and she has applauded the industry for taking to heart the seriousness of this health hazard.

But the fact is these are voluntary guidelines. The legislation will give some of the suggestions the weight of statutory law and ensure that every manufacturer abide by some of the suggestions made in the guidelines. Furthermore, it will provide the Food and Drug Administration with the resources to enforce the law.

As I said earlier, before we introduced the bill in the last Congress, and I should say that the bill introduced in the 106th Congress is very, very different than the one we'll be introducing in the 107th Congress. But before we introduced that bill, companies like Kraft and General Mills were already imposing stricter labeling standards, and we did use their labels as a model to work off of.

In addition, we enlisted the help of NFPA and GMA to help us raise awareness of the problem in the industry, and I think their guidelines show that they really have taken to heart some of the work that my boss has done and others.

To go point for point exactly what our bill does is again it requires that food ingredient statements identify in common language what if any of the eight main allergens are in a product. It closes the food additive loophole which requires that on the ingredient statements if an allergen is used in any of the spices or natural or artificial flavorings that it be labeled as such.

It preserves the Food and Drug Administration's authority to regulate the safety of certain bio-engineered products. It requires food manufacturers to include a working telephone number, including one for deaf persons in case a family has an emergency and they'd like to contact the actual manufacturer themselves to have questions answered.

It requires food manufacturers to better prevent cross-contact between food products that are produced in the same facility or on the same production line. It also would disallow the use of "may contain" language except for those that the Food and Drug Administration would allow. So that would put the FDA in charge of deciding in what instances a "may contain" language label is appropriate.

It would allow the Food and Drug Administration to assess civil penalties against processes and plants that are in violation of the labeling manufacturing requirements for food allergens. Furthermore, it would require the Center for Disease Control to attract food allergic related deaths. Fortunately, we don't have reliable and accurate statistics right now.

And lastly, it would direct the NIH, National Institutes of Health, to convene a panel of experts to develop a plan for research activities concerning food allergens. So that's the bill in sum.

In closing, I'd like to say that the bill will probably be introduced just after August recess. The bill will be introduced in both chambers. Part of the hold-up has been we've been working with Senator Kennedy on creating a bill that is suitable for both chambers so that we can have the same bill introduced on both sides of the Hill.

We've also been trying to educate other offices about the bill, let them know what we're looking to achieve, and in doing so, we've held a briefing where we had Dr. Sampson, one of the

leading doctors on food allergens, from Mount Sinai come down to the Hill and brief staff.

We've also been working very closely with some organizations like Food Allergy Initiative, FAAN and CSPI, and let them activate their base so that like the constituents who reached out to my boss to say that this is something that is needed, we need to have accurate, reliable, readable labels, that they can let their members of Congress know that this is important to them, and that they should get on board with Mrs. Lowey, Senator Kennedy, and cosponsor our legislation.

The only way this legislation is going to move is if we show that we have bicameral, bipartisan support, and I believe we do. But the only way that message is going to be made clear is if people contact their members and let them know. So it's very important that some of the groups here today, some of the families and children that are here today, get in touch with their members of Congress and let them know what's important to them and how a labeling law like this could make their daily lives easier.

I'd also like you to know that earlier this year the House passed the agriculture

appropriations bill and in that bill was report language that asked the Food and Drug Administration to act on the Attorney General petition that put forward to them suggestions on how to make labels more readable and how to address some of the concerns for food allergic families and their children.

In closing, I'd like to say I'm so pleased that FDA is having this public forum, as is Mrs. Lowey. I think this is a step in the right direction. I also think we need to get moving now. The voluntary guidelines were a huge, huge first step, but we need to ensure that every product on our shelves is readable, accurate and reliable so that families can feel confident about the food on their tables.

Thank you.

[Applause.]

DR. LEWIS: Thank you, Ms. Winkler. We'll now turn to our first panel today which addresses the source or plain English labeling. We have with us four panelists who will each make brief five minute comments on this topic, which will be followed by a discussion among the panelists themselves with input from our own FDA listening

panel.

We'll begin with Dr. Michael Jacobson, followed by Ms. Anne Munoz-Furlong, Ms. Regina Hildwine, and then Ms. Lisa Katic. Dr. Jacobson.

DR. JACOBSON: Thank you very much, Dr. Lewis, and I must say that I really appreciate the FDA holding this important meeting, the first one I can recall on food allergies. I think it indicates that the FDA is taking this issue very seriously.

Ingredient statements on food labels should be printed in a readable typeface and should clarify which ingredients might cause allergic reactions. Unfortunately, all too many ingredient lists are unreadable due to the small size and style of typeface used. Consumers shouldn't have to play the game of "Where's Waldo" when they're shopping to find the ingredients they're concerned about.

I have two examples here of some basically unreadable ingredient lists. The first one is a Stovetop Oven classic pasta--I guess it's pasta; I don't know what it is--for your inspection. And another one is a Hormel Kid's Kitchen product--the next slide, please--that really challenges people to read ingredients.

Labels such as these make a mockery of the FDA's requirement that ingredient lists shall appear prominently and conspicuously. Also, ingredient labels typically give the chemical names of additives such as sodium caseinate, lactose, albumen or gluten. That's enough of that slide, please.

This Quaker product, for instance, includes whey and sodium caseinate without disclosing that they are milk derivatives.

It can be tough for the average person to memorize all the possible derivatives of foods to which they're allergic. To help people who are sensitive to the eight major allergens and the raft of less common but sometimes no less severe allergens as well as for consumers who use ingredient lists for other purposes, the FDA should require all products to bear an entirely redesigned ingredients level which is on the poster in front of you.

Last month, CSPI formally petitioned the FDA to provide an ingredient facts label that is consistent with the nutrition facts label. The ingredients label should be printed in clearer larger type using upper and lower case letters,

major and minor ingredients should be separated out, and a clear allergy information section should alert sensitive consumers.

That section would include such statements as contains milk, soy and wheat or may contain peanuts. This particular label was designed by the same firm, Greenfield-Belser, that designed the nutrition facts label for the FDA about ten years ago. The wording and location of such information should be as standardized as possible on all packages.

It has been suggested that the sources of various food additives such as whey and albumen be declared after the names of the additives in the ingredient lists. So labels would state "whey (a milk derivative). "

If a clear ingredient facts label with an allergy information section is adopted, I'm not sure whether that redundancy is needed, whether the sources of the major allergens need to be stated in the ingredient list.

Focus groups could explore that matter and the request by the attorneys general that an "A" in a circle be printed on the front label to alert consumers about the presence of allergens.

While the FDA has focused on the eight most common allergens, I urge you to at least add sulfites to that list. Sulfites are not allergens but still cause life threatening anaphylactic reactions and must be listed on labels when present at 10 ppm, ten parts per million, or more.

Finally, the FDA should prevent consumer confusion about products that claim to be non-dairy or wheat-free or vegetarian when they actually contain additives from derived from milk, wheat or animals.

The front label of this product, for instance, says "vegetarian and soy cheese," but the manufacturer told us that the natural flavoring is actually skim milk, and the ingredient listed discloses calcium caseinate, both of which ingredients people with milk allergies and strict vegetarians would avoid. That kind of misleading labeling should simply not be allowed.

In sum, people with allergies and the rest of consumers need a clear legible ingredient fact statement with an allergy information section. That would do wonders to help people avoid the major allergens as well as other ingredients about which they're concerned. Thank you very much.

[Applause.]

DR. LEWIS: Thank you, Dr. Jacobson. Before we turn to Ms. Anne Munoz-Furlong, I'd like to remind the audience that you do have the opportunity to write questions on cards. We have several ushers who will be walking among you to pick these up. So as questions arise, please feel free to write them on the cards.

Go ahead, please.

MS. MUNOZ-FURLONG: Thank you. I have some slides. Shall I ask you to change them or do I--okay--fine. As we bring up these slides, I want to make the point that FAAN is a nonprofit organization. Our mission is to increase awareness, provide education and advance research into the conditions under which reactions and fatalities occur. We have 23,000 members. Most of these are parents of children with food allergies. Can we flip the slide and go on to the next one?

My objectives this morning--you can flip to the next one--thank you--are to give you information about the size of this problem, who is affected, and what the confusion is with the current labels. Next slide, please.

Currently, food allergies affect about

seven million Americans. About three million Americans are allergic to peanuts and tree nuts, and study after study continues to show that peanuts and tree nuts are the leading cause of severe or fatal reactions in this country.

Children are the largest group affected by food allergy. Up to six percent of children have a food allergy and eight foods account for 90 percent of the allergic reactions.

Next slide, please. Now, we know this list. The point I want to make here is that almost all of these foods have caused a fatal reaction to a child or an adult in this country.

Next slide. There is no cure for food allergies. Strict avoidance is the only way to avoid a reaction. That means the individuals must read the label for every product every time they go to the store.

Next slide. Food allergy is the leading cause of anaphylaxis. This is a larger problem than insect sting and medication allergy combined. There are about 30,000 emergency room visits a year and tens of thousands of reactions that are taken care of at home. Additionally, about 150 to 200 people die from these reactions.

Next slide. Okay. This is it. The symptoms can occur within minutes, and in every case the individual is eating something they believe is safe. So we're not talking about risk takers.

Next slide. Now let's talk about the confusion with the current labels. The first stop is when we go to the doctor and get a diagnosis, the doctor makes a diagnosis and tells the patient go home and avoid milk or eggs or wheat. They don't know that they're not going to see those names on very many products until they get to the grocery store.

If I could have the next slide, please. Now, this is just a sampling of what we call milk words. When someone has a milk allergy, they need to learn casein, caseinates, lactalbumin. These are the types of terms that they need to become familiar with, yet they're looking for the word "milk."

Then there is a whole host of situations under which the product may contain milk depending on the product, and that will change. They need to learn this as well.

Next slide. When we look at eggs, you can

see that some of these terms are very scientific and they certainly aren't consumer friendly.

Next slide. When we look at wheat, again the individual is going to the store expecting to see "wheat," but they're going to have to learn that semolina and durum and some of these other terms are what they need to avoid.

Next slide. Now, we have conferences across the country. Last year, there were 760 attendees. We conducted a survey looking at labeling and had 550 respondents.

Next slide. We asked them when they see a label, do they consider that the food labels currently on the market are easy to understand? 88 percent disagreed. 98 percent told us that the information on the label is not enough regarding allergens. 99 percent disagreed with the statement that the current labels can be understood by a seven year old. A seven year old would be about the first age that you can expect a child to start to learn to look for milk or eggs or some of the words that they're allergic to.

And 98 percent told us that the current labels are not easy to be understood by a new babysitter, a teacher, scout leader, anyone else

who is giving information or food to a child.

Now, the top three concerns--this was a write-in section to the survey--were "may contain," natural or artificial flavoring, and non-dairy. I know we have other panels to discuss "may contain" and non-dairy so I'm not going to stop here. The "non-dairy" bears mentioning for another discussion at a future meeting. This is certainly a big issue for our families.

Next slide. So when we're talking about labels, there is no cure for food allergy. Strict avoidance is the only way these people can avoid a reaction. Therefore, the labels must be clear and easy to understand. They must be consistent and reliable.

And the next slide. We recommend that these labels state in simple English terms adjacent to the ingredient panel what that product contains; that the allergens be identified when they're in these products at all times; and that there be a phone number so that the individual can contact the manufacturer whenever they have a question and we'll talk more about that as we go forward.

I want to sum up with one of the comments from our members is that we are not food

scientists, we're just mom and dad. Thank you.

[Applause.]

DR. LEWIS: Thank you. Regina Hildwine.

MS. HILDWINE: NFPA thanks FDA for the opportunity to participate in these panels today, and we will also be filing written comments. The National Food Processors Association is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs.

My remarks today are all based on the Food Allergen Labeling Guidelines issued by the food allergy issues alliance. NFPA is a member of the Food Allergy Issues Alliance, and NFPA members support the Food Allergen Labeling Guidelines. NFPA believes that it is important to present information on the major food allergens in terms commonly understood by consumers. NFPA believes that plain language presentation options should not replace but should rather augment current ingredient labeling requirements.

NFPA also believes that the approaches outlined in the Food Allergin Labeling Guidelines are sufficiently flexible to suit various

situations and serve as a useful start for this discussion.

NFPA believes that plain language labeling options should be voluntary. To require such declaration would necessitate rulemaking on several standards of identify and other existing rules, and this is an unnecessary complication.

Food allergen information presented in plain language terms will help food allergic consumers including children and other challenged readers to recognize the foods they must avoid. Plain language labeling also makes it easier for the caregivers of food allergic children to recognize the food allergens to which their charges are sensitive.

The major food allergens as defined by FDA are not all single foods. Crustaceans, fish and tree nuts represent classes of foods. Within these classes of foods, food allergen information must be presented as the common or usual name of the individual food in the ingredient declaration.

For example, for crustaceans, crab, crayfish, lobster and shrimp are the terms that would be used. For fish, the common or usual name of the fish species must be declared in the

ingredient list. Likewise, for tree nuts, the individual types of allergenic nuts must be declared.

Other foods that contain allergenic proteins should include the plain language name of the allergen. In many cases, the plain language name of the allergen is used within the ingredient declaration as the common or usual name of the food ingredient or its standardized name.

For example, hydrolyzed soy protein, buttermilk, peanut butter, cracked wheat and milk chocolate all include the plain language names of major food allergens as part of their common or usual names or standardized names. In these instances, food processors declare the plain language names of food allergens through ingredient declaration.

When the plain language name of the allergen is not declared in the ingredient list, food processors should ensure that plain language terminology is present in association with the ingredient list.

Now, standards of identity can complicate the issue of declaring plain language names for food allergens, but these complications can be

resolved.

For example, the standardized food egg albumin specifies egg, and that's required in the standard. Dried yolks, a name permitted by that standard, should be supplemented with the term "egg." The ingredient would be dried egg yolks, a name permitted by the standard, which could be declared on the ingredient list as egg yolks.

Now, despite what you heard earlier, you would not see the word "surimi" to represent egg. Surimi is derived from fish and on the ingredient list of a surimi product, you are likely to see the term "fish protein."

With respect to wheat, semolina, farina, durum flour, graham flour, and white flour, all standardized names, should include the term "wheat" and the dozens of standardized cheeses all declare "milk" as a sub-listed ingredient.

Plain language terms for the major food allergens should appear within, at the end of, or in immediate proximity to the ingredient declaration. One option is to place at the end of the ingredient declaration a statement such as "contains peanuts." It could be prefixed by a phrase that highlights attention of the food

allergic consumers such "allergy information: preceding contains peanuts."

The same effect could be accomplished with the use of a reference mark, such as an asterisk next to the name of the ingredient whose common or usual name does not include the plain name of the allergen, such as farina or casein, each followed with a reference mark. That would then refer to a corresponding notation at the end of the ingredient list that would say "wheat" or "milk ingredient." This option takes up very little space and could be useful for long ingredient declarations.

Another alternative is to use within the ingredient declaration a parenthetical statement that follows the ingredient name such as "farina (wheat)." Any of these options, "contains," reference mark, parentheses, could use bold in their other highlighting to feature the information about food allergens.

NFPA does not believe that multiple format options should be confusing to consumers provided the food allergen information is always presented in association with the ingredient declaration. This is where food allergic consumers are instructed to look for information about the

allergens in food.

Finally, plain language labeling for food allergens should be permitted on a voluntary basis. A mandatory approach would necessitate FDA revising a number of rules for standards of identity and other labeling rules. This would complicate a labeling approach that can be done, and it is now being done on a voluntary basis. Thank you very much.

[Applause.]

MS. KATIC: Good morning. My name is Lisa Katic and I am the Director of Scientific and Nutrition Policy for the Grocery Manufacturers of America. GMA is the world's largest association of food, beverage and consumer products and works at the federal, state and local level on regulatory and scientific issues.

GMA member companies are committed to meeting the needs of the food allergic community. And I'd like to commend FDA for holding this public meeting to collect information on this very important issue.

GMA along with numerous trade associations formed the Allergy Issues Alliance several years ago because the food industry wanted to be

proactively out front of and address this allergy issue.

The Food Allergy and Anaphylaxis Network is an integral part of the Allergy Issues Alliance and as the association that represents food allergic consumers, FAAN is best positioned to provide insight into the labeling practices that would be of most use to the subset of the population. We really appreciated their input and work in developing our guidelines.

As Regina has already mentioned, the voluntary program has been developed by the Alliance and was released this spring. It's a culmination of several months of work by the Alliance including FAAN and some other, as was mentioned earlier, food allergy scientific experts. Unlike a regulatory process that will take several years to develop and implement, the Alliance's voluntary program is now in the implementation stage.

GMA's Board of Directors has adopted the Alliance's labeling programs and the CEOs of each of our member companies have asked their companies to implement the program. We fully expect widespread adoption and implementation of our

labeling programs by our companies in the very near future and as was already mentioned, some companies have been actively making changes since the adoption of this program.

With regard to the plain English labeling, the Alliance's labeling program specifically addresses this issue and requires the use of plain English names on the label of foods that contain an allergenic protein that is derived from one of the major allergens.

We recognize that it can be daunting for the food allergic consumer to learn the names of all of the ingredients that may be derived from an allergin. Milk is a classic example. As Anne showed earlier, there are numerous ingredients derived from milk.

In accordance with FDA's regulations, each of these milk-derived ingredients must be declared in the ingredient statement by a different name. Casein, sodium caseinate and whey are just a few examples of the milk-derived ingredients that must be avoided by a consumer with a milk allergy.

The Alliance's labeling program makes it easier for the milk allergic consumer to identify products that he or she needs to avoid by requiring

the use of the common term "milk" in addition to the name of the ingredient on the label of foods that contain an allergenic protein from milk.

As the agency is well aware, we have a tremendously diverse food supply that uses a wide variety of ingredients. Packaging materials are different as well as packaging sizes. Given this variety, there must be flexibility in presenting the common names of the allergens. The Alliance's labeling program provides this flexibility by offering options for presenting the major allergen's common name.

For example, a manufacturer could use parenthetical statements that identify the plain English name of the allergen in the ingredient statement after the ingredient. An allergen information statement could also be highlighted or used in the ingredient declaration panel and then it would list the common name of each of the major allergens in the food.

The Alliance's program provides other means of presenting the name of the common allergen as I think Regina has already laid out. The plain English name would appear either in the ingredient statement or in immediate proximity to the

ingredient statement.

In summary, we support the use of common and plain English names on labels of foods that contain major allergens, and we believe that the Alliance's labeling program sufficiently addresses how this information should be presented.

Because we anticipate widespread adoption of this program by the food industry, we believe that the allergen-labeling regulations are unnecessary. Thank you.

[Applause.]

DR. LEWIS: Thank you very much to members of our panel, and as scheduled on the agenda, we will now begin a 15 minute discussion among members of the panel as well as with the FDA listening panel. Let me remind you that that will be followed by the opportunity for us to address the questions you may be writing down on your cards, and again there are people walking the aisles so please do take advantage of that.

Relative to source or plain English labeling, are there particular issues anyone among our panelists would like to address? Dr. Jacobson.

DR. JACOBSON: I'd just like to ask Lisa how you could rely upon that voluntary flexible

labeling when there are thousands of food producers that are not members of NFPA and GMA? Many companies have never heard of these trade associations and things can change from one management to another management. I think the consumer needs to be assured that the clear English, the labeling will always be there.

MS. KATIC: Well, no doubt I appreciate that as a definite challenge. I would say that NFPA and GMA members represent a majority of food products on the shelves. So certainly we have the bulk of what we're talking about covered within our membership.

We've talked about--through Alliance outreach we certainly plan on doing a lot of education amongst our own industry, our own industry reaching out to other smaller manufacturers that potentially are not amongst our membership. We've got some discussions already underway on how to do that as well as educating. You know we have lots of large and small and medium-sized companies within our own memberships and we think that it's imperative that some of the larger manufacturers that have long-term experience with how to make changes on labels would be best

served by educating some of our medium and smaller sized companies. So it's really all about education and outreach and we have plans underway to do that.

DR. LEWIS: Other questions? Kathy Gombas.

MS. GOMBAS: Yes. This is Kathy Gombas with FDA. I'd like to ask a question of NFPA, Regina. You had indicated that source or plain English labeling should be voluntary versus mandatory because there are a lot of manufacturers currently using voluntary labeling. Do you have a prospective on how many manufacturers are doing this today?

MS. HILDWINE: I can tell you that at the present time, the Food Allergy Issues Alliance, and NFPA, of course, is a member of the Food Allergy Issues Alliance, is developing a survey so that we can collect some baseline data from the food industry regarding their awareness of the Food Allergen Labeling Guidelines and their use of various presentation techniques. We expect to field this survey, you know, the individual associations in the Alliance to our various members probably in the next month or so.

Now, there are many more food trade associations besides NFPA and GMA and the Food Allergy Issues Alliance, and many of these are specialized food trade associations that are focused on various sectors of the food industry, and we are going to be going out to our members collecting information from food companies both large and small to get a sense of how many have now begun to use the plain language labeling that was advocated along with other things that were advocated in the Food Allergen Labeling Guidelines.

DR. LEWIS: Felicia Satchell.

MS. SATCHELL: My name is Felicia Satchell and I'm with FDA. My first question is to Ms. Katic. You had indicated that the voluntary program is currently being implemented, and I understand from Regina's last response that you are beginning to work with the industry. Is there any plan for follow-up, say, six, eight, ten months down the road to see if all of your members are implementing this, if they are complying with the program? How do you plan to track follow-up?

