FOOD AND DRUG ADMINISTRATION

COMMISSIONER'S VIDEO TELECONFERENCE

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ON BEHALF OF THE AGENCY:

RAYMOND MLECKO
District Director
Chicago District

VIRGINIA CONNELLY
Executive Officer

JOSEPH LEVITT
Director
Center for Food Safety & Applied Nutrition

DAVID ARMSTRONG
Associate Director for Research
Moffett Center

ORIGINAL

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(773) 549-6351

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I N D E X

P R O C E E D I N G S

MS. CONNELLY: I just want to thank everybody for returning for the continuation of our program today. We're going to begin the panel discussion portion of today's event.

We have three distinguished FDA panelists: Mr. Joseph Levitt, the director of the Center for Food Safety and Applied Nutrition; Mr. Ray Mlecko, the District Director of Chicago and Detroit District; and Dr. David Armstrong, the Associate Director for Research at the Moffett Center, which we heard about this morning from Dr. Henney -- or earlier this afternoon.

Mr. Levitt will be monitoring the remainder of the discussion after he makes a presentation, but let me just remind everybody to use the forms that have been provided for questions and comments, and if you'd like to make a presentation or ask your question orally, there are microphones set up in the middle aisle.

Joe?

MR. LEVITT: Thank you very much. It's a pleasure for me to be here today, but most importantly, it's a pleasure for me to see so many of you here today. Let me begin by thanking the local district staff, who organized the local end of this conference, and for getting the word

to all of you to come.

I have seen and talked to a number of people in the audience, especially our state and local counterparts and consumer industry representatives in the audience.

Also, David Armstrong will have a few words after me, and I'm just trying to figure out what they had to trade over at the Moffett Center to get that paid political announcement from Dr. Henney. But having visited it myself, I can assure you that it was well -- it has been one of FDA's best-kept secrets, and I think it's good that we are unveiling it, because it really is at the heart of a lot of our food-safety efforts that we're trying to accomplish.

I have a fair amount of information that I'm going to try to run through. A little bit I'm almost going to rush through as a way -- we can come back during questions and answers.

For those of you who do not know me, I'm the director of CFSAN, the Center for Food Safety and Applied Nutrition at the FDA and headquartered in Washington. I have been at the FDA for 20 years, and I've worked in almost every part of the FDA. I became director of this center about a year ago.

A lot of what I'm going to try to do, then, is to give you a little bit of a sense of, number one, who we have

put together as our senior team within the center, running the National Foods Program; number two, having been in the job a little more than a year, give you a little bit of a report card.

What was I saying last spring that was going to be done? How are we doing on it a year later? Note some specific accomplishments, and then talk a little about the budget. There's a lot of interest; you've heard some of that. A lot of what you're going to hear reinforces and gives you a view of the foods version of what Dr. Henney was saying.

Let me begin with the CFSAN management team. We have put together a group of, in addition to myself, five or six people that have a variety of backgrounds and experience:

Janice Oliver, who was the food spokesperson in the FDA studio audience that you saw before, has been at FDA for 30 years. Most of her background is in the field, and she's been at the center for the last ten years, and really was the person at FDA most directly responsible for getting the food-safety initiative off and going and off the ground.

Number two is Bob Lake, who has actually spent this entire year in the Center for Food Safety and Applied Nutrition; is known to especially to those that have worked

on the Hill; it's involved a lot of legislation activities.

We have just recruited -- I was very pleased when he was brought up to FDA -- Dr. Morrie Potter, who has 25 years' experience in foodborne illness down at CDC. He is known to many in Washington, because he's been in many ways the Washington connection, but he really brings a strong public-health perspective to the issue, which I think is absolutely critical.

Number four, we have Bob Buchanan, who is my senior science advisor. I'm a lawyer; people don't know that. We are a science-based agency. I pledged when I was put into the position that I would surround myself with strong scientists. Morrie Potter and Bob Buchanan are but two examples of that.

