

1 be in control of her own situation.

2 When she used to go to play dates, even
3 where the people were trained to read the labels,
4 she would say can you read it to me so I can hear
5 it because there are some words I need to know,
6 that I know to look for. It's also important in
7 terms of not the people who are only food allergic
8 and their caretakers, but all of her friends who
9 want to be able to sit with her or provide her
10 snacks, and it's very difficult when they're trying
11 to make the effort to be nice and to be inclusive
12 to say, well, you don't really understand. There
13 are ten scientific terms you have to look for. So
14 don't bother, we'll take care of it.

15 And here's Becky.

16 MS. REBECCA DUGAL: Hi. I'm Rebecca
17 Dugal. I live in Allendale, New Jersey. I'm
18 entering fourth grade at nine and a half. I have
19 anaphylaxis to peanuts, peas and lentils. I'm also
20 allergic to wheat, eggs, apples and tomatoes. I
21 believe that people need to be able to read labels
22 very easily.

23 Living with food allergies and labels is
24 hard. It's difficult in general to go places and
25 do things where food is involved. Most people

1 can't read the labels for peanut allergens unless
2 my parents have trained them. All the different
3 names for peanuts make it confusing. Ingredient
4 labels are hard to read since they are small and
5 have many scientific names such as hydrolyzed
6 vegetable protein.

7 People for whom English is not a first
8 language and children have a particularly hard
9 time. Even if my parents read the labels, they are
10 never sure whether there will be
11 cross-contamination since only some manufacturers
12 use "may contain traces of."

13 Most adults I am with prefer just not to
14 give me food. I cannot eat at play dates because
15 of the labels. Snack times at school and camps are
16 very stressful since we can't trust the labels.
17 It's scary to try new food since we never know if
18 cross-contamination is involved.

19 Since the labels aren't clear, I don't eat
20 many foods I may be able to eat. Babysitters are
21 difficult to trust with reading labels. My peanut
22 allergic friends and I have reacted to seemingly
23 non-allergic foods where the labels have not been
24 clear cross-contamination exists.

25 Breads, candies, baked goods, other nuts

1 and snack foods are some of the foods I have just
2 described. As a result, I don't eat many
3 manufactured products in these categories since I
4 don't want to take the chance of having a reaction.

5 Food labels should be made readable.
6 Mistakes can have serious outcomes. There needs to
7 be a consistency in the use of "may contain" and
8 "manufactured in a facility containing."

9 Lettering should be large enough to read
10 easily. Highly allergic foods should be listed
11 separately and not included in flavorings, spices,
12 colorings.

13 Symbols should be used for the eight most
14 commonly allergic foods in addition to the actual
15 ingredients. Symbols would be easy to implement
16 and make labels more understandable. Foods would
17 be easily identified as containing one of the eight
18 allergens. Symbols would inform the consumer to
19 read the detailed ingredient list more carefully.

20 Non-English speakers and children would be
21 able to use the symbols easily. Training of
22 non-allergic adults would be simple and they would
23 have confidence in knowing whether a food is
24 dangerous. Standardized symbols would reduce the
25 risk of mistakes and horrible reactions.

1 Simple symbols will be the easiest to
2 recognize and take up less space than words. Here
3 is an example of the peanut symbol and wheat
4 symbol.

5 The next steps you should take: you should
6 aggressively pursue the use of standard symbols;
7 make font symbol size large enough to read easily;
8 agree on a standard use of "may contain" statements
9 always with the eight most commonly allergic foods
10 separately; educate the manufacturers and
11 consumers; and review labeling of cosmetics,
12 medicines and in restaurants, including food
13 service packages.

14 You can help make my allergies easier to
15 cope with. Thank you.

16 [Applause.]

17 DR. LEWIS: Thank you very much, Rebecca,
18 and to her mom as well. Next is Anne Whelan, who
19 would be followed by Colleen Parr, if she's here.
20 If not, Leila Leoncavallo.

21 MS. WHELAN: Good afternoon. My name is
22 Anne Whelan and for the last six years I have
23 published Gluten-Free Living, a national newsletter
24 for people who like myself are gluten sensitive.

25 Without going into the details of the

1 disease, as you know, it has a cure, the gluten
2 free diet, using cure in the sense of remission as
3 long as there is no gluten in the diet. There is
4 no true for celiac disease in the sense of a
5 complete resolution. Once a celiac, always a
6 celiac.

7 At diagnosis, we are advised to follow a
8 life long gluten-free diet. Gluten is found in
9 wheat. In fact, wheat is probably the main source
10 of gluten for American celiacs. It's also found in
11 rye, barley and derivatives of these grains. Wheat
12 is far and away the most problematic because wheat
13 seems to be everywhere in this country and to be
14 found in the vast majority of American foods.