MS. KATIC: Well, as Regina just mentioned, we are developing, in the process of developing a survey that will give us a baseline of

awareness and use of the program now, and we plan on reinstituting that survey in the spring and then obviously probably next fall to track the changes in usage and awareness.

MS. SATCHELL: What type of incentive, if any, for voluntary compliance? I mean I can appreciate your doing a survey, but let's say that you have manufacturers that for financial reasons find it too costly to relabel, what are your plans for addressing members that may not be following the guidance?

MS. KATIC: Well, I think, first of all, the incentive is that no manufacturer wants to harm any consumer, first and foremost. They take this very seriously. Secondarily, there are legal issues that certainly no company wants to, you know, have an issue with again harming a consumer. So this is something that the industry has been working on for decades, for a long, long time. This is nothing new. This is something that the industry continues to look at and refine and redevelop.

So, you know, as I said in my comment, this is something that has gotten to the highest levels within our member companies. It's been

presented to our board of CEOs. Our CEOs are on board and have given their support obviously and encouragement for use of the program.

And I think through the survey, you know, we're really going to have some understanding of-- the trade associations within the Alliance will have some understanding of how it's being used and obviously if it's not, then that will modify or adjust our education and outreach efforts.

MS. SATCHELL: Thank you.

DR. LEWIS: Other questions? Dr. Falci.

DR. FALCI: This is Dr. Falci of the Food and Drug Administration. I think there is a lot of agreement that we have here and I'm pleased with that. I'm trying to turn my head around so I can see your format of ingredients that you have there, Dr. Jacobson. And I think that's a very interesting idea about having different kind of formats for ingredients in the ingredient statement.

But my question has to do a little bit with consumer education. Maybe you could think about that as I continue on here. That is consumer education as far as the formats are concerned. One of the things that I've seen is that there's a

large percentage of the population that are unfortunately not interested in food allergens because they don't have that problem, they don't have to deal with it.

So when you sit down and you think about trying to educate the consumer, it's hard to try to think of maybe the appropriate way of approaching people that might not be interested in it and to try to get them more interested in that. So my question again is how would you really begin to try to educate the consumer?

I know that Lisa Katic had mentioned that you're discussing that now. I'd be interested just maybe if you could elaborate more on it, but some of the things that came to my mind, of course, were TV advertisements, of course, which are very expensive, but maybe once you get into the school programs about potential new formats as well. So would anybody like to field that?

DR. JACOBSON: Well, I don't think we could expect any kind of well-funded government educational program that lasts for any significant period of time. Measures should be self-actuating and that's what a clear ingredient label is. It makes it possible for consumers to actually read

the label as the law suggests.

Look at some of those products in front of you. Tom, could you pass that thing over there? These labels are designed not to be read. You'll definitely need your glasses and a magnifying glass, too.

[Applause.]

DR. JACOBSON: It's all upper case, skinny little print, very small writing that may be inevitable, but it goes--there are textbooks on how to print things legibly. This violates every precept in those textbooks, and if the information is clear, it would make it a lot easier for consumers to read the label whether it's for food allergens or sugars or heart disease or hydrogenated fat or whatever people are concerned about.

DR. FALCI: Just as a follow-up to that, I think one of the reasons why such a package is created like that is unfortunately there is not a lot of food in the particular containers, not enough space on the container to have a large letters, but I don't know how you'd overcome that.

DR. JACOBSON: Well, I think there's certainly a variety of products. We found very

small print on very large packages also. But even an example like that one before you, upper and lower case printing would be a lot easier to read. You know designers can make labels that are easier to read or harder to read. Unfortunately, many companies are choosing the latter.

DR. LEWIS: One more brief comment before we move on.

MS. MUNOZ-FURLONG: In response to Dr. Falci's question about how to educate the consumers, if we're talking strictly about the simple language labeling, they are already reading labels, those that are affected, the food allergic population. The problem is they can't understand what they're reading. What we need to do is simplify the labels so that when the children and the adults and the teachers and so forth read them, they'll understand what they're reading, and also when that doctor makes a diagnosis and tells that patient to read the label, they will then be able to read it.

So in this issue I don't think it's such a concern for education as it will be in some of the other panels.

DR. LEWIS: We'll take one more brief

question from Felicia Satchell and then we'll move to the cards.

MS. SATCHELL: The question is directed to Dr. Jacobson and Ms. Munoz-Furlong. Both Ms. Hildwine and Katic mentioned three or four options in their presentation for presenting plain English labeling in conjunction with the ingredient statement. Allowing the flexibilities of these options, do you see that as being a stumbling block or confusing for allergic consumers?

MS. MUNOZ-FURLONG: On this issue, I don't think that it will be. The fact is that they reading the label. They need to have a place or a statement that they can understand. If we're looking at what they like, and I'll cover some of that in the next panel, they would prefer that we have a statement of "contains milk and eggs" immediately after that ingredient statement because then it saves them time. They don't have to read that entire paragraph in very small print. They can zoom in on that and put the package back on the shelf if it's not safe for them or put it in their shopping cart.

DR. LEWIS: Thank you very much.

DR. JACOBSON: I think there should be a

standardized label so consumers don't have to hunt around and say, oh, is there an asterisk here or is it boldfaced. It should always be in the same place and as Ms. Munoz-Furlong suggested, something at the end where it would say allergy information, and then milk, soy, whatever, is the best option.

DR. LEWIS: Thank you to the panelists. We'll now move to the questions from the audience, and I have several here that I think will probably easily take up our remaining time.

This question is about placement and it's directed to either Ms. Katic and/or Ms. Hildwine. Does the Alliance Allergy Labeling Program address labeling ingredients above and below the package seam?

For example, a Trail Energy Bar sent our son to the hospital because we were unaware that almonds were listed under the foil seam.

MS. HILDWINE: Well, that's a very difficult situation, and a consumer shouldn't be in that situation. Certainly, there are situations with respect to the design of packaging that are a challenge for the food industry.

The food companies do try to make that information as clear as they possibly can given the

constraints of the package size. In fact, food companies know that FDA has regulations regarding the sufficient prominence of food label information and, you know, NFPA does encourage its members to follow those regulations all the time.

I think you'll see in some cases, though, particular types of food are in particular types of packages that make, you know, using all the label space to present the required information very much of a challenge and we are working with our members to try and improve those situations.

MS. KATIC: The only thing I would add is that the program that was developed by the Allergy Issues Alliance does emphasize the prominence within the ingredient panel declaration, and that's what we would continue to support.

DR. LEWIS: Our second question from our attendees seems to be addressed for anyone who would like to deal with the topic. I suspect it's more oriented towards industry.

The question is what about "contains milk, wheat and egg ingredients," the way General Mills and Kellogg's are labeling? Is this accepted to the food allergic consumer? Is there data to support the way the industry should go for consumer

clarity?

MS. HILDWINE: Well, I'll start with this one as well. Certainly, those statements such as "contains milk, wheat or egg ingredients," this is one of the options that, in fact, the Food Allergy Issues Alliance included in our Food Allergen Labeling Guidelines. It is the top ranked option, as a matter of fact, in our presentation of the various options for presentation. And you know we think that a lot of food companies are starting to move in that direction to include this type of information that specifically says at the end of the ingredient statement that the product contains these ingredients. It reinforces the information in the ingredient statement.

MS. MUNOZ-FURLONG: Well, from the consumer's perspective, General Mills and Kellogg's are one of the companies that everybody talks about. They like their labels. They're in simple English and "that contains," and then the allergens in simple language is perceived as a shortcut and a very handy way to teach someone else how to read that label.

DR. LEWIS: Anything else from our panelist on this topic? We have a question to

three of the panelists regarding Dr. Jacobson's presentation, and it has to do with his small board that he presented. Do you folks support CSPI's ingredient facts proposal? Can you discuss it? Why and why not?

MS. MUNOZ-FURLONG: I can tell you that the allergy information statement, we have conducted some focus groups and people do like allergy information. It could also be substituted with "contain" statement and that would be acceptable as well.

MS. HILDWINE: Just focusing on the allergy information portion of the format for the moment, certainly that does present one of the options outlined in the food allergen labeling guidelines. I think there are things, though, in the format overall that need to be taken into careful consideration.

A couple weeks ago when Dr. Jacobson announced this new format, there was a side by side comparison of a current ingredient list and the proposed new format, and I, you know, just a minute ago talked about the challenges of fitting required label information on small packages, and if you do that side by side comparison, you will see that the

proposed new format takes up a great deal of label space. So that's a real practical problem that certainly needs to be explored further.

DR. LEWIS: My remaining cards focus largely on the issue of voluntary versus mandatory labeling. In our remaining five minutes, I'll try to summarize some of those. They are quite overlapping.

There is a question for Ms. Hildwine. Is your reason for supporting voluntary labels instead of mandatory ones that it's too confusing for manufacturers and the FDA to agree on this, and therefore it would delay implementation? And if so, why not implement voluntary rules now and work on standard regulations for all companies?

MS. HILDWINE: Well, first of all, voluntary rules is an oxymoron. There is really no such thing. And certainly the work that the Food Allergy Issues Alliance has been doing is a voluntary approach and we announced this this spring, and food companies, some had already been following the precepts outlined in those guidelines. Other companies are starting to do that now.

We've been encouraging members to adopt

these presentation options and these guidelines. Our concern is is that some food companies may say, well, if FDA is going to develop regulations to require this to adopt a mandatory approach, well, I think maybe I'll just wait to see what the agency does now.

In plain fact, going the mandatory route will delay the adoption by the industry of those presentation options that have been outlined in the Food Allergen Labeling Guidelines. So we would, you know, not just to mention the overwhelming complexity of this--you may not realize it, but when FDA, well, when the law changed to require declaration of ingredients of standardized foods as part of the Nutrition Labeling and Education Act, FDA had to open up the regulations on every one of the standards of identity.

I believe there are about 72 regulations governing cheese, and this is only one category of standardized food. FDA would have to make amendments to an overwhelming number of regulations. It's not just a simple matter of requiring this in a particular section of regulations.

So it would be very complicated. It would

take quite a long time. There is no reason to wait. The voluntary program that's been established by the Food Allergen Labeling Guidelines is in implementation now. So we don't think that anybody should wait for rules and that it should continue to be on a voluntary basis.

DR. LEWIS: Thank you. Lisa.

MS. KATIC: Well, just building one comment on top of that, I think Regina pretty well laid out the complexity, which then leads to the next point, why we think voluntary versus mandatory is the way to go is that down the road the industry sees this program as evolving.

If there is research, enough research that is done on a particular ingredient that it does prove that it becomes an allergen or is a problem for the public, that would be incorporated into the program and can be done right away, whereas waiting for regulations to, you know, move through the process could take one to two years, where as the industry can act very quickly and institute or implement something pretty quickly.

DR. LEWIS: My remaining cards really do play on this, and you may have already made your points, but I will offer these questions to you.

To Regina Hildwine, because recalls are so high, on what basis do you think voluntary guidelines will be enough, and is it enforceable?

To Anne Munoz, Furlong, does FAAN support mandatory labeling and legislation in this area?

And then finally, if a number of NFPA and GMA members already are labeling voluntarily or plan to, why is the industry opposed to FDA regulations which would reach all industry members since those already doing this voluntarily will just be ahead?

Again, those are issues you've been addressing so I'll allow you to answer those or build on other comments you've already made if you wish.

MS. HILDWINE: Just with respect to the issue of recalls, these, as I've observed them over the past several years, are very much related to undeclared allergens, outright undeclared allergens. The issue of plain language labeling is not question.

Also, oftentimes the presence, the notation of a recall is an indication that enforcement type activity may have begun with respect to FDA. We believe that FDA has plenty of

authority to enforce regulations relative to undeclared, any undeclared ingredient including food allergens. That's all I have to say for that one.

DR. LEWIS: Anne, did you want to make a comment?

MS. MUNOZ-FURLONG: Yes. Regarding whether FAAN is for or against or whatever the term was for mandatory versus voluntary. FAAN's position is that we know we need label improvements immediately. We are going to support any and all initiatives that are going to get us there be they voluntary, regulatory, legislative, because ultimately they're going to benefit the consumer.

[Applause.]

DR. LEWIS: In the last few minutes, does anyone else on the panel have one more comment or question before we take a break? Thank you. We will take a 15 minute break, which means we'll be back here just a little before 9:40.

[Whereupon, a short break was taken.]

DR. LEWIS: All right. Let's get started. We do have a special presentation. I have been asked to remind the audience to please make note of the fact that there is no eating in the auditorium.

That's a very important issue here. Please do not consume vitals here in this particular auditorium.

Our second panel addresses advisory labeling, and before we actually get to the panel presentations, we have with us today Ms. Theresa Dziuk. She is with our Minnesota District at the Food and Drug Administration, and she will be presenting a summary of inspectional findings.

If you would please welcome, Ms. Dziuk. Thank you.

[Applause.]

MS. DZIUK: I'd like to thank the center for inviting me. I feel very fortunate to be here today. When this started, I was a compliance officer with the state of Minnesota. In 2000, I joined the FDA as a consumer safety officer. In October of 1998, the Food and Drug Administration formed a partnership with both the Minnesota and Wisconsin Departments of Agriculture.

This partnership was in response to reports of consumers who experienced adverse reactions following exposure to allergic substances in foods which were not declared on the food label. In addition, there was an increase in the number of allergen related recalls, and we had concerns over

manufacturing controls of undeclared allergen residues.

The goal of our partnership was to eliminate duplicate inspections and sample collections, to ensure uniform enforcement and to obtain current information on allergy awareness and provide feedback to industry.

While it is generally believed that nearly every food can cause an adverse reaction, eight foods are known to cause 90 percent. FDA recognizes these as peanuts, soybean, milk and milk products, eggs, wheat, tree nuts, fish and crustacea.

Although this partnership looked at the control of food allergens, we focused on industries that used peanuts and eggs. Ice cream, bakery and candy manufacturers were selected for coverage. 86 inspections were planned and 85 inspections were conducted. Establishments inspected were 45 bakeries, 13 ice cream manufacturers, and 18 candy manufacturers.

Inspections performed were routine GMP inspections. That's good manufacturing practice inspections. State inspectors and FDA investigators were trained in August of 1999. To

ensure uniform application of current good manufacturing practices, inspectors and investigators were standardized during initial joint inspections.

Inspections were conducted in September '99 through March 2000. This was a small study. Establishment selection was not intended to be scientifically significant, but to provide an overview of current industry practices. Selection was made randomly of small, medium and large establishments that were licensed and inspected by the state departments of agricultures, that conducted interstate commerce, and that were jointly scheduled on the agency's workplans.

One measurement of establishment size used by FDA is annual gross sales. What you'll see here on the left side, there are nine categories of annual gross sales. We broke those down into three groupings and considered them small, medium and large. I've broken out on the slides both Minnesota and Wisconsin. We inspected 85 total establishments. 17 were small, 51 medium, and 17 large.

During our inspections, our investigators utilized a specialized questionnaire to aid in

assessing industry practices. Example of the areas investigators observed during the inspections were the use of shared equipment, production practices such as handling of rework, labeling and product changeover, and any other mechanism that related to the control of allergens. Samples were obtained based on observation.

This following series of slides has a lot of information that I will not be covering. I'm going to be presenting totals, and it's important to recognize that there weren't differences between Minnesota and Wisconsin.

Each of these graphs is broken down on the left side by total, and then they're also broken down by commodity. There are bakeries, ice cream and chocolate. And again, I'm only going to be focusing on the total, and I present this other information so that you can see from your own interest.

The product label is the primary means to inform a consumer of potential product allergens. Our questionnaire contained a section on the use of allergenic ingredients. Ingredients used in the formulation of the product were compared to the corresponding finished product labeling.

45 of the 85 firms inspected, and that's the blue bar right here, felt that they had adequate procedures in place to verify label accuracy. Of the 45 firms that felt that they had adequate procedures to verify label accuracy, our investigators found that 15 percent had incorrect finished product labels.

Of the firms that didn't have procedures to verify their labels, 51 percent had incorrect finished product labels. Only one of the 85 firms inspected had a policy against the use of advisory labeling.

One bakery inspected reported that they had received a consumer complaint. The consumer stated that they had an allergic reaction after consuming a product that normally would not contain peanuts. The consumer called the bakery and said they were allergic to peanuts and had the reaction when they consumed this product. The bakery reported to inform the consumer that the labels states it may contain peanuts. The customer appeared to be satisfied and had no additional contact with the firm.

This is an example where advisory labeling may not always be effective. An advisory labeling

statement such as "may contain" are not a substitute for good manufacturing practices.

37 of the 85 firms inspected utilized rework. Procedures for handling rework varied by industry. Of the firms that utilized rework, 48 percent had product that tested positive for undeclared allergen residues. When using shared equipment, product changeover presents an unintentional opportunity for product that contains an allergen to contaminate a product that does not contain an allergen.

Equipment cleaning is critical to the control of allergens. While only three establishments inspected utilized analytical test methods to verify their cleaning and sanitization procedures, 41 of the 85 had standard operating procedures in place to control cross contact.

During our inspections, we observed that production was frequently not scheduled. Scheduling was conducted first in/first out where the first order received would be the first order manufactured, and allergen considerations were not addressed.

Scheduling was based on the color of production. For example, a sugar cookie would be

the first product manufactured, followed by various flavored chips, then peanut butter cookies and then finally ending the production run with gingersnaps.

Many firms did not have dedicated equipment for allergen and non-allergen product lines. Non-dedicated product lines were observed to be inadequately cleaned between production. Many times equipment was rinsed with only water or the equipment was cleaned at the end of the day. Only three of the 85 firms inspected utilized personnel that were trained and dedicated to allergen control.

At this time, a tolerance for undeclared allergen residues has not been defined. A standard method has not been approved by the AOAC. For the partnership, we utilized an ELISA test kit that was developed by the University of Nebraska and manufactured by the Neogen Corporation. This was used strictly as a screening tool.

Each sample was a composite of ten eight-ounce subs and a ten part per million test kit standard and a reagent blank were used as our controls. We determined a sample positive if it was reported positive at or above ten parts per million.

Samples were not obtained at every manufacturer inspected. Sample selection was based on manufacturing practices observed during the inspection. Our samples were used to confirm our observational findings. A sample was obtained if equipment was shared and a non-allergen containing product was produced after an allergen containing product without the equipment first being cleaned.

We identified areas where there was a potential for cross contact and then took a sample. Our goal was to assist industry in defining critical control points in their process.

We collected 118 partnership samples for analysis which was performed by the state laboratories. 73 samples were obtained for undeclared peanuts and 45 samples were obtained for undeclared eggs. 73 of the 85 firms used peanuts in their production. 18 of the 73 samples obtained were found positive for undeclared peanut residues. It's important to remember that we chose these samples based on our observational findings. So we expected to find residues in these samples, and these 18 samples is equivalent to 25 percent of the samples obtained.

When we look at the total picture

comparing our observations with the sample analysis, it was observed that 49 percent of the firms had a potential for cross-contact of allergens into non-allergen containing products. Of these firms, 50 percent had positive samples for undeclared allergens. Of the firms that utilized rework, 48 percent had samples that tested positive for undeclared allergens. Of the firms that didn't have procedures for label verification, 51 percent had incorrect finished product labels.

Allergen awareness was very high in some firms and extremely low in others. We held industry workshops to provide feedback on our partnership. Three workshops were held in May of 2000. We prepared an information pack with allergen education materials and for the firms that were unable to attend, we mailed this pack to them.

We conducted follow-up. All establishments that were inspected received a copy of their establishment inspection report. They also received a copy of their analytical results. We either met or sent a letter to the firms that had samples which tested positive for undeclared allergens and explained the significance of these findings. We conducted follow-up inspections at

these firms during August of 2000.

We conducted 21 follow-up inspections and collected 18 samples. We found that industry made every effort to address and modify their good manufacturing practices. The greatest change noted was in addressing cross-contact in the form of scheduling and sequencing. Firms dedicated equipment to non-allergen and allergen-containing products. They reconsidered their use of rework.

Many firms corrected their labels. Sanitation practices were improved and verification testing of equipment and finished product was implemented. Many firms trained their employees on the significance of allergen control.

Through this partnership, we felt that the FDA and states gained credibility with industry. We found that the industry was very open and willing to share their manufacturing practices. Adherence to good manufacturing practices are essential in the reduction of undeclared allergen, and advisory labeling is not a replacement for good manufacturing practices.

We are all in this together as consumers and labeling should be addressed as a food safety concern. Thank you.

[Applause.]

DR. LEWIS: We'll now begin Panel II which addresses the topic of advisory labeling. We have four presenters. First, Ms. Lisa Katic. Second, Regina Hildwine. Third, Anne Munoz-Furlong. And last, Dr. Michael Jacobson. Lisa.

MS. KATIC: Thank you.

MS. KATIC: GMA supports the use of supplemental statements such as "may contain peanuts" consistent with the criteria established in the Food Allergen Labeling Guidelines prepared by the Allergy Issues Alliance. These guidelines clearly state that consistent with the FDA policy on this issue, supplemental allergen statements should not and cannot be used in lieu of good manufacturing practices.

In addition, the guidelines restrict the instances in which a manufacturer can use these kinds of statements. Under the guidelines, supplemental statements only can be used when:

(1) The presence of a major food allergen is documented through visual examination or analytical testing of the processing line, equipment, ingredient or product or other means;

(2) The risk of a presence of a major food

allergen is unavoidable even when current good manufacturing practices are followed;

(3) A major food allergen is present in some but not all of the product; and

Last, the presence of a major food allergen is potentially hazard.