Dr. Buchanan came from the USDA Agricultural Research Service up in Philadelphia and has a wealth of background and knowledge in a variety of programs.

And finally, our executive officer, Juanita Wills, who I'll just say, by coincidence, comes from the EPA.

And so just within this group, what I've tried to put together is people that, number one, are experienced. I'm the junior member of the team, with 20 years federal experience. Number two, they have a variety of experience:

We have the FDA field, FDA headquarters, other parts of FDA; CDC, USDA.

We have new problems. Dr. Henney talked about the changes that are happening in the food supply. We have new problems; we need new solutions, and therefore we need a variety of perspectives on the subject.

And finally, we have a commitment of people who want to work together, not only with each other, but with the other counterparts around the other agencies. And so by having people go back and forth between different agencies -- people have gone from FDA to USDA, also -- we actually now have a person stationed at CDC; CDC has a person stationed at the FDA -- we are recognizing more and more that it's critical that we think of ourselves as a single food establishment, because from the consumer's point of view, the consumer, I'm sure, doesn't look at their plate and say, Oh, I'm eating an FDA-regulated product; ooh, I'm eating a USDA-regulated product; I'm consuming something that the states are responsible for.

The consumer doesn't care. The consumer wants safe food, period, and it's our responsibility as federal and state food-safety officials to look at our missions more broadly, to look at blurring the lines but strengthening the connections, and I'm starting that internally here at the

FDA.

Now, report card from last spring: I gave a variety of speeches to a lot of groups last spring, and I stressed, number one, values that I bring -- I'll talk about that -- number two, food safety as our top priority; number three, the need to set priorities in the other areas of the foods programs, and, four, and probably most importantly, the need to show clear accomplishments. We need to show we're here and we're doing something for the benefit of consumers. So let's see at least how we're doing.

Number one, values: One of the first things I did -- I'm new to a lot of you; when I came to CFSAN, I was new to a lot of people there, too, and so one of the first things we did was say what are the values that we bring to the table; what is the foundation that is underpinning what we want to do?

We put together this rather simple slide that talks about public health and safety as I talk: priority; respect for our stakeholders, for ourselves, for the law; integrity, objectivity; dedication, and dedication to excellence. You put that down the side and you see the letters PRIDE; that's not a coincidence, obviously, and we have signs and posters throughout our center talking about CFSAN PRIDE and really trying to reinforce that we want a

system that has high standards, that is responsive to stakeholder needs but, above all, has a dedication to excellence and to safe food.

Number two, talked about the food-safety initiative, and one of my favorite slides was, knowing it's a presidential initiative, I knew my priorities: food safety, food safety, and food safety. And that really is what I at least began and still spend most of my time on.

The vision is clear: We have to reduce the incidence of foodborne illness. The numbers -- and these numbers are challenged, and we recognize they are soft, but the numbers that are out there of 9,000 deaths, 6 to 33 million illness, those are too many. It doesn't matter if it's off by 50 percent one way or another; it is too many.

And if there's one thing I could change and will try to change at the FDA, it's not so much the focus on just the product but the focus on the impact on the consumer. We've got to reduce the incidence of illnesses. That is when we'll really know if we're doing the job properly. We have systems in place to help measure and gauge that, but we really want to change vision to foodborne illness and away from just looking at the product for product's sake.

Now, how are we doing in the first year? Number one, we have what I call laid -- we spent a long time laying

a strong foundation for the program. There are six major building blocks of the food-safety program.

Number one is surveillance. Through CDC we have put in place the new FoodNet system and the new PulseNet system that are now in place. They need to be expanded and enhanced, but a major advance is to get those systems in place.

Number two, we have a clear research agenda within FDA. We have a three-year research plan; we also have a cross-government research plan for produce and other activities.

Number three, risk assessment: We really have to take a stronger look at risk assessment, be sure that we are addressing things that have the highest risk. We have a consortium of agencies to establish a risk-assessment consortium, and we are establishing a clearinghouse to collect information on risk assessment and exchange it through our collaboration with the University of Maryland.