15 For the record, barley, too, can be
16 difficult. Rye is relatively easy to avoid. We
17 have to become proficient at reading labels and as
18 we've all learned this morning, that is not easy.
19 The best case example where wheat is concerned is
20 modified food starch. We would like to see
21 modified wheat starch, modified corn starch.

22 In this area, another issue that comes up
23 for celiacs is spelt. Spelt, kamut, and triticale,
24 or triticale, are three less common grains that
25 celiacs have to avoid. Only spelt is problematic.

1 In plain language, spelt is a form of wheat. It
2 may not bother some of those who are allergic to
3 wheat, but it does bother those who are sensitive
4 to wheat.

5 Some food processors now label foods that
6 contain spelt as wheat free, and sometimes even as
7 gluten free. Neither term is correct and it should
8 not be permitted as it is misleading and dangerous.
9 It relates here because of the inclusion of wheat
10 on the list of allergens, and the understanding,
11 which may not be universal, that spelt does not
12 have the allergenic potential that wheat does. So
13 spelt should be labeled as spelt, and a product is
14 not wheat free or gluten free if it contains spelt.

15 I think specific source or plain English
16 terms should be mandatory, not voluntary, for all
17 the good reasons that we've heard this morning.

18 The phrases "made on shared equipment" or
19 "made in a dedicated facility" are a little
20 different. To a celiac, "dedicated" would mean
21 gluten containing products are not processed in the
22 same facility. And "made on shared" would mean
23 shared referring to gluten-containing products. To
24 a certain extent, those are helpful to us. They
25 don't tell us about gluten content, but they do.

1 tell us about contamination, and celiacs are
2 particularly interested in contamination because
3 the effects of gluten can be cumulative.

4 Helpful those these phrases may be, they
5 should not substitute for disclosure. Celiacs have
6 long hoped for source declarations of the contents
7 of flavoring, spice or color. They're three of the
8 main ingredients that make us uneasy. I think
9 there should be a generally applicable policy in
10 this area. I know with flavorings that the problem
11 of trade secrets is sticky. Processors should be
12 able to keep their secrets secret. That's what
13 celiacs hear when they call a food processor to
14 find out what's in it.

15 At the same time, we should be able to
16 know what's in our foods and to feel comfortable
17 about the foods that we eat.

18 In conclusion, the celiac community is
19 thankful for the opportunity to speak here and
20 looking forward to working with the FDA and with
21 the other groups on better labeling for people who
22 are celiac. I would like to thank the FDA, the
23 CPSI, and particularly the FAAN for all they have
24 done in the wheat area which helps us enormously.
25 Thank you very much.

1 [Applause.]

2 DR. LEWIS: Thank you. I believe Colleen
3 Parr is no longer with us and will not be speaking.
4 You are here? Is this Colleen Parr?

5 MS. LEONCAVALLO: No, I'm Leila
6 Leoncavallo.

7 DR. LEWIS: You're Leila Leoncavallo.

8 MS. LEONCAVALLO: Leila Leoncavallo.

9 Before I begin, I just want to disclose that I am a
10 former employee of CSPI, but today I'm here solely
11 representing myself and my daughter who is three
12 years old and suffers severe allergies to both
13 peanuts and shellfish.

14 I would just like to focus my remarks on
15 the issue of precautionary labeling. And I
16 certainly support good manufacturing practices to
17 clean up the factories as much as possible to
18 ensure that allergens are eliminated or reduced,
19 but at the same time I think that it is still
20 imperative that labeling occur even in instances
21 where the factory is cleaned, because I want to
22 make those decisions for my daughter.

23 We just heard Ms. Katic state earlier that
24 cleaning will not succeed in removing all
25 allergens. We've also seen numerous instances of

1 food recalls where presumably large companies or
2 companies that presumably would be cleaning up the
3 allergens from their machines shouldn't be having
4 to recall their foods after the contamination takes
5 place.

6 For example, Kellogg's--this is a company
7 that does not label foods on shared equipment and
8 presumably employs good manufacturing
9 practices--they had two major recalls in the past
10 year. And I don't want my daughter to be a guinea
11 pig to find out when food is safe and when it's not
12 safe. I want to see the label in place in addition
13 to the good manufacturing practices by all these
14 companies.