If some but not all of these four criteria are met, the guidelines do not allow the manufacturer to use a supplemental allergen statement. In such instances, the manufacturer must either consider an additional food allergen control measure and/or some other labeling strategy.

With regard to the placement of the supplemental allergen statement, the guidelines require the statement to appear at the end of or in immediate proximity to the ingredient statement. The guidelines require that the statement be as accurate and as conspicuous as possible. Examples of the type of supplemental statements that are being used include "may contain peanuts" and "processed on the same equipment as milk."

The guidelines provide the manufacturer with the flexibility to determine the type of supplemental statement that will best describe the

product.

Supplemental allergen statements are an integral component of the Alliance's labeling document. Although the food industry is diligent in its efforts to prevent major food allergens from inadvertently ending up in food products, the nature of the food supply and our manufacturing processes in some instances make it impossible to avoid.

Farmers generally grow numerous crops and use the same equipment to harvest, store and transport corn, soybeans, wheat, peanuts and other crops. This can lead, for example, to the presence of soy in corn or wheat in peanuts.

Inadvertent contact can also occur in the manufacturing facility where the same processing equipment is used to manufacture a wide variety of products. In an attempt to prevent the inadvertent presence of allergens in products, many in the food industry have adopted a three-tiered approach to minimize this inadvertent contact with allergens.

This approach involves dedication when possible, separation, and as a last resort labeling. First, when possible, the industry will use a dedicated system. This may be possible for

some large volume products where continual production on the same or multiple lines is needed to meet consumer demand. It is not financially possible, however, to have a dedicated system for each product that is manufactured by a company.

When a dedicated system is not a possibility, the company will use separation as a means to minimize inadvertent contact. This can be accomplished by physical barriers, the use of dedicated containers for raw materials that contain allergens, and other means to prevent the inadvertent contact of a major allergen with non-allergenic ingredients.

Companies will also schedule production so that when possible, a non-allergen containing product will be manufactured on a line before a product that contains an allergen.

Companies will also thoroughly clean a line that has been used to manufacture a product containing a major food allergen before manufacturing a product that does not contain that allergen.

Cleaning, however, will not always succeed in removing the allergens from all services of the equipment. It has been proven time and time again

that water is the most efficient method for removing allergenic proteins from processing equipment. There are numerous foods and food systems, however, where water cannot be used as part of the cleaning process due to the nature of the food or due to microbiological safety concerns.

Chocolate and peanut butter manufacturing systems are examples of processes where water cannot be used to clean the machinery because these foods do not readily dissolve in water and the use of water can lead to microbiological concerns due to the puddling of water somewhere in the system.

Water also cannot be used in the cleaning of certain packaging and electrical equipment such as baking ovens and cooling tunnels for obvious reasons. Water and electricity don't match.

In instances when water cannot be used for cleaning, the food industry frequently will use a dry process for cleaning, such as flushing the line with a safe, non-allergenic dry ingredient or food that removes the food from the system.

The use of these dry ingredients is recognized as an appropriate good manufacturing practice and in many instances is dictated by the microbiological concerns that are present by wet

cleaning.

The use of dry ingredients to clean a system, however, is not always successful in completely and 100 percent removal of the allergens. Systems that rely on this type of cleaning frequently cannot be cleaned to remove all residues of a major allergen.

In those instances when neither dedication nor separation can prevent the inadvertent contact with the major allergen, the industry will resort to labeling, labeling consistent with the four criteria established in the Alliance's labeling program that I stated earlier.

These criteria are designed to ensure that supplemental allergen statements are used only in limited situations and not as a substitute for good GMPs.

Supplemental allergen statements are designed to alert the food allergic consumer that the product in question may have an allergen that they need to avoid. We recognize that a certain percentage of a given product bearing this supplemental allergen statement may be free of the named allergen and safe for consumption for the food allergic consumer. However, the allergen may

be present in some of the foods manufactured on that line. Thus, necessitating the use of a supplemental statement that alerts the food allergic consumer to the possible presence of this allergen.

As stated in many comments earlier, we believe that the allergen labeling issues can be best addressed through the voluntary program and that additional regulations are unnecessary. Although the existing regulations do not mandate the use of common English names or establish criteria for the use of supplemental allergen statements, the industry through the Alliance has reached agreement on these labeling issues and is now in the implementation phase.

We believe that continued educational efforts will be one of the most effective means to address this issue. GMA has educated its member companies about the importance of the allergen issue, and as stated this morning, the senior management from each of our member companies has agreed to adopt the labeling program.

We recognize, however, that we also have to reach the small and medium sized companies that may not be members of GMA or of the other alliances

that are part of the Allergy Issues Alliance. The Allergy Issues Alliance is in the process of developing educational programs for these other smaller companies. Moreover, FDA has the existing statutory and regulatory tools to take enforcement action against those companies that market products with undeclared allergens.

The unacceptably high level of recalls due to the presence of undeclared allergens is perhaps the strongest evidence supporting the agency's ability under its existing regulatory framework to address this issue.

We also encourage FDA to develop and maintain a strong enforcement presence for food allergens. One of the best ways to effect change and to encourage all companies regardless of size to make certain that their products are properly labeled and that their foods are manufactured in accordance with good GMPs is through continued inspections and when necessary enforcement actions.

We believe that a strong FDA presence and the knowledge that there is a "cop on the beat," if you will, would be a much more effective use of agency resources rather than additional regulations.

In conclusion, GMA supports the use of supplemental allergen statements in those limited instances when the four criteria in the Alliance's labeling program are satisfied. Consistent with FDA's guidance on this issue and the terms of the Alliance's labeling program, supplemental allergen labeling cannot and should not be used as a substitute for GMPs. Thank you.

[Applause.]

MS. HILDWINE: Thank you very much. Episodes of inadvertent cross-contact between foods that contain major allergens and foods that are not intended to contain those allergens coupled with the resultant problem of undeclared allergens in the product where they are not intended indicate that both production controls and labeling approaches must be discussed for these foods.

FDA's questions focus on the issue of supplementary or advisory labeling, the so-called "may contain" statements. But NFPA believes that this discussion may include a mention of manufacturing practices. NFPA believes that this is the correct approach since we advocate the limited and carefully controlled use of supplementary of advisory food allergen labeling.

Food processors that prepare foods that may be exposed to inadvertent contact with major food allergens acknowledge that labeling is not a substitute for good manufacturing practices. GMPs and their resultant controls must be considered first before labeling approaches are considered. Processors should review the plant environment including storage conditions and production line architecture; should review the products, controls and practices of their supplier; should examine their own production operations, including separation, sanitation and scheduling practices; and then should create optimum conditions for food allergen control including employee training as far as they are able.

When this process is completed, if the risk that the food allergens may be present, that risk still exists, then supplementary allergen labeling must be considered. Supplementary or advisory labeling should not be an easy shortcut to bypass activities that are food processors' responsibilities, but rather should be viewed as an approach of last resort when the risk of presence of a food allergen cannot be avoided with absolute certainty.

Supplementary or advisory labels should be relatively rare, not increasingly more common. Nevertheless, given the difficulties of achieving absolute certainty that there is no risk of presence of major food allergens in a variety of operational situations, supplementary or advisory labeling is necessary and should be permitted.

The food industry has taken numerous steps over the past several years to change manufacturing processes to reduce the potential for cross-contact with major food allergens. At NFPA, we have a Food Allergens Committee that has been working, meeting for several years, to discuss these practices. As a result of these discussions, last year NFPA issued a "Code of Practice for Controlling Food Allergens," and this year we have started an elaboration of the Code of Practice, a how to implement the code of practice for the use of our members, which, by the way, cover the broad gamut of food processing, various sectors in the food processing industry.

The food industry recognizes that under existing GMP regulations, reasonable precautions must be taken to prevent cross-contact with major allergenic proteins. In instances, when

cross-contact cannot be avoided even when complying with GMPs, food and ingredient manufacturers then use labeling that informs the food allergic consumer of the possible presence of allergens in the food.

However, only supplementary label statements that are used in careful controlled circumstances would provide a food allergic consumer with enough information to make a clear decision about whether or not a food is appropriate for them to eat.

The Food Allergen Labeling Guidelines of the Food Allergy Issues Alliance outlined four conditions that spell out the carefully controlled circumstances to govern responsible consideration of supplemental food allergen statements. Lisa went through these and I'm going to do it again because we believe these are very important.

The guidelines present a reasonable yet rigorous approach to the criteria for determining whether supplemental labeling statements should be used. These type of food allergen statements should be used judiciously only when all four of the following criteria are met:

First, the presence of a major food

allergen is documented through visual examination or analytic testing of the processing line, equipment, ingredient or product, or through other means.

Thus, the first step is to affirm that the major food allergen is in the environment. This affirmation can be accomplished through examination of the physical plant, processing procedure, analytical testing where available, or through documentation.

Second, the risk of presence of a major food allergen is not unavoidable even when current good manufacturing practices are followed. This criterion signifies that all the feasible operational issues that can be addressed have been addressed with respect to control of the major food allergens, yet even under those conditions, there is not a complete certainty that one can avoid the risk that the allergen could be present.

Third, the major food allergen is present in some but not all of the product in question. Clearly, if this criterion is not met, "may contain" type label statements could not apply. If the allergen is present in all of the product, there is nothing may about it. The product does

contain the allergen.

The occasional or sporadic presence of an allergen may provide additional information that allows the food processor to diagnose a situation with a supplier, the plant environment, a piece of equipment or a processing procedure. This information would then trigger a review back to the second criterion.

If one can identify a feature that would enable the processor to control further the risk of presence of an allergen, then steps should be taken to exert additional controls.

This third criterion highlights that the review of allergen control procedures is not static, but dynamic. Review of the criteria for supplemental labeling should be undertaken whenever there is a change to one of the operating variables such as ingredients, suppliers, equipment or processing techniques.

The fourth criterion is that the presence of the major food allergen is potentially hazardous. At the present time, scientists do not agree that there is a condition under which the presence of the major food allergen is not potentially hazardous, so this particular criterion

at the present time would always apply.

Now, if some, but not all of these criteria are met, food and ingredient manufacturers should consider food allergen control or food allergen labeling strategies other than supplemental allergen statements. Meeting all four criteria will ensure that supplementary or advisory label statements are considered only after due diligence.

Meeting all the criteria also ensures that labeling statements are not used capriciously or as a theoretical precaution. For food processors, adhering to these criteria undoubtedly will have associated costs for reviews, self-inspections, audits, documentation of procedures, post-sanitation testing, personnel training and sometimes new equipment or facilities.

However, failure to be vigilant with GMPs or such widespread use of supplemental labeling that food allergic consumers no longer believe the statements, these can have consequences that are not only costly but are tragic.

If supplemental allergen labeling is used responsibly, the likelihood is that food allergic consumers will believe the statements and will

statement should be to prompt food allergic consumers to draw the conclusion that they should not consume the product.

In order to provide for different production circumstances, there should be flexibility to the presentation of supplementary or advisory food allergen statements. If such statements are to be accurate, then the one-size-fits-all approach is not feasible.

For this reason, FDA should permit but should not mandate such labeling in proximity to the ingredient declaration and food processors should adhere to the necessary food allergen controls and evaluation criteria regarding the use of these statements. Thank you.

[Applause.]

MS. MUNOZ-FURLONG: I have some slides. Okay. What I'm going to talk about I will continue to refer to as "may contain" labeling, but I really am intending for it to be all of the precautionary allergen statements.

May I have the next slide? Now my objectives here are to provide you with information about what the industry is currently doing and how that is impacting on the consumer and the consumer

last week, and the product that their child has been eating for years and years has been safe. This week, they can no longer purchase that product because it says main contain on it.

The only difference is that the "may contain" has been added to the ingredient declaration. There are no other ingredients that have changed. This is causing a lot of frustration and a lot of confusion to the allergic consumer.

Can we go back on that slide one more time? We can't go back. Okay. All right. Well, I'm going to make my point anyway. The point is that because of the proliferation of "may contain" statements, the integrity of all of the precautionary labels are being questioned by consumers.

A perfect example came to our office several days ago. One of our members was on an airplane and was given a bag of raisins. She looked at the ingredient label simply because our members are trained to read ingredients for everything. On a bag of raisins, it said may contain peanuts. You have to wonder what's going on.

Now, as a result of the proliferation of

some of these statements, some of the physicians are telling their patients to ignore these statements because they're on everything and they don't believe that they're really there for anybody but the company's safety.

As a result, some patients are making the decision on their own to ignore these statements. This to me is playing Russian roulette. The other concern I have about this is that we are talking about children and it concerns me greatly that parents and others are making decisions because they're so confused about what's going on out there.

Next slide, please. Now, as I mentioned earlier, when we asked for the write-in to our survey, what were the three major concerns from our membership, "may contain" was at the top of the list. Some of the comments that we got, and we got hundreds of comments in our book about some of these issues, were that "may contain" is perceived to be a defensive legal tactic or a way of avoiding good manufacturing practices.

Again, this is because the consumers have been left to their own to try and decipher some of these labels.

Now when we go on and look at some of the data from our study, when we asked them how the perceive these statements, if it says contains whatever the allergen is, 96 percent of the membership reported that they do not purchase that product.

When they see "may contain," 92 percent do not purchase that product. When they see "processed on shared equipment," 87 percent of the people do not purchase the product. And manufactured in a plant that also produces nuts or peanuts or whatever the allergen is, 66 percent never purchase the product.

The point I want to make here is that if a company is putting these types of statements, manufactured in a plant or processed on shared equipment, because of a risk to the consumer, because they intend that the consumer not purchase that product, we can see from this information that they're missing the mark, and there is a huge group of people that are at potential risk because they don't understand what you're trying to tell them with these labels.

Now when we drilled down a little deeper and we asked about the "may contain," how do they

interpret this, "may contain" to this group is a gray area. They live in a black and white world. If you're allergic, you avoid the food. "May contain," they ask is it in there or isn't it in there, how can we tell?

When we asked about may contain any and all of the following, and then there is usually a long list of allergens, they want to know when is it in there? How can we tell? Is there a code on the package? How does this happen that a manufacturer does not know what is in the product that I'm about to eat? And then don't they clean? They're concerned that these statements are being used in lieu of good manufacturing practices.

Next slide, please. And when we ask them about manufactured in a plant that also processes--most commonly we see this with nuts or peanuts, they questions that came back to us and that are coming back to the industry, are how far is the allergen and non-allergen containing equipment from each other, and when you give me that information, can you tell me what the risk will be to me?

Obviously, none of us can answer this question. Therefore, this kind of labeling raises

more questions to the consumer than it really answers and it causes again additional frustration. Another problem that we're seeing with this type of labeling is when we have multiple product packages, the outside of the product packaged does not match what's inside so we may have a may contains something on individual packages on the inside, but not on the outside.

Next slide, please. Now when we asked them about contains, and I mentioned this at the earlier panel, this to them is very black and white. It contains it. I'm allergic. I can't have it.

If they see the allergens bolded or highlighted or in a contains statement immediately after the ingredient declaration so that it's still within that visual range that they scan on that package, this again is a shortcut and is perceived to be a favor that a company is doing to them because it's helping them read that label very quickly and it saves time with each product that has to be read.

So, in summary, the food allergic consumers need to know what is in the product. This is a health and safety issue for this

population. The companies have a responsibility to provide accurate, reliable, consistent information about that information, and I think we all agree that we all need a standard guideline for when these precautionary statements will be used so that we can educate the consumer about what they are supposed to do when they see these statements.

We also would like all companies to use these statements judiciously. Now, the guidelines that we worked with on the industry certainly address this issue, and I applaud the companies that worked on this with us and are already doing this. However, I am concerned as I hear more and more smaller companies saying we're not going to do this until it's regulated and we will wait and see what FDA does.

So there is a lot of work that needs to be done in this issue. I'd also like to make a point that this is an international issue. We are hearing the same thing from our colleagues in other countries.

If we could have the lights, I want to read very quickly in my remaining two minutes an e-mail that is very typical of what we get in our office from our members. This is from a woman who

says my son has tree nut allergies. Recently it seems that many manufacturers are placing warning statements on their packages such as "may contain nuts," "may contain traces of peanut or other nut particles due to manufacturing," or a candy corn product that the list includes "may contain peanuts, walnuts, almonds, pecans, cashews and other ingredients."

I realize that the foods might be manufactured on the same machinery as foods that do contain nuts, but it is increasingly difficult to know the true ingredients. I'm afraid it will become likened to the boy who cried wolf and we will all start doubting the ingredients. And with that, I'd like to conclude. Thank you.

[Applause.]

DR. LEWIS: Just a quick reminder to the audience, you can write your questions on the cards and we will have someone collect them from you.

DR. JACOBSON: Contamination of food with undeclared allergens is what makes life so fearful for people with severe allergies. They live in terror that a food contains an allergen not listed on the label.

Unfortunately, such contamination occurs

fairly frequently as we heard a few minutes ago from the FDA consumer safety officer who did the study in Minnesota and Wisconsin.

That study found that in a selected sample of 85 ice cream cooking and candy manufacturers, 21 marketed products containing undeclared peanut or egg ingredients, and those are the only two allergens studied. If they had looked at others, there may have been other problems.

Similarly, the Oregon Department of Agriculture tested 62 chocolate candies that were not supposed to contain peanuts, but 23 percent of those did contain significant levels of peanuts, and University of Nebraska researchers found peanut allergens in four out of 19 packaged foods that neither listed peanuts as an ingredient nor warned consumers that the products might contain peanuts.

In some of those cases, the products may simply have been mislabeled. Others may have been unintentionally contaminated. Though actual problems from cross-contamination are very difficult to identify, at least three reports in the medical literature have found cross-contamination having caused allergic reactions.

In two different cases, toddlers suffered anaphylaxis due to milk protein in sorbets. Peanut antigen in gingersnap cookies was the cause of a 34 year old man's reaction.

"May contain" language is sometimes appropriate to inform consumers of the presence of possible allergens. But excessive use of such statements deprives sensitive consumers of choice and may cover up sloppy manufacturing practices.

We strongly support the FDA's position that quote "such labeling should not be the norm and that manufacturers should strive to eliminate the presence of allergenic materials that are not intentionally added to a specific food product."

That policy was first enunciated in Commissioner Kessler's 1996 letter to food trade associations stating that quote: "Precautionary labeling should not be used in lieu of strict adherence to good manufacturing practice to effectively reduce and eliminate the likelihood of cross-contamination, label mix-up or employee error." Five years ago.

Unfortunately, we have heard that some industry lawyers are advising manufacturers not to test for allergens because of product liability

issues. That kind of thinking underscores the need for aggressive FDA action.

Consumers must be informed whenever an allergen unavoidably might sneak into a food in which it does not belong. The challenge is to define when contamination is unavoidable and it is appropriate to say "may contain" and to distinguish that from situations of manufacturer sloppiness where "may contain" labels are not appropriate.

At one end of the spectrum, contamination clearly is avoidable when companies intentionally add rework or other material that contains an allergen into a food that is not supposed to contain that allergen.

On the other extreme, ensuring that every last residue of peanuts is cleaned out of complex equipment or a shipping container before a food that is not supposed to contain an allergen is made in that equipment or shipped in that container may be very, very difficult, especially for smaller companies.

When "may contain" statements are appropriate, they should be provided in an allergy information section of an ingredient facts label, and it should say something like: "Allergy

information: corn, wheat, may contain peanuts." "May contain" statements should be stated simply using standardized working and without explanatory language such as "manufactured on equipment that sometimes also processes peanuts." Such verbiage simply adds clutter and raises questions as Ms. Munoz-Furlong indicated in consumer's minds.

The industry's Food Allergy Issues Alliance makes a reasonable stab at deciding when "may contain" language is appropriate, but it needs improvement. First, companies that only visually inspect for allergenic ingredients, not test for them, would not use "may contain" language.

Also, the industry's guidelines are totally voluntary and some of their lawyers are advising against tests. As I mentioned, five years ago, the FDA sent a warning level to the food industry to eliminate cross-contamination. Judging from the FDA's study and the other two studies I mentioned, not enough has happened.

I think the time has long past for all this total voluntary flexible action on the part of industry.

[Applause.]

DR. JACOBSON: Therefore, the FDA should

amend its GMP regulations with a requirement for companies to take all practical measures to exclude contamination of foods with unlabeled allergens. Companies should develop HACCP plans to ensure proper cleaning of shared equipment, use of separate equipment for allergen-containing and allergen-free foods whenever possible, regular testing of products for unwanted allergens and other measures.

The best way to ensure that companies are using "may contain" only when possible contamination is unavoidable is regular unannounced FDA inspections and testing of products for major allergens.

[Applause.]

DR. JACOBSON: The FDA has already stated in its April 19 Compliance Policy Guide that undisclosed cross-contamination may cause the food to be considered adulterated. Seizures of contaminated products would protect consumers and send a clear signal to the industry that the FDA is truly concerned about food allergens and will vigorously enforce its compliance policy.

That kind of independent oversight should encourage manufacturers to maximize their

precautions. Currently FDA inspectors rarely visit factories that make cookies, pastries and other foods that may contain dangerous and unlabeled allergens. The FDA simply lacks the funds and so companies don't even have to worry about inspections.

We urge the FDA to use some of its budget increases to hire additional inspectors. In addition, we urge the FDA to seek new funding on the order of roughly $10 million a year for more inspectors, more tests, educational efforts and research to develop quick reliable testing methods.

[Applause.]

DR. JACOBSON: I hope that the food industry would recognize the value of that investment to the public's health and to its own reputation and support a funding request. In that regard, I was delighted to hear Lisa Katic say that FDA should have a strong enforcement presence, and I hope they'll join with us to lobby Congress to provide that $10 million or so in additional funding.