We have, number four, education: the public-private partnership. I see in the back the back puppet, the Fight Back campaign; Janice Oliver referenced that also. It is a critical part of what we're trying to accomplish, as well as education for retail and food-service establishments.

Fifth part of the building block is outbreak response. We have something called Force D, which is a broad coordination unit, but more important than that is at the operational level we're working very hard and diligently to get in better systems so outbreak response will really result in early detection and containment, and we are getting there, and PulseNet is helping us out with that.

And the sixth building block is really the FDA outcome, which is the inspection. We have -- are implementing this year our Seafood HACCP program, during 1998, as USDA did with meat and poultry, and we are seeing improvements across the board. So our year number one, we have the foundation. And the importance of that is the money that Congress provided is not designed to be a one-year fix.

It was designed to really change the landscape and the direction of how we're approaching these issues. And so I see that first year foundation as an investment in the future, not just what happened that year. But we do have things that happened that year, as we did inspect every seafood plant for HACCP in the calendar year as we promised that we would.

The good news is that a full 1,200-plus firms got it fully right the first time. For an industry that was

largely unregulated in the past, that is an important step forward. The bad news is we still have a long way to go. We are providing educational letters with our untitled letters to industry. We are following up with warning letters of enforcement where that is needed.

We also are putting what I call a booster shot of education. So -- but Seafood HACCP round one is finished; round two is just as important, if not more. Good agricultural practices: You have in your package in front of you a green book. This is a very significant effort in the first year.

If you think back to the earlier telecast, somebody asked the question, Are you going to get the industry involved early on? And this is a perfect example of that, because there was a decree shortly before I took over first of the fiscal year that we would do these good agricultural practices.

So the FDA quickly ran around, put together a working draft. The people who did it were very pleased with it, put it out, and had grass-roots meetings. I have to tell you, we got creamed.

We were harshly criticized for not really being in touch with agricultural practices. And we then took that, rounded more people -- got in more people from the

agricultural community, more from the states, more from USDA.

By the time we came up with our draft, the discussion had shifted from whether to do it to, Are we doing exactly right? We then went on with site visits and came out with a final guide. Within 12 months, it was endorsed by United Fresh Fruits and Vegetables. So we feel that is a good model, both in terms of speed and intensity, as well as involvement. But it is only a start.

So we have a die. That's nice if anybody's using it. I'll come up to that in Round 2. But at least in the first year, we did what we said we would. We had a proposal where we would extend HACCP for unpasteurized juice for juice products. And we put in place a label warning in time for the fall apple season that has been in place since last September.

The president of the United States himself announced that in the Fourth of July radio address, and that was really clearly one of the highlights of the year. But it's a highlight, not just because he announced it. It's a highlight because it's giving consumers the important information they need to protect themselves. You have a product that is largely not so much of a problem, but for vulnerable populations, a big problem. We have those

warnings in place. And I think that's important.

Egg safety, we've got a start on. We issued a joint notice with the USDA. We have a long way to go on egg safety. We also -- kind of a sleeper area is the antimicrobial resistance. That is really a focus of another sector. Our Center for Veterinary Medicine has the lead on that, but we have put in place again as part of the broader surveillance system, a surveillance system for resistance to antibiotics used in animals.

And we issued a progress report at the end of the year, which is available on our web. So at least we feel, in terms of the first year, we made a good start. But it is only a start. Where are we trying to go this year? Well, we're looking at, What do we feel the highest risk area is? Number one is imports.

The level of imports has skyrocketed over the last five years, and the level of FDA coverage FDA has been able to provide has lowered, and that is a bad combination. And so with the money we got from Congress last year, we are strengthening both our emphasis to borders who are also realizing we've got to have a stronger border presence. We're increasing our inspections overseas.

We're increasing our technical assistance to foreign governments. We're using a variety of mechanisms in

Latin America, in overseas further. We just this week held a national conference out of Washington on rolling out and implementing these produce guides overseas. We had over 140 representatives at that meeting. And so there was a lot of input there.