15 I know a lot of people have expressed
16 concerns with the issue of reducing food choices.
17 My daughter's food choices are already reduced. I
18 have to call all of these companies to find out
19 whether this is on dedicated equipment or not. Her
20 choices are reduced. I just want her to have safe
21 food choices. I don't think that having voluntary
22 guidelines is going to make a bit of difference.
23 It has to be regulated.

24 The label must be readable and it must be
25 reliable. As many people have mentioned today,

1 children are having to read the label, caretakers
2 are having to read the label, family members are
3 having to read the label, and it's impossible to
4 fully educate people as to what terms to look for
5 or where to look for on the label unless it is
6 regulated and reliable and easy to read.

7 Labeling must be mandatory or the
8 situation will simply be no different than the
9 status quo. We will still need to call companies
10 to get this information. This method is not only
11 time consuming and frustrating, but it's often
12 unreliable, and I just want to share a couple of
13 examples from my experiences in talking to
14 companies, and these are not just small companies.
15 These are major companies that you think would know
16 better.

17 I have a letter from April 2001 from
18 Quaker responding to whether or not their Quaker
19 Life cereal is safe for my daughter to consume,
20 whether it's made on dedicated lines, and they say,
21 and I quote: "Although we would like to help you
22 find products that meet your special dietary needs,
23 we are not able to provide the information you
24 requested. Unfortunately, the federal labeling
25 laws are not designed to indicate the presence of

1 peanuts."

2 Then I have this. These are notes from my
3 conversation with Kellogg's when I inquired about
4 their labeling policies. They say for their
5 cereals, you must look under the "best before date"
6 for these letters, B, L or S. If it says K, it's
7 not a nut-free plant.

8 Their regular and Double Chocolate Rice
9 Krispie Treats are on dedicated lines but not in
10 nut free plants. If I could just continue.
11 Scotchie and Caramel Rice Krispie Treats are on the
12 same line as peanut butter. Pop Tarts could be
13 made on the same line. Nutragrain Bars and Twists
14 are made in a nut-free plant. Nutragrain Squares
15 are on dedicated lines, but not in nut-free plant.
16 Pancakes are in a nut-free plant, but waffles are
17 not in a nut-free plant, and you must call every
18 six weeks to verify.

19 [Laughter.]

20 MS. LEONCAVALLO: Given this, I just don't
21 know how we can rely upon any type of voluntary
22 system, and I think if we have voluntary guidelines
23 in place, great, you know, that's one step forward,
24 but I'm still going to have to call the companies,
25 and I'm still going to get the same responses.

1 Thank you.

2 [Applause.]

3 DR. LEWIS: Thank you. The next on our
4 list is Andrew Finkestein. And following Andrew
5 Finkestein would be Daniel DuBravec.

6 Are either of those prepared to present?
7 Is this Daniel DuBravec?

8 MR. DuBRAVEC: Dan DuBravec.

9 DR. LEWIS: Please go ahead. Following
10 Daniel DuBravec will be Lise Borel.

11 MR. DuBRAVEC: Hi. I'm Dan DuBravec.
12 I've been a chairperson for the CSA USA, the Celiac
13 Sprue Association, for about six years in Boston
14 and now in Northern Virginia.

15 And again I appreciate you forming this
16 panel and allowing us to speak and I think it's
17 also great that there are so many people, you know,
18 representing the Celiac Sprue and bringing up our
19 cause. I've been taking notes kind of through the
20 session here, and these are some of the statements
21 I've heard today:

22 "Is looking into," "starting baseline
23 surveys," "suggesting guidelines," "encouraging
24 members to declare," "devoting energy to," "needs
25 to look into further," "contemplating issue,"

1 "looking at practices," "area that needs
2 attention," "struggling with for decades."

3 My main point I want to get across is that
4 I think the time is now for the mandatory food
5 labeling. I think the opportunity for voluntary
6 labeling has been there and there has been some
7 effort, but as you've heard from so many people,
8 it's just not there. And I think the time to act
9 for is now.

10 And as a chairperson, I speak to people
11 all the time. I've spoken to hundreds that are on
12 the wheat-free/gluten-free diet, and, you know,
13 they're always asking me what I can eat, and we try
14 to, you know, we contact the manufacturers and we
15 also get information from them. You know it's
16 information that they often do have and one area
17 and concerning cross-contamination, and I'm not
18 sure was addressed, but it probably included, was
19 the part concerning packaging.

20 You know we thoroughly look at labels, and
21 we go in the frozen food department and we pick up
22 a package of frozen broccoli, let's say. Now, it
23 could say it contains broccoli, right, and water.
24 You would never assume or even think that in
25 packaging that it may be dusted with flour, but

1 that does happen, and in terms of--I mean I have a
2 sheet right here telling me that. You know I came
3 in. I was just so shocked, and I had been with CSA
4 for a long time, and this was even surprising to me
5 that, you know, just buying frozen vegetables that
6 I have to be cautious about that.