[Applause.]

DR. JACOBSON: Finally, to further assist consumers, as the Attorneys General recommended,

the FDA should require labels to bear a toll-free telephone number that people could call to get up-to-date information about ingredients and possible contaminants. Companies periodically modify product composition and manufacturing practices.

Many people with severe allergies like to contact companies just to make sure that labels are still correct and that accidental or incidental additives have not crept into a food that had been safe to eat.

In sum, the FDA should press industry to clean up their manufacturing practices; "may contain" statements should be used to inform consumers, but only when cross-contamination is unavoidable. And the FDA should enforce its policies by conducting more inspections and testing more products. Thank you very much

[Applause.]

DR. LEWIS: I'd like to thank all of our panel speakers for Panel II Advisory Labeling, and we will now begin a discussion either among the panel members themselves or with the FDA listening panel. Does anyone have an opening question, comment?

Dr. Wilcox?

DR. WILCOX: I'd like to address a question to Ms. Munoz-Furlong. Much of the industry discussion on good manufacturing practice and labeling focus on the eight major allergens. Does your organization agree that at this time that's the appropriate focus or do you think additional efforts also need to be placed on the less common allergens?

MS. MUNOZ-FURLONG: My belief is that if we focus on the eight major allergens, we've covered 90 percent of the problem, and once we clear that up, we should start looking in other areas, but keep it to the eight so that we can focus there.

DR. LEWIS: Another question?

DR. FALCI: This is Ken Falci of the Food and Drug Administration. Well, first of all, I think it kind of disturb me that when you take a look at the different kinds of advisory statements like "may contain" compared to "peanuts were also made in this facility," that consumers get a different kind of perspective, and that was brought out pretty well by Anne's slides.

I was just wondering does the panel feel

that that makes sense? That there is a different perception and risk as far as when people read these different kinds of terms, and is there any other survey that industry is potentially doing or anybody else that has other data that could confirm?

MS. HILDWINE: I would say that this is an area that concerns the food industry as well, and while we have not actually done a survey, I mean it's appropriate to survey consumers as to their perceptions of that labeling, and our members really aren't in a position to be able to provide that information. However, that said, the food industry is working with food companies to help them improve their good manufacturing practices to the best of the ability of those food companies.

In other words, do the best job you can. We as the association representatives are here to help you. At NFPA in particular, we have a lot of scientific expertise on staff that can be of assistance to members relative to good manufacturing practices.

Now if good manufacturing practices are sharpened, are applied in the correct way, and food products are produced in accordance with those good

manufacturing practices, then any use of a supplementary or advisory label statement that follows that will have true meaning behind it. It won't be used simply as a theoretical precaution. It will mean something, and that's what the food industry wants with those label statements.

They want them to mean something to the food allergic consumer because they want the food allergic consumer to believe them. The food industry wants food allergic consumers to see these statements and to take away the meaning that if they're allergic to the substance that's named in that statement, they should not consume that food.

Now, do we have a long way to go? We have a lot of work to do. NFPA has been working on this for a number of years. We recognize that we need to help our members more and more all the time. But we're committed to doing that and we're working on that everyday.

DR. FALCI: As a follow-up, but again the two different kinds of statements that would be out there like "may contain" or "made in a processing facility," and these would be like suggestives, precautionary statements, that the agency might want to look at maybe in the future as guides or

regulations, and the problem there is the consistency in the mind of the consumer when they actually read these kinds of different statements, and I'm just wondering that it sounds like you do agree that there is some inconsistency when you do use these kind of advisory statements.

MS. HILDWINE: The issue of the inconsistency is something that we're going to have to work on, but I would say that, first of all, since it is a label statement, it has to be true. If the food is not processed on shared equipment, then it should not use the shared equipment type statement. If it's not processed in a shared facility, it shouldn't use a shared facility type statement.

So those statements have to be true. And in order for those statements to be true, those good manufacturing practices have to be applied first.

DR. FALCI: I guess as another follow-up, when you look at "may contain," and you look at the other statement like "made in a plant that processes peanuts," though, you still get, I mean as a consumer why not not use "made in a plant that processes peanuts" even though it might be true?

Why not use "may contain"?

MS. HILDWINE: Well, "may contain" would be true.

DR. FALCI: Right. And less maybe confusing?

MS. HILDWINE: This is something that we certainly do have to continue to look at.

DR. JACOBSON: Can I ask a question?

DR. LEWIS: Dr. Jacobson, please.

DR. JACOBSON: May I ask a question? And I'll just be very blunt about this. Can I ask both of the industry representatives, and especially Lisa, you know that the FDA doesn't have resources to inspect very many manufacturing facilities. You know that the FDA has been focused on microbiological problems and looking at those factories, not factories that use food allergens.

Would your two associations support $10 million in increased funding for the FDA to conduct more testing, enforcement and research in this area?

MS. KATIC: Actually, Michael, I'll be very blunt right back. Our associations are both actively looking at more than $10 million in funding for FDA, whether it be for allergy,

microbiological inspection, or anything else that's under their purview. We think that that gives or maintains the credibility of FDA both domestically and internationally and, you know, we have seen a decline in resources, as you have, for FDA, and we think that's in the best interest of everybody including the industry that they get that funding.

[Applause.]

MS. HILDWINE: And I would just add that we're certainly not just going to wait for FDA to advance the ball relative to the research. NFPA is conducting research into testing for rapid methods that can be validated. I mean that's part of the problem, that there are some problems relative to the number of validated test methods that are out there for food allergens, and certainly NFPA is doing its part, and I know a lot of other organizations are doing their part to advance research in this area as well.

DR. LEWIS: Other questions, panelists?

DR. FALCI: Just one more--

DR. LEWIS: Dr. Falci.

DR. FALCI: --I promise. This word "unavoidable" is a troublesome word because when one has to make a decision, I guess, in industry or

in processing plants when an allergen is particularly unavoidable, and I would encourage everyone in the industry to just be more clear about the conditions that are around this term "unavoidable" in the future so that we can get a better feel for what's particularly involved.

And I guess if you want to expand on that thinking, and you start thinking about different kinds of food industries, that the word "unavoidable" might mean different things to different industries. So that you had mentioned that I believe peanuts, peanut butter plants or chocolate plants were difficult to clean, for instance, with water, and so these kinds of industries might have different kinds of unavoidable kinds of problems and maybe different kinds of good manufacturing practices that you mentioned.

And so one could lead oneself to the thinking in the future that there might be good manufacturing practices that might be applicable to different industries if one were to think about allergen control procedures. And so that's sort of a question, but it's sort of a statement, and if you have comments on that, I would be glad to take

them.

MS. HILDWINE: When we talk about unavoidable, it is always in connection with good manufacturing practices, and essentially it's, you know, the bottom line where a company goes through a process and evaluates its practices and at the end, that company says we have done the best that we can, and we still can't get rid of it. And in that case, that's unavoidable.

Now, again, different sizes of companies, different sectors of the industry, certainly are going to have to different kinds of applications of good manufacturing practices. And we are committed to working with all of our members regardless of size to help them improve their GMPs. So that if they go through the process and then have to use or have to consider supplementary labeling, that that supplementary labeling will have true meaning to the food allergic consumer.

DR. JACOBSON: I think that you're going to have to end up deciding what's avoidable and what's unavoidable. I mean drawing a distinction, it's like drawing a line in the Potomac River. It's not going to be very clear. But it's going to be, I'd much rather trust FDA inspectors evaluating

when a "may contain"--when an ingredient is avoidable or unavoidable than a manufacturer's discretion.

DR. LEWIS: Kathy.

MS. GOMBAS: Yes, this is Kathy Gombas with FDA, and this is actually an Alliance question so either GMA or NFPA. We're talking about GMPs, I'm wondering if the Alliance has started looking at and identifying specific GMPs for the various products and processes that are out there that would minimize allergen cross-contact?

MS. HILDWINE: Okay. I'm doing this one, too. First of all, just to clarify, Anne Munoz-Furlong is also a member of the Food Allergy Issues Alliance, but that said, a number of the associations that are members of the Food Allergy Issues Alliance have already developed guidance relative to GMPs for their members, and these associations within the Alliance, many of them are specialized associations that represent particular sectors of the industry. I don't know if you guys want me to name you, but there's bakers, there's candy and convection, there's dairy product associations, there are a number of associations whose manufacturing practices have some very

specific concerns related to food allergies and they have already done a lot of this work.

They've shared this work with the Alliance and so we're all learning from that. NFPA is working on this now. This issue is what resulted in our code of practice. And now we are developing some additional guidance to help our members regardless of what sector they are in to improve their GMPs. So there's a lot of work to go around for everybody and every association that's in the Food Allergy Issues Alliance has been dedicating a lot of energy over the past several years to this particular issue on behalf of their members and we're no exception.

MS. KATIC: Just adding on to that, ditto everything that Regina said, but we have looked at that as an item for future discussion and further review specifically because we've been focusing so much on our labeling program. That's obviously taken up the bulk of our time, but certainly have not discounted that there might be a need to look further into what you asked down the road once we've got the labeling part well defined.

DR. LEWIS: Other comments from panelists? Well, while you're cogitating for a few moments

because your time is not up, we'll move to some of the questions we have. We have quite a few. I do want to mention that we've received several questions for Theresa Dziuk, who reported on the Food Allergen FDA/State Partnership. Relative to any of those types of questions, you may access any information that the agency has on the website. It is at cfsan.fda.gov. And the search for the word "food allergens," which again is on our web page.

In addition, we mentioned the state attorneys general petition. That also is available at Dockets and the contact information is in your Federal Register. So questions on that can be answered elsewhere.

We do have a series of questions. Again, if the panel has something to add, please do feel free to jump in. But one question is how would the panel, and this is obviously directed to all of you, how would the panel suggest dealing with imports? States have reported more allergy labeling problems with imported foods than with domestically produced foods, according to this question.

MS. MUNOZ-FURLONG: I'm going to give you the consumers' perspective. You raise an

interesting point because we have consistently found that when one of our members has a problem, and it's caused by an imported food, we have no recourse. We can't call the company like we could with a domestic product, and they're on it and instantly we are correcting the information, getting the news out to our membership.

So as a result of that, we advise our members not to eat imported products because we can't guarantee that the label is correct, and that we will be able to trace back any information they might need if they have a reaction.

MS. HILDWINE: Imports are a particularly challenging issue. I mean if you look at recall track record, there is a lot of imports on a regular basis and food allergen related recalls.

All the audience may not know this, but this is a true fact. Imported foods are subject to the same requirements as foods that are produced and sold domestically. So imports should be observing good manufacturing practices and labeling accuracy as well as domestic production.

Now, that said, the Food Allergy Issues Alliance has, in fact, worked some outreach relative to other nations. As we were developing

our food allergen labeling guidelines, we had representative from the Canadian food industry who worked with us on that, and we are of the understanding that food allergen labeling guidelines and, of course, the good manufacturing practices sector that's included in there on supplementary labeling, that that's under review for adoption by the food industry in Canada.

In addition, we as a food industry have liaisons with food industry around the world. We've made sure that the Food Allergen Labeling Guidelines are in the hands of a number of representatives for sharing with their producers in other countries, and certainly we are doing the best that we can as an Alliance to make sure that the concepts in the Food Allergen Labeling Guidelines, that these are known around the world.

A number of our members are multinational corporations that are disseminating food allergen GMP and labeling information to their companies in other nations. So we are really I would say engaged in a vigorous effort to make sure that this information gets known around the world.

The United States is probably in the lead in terms of its contemplation of this issue.

Certainly, the advancement of science in the U.S. is far ahead, I think, of what's going on in other nations, and we are trying to bring the rest of the world along on this issue.

DR. LEWIS: Any other comments on imports? We have a question concerning legal liability. The question is really in two parts. What is the legal liability risk to a manufacturer if a consumer is injured by an undeclared allergen? And then also the legal liability risk if undeclared allergens are found in a food, thereby putting a significant number of individuals at risk?

So again I think the question is asking for some clarification as to how legal liability is perceived here.

MS. HILDWINE: I'll do this one. I'm not a lawyer. I don't think we have any attorneys on this panel. And so I'm not going to be able to answer this question directly. However, the last thing that any food company wants to do is to cause harm to anybody. And so the issue of risk is certainly something that all food companies have to take into consideration as they engage in their normal operations.

DR. LEWIS: This question talks about

preventing manufacturers from using "may contain." That is how can you prevent manufacturers from using "may contain" as a substitute for GMPs? What controls are or should be in place? And this is important since it artificially restricts consumption of those products, artificially restricts consumptions of products for those who already have limited choices.

Does anyone care to address that question? Regina, I have a question directly for you next so I would suggest you hold off for a second.

MS. KATIC: Could you repeat the beginning of it? It's about how to prevent?

DR. LEWIS: How can you prevent manufacturers from using "may contain" as a substitute for GMPs?

MS. KATIC: Well, I think this has already come up in some form briefly, but certainly I think Dr. Jacobson and I are in agreement that FDA has the authority to enforce and we certainly support full enforcement of FDA inspecting and maintaining these practices within plants.

As I stated in my comments, this is being done within all of our member companies which make up probably 90 percent of, as Anne stated, the

allergens that we're talking about. So, you know, you could mandate the fact that we can't use "may contain," but then you're faced with as, I tried to lay out, some very clear examples of when "may contain" is absolutely necessary to preserve for manufacturers.

This is also why the industry responded so quickly and got on board with our labeling program through the Allergy Issues Alliance because we understand that this is a critical problem. It's one that we want to fix or work toward providing a solution so that "may contain" can be preserved and therefore believed and used by the food allergic consumer.

DR. LEWIS: Go ahead, Dr. Jacobson.

DR. JACOBSON: When you say the industry reacted so speedily, were you referring to the response to the 1996 letter?

MS. KATIC: Well, I think we've, you know, as has been indicated by both Regina and I, this is an issue that the industry has been dealing with much longer than the '96 letter.

I don't think you can point out from that letter, unless you have some very specific examples, I don't think that you can say that

industry has not responded or developed good manufacturing practices.

Certainly, they continue to look at their practices to see where they can do better. You know I'm sure that most of our member companies have done that since the letter in '96. I guess that's pretty much it.

DR. LEWIS: And actually building on a point you raised earlier, Lisa, we have two questions that are more or less related. How many companies in the U.S. are not members of GMA or NFPA and how does GMA and NFPA plan to ensure compliance of its new labeling and manufacturing guidelines both among members and what might you do about non-members?

And then related to that, is there currently a penalty for companies using "may contain" warnings when not meeting the four criteria? If so, what is it? If not, what motivation do they have?

MS. KATIC: Well, I guess I wish we knew how many companies are out there that are not members of either association. I don't know that anybody has those numbers or figures. As I stated earlier, we do see that as an area in need of some

attention, and also have stated that we've already looked at through the Alliance how we would reach out not only to members, smaller members within our associations, but also those small manufacturers that are not members of associations.

And I think through the Alliance as we've said we have a broad group of about 20 associations. I think every association knows, you know, who some of those members are that aren't a part of their association. So just by nature of the type of business that they do, we would already be able to name I would say quite a few.

You know the real challenge is getting to the real mom and pop type operations and I think we probably need to have a discussion about that collectively on how we reach those types of operations. I've now forgotten the rest of the question so I--

DR. LEWIS: It regards penalties for using "may contain" when not meeting the four criteria.

MS. KATIC: Penalties within our, I guess--

DR. LEWIS: Presumably, yes.

MS. KATIC: --our program. Well, we don't have anything necessarily laid out. I can tell you

that in working with the industry for some time, we mentioned earlier that we have a baseline survey that we're starting and will continue to survey membership amongst all of the trade associations in the Alliance, and it's generally that when industry seems a program picking up, and really gaining some significance, it's rare that--I mean certainly there are companies that don't adopt it, but it just adds to, I think, the importance of the program and makes it almost imperative that companies do adopt the program and basically get on board.

So I think just by nature of them hearing that this is something that's really gaining significance amongst the entire industry, by nature of competition, if you will, it encourages those that are outside the program to participate. So there is not an outright penalty, but there is an incentive there.

MS. HILDWINE: And just to elaborate a little further on some of the things that Lisa said, the Food Allergen Labeling Guidelines have been made public. They certainly are in a public area of NFPA's website. I know they're in the public area of a lot of food companies' web sites.

I personally sent, made sure that companies that are not members of NFPA received the guidelines when they asked for them. Now that was followed up with a call from our membership office.

Nevertheless, we have reached out beyond our memberships to other food companies and, of course, every member of the Alliance has been presenting on their website Food Allergen Labeling Guidelines.

I think, Anne, you have them on your website, too. So these are not a secret. They are readily available, and if anybody is not a member of NFPA and would like the Food Allergen Labeling Guidelines, just give me a call, and we'll make sure that you get a copy of the guidelines so that you can start to get on board with this very important initiative.

DR. LEWIS: And while you still have the microphone, a question specifically for you. Does the food industry currently have standard definitions for the various precautionary statements? If so, can they be located? If not, what can a consumer use as a guide for interpreting?

MS. HILDWINE: Right now through the work

of the Food Allergy Issues Alliance, we did discuss three types of statements, and they're the statements that FDA has asked questions about in the Federal Register notice.

Now, as to standard definitions, unfortunately there are none. However, since any information that appears on a food label has to be true, those statements would have to represent what they say. In other words, if it's processed on shared equipment, it would have to mean that it's processed on shared equipment. Now, as to a measure of risk, which I understand is probably at the underpinning of this question, again, I don't think that this is an area where the food industry wants to encourage food allergic consumers to try and understand relative risk.

The whole purpose of those supplementary or advisory statements "may contain" is to send a message to the food allergic consumer do not eat this product if you are allergic to this food. In other words, to believe what it says, because we believe that food companies are using these statements responsibly. And that proportion is increasing because of the Food Allergen Labeling Guidelines, and certainly we hope that over time

these statements will become increasingly more believed, and secondly, increasingly rare.

DR. LEWIS: For Anne Munoz-Furlong, we have a question. Isn't the lesson here that it's important to look at all food labels all the time? Why is there a different standard if the label adds "may contain" versus peanut as an ingredient?

MS. MUNOZ-FURLONG: Absolutely, you need to read the label all of the time. We are talking about the additional information that is being put on these labels and how the consumer is interpreting them, and what the impact of the proliferation of these statements has been on the consumer's purchasing decisions and purchasing habits.

But the first place that a food allergic individual has to go is that ingredient statement. Unfortunately, if you take the example that I gave with the raisins on the airplane, there's a bag of raisins. There are raisins in the bag. You have looked at the ingredient declaration. It says raisins and then underneath it, it says may contain peanuts. What are you going to do if you're allergic to peanuts? That's the answer we are looking for from industry and the FDA.

How are you to behave when you see that? Are you never to eat raisins again because they all may contain peanuts? That's unclear to us at this point.

DR. LEWIS: This next question is to Dr. Jacobson as well as all members of the panel. It says Ms. Katic stated that cleaning will not succeed in removing all allergens. Given this, would you support precautionary labeling for all food manufactured on safe equipment and if not, why not?

DR. JACOBSON: What was that? Would I support?

DR. LEWIS: Support labeling for all food manufactured on shared equipment.

DR. JACOBSON: Well, I would assume that some--that it's possible to clean well some shared equipment. And it's something where the FDA would have to go in and make some evaluations. Maybe chocolate, you can't clean it adequately and maybe that's where dedicated lines should be used if at all possible. But I would think it's a judgment call, not a blanket rule saying always use "may contain."

DR. LEWIS: Others have comments on that?

MS. MUNOZ-FURLONG: I would agree with that. What we want to do is move away from "may contain," not add it to every single ingredient, because as we see now, there is so much confusion and limited food choices perhaps unnecessarily. We want to move away from that.

DR. LEWIS: This question goes to the four pronged test. It's know that microscopic amounts of allergens can harm sensitive people. Please explain why the first prong of your four-prong test for precautionary labeling is adequate. It allows for visual inspections alone.

MS. KATIC: I think, first off, what we mean by visual is you know you're using, you know, an ingredient that has an allergen in it. So I think to me that's kind of obvious. Maybe that's not to everybody else. It also states there that analytical testing can be used for purposes or situations where it might not be as visually obvious.

MS. HILDWINE: The first prong of the four-prong test reads exactly: The presence of a major food allergen is documented through visual examination or analytical testing of the processing line equipment, ingredient or product or other

means, so visual examination is only one thing that's mentioned there. Lisa mentioned also that analytical testing is there.

Certainly documentation, paper trail, may also demonstrate that the major food allergen is in that environment. So we're not relying on visual examination alone.

DR. LEWIS: I'm going to stop with the questions there, but turn back to both the FDA listening panel as well as our presenters and ask if there are any further comments or questions from you folks. Kathy.

MS. GOMBAS: Kathy Gombas with FDA. Regina, in the first panel, you had indicated that perhaps it was the Alliance that was going to conduct a survey to get more information on who had gone to voluntary labeling for plain English. Are you going to do the same thing for the advisory labeling, and if so, are you going to ask them why they're using advisory labeling?

MS. HILDWINE: That's in the survey as well. The survey covers all of the areas that were addressed in the Food Allergen Guidelines. So we do ask them if they have control procedures and various other questions related to supplementary or

advisory labeling. And the data that we're collecting will essentially be baselines.

DR. JACOBSON: Can I ask a question of FDA for informational purposes only?

DR. LEWIS: As I recall, we're in a listening mode, Dr. Jacobson, but feel free to put it on the table.