Number two, that leads me into the roll-out of the good agricultural practices. We work closely with USDA. We're working jointly so that -- because they have the extension service here. They have the lead domestically. We get the lead internationally. We made -- sponsored the conference in Orlando two weeks ago. Domestically, we did the international conference in Washington this week. And so that is well on its way.

Seafood HACCP-Round 2: I alluded to this already. We are going back this year and we will be less patient. We are going to be providing more education along the way. We're also -- we're saying we're going to get serious. Warning letters have already started to go out and if we need to take enforcement, we will do that, because we need to get that entire industry up to snuff.

Juice HACCP: We have to go forward with a final rule on that. We have a proposed rule getting ready to come out starting to address the issue of Salmonella in eggs, focusing on retail, refrigeration and on consumer safe-

handling practices following on a transportation regulation that USDA issued last year.

And we have a broad number of issues under the umbrella of the President's Council for Food Safety involving, as the Commissioner said, in moderate term strategic plan and coordinated budget, a better -- and even better coordinated research across the government. So I think in food safety, we have made a good start. We have to realize this is going to be a multi-year effort and is really challenging us in very many ways.

I think, if you will, the good part of it is that, number one, we are recognizing -- I think more people are recognizing more and more this is a real problem. It is a real problem because of some of the things Dr. Henney mentioned. We have a change in the food supply. We have different distribution practices. We are eating at different places.

We're actually -- believe it or not, 50 percent of the dollars Americans spend are on food prepared outside the home. And so the retail food service is an important area. We also have an increasing vulnerable population. If you take the very young, the elderly, the immune-suppressed, pregnant women, that's almost 25 percent of the U.S. population.

Think about it. Twenty-five percent are at high risk. This is not a small amount. It is a very high amount and makes the issue more compelling. The fact that the issue is more compelling -- is so compelling is making us break down a lot of barriers that did exist in the past. And so people like me at the FDA are now talking about reducing foodborne illness, not just about: Are we getting good regulations on the product?

We have a recent MOU that we've signed with the Food Safety and Inspection Service at USDA in plants of joint jurisdiction. We have closely worked with CDC. Can we do better? Yes. Can we do more with the states? Yes, also. But the issue is sufficiently compelling. We're seeing that. And the good news is that people are rising to the occasion of what is needed.

But we move on. Priority setting: I've already told you the top three priorities. We also have a responsibility over a lot of other aspects of the food supply and the food regulation. And so what I said last year was, Okay. After we take care -- we at least get going on food safety. We even looked across the foods program and asked the simple basic questions.

We can't do everything that Dr. Henney said. Where we do most good to consumers, that's where I'm going

to direct that our time be devoted. We have established as always having an open and participatory priority-setting process for the year we're in now and to develop a blueprint for our foods program. Again, it's what I said last spring.

We held a stakeholder meeting. This was the birth of the FDA stakeholder meeting that the Commissioner mentioned in June. We had -- you see a number of oral written presentations. It was at that meeting that I first showed this chart. And I'll dwell -- pause on this for a moment. So I've worked for FDA for 20 years. I took a job as director of CFSAN.

I consider myself knowledgeable enough that I knew something what I was getting into. But I was surprised -- genuinely surprised when I saw this chart. The Center for Food Safety, if you go back 20 years, which isn't just the day I started and it isn't just 20 years as a round number -- it also, in fairness, is the peak of the foods program.

This is the year that the Food Center had the most people. It was just under 1,000 -- 995. Now, what you see clearly is ten years of constant reductions. That is common among a lot of agencies across government. You see now early '90s start to get better. Almost all of that getting better was in the seafood area. There was a lot of

visibility on seafood.

We had some small increases for imports, as well as some small increase for our nutrition labeling, somewhat after the fact, and some very recent at FSI that doesn't really show up here because it was the first year. But you see even with those increases, we still are 200 people below where we were 20 years ago.