7 So I, you know, mandatory labeling,
8 please. And, you know, "may contain," even though
9 it may eliminate many products that may or may not
10 contain it is very helpful for people who are on
11 such a sensitive gluten-free diet. Thank you.

12 [Applause.]

13 DR. LEWIS: Thank you. Next would be Lise
14 Borel. And if Lise Borel is not here, I understand
15 Wendy Reinhardt will be substituting for Dave
16 Schmidt.

17 MS. REINHARDT: Hi. My name is Wendy
18 Reinhardt. I'm with the International Food
19 Information Council Foundation, and just a quick
20 note, as we consider many ways to try to make food
21 allergy more understandable for consumers. The
22 International Food Information Council would like
23 to make everyone aware of our foundation resources
24 which are informational resources on food allergy.
25 Particularly outside you can get a copy of our

1 latest IFIC Review: Understanding Food Allergy,
2 which is a reference white paper for opinion
3 leaders.

4 And you can also get a copy of our
5 consumer brochure, Understanding Food Allergy,
6 outside. These resources as well as many other
7 resources related to food allergy are available
8 outside and then also on our website, ific.org.
9 Thanks.

10 [Applause.]

11 DR. LEWIS: Thank you. Next on our list
12 is Jerry Shier. And following Jerry Shier would be
13 Kimberly Scott.

14 DR. SHIER: Good afternoon. I'm Jerry
15 Shier. I'm a board certified allergist
16 immunologist in private practice in Rockville and
17 Silver Spring, Maryland, as well as an Assistant
18 Clinical Professor at George Washington University
19 School of Medicine.

20 Today, I'm representing the American
21 Academy of Allergy, Asthma and Immunology. This is
22 the largest academic organization in the United
23 States representing physicians who care for
24 individuals with allergic diseases. Food allergy
25 is of great concern to the Academy, so much so

1 there's a special academic section within the
2 organization to further its members' education,
3 monitor research, and create treatment guidelines.

4 There are approximately six to seven
5 million Americans with true food allergy, with
6 children being the largest group. Food allergy is
7 the leading cause of anaphylaxis outside the
8 hospital. Anaphylaxis is a full-bodied allergic
9 reaction that can occur in minutes. Symptoms
10 including hives, welts on the skin, asthma like
11 symptoms, gastrointestinal symptoms, cramping,
12 diarrhea, bloody stools, swelling of the lips, eyes
13 and tongue.

14 An estimated 200 deaths occur each year
15 from anaphylaxis from foods. There are
16 approximately 30,000 emergency room visits from
17 food allergic reactions. In my practice, I hear
18 about food allergic reactions on a daily basis.
19 Since there is no cure, the physician's goal is to
20 teach the patient how to recognize and manage an
21 allergic reaction.

22 But more important is preaching strict
23 food avoidance. Part of the avoidance is vigilant
24 label reading. The subject of label reading is why
25 we're all here today. I have no other treatment

1 recommendations other than avoidance. In the case
2 of asthma, another common allergic disease, I can
3 preach avoidance of airborne allergens, but I also
4 have numerous medicines to prevent the symptoms,
5 medicines to treat active symptoms, and a method
6 to desensitize patients to allergens that
7 precipitate their symptoms.

8 It's clear from this comparison to other
9 allergic diseases that the consumer's ability to
10 identify food allergens is their only treatment
11 because the use of medicine is not the treatment of
12 food allergy, it is the treatment of either an
13 accidental or unknowing exposure that led to an
14 acute, potentially life threatening allergic
15 reaction.

16 Our goal should be to prevent this from
17 occurring. The American Academy of Allergy,
18 Asthma, Immunology is in full support of the easy
19 identification of the most common food allergens on
20 all labels. These include milk, egg, wheat, soy,
21 tree nuts, peanuts, fish and shellfish.

22 What do I mean by easy identification?
23 Let consumers know that these allergens are in the
24 products they are purchasing by using the real name
25 of the food: milk, egg or wheat, not casein,

1 ovalbumin or farina. This should not be Russian
2 Roulette. The FDA must make it mandatory that
3 major food allergens appear on labels if they are
4 used as an ingredient in a way that our food
5 allergic patients can easily identify the allergen.

6 What does "ingredient exempted from
7 declaration" mean? If the food allergen is in a
8 processed food, what's labeled as such. Major
9 allergens are found in ingredients labeled as
10 flavoring or spices or colors. Low levels of
11 allergens can be responsible for an allergic
12 reaction which sometimes can be life threatening.