DR. JACOBSON: For informational purposes, I wonder if Dr. Falci could give us some sense of how frequent inspections are, say, of a cracker or cookie company of $25 million a year in sales? How many times a year, a decade, ever an FDA inspector will look at these allergen issues?

DR. LEWIS: We actually get frequently questions about how often that happens, and to be honest, Dr. Jacobson, I don't have that information for you right now, but we'll try to get back to you with it.

I do want to turn to some administrative issues concerning the public speakers who are scheduled to present this afternoon. We will be using the first three rows of what for you is the left-hand section, for me the right-hand section.

So for those of you that have registered to speak as public commenters, please either gather

a little earlier from lunch or at least plan to sit here as soon as you return. Our lunch break is scheduled to go until one o'clock, and I can promise you we will begin promptly at one o'clock, so please do feel free to take a lunch break, but remember we will be starting at one o'clock, with our third panel. Thank you.

[Whereupon, at 12:10 p.m., the meeting was recessed, to reconvene at 1:05 p.m., this same day.]

A F T E R N O O N S E S S I O N

[1:05 p.m.]

DR. LEWIS: Panel III focuses on the labeling of ingredients exempted from declaration. There's two categories here: common or usual names and incidental additives.

Before I begin, I would like to introduce a new member of our panel, Mr. John Hallagan. As we said, he was General Counsel for FEMA, ASTA and IACM, and he's replaced Ms. Katic on our panel.

Our procedure at this point will be to allow our four panel members, Dr. Jacobson, Ms. Munoz-Furlong, Ms. Hildwine, and Mr. Hallagan, to each address the topic of labeling ingredients exempted from declaration, and then we will move to discussion.

Dr. Jacobson.

DR. JACOBSON: Currently, food labels are not formally required to disclose allergens such as peanuts, wheat, casein or carmine when they serve as flavorings, spices or non-certified colorings. However, undeclared colorings and flavorings have caused occasional allergic reactions. Examples include carmine, saffron and annatto colorings, partially hydrolyzed casein and peanut flour. Also

such spices as allspice, cardamom and coriander have caused occasional allergic reaction.

While disclosure is not required, in 1996, the FDA sent a warning label to companies urging that they voluntarily declare on labels any allergenic components of such ingredients. I agree with University of Nebraska food allergy experts, Steve Taylor and Sue Hefle, who wrote in a paper if an ingredient is known to be allergenic even on a rare basis, such as carmine or papain, then it should be declared on the ingredient statement.

Unfortunately, the FDA has not determined that it has legal authority to require labeling of those additives when health is at issue. It should assert that authority by commencing a rulemaking as requested by the nine attorneys general more than a year ago. CSPI also will be submitting a formal request for that action in the near future.

The FDA could take several legal approaches. It could assert that the general misbranding section of the act trumps the flavoring/spices/colors exemption because the ingredients can cause severe allergic reactions.

Alternatively, for allergenic flavorings, spices or colors that are considered generally

recognized as safe, the FDA could determine that those substances are not safe. They can only determine it safe if labels disclose the presence of those substances.

Third, in the cases of approved color additives and food additives, the Act allows the FDA to set conditions of use, such as label disclosure. Thus, FDA should amend its regulations to specify that any allergenic coloring or flavoring additive must be declared on the label, as it has for Yellow 5, or monosodium glutamate, and certain other foods.

We urge the FDA to require disclosure not just of the major eight allergens but others as well. To someone with an allergy to corn or carmine, it's no satisfaction that wheat and shrimp are disclosed.

The cost and inconvenience to companies of providing disclosure is a small price to pay for protecting the health of sensitive consumers.

Therefore, as a general policy, the FDA should require, not just strongly encourage, labels to disclose allergenic ingredients in the flavorings, colorings, and spices. Labels should simply declare something like colors includes

carmine or natural flavoring includes peanuts, and then in the allergy information section of the label, the presence of the major allergens should be highlighted.

Moving now to incidental additives. Those are substances that are present at insignificant levels in food and that don't serve any technical or functional effect. Incidental additives have never been disclosed on labels, but in 1996, the FDA told the food industry that such additives are not insignificant if they might cause serious allergic reactions and that they had to be labeled.

And that was incorporated into the FDA's compliance policy guide earlier this year. While incidental additives are present at low levels, and to my knowledge have not caused known allergic reactions, it's worth noting that the EPA recently expressed concern about the allergenicity of StarLink corn. It banned--it banned the presence in food of any amount, even under 20 parts per billion, of StarLink even without proof that it ever caused an allergic reaction.

Today, no one is talking about banning wheat, corn or other allergin, but only requiring label disclosure. The FDA's policy concerning

allergenic incidental additives should be incorporated into a regulation that states explicitly that any incidental additive that may cause a serious allergic reaction should be presumed to pose a risk and be declared in the ingredient list.

If an incidental additive is one of the main food allergens, or sulfites, it also should be declared in the allergy information section of the ingredient facts label. Regulations could allow waivers if companies can demonstrate that the amount of allergen present is truly too small to cause any reactions. Thank you very much.

[Applause.]

MS. MUNOZ-FURLONG: Before I begin, I want to also again clarify that when I talk about flavors during my presentation, I really do intend this to apply to flavors, colors, spices and incidental additives.

Next slide, please. My objectives here are going to be to provide the consumer's perspective on these incidental additives and provide information about the industry's response to the concerns of the food allergic consumer, and that's going to be based on information from our

members and the industry itself.

Next slide. First of all, from the consumer's perspective, we know that strict avoidance is the only way to avoid an allergic reaction. We know that major allergens can be included in flavors, spices and colors and incidental additives. We also know that they are currently not required to be listed on the label, and that children have had allergic reactions to proteins even in the low levels that you're going to find them in these categories.

A good example of this came to us several years ago when a cereal was put on the market. Within weeks after launching this cereal, we started to receive calls all over the country about children having allergic reactions. We contacted the manufacturer. They found that, in fact, the flavorings contained milk ingredients.

Now, to their credit, they changed the label to reflect that information, and we have not had any reports of incidences to that cereal since then.

Next slide. When a consumer sees natural flavors on the market, they have several options. The first one is avoid that product completely. If

any of you have ever looked at the ingredient statement, you will know that if you avoid the products that say flavors, colors, or spices, you're going to have no food choices at all.

The second is to take a chance. Again, we're talking about children, so this is not acceptable as an option.

The third is to decide to call the manufacturer and ask very specifically does the flavor contain whatever the protein you're trying to avoid. If you make that determination to be your decision, then you need to hope, first of all, that there's a phone number listed on that package to help you make that phone call.

Many of these calls are being made at the grocery store on cell phones as people look at a package, want to make a purchasing decision on the spot, or at dinner time when they are taking a product off the shelf in their pantry and notice an ingredient that they don't understand. So the need for information in a timely fashion is critical in these situations.

Next slide, please. Now, currently some companies will divulge the information willingly and quickly over the telephone. We applaud their

efforts. However, other companies will consider this information proprietary and will not release it.

We have had some companies tell our members that if they have a reaction, their doctor can call the company, and then they will divulge all this information. This doesn't seem to be the way we should be doing this.

Some of the companies will provide the information, but in writing, and it takes several weeks to get this information that will not satisfy the need of our members to get information quickly. There are a few companies that will provide this information in a timely fashion. They will put it on the label.

For example, natural butter flavor or natural flavors contains milk. This saves time. It's simple English and it's very easy to understand.

Next slide. Now, again, going back to the survey that I've mentioned today several times. Second on the list of top three concerns in the write-in portion of our survey was natural or artificial flavors or colorings. The concern from our members is that this has hidden ingredients,

and if you recall from my first presentation, reactions occur because someone is eating something they think is safe. If they don't know the allergen is in there, they can't avoid it.

Next slide, please. The conclusions from our survey showed that food allergic individuals are reading the ingredient label diligently. They are making purchasing decisions that affect their health based on that information.

We also know that they believe that the information on the package is not complete. Four out of five of them report calling manufacturers for additional information. I want to make the point that our members are one of the best educated, highly motivated people in the food allergy community and this country. If they are struggling with these labels, I can only imagine what the general public is going through.

Now, the final slide, in summary, flavors, spices, colors and incidental additives can contain hidden ingredients. Even the low levels of allergens that would be present in this could cause a reaction affecting children most often. Therefore, we recommend that allergens should always be declared on the label when they're

present in a product.

Thank you.

[Applause.]

MS. HILDWINE: Thank you. At the outset of the discussion on labeling allergenic components of flavors, colors, spices and incidental additives, it's important to note that major food allergens are proteins. There are numerous components in flavors, colors and incidental additives that are not proteins.

Often these components include alcohols or oils that may be derived from the major food allergens, but are so highly refined that they do not contain protein. Bleached, deodorized and refined soybean oil that may be used as a carrier for flavor or color or a component in a food additive in some food applications is a good example of the type of product that should be considered outside the scope of today's discussion.

Furthermore, there is no spice included among the list of the eight major food allergens that is the focus of FDA's discussion today, so it is clear that in this session, we really are speaking of spices only in concept.

This observation leads one to the

conclusion that FDA should continue to address the labeling of allergenic components in flavors, colors and spices on a case-by-case basis. Creating a generally applicable policy most likely would encompass substances that are not at issue for the labeling of food allergens.

We know from our discussions with NFPA members that they receive information from their suppliers of flavors, colors, spices and additives with respect to the allergenic components present. NFPA believes that suppliers should always volunteer this information to their food processor customers with the understanding that food companies are not interested in knowing the formulation of the flavor, color, spice or additive, just in knowing which allergenic proteins are present.

NFPA also is of the view that food processors should carry forward to their own labels information on the presence or possible presence of those major food allergens and flavors, colors, spices and incidental additives.

NFPA believes it is appropriate to present plain language information on the allergenic components of flavors, colors, spices and

incidental additives in association with the ingredient declaration of the finished food.

This information should be in the ingredient list where the flavor is declared or at the end of the ingredient list as appropriate to the food and the flavor or other component.

The presentation options--"contains," use of a reference mark or use of parentheses--as discussed in this morning's session on plain language, all are valid presentations as would be any plain language representation of the name of the allergin in the common or usual name of the flavor.

NFPA would not support rulemaking to make mandatory the ingredient declaration of the plain language terms for major food allergin components of flavors, colors or spices. Many of our members already declare information on these allergenic components on a voluntary basis.

NFPA believes it is the responsibility of food processors to obtain this information from their suppliers and carry it forward to the finished product labeling. Many of our members use checklists and other techniques to ensure that they've received this information from their

suppliers.

Because some of the major food allergens are common in the food supply, milk, wheat, egg and soy, for instance, our members do not limit their information collection to the obvious or major ingredients.

Egg protein that may be a component but not a characterizing flavor of a sauce is a good illustration of this. The food processor that uses the sauce in the formulation of the food will obtain information from the supplier that egg protein is present, usually from the ingredient labeling on the sauce. And that information will be carried forward to the label of the finished food.

Regarding major food allergens that are components of additives that might qualify for the incidental additives declaration exemption, NFPA believes that FDA has already made its views very clear that such allergenic components are not exempt from declaration. NFPA advises its members in a way that's consistent with FDA's interpretation and policy.

Although scientists have been studying the issues of threshold levels of allergenic proteins

that trigger an allergic reaction, so far there are no established thresholds. This raises questions regarding the meaning of both insignificant quantities and absence of technical or functional effects in the finished food with respect to those food allergens, and both those conditions must be met in order to qualify for the incidental additives exemption.

In addition, the absence of solid scientific knowledge about the quantities of major food allergens needed to trigger allergic reactions argue strongly for FDA not to codify the specific exclusion of major food allergens from the incidental additives exemptions. The reason for this is plain. As food allergy science advances, it is likely to become increasingly evident that there are reaction thresholds. That is quantitative levels of food allergens below which allergic reactions do not occur.

Discussing the threshold concept is a meeting for another day with a group of experts different from this panel. Nevertheless, we urge FDA to be cautious and refrain from codifying an allergen exclusion of the incidental additives exemption at this time. If FDA were to codify this

exclusion, it would be a very difficult and long process to reverse the rule or selectively reverse the rule which is more likely to be the case. Thank you very much.

[Applause.]

DR. LEWIS: And Mr. Hallagan, please.

MR. HALLAGAN: I'd like to thank the agency and our allied associations for the opportunity to participate today. I'm representing three trade associations today: the American Spice Trade Association, the Flavor and Extract Manufacturers Association, and the International Association of Color Manufacturers.

Our members manufacture spices, flavors and colors that are included in a wide variety of foods and beverages.

One point I'd like to make to start is that our products, the bulk of our products, go into consumer products, foods and beverages, and are therefore not sold directly to consumers so our labeling requirements are different from consumer product labeling requirements.

But our main mission is to support our customers and to provide them with all the information they need to comply with all labeling

requirements or all labeling needs such as allergy labeling.

All of our member associations are members of the Food Allergy Issues Alliance and all support the guidelines.

Spices are listed by the FDA in the Code of Federal Regulations. There's a very long list of spices and has been mentioned, none of them are listed as allergens or considered allergens or the source of allergenic protein material.

The current FDA labeling rules do allow for the generic declaration of spice as providing for the inclusion of a variety of spices in a food product. Other materials that may be included in a mixture must be labeled and are subject to other labeling requirements, but an important point to keep in mind is that the spice industry is fully committed to providing information to its customers, in other words, food and beverage companies that incorporate spices into finished foods.

So if a material that originates from one of the eight materials that are considered allergens, if proteinaceous materials from those eight are used in a spice mixture, then the spice

manufacturer is committed to providing that information on its label so its customer can label as well.

In terms of flavors, the FDA has listed a variety of flavor materials in the CFR, and I've provided the citation. In addition, there is a longstanding industry GRAS panel known as the FEMA expert panel, which has done thorough safety evaluations on about 2,000 flavoring substances, and this list is available from FEMA and we're happy to provide it upon request.

This information has also been shared with FDA and these additives are included in the agency's database. None of the single chemically defined flavoring substances are considered allergens. These are individual substances that may be derived from natural sources or produced synthetically. None of them include proteinaceous material which would cause an allergic reaction.

The current FDA labeling rules, as I provided the citation for here, allow that flavor may be declared in a generic manner, but it's important to note that other materials included in a flavor would have to be labeled for with the exception, of course, of incidental additives and

processing aids, but the flavor industry, like the spice industry, is committed to providing information on allergenic materials that may be used in a spice mixture because flavors are complex mixtures.

They are a number of individual flavoring substances and other materials that are combined to provide the flavor that provides the taste to the variety of foods and beverages that we all consume.

FEMA has been very active in the allergy area beginning in 1997 when FEMA sponsored an education session for its members, the FEMA Allergy Workshop. The impetus for this workshop was the release of the 1995 FAO Technical Consultation on Food Allergens, and FEMA took the big eight list from that FAO consultation, made it available to its members, and in a self-regulation program established guidelines for the labeling of flavoring substances that are sold to consumer products companies. We had very good compliance with self-regulatory initiatives, as evidenced by the FEMA GRAS program. So we've had very good compliance so far with the allergy guidelines.

The FAO guidelines are very largely consistent with the Food Allergy Issuance Alliance

guidelines as well.

In terms of colors, the last group of substances I'd like to deal with this afternoon, large number of color additives are listed for use by FDA. They've been very thoroughly evaluated for safety. None of them are listed as allergens, but as Dr. Jacobson mentioned earlier, some scientific data indicate that carmine and cochineal may be able to cause allergic reactions.

We have encouraged our members, of course, to declare that whenever it's present in a mixture, and a number of consumer products companies also voluntarily declare it.

Certified colors must be labeled already specifically on the ingredient line. Exempt colors may be declared generically, but again any components that are derived from the big eight, we are encouraging our members to declare.

Thank you.

[Applause.]

DR. LEWIS: Just before we begin our panel discussion, let me remind you that if you do have questions, please do write them on the cards, pass them to the aisles. They will be collected.

Okay. For this particular panel, who

would like to open with a comment or a question? Dr. Falci.

DR. FALCI: This is Dr. Falci of the Food and Drug Administration. My question is generally I guess about flavors and colors and spices in the sense that I agree with you. A lot of them apparently don't appear to be allergenic per se, and I was trying to get a feeling for exactly how many times, for instance, you would put a flavor, for instance, as a single chemical entity into a food per se, or would it be mostly put into a food via a delivery system where the flavor would be on some set of substances and then potentially sprayed on a food product, for instance?

Isn't it mostly true that the delivery system for flavors, even colors and spices, would be sprayed on foods and that the delivery system would have potentially allergenic components in it, and that it wouldn't necessarily be that a matter of the flavor being there in a small amount, but the fact that the allergen is in the delivery system, per se?

MR. HALLAGAN: Well, flavors are used in a variety of ways. Dr. Falci has just described what we refer to as a spray dry flavor system. Dr.

Falci is correct. Flavors may be used in that way in addition to other ways. If a flavor is delivered on a system, in other words, incorporated into the food on a system which, for example, may contain a carbohydrate matrix or a carbohydrate substance to carry the flavor, then we have encouraged our members to declare that substance if, in fact, the delivery system contains a proteinaceous material from one of the eight listed groups of allergens.

So, yes, flavors are used in that way, and we have asked our members to declare those substances if they are contained in the delivery system.

DR. FALCI: And how often would this particular type of delivery system by used per se? I mean are flavors, colors and spices delivered 90 percent of the time in this matter in a food product?

MR. HALLAGAN: I don't know what the actual proportion is, but we could certainly get that information for you, but it is accurate to say that all three--flavors, colors and spices--can be used in that way. And, for example, flavors going into a beverage would not be delivered that way,

and that's a very large proportion of the flavor used; same with the candy. Spray dry flavors or colors or spices would be used on snack foods, for example, and again I'm not a technologist, but I can get that information for you.

DR. FALCI: Okay. Thank you.

DR. LEWIS: Other questions, comments? Michael?

DR. JACOBSON: Mr. Hallagan, you mentioned that your association favors voluntary labeling of substances like carmine that have been demonstrated to cause allergic reactions. Instead of relying on voluntary action from companies, would you support mandatory labeling of those through legislation or regulation?

MR. HALLAGAN: Well, our members' products are not the products that consumers actually consume in the majority of circumstances. It's our customers' labels that would be impacted. We're committed to providing that information to our customers and for flavors, colors and spices, as far as we're concerned, the initiative can be mandatory or voluntary.

Our members intend to provide that information to the customers, and that's our

commitment and that's what we've been doing for the last about four years.

DR. LEWIS: Other questions from the various panelists?

DR. FALCI: One more. Incidental additives--sort of it could be a learning curve here as far as incidental additives are concerned. There's been a lot of opinions or opinions expressed that incidental additives simply were not put on labels in the past, and although the agency has expressed the desire to have the food allergen in incidental additives put on the label, we started that policy and we suggested that policy back in 1996, it takes time to get through the industry.

But could you, maybe members of the panel here, suggest ways of making industry more aware that incidental additives are really to be put on the label when a food allergen is present? What are the types of things that you would do to try to improve that in the industry?

MS. HILDWINE: Well, I'll tell you the very first thing that I do is remind our members that the incidental additives exemption is not easy to come by. That regardless of whether your food

ingredient is identified as one of those suitable classes of ingredients that may qualify for the incidental additives exemption, that, in fact you have to pass two parts of--well, you have to pass both parts of a two-pronged test in order to qualify for the exemption.

Now, typically, these incidental additives are going to be ingredients carried over from a previous component of a food, but the regulation, I think, reads very clearly that that component in order to be exempt from declaration must be present in the food at an insignificant level and have no technical or functional effect in the food. One of them is not sufficient for declaration.

And I like to draw the example of, say, a flow agent in a seasoning blend. Say, the flow agent silicon dioxide has a functional effect in the seasoning blend. When that seasoning blend is added to a wet ingredient, the silicon dioxide loses all of its technical or functional effect. So when you add the seasoning, probably at a low level, to a food, and it's got the silicon dioxide, then, in fact, that substance may pass both prongs of the test, that it is present in the finished food in an insignificant amount and has no

technical or functional effect in the finished food.

Well, what applies to silicon dioxide in the seasoning blend may not, for example, apply to say a wheat extracted ingredient that's in the same seasoning blend, and that would not be exempt, so you really have to look at this component by component and make sure that every component that's carried forward passes both prongs of the test. So we do a lot to educate our members on just exactly what that exemption means.

DR. FALCI: How do you do that? Do you call them in? Do you have conferences? What?

MS. HILDWINE: Well, what I just told you that seemed to appear off the top of my head, you know, is not spontaneously there. It comes from years of advice to our members one on one, as we go--we do their label reviews. NFPA does this, reviews labels, as one of its benefits to members, and answering their questions. When they ask for clarification on the incidental additives exemption, I get a lot of questions regarding the incidental additives exemption and personally walk them through it every time.

DR. JACOBSON: Dr. Falci, the FDA

certainly could accelerate the learning process by identifying some products that have unlabeled incidental additives and find them misbranded, the allergenic incidental additives, and find them misbranded and remove them from the market. That would speed up the learning process considerably, I believe.

[Applause.]

DR. LEWIS: Other questions? Well, while you're thinking of more questions, we do have three from the participants here today. One is for Anne Munoz-Furlong. It's actually a two-parter, Anne.

Would milk allergic individuals know to avoid butter or cream or should these be identified in the ingredient panel as milk?

And the other is should only the top eight allergens be disclosed in favors and spices or more?