Now, another way to look at it if you worked in the Center, if you take away those added targeted resources -- that they were mostly for seafood, but also some for imports and nutrition labeling and the first little wave of food safety -- we're down a full 33 percent. And most of the people -- or at least a lot of people that work in CFSAN -- number one, they've been there 20 years, because the last big hiring binge in foods in FDA was the 1970s, following the Bon Vivant incident -- those with good memories.

Number one, they've been there. They look around. They know how many were in their branch. But I went around around from office to office. One person, when it got to her turn, she filled out a sign -- held up a sign that said, Small but mighty, proud but poor; my division could sure use a lot more. And I actually took that. I framed it.

Dr. Henney took it recently across to show the secretary, because it reflects, unfortunately, a lot of what is going on across FDA. As Linda Suydam said on the tape before, there are a number of programs in FDA that are getting very well funded: the prescription drug user fee program, the mammography program. Now we're starting to get there with the food safety program.

But when you look at all the other programs, they're the ones that are really getting squeezed, and this shows it very graphically. At the same time, of course, Congress passed all these laws adding new responsibilities. I'm the new center director; I look at these charts, and I say, Wow. We have got to set priorities.

And so we did. We then tried an internal process. Each program presented what they thought priorities should be. We did cross-cutting priorities. We shipped aside traditional comprehensive plans. The Commissioner joined us as we were finishing up that. We took her priorities, which overlapped strongly with foods, and we wrapped those in, and we came out in January with this CFSAN priorities document.

Internally, we call this the bible, because this is not just our work plan; this is what we are doing this year and what we are committed to finishing. What you find

from looking at it is, number one, food safety covers about 50 percent of our priorities.

It's also now about 50 percent of the Center's resources are devoted to food safety initiative work, which is a translation for anything related to microbiological contamination falls under that general umbrella.

And so I will not go through those since you have it all in front of you, but we have specific objectives that we will accomplish in imports and HACCP and produce and additional prevention efforts, in surveillance and outbreak response research, risk assessment, and education, to continue a growing emphasis in this area.

Number two, you'll find we identify five other program areas that need emphasis: premarket review of food ingredients, nutrition, health claims and labeling, dietary supplements -- and one of the speakers is going to be addressing that after me, an area of growing interest -- chemical and other contaminants.

I'll tell you, if you looked at this same slide from a previous director a decade ago, you would see it reversed. You would see chemical contaminants way up there high and microbiological problems much lower in priority. We've seen a real reversal in that. That's good for the microbiological problems. At some point, we're going to

have to start readdressing a number of the chemical issues, as well, and finally cosmetics. We also have cross-cutting areas and shrinking of the science base; increasing federal, state, local collaboration; establishing what I'd call an affirmative international agenda. There are lots of international meetings codexed in other areas.

I want to be sure that not only are we prioritizing where and how we go, but we go with a mission to accomplish something positive for American consumers. I think Linda Suydam said, We see harmonization as an opportunity to be world leaders. And we want to be there.

But to do that, we have to think about it. We can't just get an agenda to a meeting, go there and come up with a position, you know, immediately prior to that. And we have to spend more attention internally to the resources. You have all the specifics on here. Again, I ask you to take it and look at it. You will find simple one-line listings of each item to just very clearly say, This is what we're going to try to do.

We also have what I call the A list and the B list. The A list means we will do it. It doesn't mean we're going to try to do it. We're going to do it. And there are 79 of those. I am well known for telling my story about the pebbles and the boulder. And what it basically

means is I've always thought that FDA makes the mistake of spreading ourselves too thin.

And I think it likes taking 100 pebbles, pushing them up a mountainside one mile an hour. After 50 years, what have you got? A mountainside of rubble. And I would rather identify a fewer number of boulders, get them up and over the hill; show the consumer we are something -- you know, the taxpayer has gotten something. There was something to show for ourselves and some real accomplishments.

Even though we've whittled this list down and down and down and down, we still came up with 79 boulders. And people are challenging me on whether my pebble/boulder theory works. And I said, Well, we started with a thousand, so I think we're in the right direction. It is a management challenge, but it's something I'm gladly taking on, because I believe if we focus on specific things, we can do them and we will.