13 Please just let me finish. The FDA needs
14 to require food manufacturers to place the names of
15 major food allergens on labels regardless of the
16 amount.

17 Finally, I applaud the companies that have
18 voluntarily instituted labeling that a major food
19 allergen may be present, even though it's not a
20 known ingredient. This is usually due to the use
21 of shared equipment to produce a food that does and
22 one that does not have a food allergen.

23 Unfortunately, there are companies now
24 that have been begun labeling foods as having major
25 allergens, purely on a liability basis, versus a

1 true risk. In addition, there is no uniformity on
2 how the information is presented.

3 The American Academy looks to the FDA to
4 create standards for the food industry's proper use
5 of these statements and consistent verbiage of
6 these statements so that we can educate our
7 patients.

8 In conclusion, although I sit here today
9 representing a large body of health care providers,
10 I can tell you first hand that labeling systems
11 need fixing, and that there are many Americans,
12 especially parents of children, that have a fear
13 that is indescribable, a fear of food that can be
14 paralyzing.

15 The solution appears simple. If the major
16 food allergen is present, label it so we can all
17 understand it. If there is a real contamination,
18 then label it in a uniform way. The food allergic
19 individual is already restricted from eating
20 outside the home because it's so difficult to
21 identify all the ingredients and the potential for
22 cross-contamination in restaurant foods. So let's
23 make eating at home safe for those with potentially
24 life threatening conditions. Thank you.

25 [Applause.]

1 DR. LEWIS: Next is Kimberly Scott, to be
2 followed by Sarah Gitlin.

3 MS. SCOTT: Good afternoon. My name is
4 Kimberly Johnson Scott, and I appreciate this
5 opportunity to provide oral comments on allergen
6 related labeling issues. Today I am speaking both
7 as a mother of Sidney Scott, our energetic 21 month
8 old, and as the co-founder of the SOS Foundation.

9 On March 27 of this year, my husband and I
10 were shocked to learn that our daughter Sidney had
11 a life-threatening allergy to peanuts, tree nuts
12 and eggs. In a moment, the security we had
13 previously felt in selecting food for our family
14 evaporated into thin air.

15 The exact same labels upon which we had
16 previously relied and which as parents we found
17 reassuring suddenly took on a potentially life or
18 death prominence in our household. Questions
19 replaced confidence.

20 What does it mean when "contains peanuts"
21 isn't on the label, but "natural flavorings" is?
22 Did I read over those ingredients with 15 syllables
23 in it and did not recognize that it was an egg
24 protein because I didn't see the word "egg"? Why
25 would the label say "may contain nuts" when I read

1 the label ten times and I didn't see nuts anywhere?

2 While devoting time to reading food labels
3 clearly and deliberately is a small sacrifice to
4 make for those we care about, we need the FDA to
5 help empower parents by requiring clear and
6 comprehensive labeling of products. Through our
7 desire to help our daughter and other similarly
8 situated families, my husband Stuart and I have
9 co-founded the SOS Foundation, a not-for-profit
10 organization which has pledged financial, emotional
11 and practical support to those who struggle to meet
12 the challenges of living with a chronic condition.

13 In order to help improve the lives of
14 individuals with food allergies, SOS will serve as
15 an additional vehicle to-advocate for accurate food
16 labeling, practical food labeling legislation,
17 effective research and increased awareness. In the
18 coming year, the SOS Foundation will join forces
19 with organizations and individuals who have long
20 dedicated themselves to this effort. We hope to
21 work in partnership with the FDA in bringing
22 together industry, consumer, medical and scientific
23 groups for the purpose of better educating the food
24 industry and enhancing the level of public
25 awareness of the public health risk of incomplete,

1 inaccurate, inconsistent, and incomprehensible
2 labeling of food products.

3 I would like to briefly comment on the
4 specific matters under consideration at this
5 meeting. A condition such as anaphylaxis is
6 unpredictable enough without the added stress of
7 trying to decipher food labels. Plain English in
8 the labeling of food ingredients is critical to
9 empowering individuals to take control of their
10 condition, restoring a certain amount of
11 independence and equally as important is the power
12 and freedom it gives to friends and relatives of
13 non-food allergic individuals to make responsible
14 selection of food items to share with or entertain
15 their food allergic friends and relatives as will
16 responsible use of advisory labeling.

17 When a food company manufactures five
18 products without nuts but also manufactures one
19 with nuts, and places advisory labels on all six
20 products, this greatly reduces the already limited
21 choices of those who are searching for a list of
22 can haves in a world of cannot haves.