MS. MUNOZ-FURLONG: Okay. The question about whether the milk allergic individual, what their understanding of milk products and byproducts are is going to be depend on each individual. The people that are more aware of it, probably the parents, the people closer to the patient, are going to be very aware that yogurt or butter are

milk derived. People as we move away from the circle of care for that child may not necessarily make the connection and we see this over and over again when we're talking to grandparents and other caregivers of the child.

So our suggestion would be to always err on the side of safety and declare that it is milk after butter or any other of these terms to make it very, very simple to follow.

The second part of the question should we look at only the top eight or all of the allergens, I know there's a study that's been done that looked at the foods that had been implicated in reactions, and there were somewhere around 160 foods on that list. That's an enormous task.

What we would recommend again is to stay focused on the 90 percent of that problem. Once we figure out what the solutions are there, we can hopefully then quickly come by and address some of these other issues.

DR. LEWIS: The next question I have is stated as follows: If spices are not considered allergens, then how can one have an allergic reaction to allspice as referenced by Ms. Munoz-Furlong? If there have been reactions to

spices, then what motions are in place to address these issues?

MS. MUNOZ-FURLONG: I want to clarify my position. I am not aware of any reactions to a particular spice. The bulk of the work that we do is to look at those top eight allergens. If they appear in anything, such as a color, spice or flavoring, then we want those listed out on the label.

DR. JACOBSON: I was actually the one who mentioned allspice, cardamon and coriander. In the paper, Sue Hefle's paper, listing 160 or however many allergenic foods, those are included, and there are varying levels of evidence for those allergens, and I think there's going to be a gray area where there will be for some of the foods, there will be very limited, more anecdotal evidence. For other foods, there will be double-blind controlled studies, food challenges, that establish that it is allergenic, and then I think somebody will have to decide, well, how much evidence do you need?

How many cases of demonstrated allergenicity do you need before you require disclosure?

DR. LEWIS: The next question I have focused on the concept of thresholds. What would be the threshold that is the minimum level of an allergen that would have to be declared? If the level is zero, how would the manufacturers test for that?

MS. HILDWINE: I brought this up so I think I better field it. There is a lot of scientific work that's going on in this area. I'm not an expert on thresholds and certainly I really couldn't speak to quantities, but a lot of scientists are devoting a lot of attention to determining what are the levels that would trigger allergic reactions.

The author of this question has definitely pinpointed a problem, and that is that if we are talking absolute zero, then that's very, very difficult to achieve with respect to allergenic ingredients or for anything for that matter.

DR. JACOBSON: I agree that it's a tough problem. Fortunately, the assays don't get down to parts per billion, but they're measuring levels that presumably are allergenic. I think the presumption should be that the substance is listed, the wheat or soy or whatever, if it's known to be

there as an incidental additive.

But perhaps companies should have an opportunity to demonstrate that at such and such a level, something does not pose any risk of allergenicity. And right now I don't know that there's any evidence for a threshold, but there should be an opportunity to exclude labeling of incidentals if they do fall below some demonstrated threshold.

DR. LEWIS: I'll wrap my last two questions into one large question, although they're not entirely similar. The first is isn't it time that out of the three issues discussed today, this, meaning Panel III, holds the most risk for the food allergic consumer? Is the industry doing anything to prioritize this as the first issue?

And then a second part of this: Mandatory labeling is a zero sum equal expense for all manufacturers. What incentives are there for manufacturers to deal with the cost of voluntary labeling?

MS. HILDWINE: Well, I'm not absolutely certain that this is where the bulk of the problem of undeclared allergens is. I think we spent a lot of time in our second panel this morning talking

about good manufacturing practices, and let's say significant levels of food allergens that are undeclared in food products. So I think you've got some good sense of what that's like from the report of the FDA inspections.

So I think that certainly manufacturing practices are really where we may need to spend a lot of attention, you know, in resolving labeling things.

The issue of undeclared allergens that may be present in flavors, colors, spices and incidental additives certainly is also a very important issue because it involves undeclared allergens and that's an important public health concern. But whether that is top of the list I think is still open to some discussion.

As to incentives for the food industry to pursue voluntary labeling, nothing is quite as effective in the food industry as what we call peer pressure or the competitive marketplace, and certainly we know from the experience of food allergic consumers that they very much appreciate when food companies go to the trouble of putting food allergen information on their labels on a voluntary basis.

More and more companies are doing this, and they're beginning to be much more responsible about the way they do this, and consequently, you know, particularly if you're in a sector of the industry where you compete with some major companies that are already doing food allergen labeling of an advisory nature, this is something that you're considering because food allergic consumers more often than not are calling you up and asking you why isn't it there?

And in addition to the pressures of the marketplace, the pressures of consumers certainly have something of an impact on what the food industry does.

DR. LEWIS: Any last comments or questions from anyone else on the panel? If not, what we'll do now is turn to the last component of our program, the public comment.

Just a couple of announcements and reminders before we do that. The first is that for these issues, the FDA docket is still open. People who are interested in submitting written comments on these particular topics are more than welcome to do so. The docket is still open.

Secondarily, I need to be very clear about

what are the issues that are being addressed today. It is food labeling. It is not latex gloves. It is not celiac sprue, and it is not restaurant labeling. Those are not topics of today's discussion.

What we'll do at this point is take a 60 second stretch break while this podium is lowered down so that our speakers will be able to make their comments from the floor. So bear with us for 60 seconds while we arrange up here and then we'll be right back with our first speaker.

[Whereupon, a short recess was taken.]

DR. LEWIS: All right. The procedure is that we will go down the list of persons who have registered to speak. We ask that you very briefly introduce yourself. You are being timed for three minutes. I do apologize if I mispronounce your name. I'll try the best that I can. You can correct me once you do get up there, but again it's three minutes and we would appreciate your moving along appropriately.

The first on my list is Victoria Geduld.

MS. GEDULD: My name is Victoria Geduld. I'm a concerned citizen and mother and I am with my daughter Nancy Geduld, who is six years old and a

student. Due to time constraints, I will not go into a lengthy of history. Suffice it to say that Nancy loves playing with her friends and sisters and going to the park.

It's a sunny day in August and rather than doing all these things on this Monday, she chose to sit with me because the most important thing in her life is safe food. Misleading and unclear labels can kill her and she knows this firsthand.

My daughter Nancy has an acute anaphylactic reaction to peanut proteins which is a fancy way to state the simple fact that trace amounts of a simple and common food can kill her.

A few years ago, Nancy ate a chocolate Kellogg's Rice Krispie treat that said nothing of peanuts or peanut traces on the label. After a few bites, she said, Mommy, this has peanuts. I read the label. Nothing. She began to swell. I gave her medicine and we were fine. Within a few months, these same treats began to carry the label "may contain peanuts."

The traces must have been small. Were the traces larger, we know from history, Nancy would have had an injection and she would have been hospitalized, if she had survived. At four years

old, Nancy learned not to trust labels.

Foods must be labeled in plain English so that Nancy at six and myself, her father, grandparents, relatives, teachers or caregivers can read the label and know what's inside. If I have as a consumer have a question regarding the food, I should have a number on the label to call.

In a recent example, the outside container of the same Kellogg's chocolate rice krispie treats said that they did not contain nuts, the individually wrapped treats inside said "may contain peanuts." As it turned out, the line had been changed and made peanut free, and the labels on the outside had been changed to reflect this.

The individual wrappers inside had not. A confused consumer should be able to contact a food manufacturer. Small packagers can get waivers from the government, but luckily there are few who would qualify. Most packages are large and should be required to provide access to the company in the case of an accidental ingestion or an emergency or a question.

In addition, any information about the ingredients in the food should be listed in the ingredients section of the label. "May contain"

warnings do not help at the bottom of a package if the ingredients are printed on the top. We had a near accident in such a case. The warning was next to the company's address, catty-corner to the ingredient section.

If it has to do with the ingredients, put it in the ingredients listing. With the purchase of food for an allergic individual, there is a ripple effect. For the millions of allergic people, there are tens of millions who are affected. Think of the number of people who are involved in feeding a single child.

All these people will be served with government legislation demanding accurate and readable labels. In addition, all these people will be unnecessarily inconvenienced by a "may contain" label spread on packages. No matter what manufacturers must not be allowed to put a warning label on foods because it is easier or more convenient than actually monitoring the food supply. The government must ensure that labels are accurate, not just slapped on.

In order for my daughter to trust her food supply and get back to the business of being a child, any allergens must be included in the

ingredients section. There can be no exemptions. Thank you.

[Applause.]

DR. LEWIS: Thank you. Next please Pamela Hughes. If Pamela Hughes is not here, we will move to Joseph LaRochelle.

MR. LaROCHELLE: My name is Joe LaRochelle and I would like to tell you what it is like to have a life threatening food allergy and why it is so important to have accurate and dependable food labels. I'm a 21 year old who lives in Dairy, New Hampshire and a senior at St. Anthem College in Manchester, New Hampshire.

Besides having asthma, I'm also deathly allergic to peanuts and tree nuts. If I eat even a trace of these, I don't just get a stomachache. In my short life time I have had more than ten severe allergic reactions. When I was 13, I almost died. I had a chocolate chip cookie that contained walnuts. My symptoms started with a simple stomachache, but after less than one hour, I started having hives, itchy mouth and throat, breathing problems. All the while my throat started to close and I began to lose consciousness.

Doctors said that if I wasn't not a mile

from the hospital, that I probably wouldn't be standing here right now. After two to three injections of epinephrine, two shots of benedryl, two nebulizer treatments and a oxygen mask, I was released from the hospital five hours later when my condition stabilized.

Every minute of my life I must be on guard by reading all ingredient levels with how to read a label card handy and my epinephrine in the case of a severe allergic reaction.

It is critical that food labels be accurate, clear and dependable to help me avoid potential life threatening allergic reactions because peanuts and tree nuts often show up unexpectedly in the most unlikely of places.

Besides reading all ingredient labels, I am constantly watching for product recalls because of undeclared peanut or tree nuts. Because of that, I give high priority to the Food Allergy and Anaphylaxis Network's special food allergy alerts that notify me in the event these things happen.

In the last few months in my state, an ice cream manufacturer recalled product with undeclared pistachios, a cereal maker had undeclared almonds, potato chips with undeclared peanuts, brownies with

undeclared almonds, yogurt raisins with undeclared peanuts, and I could go on.

This simply underscores the fact they all don't get it right all the time. I would just like to briefly comment on the "may contain" statements. I never eat foods that say may contain peanuts or tree nuts, processed in the same facility as peanuts or tree nuts, or processed on shared equipment.

I'm grateful that some manufacturers have alerted me to the potential presence of an allergen, but would prefer they take the necessary steps to prevent cross-contamination in the first place.

In recent years, I have seen many more products with these statements on the label, a trend that is limiting my choice for foods that I can safely eat. Thank you.

[Applause.]

DR. LEWIS: Thank you. Next, please, Julie Reinhard.

MS. REINHARD: My name is Julie Mendel Reinhard. I am the mother of a three-year old peanut allergic son. I am here not only on behalf of my family, but on behalf of 2,945 consumers

representing 27 states who have signed a national grassroots petition seeking regulations to make food labels more accurate.

Since I learned about my son's allergy the hard way, in the emergency room as doctors battled to save his life, I have been challenged with keeping him in a peanut free environment. This means that I must read the label of every product that comes into our home and indeed every label of food my child may eat or come into contact with outside the home.

But that's just the beginning. After reading the food label, I must call the manufacturer to determine if the food has been made on shared equipment and therefore has the possibility of cross-contamination.

This is because manufacturers do not reliably state whether peanuts are or are not in the product. Furthermore, even after I call the manufacturer, I often do not get accurate information. Sometimes I leave a message on an answering machine that can go unanswered for a period of weeks, and sometimes forever.

Other times I talk to a consumer rep who reads from a written policy statement, but won't

send it, and is unable to answer basic questions. Often I have to make at least three calls before I even talk to an informed person. The first call is typically to get the phone number of the company.

Worse, it is the rare occasion when I am told that the risk of cross-contamination is de minimis. Therefore, I am unable to rely on the label itself to know if the food is safe for my son, and yet strict avoidance is the only sure way to keep him safe.

In addition to the FDA's inspection, research at the University of Nebraska documented that peanut residues were detected in 21 out of 111 products with either precautionary labeling on peanut listed as a last ingredient and in 33 percent of foods with no labeling in any form.

The researchers concluded that quote, "Despite vigilant monitoring of food ingredient statements by peanut allergic individuals, significant levels of unlabeled peanut residues can be encountered in food products."

Finally, a study published in 1997 found that while the threshold dose of peanut protein varies, as little as 100 micrograms provoked symptoms in some peanut sensitive individuals. For

each of these reasons, I strongly urge the FDA to prescribe regulations requiring manufacturers to use plain English and commonly understood terms in the ingredient statement like egg, milk and peanut, rather than a scientific term, and to adopt the proposed ingredient facts label put forth by CSPI.

Further, I implore the FDA to mandate that allergens contained in natural flavors and spices be listed in a parenthetical after the general term is used, and to clarify the incidental additive regulations by stating that those containing allergens are significant and therefore not exempt from label declaration including substances migrating to food from equipment.

Third, I ask you to adopt the allergen control procedures recommended in the attorneys general citizen petition.

Finally, it is with profound gratitude to the cochairs of this national grassroots campaign that I submit the following petition to the FDA for its careful consideration. Here it is:

(1) Put allergen regulations as an "A" priority on their 2002 agenda;

(2) Prescribe allergen control procedures for companies to follow in cleaning equipment to

reduce or eliminate the unintentional presence of a known food allergen in the finished product;

(3) Mandate precautionary labels on foods if allergen control procedures and GMPs do not eliminate the unintentional presence of a known food allergen and the presence of such allergen poses a risk to human health;

(4) Inspect manufacturing plants to determine if they are complying with the laws and regulations; and

(5) Punish companies who are not in compliance with the laws and regulations.

As the governmental body responsible to protect the health and safety of our Americans, these relatively simple measures can profoundly impact the safety of millions of Americans who suffer from food allergies. Thank you.

[Applause.]

DR. LEWIS: Thank you. Next we have Elizabeth Carus and in order not to surprise you folks, after Elizabeth Carus, we would be addressing Gayle Rubin. Is Elizabeth Carus here?

MS. CARUS: My name is Elizabeth Carus, and in addition to being severely allergic to wheat, I also have celiac disease. Prior to being

diagnosed with celiac disease, I was trying to follow a wheat-free diet. I know how to read the labels. I know what to look for, and until I went and had to follow a gluten-free diet, I was obviously missing a lot of hidden wheat.

Upon going on a gluten-free diet, I ceased having asthma problems, which included going to the emergency room quite a few times, and obviously there was enough in the food that's hidden even after calling companies to have given me problems.

When I call companies to verify whether things are wheat free and gluten free, the biggest problem I have beyond being told yes, it is, having the allergen so I can't eat it at all, is to find out that the company will tell me that they don't know if there's cross-contamination, not because in their company they have a problem, but they don't know from their suppliers. And when the company tries to find out from their suppliers, because they do want to know whether it's gluten free since that's where I'm at, it can take them months.

They can write many letters and in the end they can say we don't know because we can't find out from our suppliers. And that to me is a big problem. And that's probably about half the

companies I call is what I find out. And these are companies that want to be able to tell me that things are okay, that are being careful about telling me what's in their food, and they don't feel comfortable telling me because they don't know if there might have been a cross-contamination.

And basically that's what I wanted to pass on to you about that with the food products and things.

[Applause.]

DR. LEWIS: Thank you. Next is Gayle Rubin and following Ms. Rubin, if she's here, Judith Schreiber.

MS. RUBIN: I brought some props. Hi. My name is Gayle Rubin, and I'm here supporting the celiac support groups. It says something different on your listing. I'm not sure what that was.

Anyway, what I wanted to tell you is that gluten intolerance of celiac disease is a genetic disease that affects between one in 150 or between one in 250 Americans. And that is basically new information, and if you take that and you add that to--figure out from what our total population is, you're looking at 1.5 million people roughly.

If you take the related disorders, such as

Addison's Disease, other allergies, asthma, arthritis, attention deficit disorder, autism, cancer, diabetes, epilepsy, irritable bowel syndrome, lactose intolerance, mental disorders, multiple sclerosis, osteoporosis, psoriasis, scleria, sleep disorders, which affect another six or seven million people, you're talking about a lot of people who need label clarification.

That's basically the reason I want you to understand it's not--somebody made mention of--it's not about celiac disease. It's not about celiac disease. It's about people who have to know what's in the foods they eat. It's a lot of people.

And as you do know, or you probably already know, celiac disease requires a strict adherence to 100 percent gluten-free diet for life. That includes trace amounts, and we can't have it. So I did want to show you a picture of what celiac--I've taken this out of a medical book. It's actually Fishbind's, and I wanted to show you a picture of what it looks like, when you don't adhere to 100 percent gluten free diet.

That comes about because the villi, which is the way you normally ingest food are stunted, they're cut off, and then what happens is, you

know, you can't get food. You start malabsorbing. You can't get nutrition to yourselves so I mean it's not minor.

The other part, I guess, of that is that there's many, many places of hidden sources of gluten that are found in ingredients of processed foods, and I can show you, you know, these Lays potato chips are totally gluten free. These Lays potato chips are not gluten free. And without calling the manufacturer, you don't know that.

Another type of example I brought you is this is a package from Europe, and this is what it looks like when they say it's gluten free. They actually have this little wheat symbol with like a no smoking slash through it, and they have that sign one, two, three places on the package, plus in five languages it's written gluten free, and it's written one location, two locations, on the top. I mean so there are six locations on a label that our American manufacturers say there isn't enough room on the package to put anything. So I will cut off at that point. Thank you.

[Applause.]

DR. LEWIS: Thank you. Judith Schreiber and then I believe Peter Skinner following.

MS. SCHREIBER: Hello. My name is Judy Schreiber. I'm a senior public health scientist in the New York State Office of the Attorney General Elliott Spitzer. And I am here today to offer our comments on the important public health issues of labeling food products containing allergens.

As one of nine states' attorneys general, our office submitted a petition to the FDA to amend its regulations on food labeling and manufacturing practices to better protect consumers from exposure to potentially life threatening food allergens. We are grateful that the FDA is taking consumers' concerns seriously and has made strides to address these important public health issues.

In the May 2000 petition, the attorneys general asked that the FDA: (1) require food manufacturers to label products with actual or possible presence of allergenic substances in foods; (2) require food manufacturers to provide a toll free number to enable consumers to contact knowledgeable customer service representatives about the ingredients contained in the foods; (3) to require manufacturers, food manufacturers, to declare natural and incidental additives derived from the big eight allergens; and, finally, to

require food manufacturers to adopt good manufacturing practices aimed at preventing cross-contact with allergenic substances.

Regarding some of the questions that you posed for this hearing, we do believe that mandatory language is the only way to assure that the label contains the necessary information upon which the consumer can make an educated choice about the safety of the food for their family's circumstances.

Two, we do recommend that the labeling and good manufacturing processes be exercised--the FDA should exercise its authority and adopt the recommendations in the attorneys' general petition. The New York State Attorney General is considering future steps if the FDA neglects this important public health role.

Finally, we agree with the FDA that the declaration of allergenic ingredients and incidental additives in flavoring, spices and colors is necessary for consumer protection. The petition of the attorneys' generals recommends amending certain parts of the regulation, and we will be submitting written comments elaborating on where we feel these changes could be made.

We strongly urge the FDA to codify its policy, to specifically state that incidental additives that are food allergens are not exempt from labeling and must be declared in the ingredient statement on the label.

We also urge the FDA to require mandatory labeling to appear prominently and conspicuously on the information panel so that consumers can readily identify where that information is located.

A speaker earlier today said that the FDA product recall program for allergenic contamination demonstrates that the system is working. I would say that that same example shows, in fact, that the system is broken and that it must be fixed. Having to recall products or having to have children and adults go to emergency rooms for care is not a preventative public health measure, and I urge that the system being broken, let's fix it. Let's give consumers the life line they need by having adequate labeling on food products. Thank you.

[Applause.]

DR. LEWIS: Thank you. Is Peter Skinner with us today?

MS. SCHREIBER: No. He was unable to make it. His wife went into the hospital.

DR. LEWIS: Thank you. And our next scheduled speaker is Catherine Tretheway. Following Catherine Tretheway will be Javier Trujillo Arriaga.

MS. TRETHEWAY: Hello. My name is Catherine Tretheway. I am an attorney and I assisted the New York State Attorney General in the preparation of the petition which has been the subject of today's discussion. More importantly, I am the mother of a five year old daughter who has a life threatening allergy to peanuts.

I am also an active member of a support group for families who are dealing with peanut and nut allergies. I asked to speak today because I think it is important that the FDA know the source of this petition. This is truly a document prepared by consumers for consumers. In drafting the petition, I not only drew from my own experiences as the parent of a food allergic child, but also from the experiences of the many parents with whom I have talked or corresponded with during the recent years that I have started my work on food allergy issues. Many of those parents are in the audience today.

The petition is not a wish list for food

allergic consumers. Rather it represents what consumers truly need to protect themselves and their loved ones from unintended consumption of food allergens.

We need better manufacturing practices to avoid cross-contamination. We need accurate labels. We need clear and easy to read labels. We need phone numbers on the labels so we can contact manufacturers with our questions. Above all, we need consistency in labeling and manufacturing practices so that my mother-in-law, my child's babysitter, and others, and especially my own daughter, can look to one spot on a food label and readily and quickly ascertain whether a food is safe.

As the parent of a food allergic child, I appreciate the efforts of the Food allergy Issues Alliance in issuing guidelines for better good manufacturing practices and labeling. However, even after all our discussion today, I can only conclude that consistency in labeling can only be achieved through regulatory reform. I urge the FDA to adopt the proposals set forth in the attorneys' general petition. Thank you very much for your time.