The B list means not the opposite, but a separate -- these are things we know they're important. We want to make progress on them. I would love to see them all on the A list. But with them all, they will neutralize each other and not get done. So these are the ones we will make progress on as we can.

We are monitoring very clearly all the boulders, and I promise to have four-month reviews and modifications as new things happen during the year. And the first one is coming up at the end of this month.

Accomplishments: I noted earlier I don't believe that in jobs such as ours it's enough to have nice plans. It's important to have nice plans, but they really don't mean a lot unless you have real accomplishments that we're doing. I am going to run through these ever so quickly. The copies of these slides are on our website, so you can access them and go back and look at them.

But just to note: In addition to food safety that I mentioned, in food additives, we approved last year two new artificial sweeteners, did a postmark review of Olestra, approved a new food additive, chlorine dioxide. And because of that that was one of the stimulants to focus on creating expedited review for food-safety related petitions.

And so we have a new program now that says if you in the industry have a new chemical, have a new process that's going to make the food safer, that's going to kill pathogens, we are not going to put that on the routine track; we're going to move that to the front of the line. We want to create an incentive for companies to invest in

these products. We don't want FDA to be the logjam for that. And that has been put in place now.

In the area of health claims and food labeling, you can read them up there. We are having a public meeting in May 11 to look at the issue of authoritative statements. It is a somewhat controversial area. You'll see amongst up here psyllium we said yes to; soy protein, we said yes to. The first nine notifications, we said no to.

And our pledge is to work on the basis of science and openness. But we also want to be sure we have a process that people understand and is consistent with the law. And so we're having a meeting to try and address that.

Dietary supplements: We issued a structure function proposed rule last year -- very controversial -- a lot of comments and questions about that.

We issued a proposed rule extending to dietary supplements, the same provisions of FDAMA that apply to conventional foods on authoritative statements. And we have coming in place -- and this was referenced earlier very quickly. Just like the food nutrition panel, we have now the same kind of panel focus on supplements that became effective this past month for dietary supplements.

It's called supplement facts. It gives very clear information on what's in there: vitamins, minerals,

amino acids, herbs. Within herbs, it tells you if it's from the root, if it's from the leaf, if it's from the stem. If there's a daily reference value, it gives you the percent. It's in the same format you're used to seeing on the food label. It's just that it's focus is what I call the bottom half of the label instead of the top half of the label.

In foods, I think most people look at fat, saturated fat, sodium, cholesterol, fiber and so forth. This is focusing in dietary supplements more on the vitamin, mineral, amino acid, botanical section. But that is coming out. That is effective now. And consumers will start to see that on shelves.

Federal-state collaboration, an increasingly important area: The scope of the Food Safety Initiative, as such, as I meant before, that nobody can do it ourselves individually. And we're devoting major efforts in this area. Number one, we have come out with the latest -- really first real and widely endorsed provision of the Food Code.

As I mentioned before, if 50 percent of our dollars are spent on food prepared outside the home, and a lot of those foods prepared outside the home are institutions that deal with individuals at high risk of foodborne illness -- nursing homes, hospitals, day care

centers -- then the Food Code really becomes a very important vehicle.

Secretary Shalala, Secretary Glickman have written to all 50 governors. We are seeing -- and I'd be interested in feedback from our state colleagues here -- increased receptivity in the states. But that will clearly be a major effort. We have sponsored a series of what we call national integration meetings.

We have representatives from all states -- state health departments, Ag departments, FDA, USDA, CDC, state epidemiologists -- Janice Oliver referenced that -- focusing first on outbreak response, laboratory capabilities and findings and techniques, and finally on inspections. We work very closely with the ISSC on the specific issue in shellfish safety in the state of Florida. And if people want to know more about that, we can address that in the question and answer period.

Budget: Let me focus a little bit on the budget. Let me give the usual caveats, which is that federal officials, including myself, are not permitted to either lobby individuals or ask people to lobby on their behalf. And I clearly am not trying to desiring to do that.