23 Finally, we must realize that listing the
24 major food allergens must not be limited to those
25 found in significant amounts, but also extend to

1 those found in trace amounts. This boils down to
2 an issue of trust. Can I trust what is on the food
3 label is actually what's in the product?

4 With that trust comes the opportunity to
5 regain the power to monitor and maintain one's
6 health to the best of their ability until the day a
7 cure is found. This is a chance to be free of the
8 agonizing choice of whether to risk an anaphylactic
9 reaction every time you take a bite.

10 With the FDA's help, we have before us the
11 opportunity to release those who suffer from this
12 condition from a food prison so that they may not
13 just eat to live, but that they may also eat and
14 live. I thank you for this opportunity.

15 [Applause.]

16 DR. LEWIS: Next will have Carol Schragar.
17 Sarah Gitlin, first. Sarah Gitlin is here.

18 MS. GITLIN: Good afternoon. My name is
19 Sarah Gitlin. I am ten years old. I am deathly
20 allergic to peanuts, tree nuts and fish. When I
21 learned to read, five years ago, in kindergarten, I
22 started with Dr. Seuss, Mother Goose, and
23 ingredients labels.

24 [Laughter.]

25 MS. GITLIN: I knew that Dr. Seuss and

1 Mother Goose wouldn't lie to me, but ingredients
2 labels, I couldn't be so sure. I have to be able
3 to trust these labels. For if I eat something I'm
4 allergic to, even a tiny trace of it, and couldn't
5 get proper treatment, I could die within minutes.

6 I try very hard only to eat what I know is
7 safe, not to risk it if the food might contain
8 anything I'm allergic to. But who would guess that
9 a common popcorn brand would use the words "natural
10 flavors" to mean peanuts? And who would guess that
11 the words "vegetable protein" and "plant protein"
12 would be food companies' code words for tree nuts.

13 These words as well as incomplete
14 ingredients labels are life threatening for food
15 allergic children. That is why I am here today to
16 urge the FDA to enact regulations that require
17 ingredients labels with an accurate list of every
18 ingredient in the product.

19 Some food companies already do this
20 voluntarily. And that's great. But I need 100
21 percent to do it. My life depends upon it. I'm
22 not asking you to tell food manufacturers to change
23 their recipes. I'm not asking you to tell them
24 what they can or can't add to their products. I'm
25 not asking you to tell them that they have to

1 change their manufacturing processes.

2 All I'm asking you to do is to make them
3 tell me what recipes they're using, tell me what
4 they already add to their products, tell me whether
5 they're manufacturing processes result in adding
6 even traces of the food I am so deathly allergic
7 to.

8 Reading ingredients is a large part of
9 food allergic children's lives. So large that the
10 Food Allergy and Anaphylaxis Network published this
11 story:

12 A mother was trying to teach her food
13 allergic child not to talk to strangers. So, she
14 asked her daughter, if a stranger in a car pulled
15 up and offered you a candy bar, what would you do?
16 Without missing a beat, the little girl responded I
17 would ask them to read me the ingredients.

18 [Laughter.]

19 MS. GITLIN: That girl knew what was
20 really dangerous. Because food allergies are so
21 dangerous, food allergic kids and their families
22 around the country urge you to protect our lives by
23 requiring ingredients labels to be complete,
24 accurate and in plain English so that we can really
25 know what's in the food we are eating. Thank you.

1 [Applause.]

2 DR. LEWIS: Thank you, Sarah. I now
3 believe it's Carol Schrager.

4 MS. SCHRAGER: Good afternoon. I'm
5 Sarah's Mom, and I'm a member of the Food Allergy
6 Initiative and the Food Allergy and Anaphylaxis
7 Network.

8 Raising a food allergic child without
9 complete and accurate ingredients labeling is like
10 walking through a mine field. No matter how
11 carefully you watch your step, you never know when
12 there will be an unexpected explosion. It's hard
13 enough to avoid the dangers that we know about, but
14 it's impossible to rest easy when we know that
15 there are dangers hidden in foods that Sarah might
16 eat, but we don't know which foods and we don't
17 know which dangers.

18 So we turn to you, the Food and Drug
19 Administration, the agency charged with protecting
20 American lives by regulating the practices of food
21 and drug manufacturers.

22 We need you to help us protect the lives
23 and health of the seven million Americans with food
24 allergies by enacting regulations that are
25 stunningly simple, the kind of regulations that

1 most Americans assume already exist, the kind of
2 regulations that most people are shocked to find
3 out do not already exist.