[Applause.]

DR. LEWIS: Thank you. Next Javier Trujillo Arriaga, if that person is present. If not, Claudette McIntyre. Neither Claudette McIntyre or Javier Trujillo Arriaga. Then the next is Ron Barenburg.

MR. BARENBURG: Thank you. My name is Ron Barenburg. I'm from a company named Lynx Street. We're involved in bar code symbology. There's a new bar code called reduced space symbology and composite symbology that allows more information to be put into less space.

Now, next one, please. I'm sorry. That's the wrong one. I'll go from here. Just forget it. How reduced symbology and composite symbology, which are globally recognized as bar code standards, can alert consumers to allergies in food products. Today manufacturers use what's called a UPCA code. That's the bar code sticker that's on every product. The upgraded version of it approved by the Uniform Code Council is also a UPCA bar code, but what's different about it, it is a portable database in that it can contain a lot more information.

Right now it's available today. It can be

implemented by manufacturers phasing into RSS-UPCA bar codes. Retailers can upgrade or change their scanners on their normal scanner cycle. Today's UPCA bar code contains only the manufacture number and the product ID number. With the allergen warning using RSSCS-UPCA bar code, the following can contain this information. This is what today's bar code looks like. That's what's on every product that comes to market.

With using and phasing into as an adjunct to the warning level in human readables, scanned with the same UPCA code, it can say warning: contains eggs. If you wanted to put a warning: contains eggs and best used by date, it would be a similar label. It would just be a little larger. All these can be put into the same space that a normal UPCA code can use today.

The benefits to the retailer. Besides the obvious concern for their customer's health, it would provide evidence that the consumer was given documented warnings with receipt of their purchase. Retailers will eventually upgrade anyway to support produce at variable weights and measures converting to RSS-CS.

The benefits to the consumer are obvious.

Besides having the "may contain" warning in human readables, the scan bar code would print it out on the receipt alerting the consumer to the allergen warning, and if the consumer has a question, a checkout clerk would scan the product and verbally advise about any allergen danger before purchase.

In conclusion, RSS bar codes can provide more information in less space, not only for allergen warnings, but for best used by dates, contraindications for other foods or drugs, and by providing batch and lot numbers, trace contaminated foods more quickly.

I was drawn to this when I went to do some research on this and realized when I picked up with my 57 year old eyes a label and tried to read it, and I didn't have my reading glasses, how nice it would be just to be able to scan it at the register and see it in big letters, and I think it would help consumers tremendously. Thank you.

[Applause.]

DR. LEWIS: Thank you. Next, Joanie Janicki. And following Joanie Janicki would be Cliff Blaker.

MR. JANICKI: That's a bit of a discrepancy here. J. Janicki.

DR. LEWIS: J. Janicki. Our apologies.

MR. JANICKI: Regulation 21 CFR 1001.4(a) deals with food designation of ingredients, and the problem here is that the criteria are fairly vague. The regulations above, the FDA states that natural flavors and/or artificial flavors may be listed in a vague manner. As an example of this would be the problem that most commercial products contain certain ingredients such as modified food starch and/or natural flavorings. It is not possible to tell by this type of labeling what ingredients the product actually contains such as corn, potato or wheat which are common allergens.

This type of labeling can have serious ramifications to individuals with food allergies and celiac disease. I along with many other individuals who have food allergies urge the FDA to require manufacturers to list all the ingredients including trace amounts.

As a first step, my recommendation would be to simply add a line after the words "modified food starch natural." Instead of modified food starch or garlic oil rather than spices. In Europe, they specify yes or no gluten and have a sign in front of the package similar to that of a

has one place to go to look for the information on the product label.

Now, there is one area where I think my experience as a businessman makes me an expert and that's the talk about voluntary compliance rather than mandatory compliance.

Now, I think the voluntary efforts that have been spoken about today should be applauded, but they cannot really eliminate potential problems. Some companies will be more proactive than others, but there will always be companies that will drag their feet and not comply.

It's the nature of industry to resist regulation and to minimize costs. What we have here is a balance between cost and public health and it's the FDA's mandate to decide in favor of public health.

When statements were made about advisory labeling with the "may contain" wording, I think that what was identified as unavoidable cross-contamination in many cases really means contamination that's too difficult to avoid or too expensive to eliminate. Again, I think it's the FDA that has the responsibility to protect the public and not leave these critical decisions up to

individual companies to make, and I urge the FDA to keep that in mind.

Thank you.

[Applause.]

DR. LEWIS: Thank you. Next Jorge Hernandez Baez, followed by Gustavo Trevino. Mr. Baez, Mr. Trevino? Martin Shunemann. Anne Bailey. Mary Thorpe. Mary Thorpe will be followed by Anne Clarke.

MS. THORPE: My name is Mary Thorpe. I'm currently working at the Center for Celiac Research at the University of Maryland Baltimore, and I'm also representing myself as a person who is attempting to follow a gluten-free diet and thus a wheat free diet.

And as such, I can speak for other celiacs around the country. I would just like to focus on some of my frustrations in following food labels that haven't been touched on very well. Gayle Rubin mentioned secondary sources, and reading labels myself I notice that some cans of tomato paste list wheat flour as an ingredient. Don't ask me why it has to be there, but it is.

And then when I look at a jar of spaghetti sauce of barbecue sauce, it has tomato paste as an

ingredient, I'm left to wonder does that tomato paste have wheat flour in it or not. Sometimes you might see a parentheses that tells the ingredients in that secondary ingredient, but usually you do not. And that's something I haven't heard touched on very much.

So this indicates that some manufacturers are voluntarily doing this, but others are not. The same thing goes for soy sauce. Again, soy sauce has wheat in it most of the time. When soy sauce is a secondary ingredient, you don't know. So we have to avoid these things unless the labeling were there.

And I think that's what we'd like to ask for today is that the labeling be there so that we know and can make the choices for these sources of things. There are many products. Somebody just mentioned modified food starch. This is a question mark. You don't know the source of the food starch.

Some manufacturers are voluntarily saying modified corn starch so we can make an informed choice, but we'd like to see everybody doing that. Or say modified wheat starch if that's what it is. But just let us know.

There are other products like citric acid, MSG, stabilizers, monodiglycerides, dextrines, that can be made from different sources--corn, sugar or wheat--and we would like to know the source for those properties. All you have to do is put it in parentheses--(from wheat)--for each one. It wouldn't take up much space.

Alcohol and vinegar are controversial, but they may have wheat origins. There should not be protein products in those substances, but there might be. Some people are explicitly sensitive. We don't know the threshold of tolerance and so not knowing, we'd rather err on the side of safety. And just let us know what the source is so we can make our informed choice.

So whether it comes down to voluntary compliance by manufacturers or FDA codification, I would agree with many who would say that the manufacturers are trying, but we're still not there yet. It's been excruciatingly slow, and we'd like to see whatever is needed to speed up the process. We would hope the regulations wouldn't slow it down, but we just want it to be done. Thank you.

[Applause.]

DR. LEWIS: Thank you. Next is Anne

Clark, to be followed by Esah Yip.

MS. CLARK: Good afternoon. My name is Anne Clark. The FDA has made the presence of allergens in food high priority. This is a good thing. Labeling food that contains peanut or tree nut allergens is a very good thing.

Labeling food that has or may have been handled with natural rubber latex gloves is not an acceptable solution or labeling as contains or may contain the incidental food additive allergen NRL. Currently natural rubber latex, or NRL, is approved by the FDA as an indirect food additive in light of the over 500 NRL lawsuits working their way through the American justice system concerning wrongful death, product liability, workmen compensation, and American with Disabilities accommodation. Manufacturers of NRL gloves have already begun the labeling process.

Standard wording reads something like this one:

In the unlikely event of an allergic reaction to these latex gloves, discontinue use and consult your health care provider. Caution: this product contains natural rubber latex which may cause allergic reaction. Great for food handling.

It says that on there. This product meets the U.S. Department of Agriculture specifications for food handling.

Now, I have seen and submitted to the USDA advertisements for NRL gloves which claim to be USDA approved and USDA accepted. I've been told by the USDA that they do not approve products. There is no such thing.

These gloves which I purchased contain a warning, a label, that really disturbed me. Some individuals may experience an allergic reaction to natural rubber latex products. Discontinue use if any reddening, burning or irritation is experienced. This manufacturing company will not be liable to individuals who experience allergic reactions to natural rubber latex.

Now, this manufacturer understands that their product can harm. Those of us who have experienced or witnessed someone having an allergic reaction to food handled by latex gloves understand these gloves can harm. There are safe, affordable alternatives. The allergens that are transferred on to food do not add to the nutritional value, preservation or flavor enhancement of the food.

This is important. We know of no way with

current scientific knowledge to determine a protein threshold level that would be safe for all users and would not trigger any allergic reaction to NRL.

Furthermore, the current FDA food code alerts the food service industry of the potential for serious adverse reactions from latex to latex sensitive individuals. Gloves made of NRL must be declared an unsuitable utensil for food handling. NRL approval must be amended so that gloves made of NRL are not an approved indirect food additive. Labeling in this instance is not the solution. Thank you.

DR. LEWIS: Esah Yip or Anita Klein? Next, Carol Roberts. Carol Roberts is here.

MS. ROBERTS: My name is Carol Roberts. I'm a 62 year old grandmother who has had many allergies to deal with most of my life underlined by celiac, but I'm not going to speak to that today at all. I'll send some information in. I would like to make a very simple suggestion and as I read through all three areas, and as I know that I've experienced just about every single one of the things that have come up in one way or another, I used to teach school, elementary school, and I used to be an elementary school principal, and I've

worked in the corporate world and done diversity training and done many things.

But what I thought about is we have a lot of people in this country who don't speak English. We have a lot of people in this country who don't know how to read. We have a lot of people in this country who don't have any knowledge whatsoever about what hydrolyzed protein or caseinate or any of these things are.

And I proposed a question to one of the panelists before who is not here about the integrity of whether or not if a person is allergic, say, to eggs, will they be allergic or sensitive to any byproduct from eggs? The answer was yes. And so, therefore, why do we need any other words except "eggs" on a label in terms of food being contained?

What I did was take a little bit of time and I used pictorial chart. And this is just an idea and a suggestion of taking the different food allergens of the eight allergies and I took and did a diagram of each one of them that's understandable by children. In the next column, I put the contains fish or seafood, listing the types, contains wheat or byproducts in words, and listing

all of the different names.

The symbols can have checks through them, next to them, into them, whatever would make the most sense and be least confusing to those who looked at a label. So each one of these things in terms of the terminologies that have been developed by each of the groups that are working on this could be incorporated into a glossary, put into a simple pamphlet.

These charts could be done in such a way that you have them in a very organized simple way. They could be laminated, put into posters, put into grocery stores, hospitals, nursing homes, anywhere where anyone is affected by these kinds of things in terms of it.

In terms of signaling where they go, using caution, yellow label--everyone knows yellow is caution--put it there right on the label right there and put the words in there with a little picture that says what it is, or use a stop sign, which is also a universal safety sign which children understand, so that if anyone just picks up that product, they know that they need to go and look at information on that label.

And so I would just suggest a very simple

adage like this to be able to simplify it down. You've got eight allergens. Use those eight words. We really don't need all the rest of them. Manufacturers could help by leaving a lot of products out of--a lot of these additives and so on out of their products in the first place and let's get back to basics and good nutritional food.

[Applause.]

DR. LEWIS: Thank you. Next, Rebecca Dugal, and following Rebecca Dugal, Anne Whelan. Rebecca Dugal. I take it this is Rebecca Dugal.

MS. DUGAL: This is Rebecca Dugal. I just wanted to say a few words while she's getting set up. We have some slides.

DR. LEWIS: Please continue.

MS. DUGAL: I wanted to thank the FDA for hosting this panel. I think it's wonderful that we're kind of moving along with food labeling and to all of the panel participants. I also wanted to thank my daughter for urging us to come and for not letting up on me in terms of making sure we could make the trip down here from New Jersey and help her with her presentation. This is something that's very important to her since she was about four in terms of being able to read the labels and

be in control of her own situation.

When she used to go to play dates, even where the people were trained to read the labels, she would say can you read it to me so I can hear it because there are some words I need to know, that I know to look for. It's also important in terms of not the people who are only food allergic and their caretakers, but all of her friends who want to be able to sit with her or provide her snacks, and it's very difficult when they're trying to make the effort to be nice and to be inclusive to say, well, you don't really understand. There are ten scientific terms you have to look for. So don't bother, we'll take care of it.

And here's Becky.

MS. REBECCA DUGAL: Hi. I'm Rebecca Dugal. I live in Allendale, New Jersey. I'm entering fourth grade at nine and a half. I have anaphylaxis to peanuts, peas and lentils. I'm also allergic to wheat, eggs, apples and tomatoes. I believe that people need to be able to read labels very easily.

Living with food allergies and labels is hard. It's difficult in general to go places and do things where food is involved. Most people

can't read the labels for peanut allergens unless my parents have trained them. All the different names for peanuts make it confusing. Ingredient labels are hard to read since they are small and have many scientific names such as hydrolyzed vegetable protein.

People for whom English is not a first language and children have a particularly hard time. Even if my parents read the labels, they are never sure whether there will be cross-contamination since only some manufacturers use "may contain traces of."

Most adults I am with prefer just not to give me food. I cannot eat at play dates because of the labels. Snack times at school and camps are very stressful since we can't trust the labels. It's scary to try new food since we never know if cross-contamination is involved.

Since the labels aren't clear, I don't eat many foods I may be able to eat. Babysitters are difficult to trust with reading labels. My peanut allergic friends and I have reacted to seemingly non-allergic foods where the labels have not been clear cross-contamination exists.

Breads, candies, baked goods, other nuts

and snack foods are some of the foods I have just described. As a result, I don't eat many manufactured products in these categories since I don't want to take the chance of having a reaction.

Food labels should be made readable. Mistakes can have serious outcomes. There needs to be a consistency in the use of "may contain" and "manufactured in a faculty containing."

Lettering should be large enough to read easily. Highly allergic foods should be listed separately and not included in flavorings, spices, colorings.

Symbols should be used for the eight most commonly allergic foods in addition to the actual ingredients. Symbols would be easy to implement and make labels more understandable. Foods would be easily identified as containing one of the eight allergens. Symbols would inform the consumer to read the detailed ingredient list more carefully.

Non-English speakers and children would be able to use the symbols easily. Training of non-allergic adults would be simple and they would have confidence in knowing whether a food is dangerous. Standardized symbols would reduce the risk of mistakes and horrible reactions.

Simple symbols will be the easiest to recognize and take up less space than words. Here is an example of the peanut symbol and wheat symbol.

The next steps you should take: you should aggressively pursue the use of standard symbols; make font symbol size large enough to read easily; agree on a standard use of "may contain" statements always with the eight most commonly allergic foods separately; educate the manufacturers and consumers; and review labeling of cosmetics, medicines and in restaurants, including food service packages.

You can help make my allergies easier to cope with. Thank you.

[Applause.]

DR. LEWIS: Thank you very much, Rebecca, and to her mom as well. Next is Anne Whelan, who would be followed by Colleen Parr, if she's here. If not, Leila Leoncavallo.

MS. WHELAN: Good afternoon. My name is Anne Whelan and for the last six years I have published Gluten-Free Living, a national newsletter for people who like myself are gluten sensitive.

Without going into the details of the

disease, as you know, it has a cure, the gluten free diet, using cure in the sense of remission as long as there is no gluten in the diet. There is no true for celiac disease in the sense of a complete resolution. Once a celiac, always a celiac.

At diagnosis, we are advised to follow a life long gluten-free diet. Gluten is found in wheat. In fact, wheat is probably the main source of gluten for American celiacs. It's also found in rye, barley and derivatives of these grains. Wheat is far and away the most problematic because wheat seems to be everywhere in this country and to be found in the vast majority of American foods.

For the record, barley, too, can be difficult. Rye is relatively easy to avoid. We have to become proficient at reading labels and as we've all learned this morning, that is not easy. The best case example where wheat is concerned is modified food starch. We would like to see modified wheat starch, modified corn starch.

In this area, another issue that comes up for celiacs is spelt. Spelt, kamut, and triticale, or triticale, are three less common grains that celiacs have to avoid. Only spelt is problematic.

In plain language, spelt is a form of wheat. It may not bother some of those who are allergic to wheat, but it does bother those who are sensitive to wheat.

Some food processors now label foods that contain spelt as wheat free, and sometimes even as gluten free. Neither term is correct and it should not be permitted as it is misleading and dangerous. It relates here because of the inclusion of wheat on the list of allergens, and the understanding, which may not be universal, that spelt does not have the allergenic potential that wheat does. So spelt should be labeled as spelt, and a product is not wheat free or gluten free if it contains spelt.

I think specific source or plain English terms should be mandatory, not voluntary, for all the good reasons that we've heard this morning.

The phrases "made on shared equipment" or "made in a dedicated facility" are a little different. To a celiac, "dedicated" would mean gluten containing products are not processed in the same facility. And "made on shared" would mean shared referring to gluten-containing products. To a certain extent, those are helpful to us. They don't tell us about gluten content, but they do

tell us about contamination, and celiacs are particularly interested in contamination because the effects of gluten can be cumulative.

Helpful those these phrases may be, they should not substitute for disclosure. Celiacs have long hoped for source declarations of the contents of flavoring, spice or color. They're three of the main ingredients that make us uneasy. I think there should be a generally applicable policy in this area. I know with flavorings that the problem of trade secrets is sticky. Processors should be able to keep their secrets secret. That's what celiacs hear when they call a food processor to find out what's in it.

At the same time, we should be able to know what's in our foods and to fill comfortable about the foods that we eat.

In conclusion, the celiac community is thankful for the opportunity to speak here and looking forward to working with the FDA and with the other groups on better labeling for people who are celiac. I would like to thank the FDA, the CPSI, and particularly the FAAN for all they have done in the wheat area which helps us enormously. Thank you very much.

[Applause.]

DR. LEWIS: Thank you. I believe Colleen Parr is no longer with us and will not be speaking. You are here? Is this Colleen Parr?

MS. LEONCAVALLO: No, I'm Leila Leoncavallo.

DR. LEWIS: You're Leila Leoncavallo.

MS. LEONCAVALLO: Leila Leoncavallo. Before I begin, I just want to disclose that I am a former employee of CSPI, but today I'm here solely representing myself and my daughter who is three years old and suffers severe allergies to both peanuts and shellfish.

I would just like to focus my remarks on the issue of precautionary labeling. And I certainly support good manufacturing practices to clean up the factories as much as possible to ensure that allergens are eliminated or reduced, but at the same time I think that it is still imperative that labeling occur even in instances where the factory is cleaned, because I want to make those decisions for my daughter.

We just heard Ms. Katic state earlier that cleaning will not succeed in removing all allergens. We've also seen numerous instances of

food recalls where presumably large companies or companies that presumably would be cleaning up the allergens from their machines shouldn't be having to recall their foods after the contamination takes place.

For example, Kellogg's--this is a company that does not label foods on shared equipment and presumably employs good manufacturing practices--they had two major recalls in the past year. And I don't want my daughter to be a guinea pig to find out when food is safe and when it's not safe. I want to see the label in place in addition to the good manufacturing practices by all these companies.

I know a lot of people have expressed concerns with the issue of reducing food choices. My daughter's food choices are already reduced. I have to call all of these companies to find out whether this is on dedicated equipment or not. Her choices are reduced. I just want her to have safe food choices. I don't think that having voluntary guidelines is going to make a bit of difference. It has to be regulated.

The label must be readable and it must be reliable. As many people have mentioned today,

children are having to read the label, caretakers are having to read the label, family members are having to read the label, and it's impossible to fully educate people as to what terms to look for or where to look for on the label unless it is regulated and reliable and easy to read.

Labeling must be mandatory or the situation will simply be no different than the status quo. We will still need to call companies to get this information. This method is not only time consuming and frustrating, but it's often unreliable, and I just want to share a couple of examples from my experiences in talking to companies, and these are not just small companies. These are major companies that you think would know better.

I have a letter from April 2001 from Quaker responding to whether or not their Quaker Life cereal is safe for my daughter to consume, whether it's made on dedicated lines, and they say, and I quote: "Although we would like to help you find products that meet your special dietary needs, we are not able to provide the information you requested. Unfortunately, the federal labeling laws are not designed to indicate the presence of

peanuts."

Then I have this. These are notes from my conversation with Kellogg's when I inquired about their labeling policies. They say for their cereals, you must look under the "best before date" for these letters, B, L or S. If it says K, it's not a nut-free plant.

Their regular and Double Chocolate Rice Krispie Treats are on dedicated lines but not in nut free plants. If I could just continue. Scotchie and Caramel Rice Krispie Treats are on the same line as peanut butter. Pop Tarts could be made on the same line. Nutragrain Bars and Twists are made in a nut-free plant. Nutragrain Squares are on dedicated lines, but not in nut-free plant. Pancakes are in a nut-free plant, but waffles are not in a nut-free plant, and you must call every six weeks to verify.

[Laughter.]

MS. LEONCAVALLO: Given this, I just don't know how we can rely upon any type of voluntary system, and I think if we have voluntary guidelines in place, great, you know, that's one step forward, but I'm still going to have to call the companies, and I'm still going to get the same responses.

Thank you.

[Applause.]

DR. LEWIS: Thank you. The next on our list is Andrew Finkeistein. And following Andrew Finkeistein would be Daniel DuBravec.