What I have found, however, is people just surely do not understand our budget. I'll tell you most people in

FDA don't understand our budget. And we have found it valuable, both inside and outside, to just lay out -- What is it? What is the budget? What has it been? What is our budget request? What does it mean? What do we get this year?

And I will try to do that quickly for you. Number one: FY '99 budget increases for all of FDA. There is a wide perception that the food sector of FDA does not get sufficient interest when it comes to funding.

There may be some historical basis for that, but that is being turned around under the auspices of the Food Safety Initiative. You see here just from last year virtually all of the money given to FDA as an addition in FY '99 was for the foods program.

Number two, with the Food Safety Initiative $25 million, we devoted about 14 to the field, nine million to the Center, a small piece, 1.3 million, to veterinary medicine for antimicrobial resistance and a half million to NCTR, our Arkansas research facility, for research. The allocation was done this way because the purpose of the money was to really devote on imports and on produce, and a lot of that is done in the field with headquarter's help and direction.

We also got a number of very small but targeted

increases for cosmetics, for food contact substances and for seafood, which was to be devoted to equivalency assessments with border countries. Now, let's see. I'll go back. This is part 2 to the same chart you saw before. Let's see what impact -- certainly, the last chart looked good.

We see the good news is for the first time in a number of years the FTE Base within my Center has increased, and that's very good. And we are devoting it to those programs that are essential to the food safety effort. And so we're starting to get that. Even so, we're still, of course, a long ways away from 1978 laws.

But remember the second chart I showed. If you're a part of the base program, non-Food Safety Initiative part of the Center, you took an additional cut. Because what happened within FDA each year now is that -- and this has been so for about the last five years -- we need to absorb inflationary increases.

And so if the base program gets the same amount of money as the year before, we can't sustain the same program the year before, because costs have increased. The payroll cost increase; other costs increase. And so we need to not replace people, because we need what would have gone to their salaries to make up for that shortfall. And this has been happening for about five years in a row at the FDA.

And so you see, even with those increases, the base program is going down. And were it not for that cosmetics restoration, which I put it here because that was part of the base program, it would have gone down even further. And so this is very important to understand as we are allocating resources. The good news is that the new money is going to where the biggest problems are in the area of food safety.

The not-so-good news is that the base program, as Linda Suydam says, is being eroded. And this is the best chart I know to try and illustrate what the facts are there.

2000 budget, looking ahead: Because of that -- I just want to come back for one second there. This chart is not unique to foods. I know we're here; I'm supposed to talk about foods. But I'll take advantage of the fact that I've worked in all parts of FDA.

And it is certainly true in the field. You ask anybody here in the Chicago district or Detroit district. People realize that the base programs across have been eroded. And we all got together last spring and all the center directors realized we have issues, say, more common than you think.

There's nothing like a common problem that can band people together, whether you're in food or drugs or

devices. And we realized that we need to seriously address that. And so this year for the 2000 budget, which is what is before the Congress -- we had our Senate hearing yesterday -- FDA -- the president has proposed a $216 million increase for FDA above last year's appropriation. That's an 18 percent increase.

If enacted, it would be the largest one-year increase, at least any of us can remember. The Secretary Shalala is getting directly involved. She wrote the Health Appropriations Committee in February, "The president's budget request for FDA for FY 2000 begins a fundamental rebuilding of this agency and its science base."

I would focus on a number of things, starting with "fundamental," but also focusing on "begins." I think Linda Suydam used the phrase "downpayment" in terms of strengthening the Agency and its science base.

Now, let's see where those monies are put. There was a question on the telecast about injury reporting and adverse event reporting. There's 15 million there.

I'll show you later where the food pieces are in all of this. Product safety assurance: Most of that is for drug and device inspections; there's also money for an L.A. lab within there; premarket approval across a number of areas; Food Safety Initiative is a separate line item;

tobacco and bioterrorism.