4 What we urge you to require is merely
5 this: that every packaged food has a label that
6 states in plain English every ingredient that is in
7 the product, both ingredients that are part of the
8 recipe, including spices and natural flavors, and
9 ingredients that are unavoidably present because of
10 cross-contamination with other foods.

11 These regulations would save lives with
12 virtually no downside for food manufacturers. Yes,
13 it may cost the manufacturers a little bit more to
14 assure that their labeling is accurate, but such
15 costs are trivial when balanced against the
16 precious irreplaceable lives of our children. And
17 remember, the number of Americans with food
18 allergies is growing exponentially. So
19 manufacturers actually have a lot to gain from
20 these regulations because the market for their
21 products will expand.

22 As food allergic consumers and their
23 families and friends who now will not buy products
24 that are said to contain, for example, natural
25 flavors will feel safe consuming them once they are

1 assured that the allergens are not present.

2 Under the regulations we support, food
3 manufacturers would not have to change a single
4 thing that they do. They could include any or all
5 allergens in any or all of their products. They
6 could process foods on shared equipment without
7 cleaning the production line in between runs. They
8 could do anything they want to do, anyway they want
9 to do it. All that we ask you to require them to
10 do is tell us what they're doing and tell us how
11 they're doing it, so that we can make intelligent
12 choices to protect our children's lives, so that we
13 can walk through a field with our children without
14 fear of an explosion.

15 Thank you very much for listening to our
16 concerns and to giving my daughter a close-up and
17 personal lesson in participatory democracy. We
18 appreciate it very much.

19 [Applause.]

20 DR. LEWIS: Thank you. Next we have
21 listed Barbara Solan. And following Barbara Solan,
22 we have Ben Wilson.

23 MS. SOLAN: Thank you for the opportunity
24 to speak. I don't usually do podiums. I think
25 democracy is a wonderful opportunity and to stand

1 find them confusing. And I think they will only
2 muddle the issue.

3 I like the General Motors--General
4 Motors--I come from the Detroit area--General Mills
5 model that says food allergy consumer or allergy
6 information: contains nuts, soy. That helps me.
7 And I'll go very quickly on this. I think we need
8 to set priorities. There's a lot of issues about
9 food allergies. I've lived with them for 11 years.
10 Some are bigger than others. And we should grab
11 the big ones. We should think out of the box and
12 we should be creative in our problem solving.

13 Thank you.

14 [Applause.]

15 DR. LEWIS: Thank you. Next we have
16 listed Ben Wilson, who will be followed by C.
17 Gordon Brown.

18 MR. WILSON: I'm Ben Wilson and I'm
19 Director of Regulatory Compliance for Sensient
20 Flavors, a food flavor company. I'm feeling a
21 little at risk on this side of the audience this
22 afternoon.

23 [Laughter.]

24 MR. WILSON: But we need some help from
25 FDA as well. I answer the questions from our

1 customers and from their customers, the consumers,
2 about allergens and what's contained in a food, but
3 the questions I get go much beyond the simple
4 allergens. Today people want to know about GMO,
5 they want to know about organic, they want to know
6 about consumer interests in different things, they
7 want to know about specific issue products.

8 They're very important to these people
9 that ask them. In some cases, they're
10 significantly life threatening like allergens, but
11 the responses that we give and when trying to
12 provide the information seem to confuse the food
13 companies. They will ask us does this product
14 contain soy? And we will answer yes, but the soy
15 that's in it may be a partially hydrogenated
16 soybean oil, has no protein, has no allergen issue.
17 It's been highly refined, it's been modified, the
18 proteins are gone.

19 That may be of interest to a specific few
20 who have a different type of soy reaction. It may
21 be of interest to our customer because he's looking
22 at a GMO issue for soy. He may be looking for
23 Europe. We need some clarification from FDA as
24 they look into these products and allergen and
25 either guidelines or rules or whatever, but what

1 are the allergens, what are the things that we need
2 to talk about?

3 Are we going to talk about the big eight
4 in general as allergens, not the big eight of soy,
5 which contains a lot of things that aren't
6 allergens, or of corn, which is an issue, but for
7 most people not an allergen? Wheat--is that an
8 allergen issue to wheat or is that an issue of
9 sprue celiac where it includes the glutens, the
10 spelt, the rye, the barley?

11 Does this include different extracts which
12 may or may not have allergen potential? We need to
13 make that clear. That needs to be very clear in
14 what we're doing of whether we're addressing
15 allergens, whether we're addressing big groups, and
16 that's it. And that's what I want to say for
17 today. Help us help the food manufacturer put the
18 correct information on the label by giving us some
19 clear guidelines of what we're talking about and
20 what the things are of concern. Thank you.