Are either of those prepared to present? Is this Daniel DuBravec?

MR. DuBRAVEC: Dan DuBravec.

DR. LEWIS: Please go ahead. Following Daniel DuBravec will be Lise Borel.

MR. DuBRAVEC: Hi. I'm Dan DuBravec. I've been a chairperson for the CSA USA, the Celiac Sprue Association, for about six years in Boston and now in Northern Virginia.

And again I appreciate you forming this panel and allowing us to speak and I think it's also great that there are so many people, you know, representing the Celiac Sprue and bringing up our cause. I've been taking notes kind of through the session here, and these are some of the statements I've heard today:

"Is looking into," "starting baseline surveys," "suggesting guidelines," "encouraging members to declare," "devoting energy to," "needs to look into further," "contemplating issue,"

"looking at practices," "area that needs attention," "struggling with for decades."

My main point I want to get across is that I think the time is now for the mandatory food labeling. I think the opportunity for voluntary labeling has been there and there has been some effort, but as you've heard from so many people, it's just not there. And I think the time to act for is now.

And as a chairperson, I speak to people all the time. I've spoken to hundreds that are on the wheat-free/gluten-free diet, and, you know, they're always asking me what I can eat, and we try to, you know, we contact the manufacturers and we also get information from them. You know it's information that they often do have and one area and concerning cross-contamination, and I'm not sure was addressed, but it probably included, was the part concerning packaging.

You know we thoroughly look at labels, and we go in the frozen food department and we pick up a package of frozen broccoli, let's say. Now, it could say it contains broccoli, right, and water. You would never assume or even think that in packaging that it may be dusted with flour, but

that does happen, and in terms of--I mean I have a sheet right here telling me that. You know I came in. I was just so shocked, and I had been with CSA for a long time, and this was even surprising to me that, you know, just buying frozen vegetables that I have to be cautious about that.

So I, you know, mandatory labeling, please. And, you know, "may contain," even though it may eliminate many products that may or may not contain it is very helpful for people who are on such a sensitive gluten-free diet. Thank you.

[Applause.]

DR. LEWIS: Thank you. Next would be Lise Borel. And if Lise Borel is not here, I understand Wendy Reinhardt will be substituting for Dave Schmidt.

MS. REINHARDT: Hi. My name is Wendy Reinhardt. I'm with the International Food Information Council Foundation, and just a quick note, as we consider many ways to try to make food allergy more understandable for consumers. The International Food Information Council would like to make everyone aware of our foundation resources which are informational resources on food allergy. Particularly outside you can get a copy of our

latest IFIC Review: Understanding Food Allergy, which is a reference white paper for opinion leaders.

And you can also get a copy of our consumer brochure, Understanding Food Allergy, outside. These resources as well as many other resources related to food allergy are available outside and then also on our website, ific.org. Thanks.

[Applause.]

DR. LEWIS: Thank you. Next on our list is Jerry Shier. And following Jerry Shier would be Kimberly Scott.

DR. SHIER: Good afternoon. I'm Jerry Shier. I'm a board certified allergist immunologist in private practice in Rockville and Silver Spring, Maryland, as well as an Assistant Clinical Professor at George Washington University School of Medicine.

Today, I'm representing the American Academy of Allergy, Asthma and Immunology. This is the largest academic organization in the United States representing physicians who care for individuals with allergic diseases. Food allergy is of great concern to the Academy, so much so

there's a special academic section within the organization to further its members' education, monitor research, and create treatment guidelines.

There are approximately six to seven million Americans with true food allergy, with children being the largest group. Food allergy is the leading cause of anaphylaxis outside the hospital. Anaphylaxis is a full-bodied allergic reaction that can occur in minutes. Symptoms including hives, welts on the skin, asthma like symptoms, gastrointestinal symptoms, cramping, diarrhea, bloody stools, swelling of the lips, eyes and tongue.

An estimated 200 deaths occur each year from anaphylaxis from foods. There are approximately 30,000 emergency room visits from food allergic reactions. In my practice, I hear about food allergic reactions on a daily basis. Since there is no cure, the physician's goal is to teach the patient how to recognize and manage an allergic reaction.

But more important is preaching strict food avoidance. Part of the avoidance is vigilant label reading. The subject of label reading is why we're all here today. I have no other treatment

recommendations other than avoidance. In the case of asthma, another common allergic disease, I can preach avoidance of airborne allergens, but I also have numerous medicines to prevent the symptoms, medicines to treat active symptoms, and a method to desensitize patients to allergens that precipitate their symptoms.

It's clear from this comparison to other allergic diseases that the consumer's ability to identify food allergens is their only treatment because the use of medicine is not the treatment of food allergy, it is the treatment of either an accidental or unknowing exposure that led to an acute, potentially life threatening allergic reaction.

Our goal should be to prevent this from occurring. The American Academy of Allergy, Asthma, Immunology is in full support of the easy identification of the most common food allergens on all labels. These include milk, egg, wheat, soy, tree nuts, peanuts, fish and shellfish.

What do I mean by easy identification? Let consumers know that these allergens are in the products they are purchasing by using the real name of the food: milk, egg or wheat, not casein,

ovalbumin or farina. This should not be Russian Roulette. The FDA must make it mandatory that major food allergens appear on labels if they are used as an ingredient in a way that our food allergic patients can easily identify the allergen.

What does "ingredient exempted from declaration" mean? If the food allergen is in a processed food, what's labeled as such. Major allergens are found in ingredients labeled as flavoring or spices or colors. Low levels of allergens can be responsible for an allergic reaction which sometimes can be life threatening.

Please just let me finish. The FDA needs to require food manufacturers to place the names of major food allergens on labels regardless of the amount.

Finally, I applaud the companies that have voluntarily instituted labeling that a major food allergen may be present, even though it's not a known ingredient. This is usually due to the use of shared equipment to produce a food that does and one that does not have a food allergen.

Unfortunately, there are companies now that have been begun labeling foods as having major allergens, purely on a liability basis, versus a

true risk. In addition, there is no uniformity on how the information is presented.

The American Academy looks to the FDA to create standards for the food industry's proper use of these statements and consistent verbiage of these statements so that we can educate our patients.

In conclusion, although I sit here today representing a large body of health care providers, I can tell you first hand that labeling systems need fixing, and that there are many Americans, especially parents of children, that have a fear that is indescribable, a fear of food that can be paralyzing.

The solution appears simple. If the major food allergen is present, label it so we can all understand it. If there is a real contamination, then label it in a uniform way. The food allergic individual is already restricted from eating outside the home because it's so difficult to identify all the ingredients and the potential for cross-contamination in restaurant foods. So let's make eating at home safe for those with potentially life threatening conditions. Thank you.

[Applause.]

DR. LEWIS: Next is Kimberly Scott, to be followed by Sarah Gitlin.

MS. SCOTT: Good afternoon. My name is Kimberly Johnson Scott, and I appreciate this opportunity to provide oral comments on allergen related labeling issues. Today I am speaking both as a mother of Sidney Scott, our energetic 21 month old, and as the co-founder of the SOS Foundation.

On March 27 of this year, my husband and I were shocked to learn that our daughter Sidney had a life-threatening allergy to peanuts, tree nuts and eggs. In a moment, the security we had previously felt in selecting food for our family evaporated into thin air.

The exact same labels upon which we had previously relied and which as parents we found reassuring suddenly took on a potentially life or death prominence in our household. Questions replaced confidence.

What does it mean when "contains peanuts" isn't on the label, but "natural flavorings" is? Did I read over those ingredients with 15 syllables in it and did not recognize that it was an egg protein because I didn't see the word "egg"? Why would the label say "may contain nuts" when I read

the label ten times and I didn't see nuts anywhere?

While devoting time to reading food labels clearly and deliberately is a small sacrifice to make for those we care about, we need the FDA to help empower parents by requiring clear and comprehensive labeling of products. Through our desire to help our daughter and other similarly situated families, my husband Stuart and I have co-founded the SOS Foundation, a not-for-profit organization which has pledged financial, emotional and practical support to those who struggle to meet the challenges of living with a chronic condition.

In order to help improve the lives of individuals with food allergies, SOS will serve as an additional vehicle to advocate for accurate food labeling, practical food labeling legislation, effective research and increased awareness. In the coming year, the SOS Foundation will join forces with organizations and individuals who have long dedicated themselves to this effort. We hope to work in partnership with the FDA in bringing together industry, consumer, medical and scientific groups for the purpose of better educating the food industry and enhancing the level of public awareness of the public health risk of incomplete,

inaccurate, inconsistent, and incomprehensible labeling of food products.

I would like to briefly comment on the specific matters under consideration at this meeting. A condition such as anaphylaxis is unpredictable enough without the added stress of trying to decipher food labels. Plain English in the labeling of food ingredients is critical to empowering individuals to take control of their condition, restoring a certain amount of independence and equally as important is the power and freedom it gives to friends and relatives of non-food allergic individuals to make responsible selection of food items to share with or entertain their food allergic friends and relatives as will responsible use of advisory labeling.

When a food company manufactures five products without nuts but also manufactures one with nuts, and places advisory labels on all six products, this greatly reduces the already limited choices of those who are searching for a list of can haves in a world of cannot haves.

Finally, we must realize that listing the major food allergens must not be limited to those found in significant amounts, but also extend to

those found in trace amounts. This boils down to an issue of trust. Can I trust what is on the food label is actually what's in the product?

With that trust comes the opportunity to regain the power to monitor and maintain one's health to the best of their ability until the day a cure is found. This is a chance to be free of the agonizing choice of whether to risk an anaphylactic reaction every time you take a bite.

With the FDA's help, we have before us the opportunity to release those who suffer from this condition from a food prison so that they may not just eat to live, but that they may also eat and live. I thank you for this opportunity.

[Applause.]

DR. LEWIS: Next will have Carol Schrager. Sarah Gitlin, first. Sarah Gitlin is here.

MS. GITLIN: Good afternoon. My name is Sarah Gitlin. I am ten years old. I am deathly allergic to peanuts, tree nuts and fish. When I learned to read, five years ago, in kindergarten, I started with Dr. Seuss, Mother Goose, and ingredients labels.

[Laughter.]

MS. GITLIN: I knew that Dr. Seuss and

Mother Goose wouldn't lie to me, but ingredients labels, I couldn't be so sure. I have to be able to trust these labels. For if I eat something I'm allergic to, even a tiny trace of it, and couldn't get proper treatment, I could die within minutes.

I try very hard only to eat what I know is safe, not to risk it if the food might contain anything I'm allergic to. But who would guess that a common popcorn brand would use the words "natural flavors" to mean peanuts? And who would guess that the words "vegetable protein" and "plant protein" would be food companies' code words for tree nuts.

These words as well as incomplete ingredients labels are life threatening for food allergic children. That is why I am here today to urge the FDA to enact regulations that require ingredients labels with an accurate list of every ingredient in the product.

Some food companies already do this voluntarily. And that's great. But I need 100 percent to do it. My life depends upon it. I'm not asking you to tell food manufacturers to change their recipes. I'm not asking you to tell them what they can or can't add to their products. I'm not asking you to tell them that they have to

change their manufacturing processes.

All I'm asking you to do is to make them tell me what recipes they're using, tell me what they already add to their products, tell me whether they're manufacturing processes result in adding even traces of the food I am so deathly allergic to.

Reading ingredients is a large part of food allergic children's lives. So large that the Food Allergy and Anaphylaxis Network published this story:

A mother was trying to teach her food allergic child not to talk to strangers. So, she asked her daughter, if a stranger in a car pulled up and offered you a candy bar, what would you do? Without missing a beat, the little girl responded I would ask them to read me the ingredients.

[Laughter.]

MS. GITLIN: That girl knew what was really dangerous. Because food allergies are so dangerous, food allergic kids and their families around the country urge you to protect our lives by requiring ingredients labels to be complete, accurate and in plain English so that we can really know what's in the food we are eating. Thank you.

[Applause.]

DR. LEWIS: Thank you, Sarah. I now believe it's Carol Schrager.

MS. SCHRAGER: Good afternoon. I'm Sarah's Mom, and I'm a member of the Food Allergy Initiative and the Food Allergy and Anaphylaxis Network.

Raising a food allergic child without complete and accurate ingredients labeling is like walking through a mine field. No matter how carefully you watch your step, you never know when there will be an unexpected explosion. It's hard enough to avoid the dangers that we know about, but it's impossible to rest easy when we know that there are dangers hidden in foods that Sarah might eat, but we don't know which foods and we don't know which dangers.

So we turn to you, the Food and Drug Administration, the agency charged with protecting American lives by regulating the practices of food and drug manufacturers.

We need you to help us protect the lives and health of the seven million Americans with food allergies by enacting regulations that are stunningly simple, the kind of regulations that

most Americans assume already exist, the kind of regulations that most people are shocked to find out do not already exist.

What we urge you to require is merely this: that every packaged food has a label that states in plain English every ingredient that is in the product, both ingredients that are part of the recipe, including spices and natural flavors, and ingredients that are unavoidably present because of cross-contamination with other foods.

These regulations would save lives with virtually no downside for food manufacturers. Yes, it may cost the manufacturers a little bit more to assure that their labeling is accurate, but such costs are trivial when balanced against the precious irreplaceable lives of our children. And remember, the number of Americans with food allergies is growing exponentially. So manufacturers actually have a lot to gain from these regulations because the market for their products will expand.

As food allergic consumers and their families and friends who now will not buy products that are said to contain, for example, natural flavors will feel safe consuming them once they are

assured that the allergens are not present.

Under the regulations we support, food manufacturers would not have to change a single thing that they do. They could include any or all allergens in any or all of their products. They could process foods on shared equipment without cleaning the production line in between runs. They could do anything they want to do, anyway they want to do it. All that we ask you to require them to do is tell us what they're doing and tell us how they're doing it, so that we can make intelligent choices to protect our children's lives, so that we can walk through a field with our children without fear of an explosion.

Thank you very much for listening to our concerns and to giving my daughter a close-up and personal lesson in participatory democracy. We appreciate it very much.

[Applause.]

DR. LEWIS: Thank you. Next we have listed Barbara Solan. And following Barbara Solan, we have Ben Wilson.

MS. SOLAN: Thank you for the opportunity to speak. I don't usually do podiums. I think democracy is a wonderful opportunity and to stand

here and say what I think that I've waited a long time to say is very, very gratifying.

First of all, I'm the mother of an asthmatic food anaphylactic daughter. I've been reading labels for 11 years and I do that probably about five times a day, 365 days a year, many, many labels. Prior to becoming a professional label reader, I was a nurse in the U.S. Public Health Service, and I worked in the Indian Health Service and at the National Institutes of Health, and I've been involved in quality assurance.

Two of the things that I tried to bring with me to this meeting are my common sense and my creative problem solving. And as I listened today and as I have read every article I have found on the topic, I have some comments to make.

First of all, we need to do something because the 2001 Healthy People statement says that we're going to reduce food anaphylactic deaths in the next decade so we need to address that issue. It's out there. It's a goal. It's a national priority.

Second of all, the FDA is a public health agency and it is charged with protecting American consumers by enforcing the FDCA and other related

public health laws. It's a charge.

The other thing that is very gratifying to me is--and the first time that I have heard in all my years--is that someone has finally declared food allergens as a serious public health issue, and I can't thank you enough for that.

I think it's important to look at the demographics of what's going on in our society as we address these issues and not just look at today's issues. We've got a growing immigrant population. We've got a growing allergy issue, and I think we shouldn't just look at what's right on the table, but where we're headed.

And to specifically the comments about the questions you all asked. I favor plain labeling with the eight allergens. I want it bolded. It's like reading the newspaper, The Washington Post with no headlines, and that's what we do all the time. If you give us some headlines, it helps us. It's very tedious. It's also not safe.

I think that certain font size should be addressed, and I think we need to pay attention to the contrast background and materials used in products for labeling. Some things are pretty difficult to read. I do not like asterisks. I

find them confusing. And I think they will only muddle the issue.

I like the General Motors--General Motors--I come from the Detroit area--General Mills model that says food allergy consumer or allergy information: contains nuts, soy. That helps me. And I'll go very quickly on this. I think we need to set priorities. There's a lot of issues about food allergies. I've lived with them for 11 years. Some are bigger than others. And we should grab the big ones. We should think out of the box and we should be creative in our problem solving.

Thank you.

[Applause.]

DR. LEWIS: Thank you. Next we have listed Ben Wilson, who will be followed by C. Gordon Brown.

MR. WILSON: I'm Ben Wilson and I'm Director of Regulatory Compliance for Sensient Flavors, a food flavor company. I'm feeling a little at risk on this side of the audience this afternoon.

[Laughter.]

MR. WILSON: But we need some help from FDA as well. I answer the questions from our

customers and from their customers, the consumers, about allergens and what's contained in a food, but the questions I get go much beyond the simple allergens. Today people want to know about GMO, they want to know about organic, they want to know about consumer interests in different things, they want to know about specific issue products.

They're very important to these people that ask them. In some cases, they're significantly life threatening like allergens, but the responses that we give and when trying to provide the information seem to confuse the food companies. They will ask us does this product contain soy? And we will answer yes, but the soy that's in it may be a partially hydrogenated soybean oil, has no protein, has no allergen issue. It's been highly refined, it's been modified, the proteins are gone.

That may be of interest to a specific few who have a different type of soy reaction. It may be of interest to our customer because he's looking at a GMO issue for soy. He may be looking for Europe. We need some clarification from FDA as they look into these products and allergen and either guidelines or rules or whatever, but what

are the allergens, what are the things that we need to talk about?

Are we going to talk about the big eight in general as allergens, not the big eight of soy, which contains a lot of things that aren't allergens, or of corn, which is an issue, but for most people not an allergen? Wheat--is that an allergen issue to wheat or is that an issue of sprue celiac where it includes the glutens, the spelt, the rye, the barley?

Does this include different extracts which may or may not have allergen potential? We need to make that clear. That needs to be very clear in what we're doing of whether we're addressing allergens, whether we're addressing big groups, and that's it. And that's what I want to say for today. Help us help the food manufacturer put the correct information on the label by giving us some clear guidelines of what we're talking about and what the things are of concern. Thank you.

[Applause.]

DR. LEWIS: Thank you. Next, we have C. Gordon Brown, who would be followed by Carolyn Garrett.

MR. BROWN: Thank you very much. I'm

Gordon Brown, Senior Vice President of Scientific and Regulatory Affairs for the International Dairy Foods Association. We thank you very much for providing this forum and for providing an opportunity for us to get our positions out there.

The following comments are made on behalf of the International Dairy Foods Association. IDFA is the nation's leading trade association representing the dairy industry. Our member companies manufacture the entire range of dairy products and include processors, manufacturers, marketers, distributors and suppliers.

IDFA consists of three constituent organizations: the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute.

Member companies in these groups account for 85 percent of the dairy products consumed in the United States. IDFA is a member of the Allergy Issues Alliance, the coalition of food trade associations and a leading food allergy consumer group. IDFA helped develop new guidelines for clear labeling of allergenic compounds.

IDFA strongly supports implementation of these guidelines, encourages disclosure of

allergenic ingredients in clear and simple language and is dedicated to assisting dairy processors to prevent cross-contamination.

Our commitment to the allergen initiative is demonstrated through our member outreach. Although dairy processors are conscientious about compliance with labeling requirements for allergenic ingredients, IDFA still urges all members to review their policies and verify that they are operating within the new allergen guidelines and we provide a whole lot of one on one contact and information to our members who request information.

Further, we recommend that member companies follow the following recommendations:

(1) Review formulations to identify the presence if any of the eight major allergens;

(2) Contact ingredient suppliers to determine if ingredients they supply contain any allergens including components of flavors, colors, incidental additives and processing aids that may not be required to be labeled.

We also suggest they review their current labels to ensure that if any allergens are present, they are included in the ingredient declaration in

terms that are easily understood by consumers.

Number four, advisory statements should not be used as a substitute for good manufacturing practices. Only use advisory label statements such as "may contain" blank when all of the criteria established in the allergen guidelines are met, and I won't go into those now, but they are available.

The dairy industry has a good track record on the allergen issue. Recalls for undeclared allergens and dairy products are rare. However, we are committed to continuous improvement and this is demonstrated by our efforts to educate our members on the important issues through a variety of outreach programs.

These programs include (1) providing publications to member companies on implementation of the voluntary food allergen labeling guidelines; (2) instructions for labeling manuals for milk, cheese and ice cream; (3) we provide workshops on allergens and proper food labeling on a periodic base. These are open to the entire dairy industry as well as ingredient suppliers. (4) We provide education for ice cream manufacturers through a workshop entitled "Ice Cream Best Practices" to explain the allergen issues and industry's labeling

requirements.

In summary, the dairy industry is committed to maintaining the safety of its products and is currently engaged in this effort to make sure that we protect the health of allergenic consumers. Thank you.

[Applause.]

DR. LEWIS: We now have Carolyn Garrett on our list. Carolyn Garrett is not here. That completes my list of registered speakers. So I believe that the meeting is now coming to an end.

My closing comments are quite succinct. I think this was an extremely useful meeting for the agency. I felt a lot of important information was obtained by us.

Again, the docket is open so comments are still possible to this particular series of questions by the agency. I do want to thank all the members of the panel who provided some very useful discussion points for us, as well as the FDA support staff who made this meeting possible.

So thank you very much. The transcript will be available in about a month and information on obtaining that is in your Federal Register documents. Thank you.

[Applause.]

[Whereupon, at 3:20 p.m., the meeting was adjourned.]

CERTIFICATE

I, **VICTORIA S. McLAUGHLIN,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

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