21 [Applause.]

22 DR. LEWIS: Thank you. Next, we have C.
23 Gordon Brown, who would be followed by Carolyn
24 Garrett.

25 MR. BROWN: Thank you very much. I'm

1 Gordon Brown, Senior Vice President of Scientific
2 and Regulatory Affairs for the International Dairy
3 Foods Association. We thank you very much for
4 providing this forum and for providing an
5 opportunity for us to get our positions out there.

6 The following comments are made on behalf
7 of the International Dairy Foods Association. IDFA
8 is the nation's leading trade association
9 representing the dairy industry. Our member
10 companies manufacture the entire range of dairy
11 products and include processors, manufacturers,
12 marketers, distributors and suppliers.

13 IDFA consists of three constituent
14 organizations: the Milk Industry Foundation, the
15 International Ice Cream Association, and the
16 National Cheese Institute.

17 Member companies in these groups account
18 for 85 percent of the dairy products consumed in
19 the United States. IDFA is a member of the Allergy
20 Issues Alliance, the coalition of food trade
21 associations and a leading food allergy consumer
22 group. IDFA helped develop new guidelines for
23 clear labeling of allergenic compounds.

24 IDFA strongly supports implementation of
25 these guidelines, encourages disclosure of

1 allergenic ingredients in clear and simple language
2 and is dedicated to assisting dairy processors to
3 prevent cross-contamination.

4 Our commitment to the allergen initiative
5 is demonstrated through our member outreach.
6 Although dairy processors are conscientious about
7 compliance with labeling requirements for
8 allergenic ingredients, IDFA still urges all
9 members to review their policies and verify that
10 they are operating within the new allergen
11 guidelines and we provide a whole lot of one on one
12 contact and information to our members who request
13 information.

14 Further, we recommend that member
15 companies follow the following recommendations:

16 (1) Review formulations to identify the
17 presence if any of the eight major allergens;

18 (2) Contact ingredient suppliers to
19 determine if ingredients they supply contain any
20 allergens including components of flavors, colors,
21 incidental additives and processing aids that may
22 not be required to be labeled.

23 We also suggest they review their current
24 labels to ensure that if any allergens are present,
25 they are included in the ingredient declaration in

1 terms that are easily understood by consumers.

2 Number four, advisory statements should
3 not be used as a substitute for good manufacturing
4 practices. Only use advisory label statements such
5 as "may contain" blank when all of the criteria
6 established in the allergen guidelines are met, and
7 I won't go into those now, but they are available.

8 The dairy industry has a good track record
9 on the allergen issue. Recalls for undeclared
10 allergens and dairy products are rare. However, we
11 are committed to continuous improvement and this is
12 demonstrated by our efforts to educate our members
13 on the important issues through a variety of
14 outreach programs.

15 These programs include (1) providing
16 publications to member companies on implementation
17 of the voluntary food allergen labeling guidelines;
18 (2) instructions for labeling manuals for milk,
19 cheese and ice cream; (3) we provide workshops on
20 allergens and proper food labeling on a periodic
21 base. These are open to the entire dairy industry
22 as well as ingredient suppliers. (4) We provide
23 education for ice cream manufacturers through a
24 workshop entitled "Ice Cream Best Practices" to
25 explain the allergen issues and industry's labeling

1 requirements.

2 In summary, the dairy industry is
3 committed to maintaining the safety of its products
4 and is currently engaged in this effort to make
5 sure that we protect the health of allergenic
6 consumers. Thank you.

7 [Applause.]

8 DR. LEWIS: We now have Carolyn Garrett on
9 our list. Carolyn Garrett is not here. That
10 completes my list of registered speakers. So I
11 believe that the meeting is now coming to an end.

12 My closing comments are quite succinct. I
13 think this was an extremely useful meeting for the
14 agency. I felt a lot of important information was
15 obtained by us.

16 Again, the docket is open so comments are
17 still possible to this particular series of
18 questions by the agency. I do want to thank all
19 the members of the panel who provided some very
20 useful discussion points for us, as well as the FDA
21 support staff who made this meeting possible.

22 So thank you very much. The transcript
23 will be available in about a month and information
24 on obtaining that is in your Federal Register
25 documents. Thank you.

1 [Applause.]

2 [Whereupon, at 3:20 p.m., the meeting was

3 adjourned.]

C E R T I F I C A T E

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.

Victoria S. McLaughlin

VICTORIA S. McLAUGHLIN