Now, coming to food and back about Secretary Shalala, food safety is a compelling public health issue and is a critical responsibility of my Department. The requested new funds will reduce a persistent hazard. And so we are clearly very much in view of what is needed. Now, how is this translating to FDA to the food program? Again, the full 30 would go to the foods program.

Within food and color additives, that was approved on the review section. There was 11.4 million, most of which would be in review fees. I'm going to come back to that. Injury reporting is a two-and-a-half million dollar piece. Most of that would go to dietary supplements, food ingredients and cosmetics. We are moving to a new modernized facility in College Park in two years. That is very good.

We need to start getting the basic funding. Construction has been funded, but there are moving costs. And we're starting to request both funds this year. This money, by the way, will just wire the new building. It is important to have the building wired, obviously, and that's what that money is for. But is all that money would cover.

We also have a proposed transfer of a seafood inspection program from Department of Commerce to the FDA.

That is also a fee for service program, and that would be a transfer. But total affirmative increase of FDA in the foods areas are off $64.2 million. Now, breaking that down a little bit, what would we do with the money?

You've heard me stress I believe in results. In terms of inspection capability, we want to be able to inspect once a year all of the facilities that have food that we believe is at high risk of microbiological contamination. There are about 6,200 such firms nationwide. That includes seafood. We will more than double our foreign inspections.

And we also have to devote money to the necessary research and so forth to give our inspectors the right tools to do the job. We need better rapid tests. We need other methods that inspectors can use to really detect food safety issues.

Outbreak response: The good news on surveillance; we have a better system. The bad news is it's going to detect more things. And we have to be available and ready. Probably one of, I think, the few mistakes I've seen in the food safety funding is outbreak response was never budgeted in the first two years. And I can tell you -- and I'm sure Ray Mlecko would tell you from the field -- if it happens, we will do it. And if we do it, it

comes off the top, but it works -- it cuts into the time that otherwise could have been spent on inspections.

So we have to realize we have a better surveillance system. It's going to reveal more outbreaks. We have to have the resources to have the kind of rapid response teams to develop them. We have to have the life support. We have to increase the hook-ups to the PulseNet system.

We also have to focus more on retail and food service -- training in the Food Code -- you've heard me talk about that -- antimicrobial resistance contained in the surveillance there. Injury reporting: As I said, 2.5 million in these areas. Food additives: I'll pause it here a moment. There's 1.4 million in appropriated funds. There are two related feed-based requests. One is for food contact substances.

This is actually a provision in FDAMA. These are the so-called indirect additives, something used in the packaging that might leach into the food. There is a $6 million request there. There is also -- and that would essentially fully fund that program. There also is a $4 million request for direct food and color additives. That would be a beginning to the funding of that program.

Both of those will be based on a successful model

of having fees that are dedicated to the task, clear performance goals, and accountability all around. So here's a slide I used last year. The challenge is still there. Number one, we have to be identifying real public health issues and be sure they are being addressed properly. That's why food safety, food safety and food safety is our top priority.

Number two, we have to establish clear priorities and stick to them. We've established priorities. We have to stick to them. I will tell you I meet with people frequently now that want me to do this, that, or the other thing. And I have this book out and I say, Show me something on here that is more important than.

We have to realize, as Dr. Henney said, that we cannot do everything. I'd rather do something well than everything poorly. We have to be able to stick to them. I hope you folks will support me in trying to stick to them. To me, that is our best way of matching expectations with resource availability and finally enhancing a two-way communication with stakeholders.

In that connection, we have established a website within the Center that is very popular. We are establishing a new information center. We have special mailings, stakeholder meetings. On here, just a listing of the food

stakeholder meetings Mark Barnett set. Today is not an isolated event.

In addition to the one that I talked about last summer, we had one on cosmetics to deal with the restoration, one on an international scheduling issue, one on food contact substances, today's; I referenced the one on health claims, and finally, we are scheduling one on dietary supplements. So that's very important.

In conclusion, last spring I just took the job. I saw the excitement, the challenge. I said to everybody, It really is -- I mean it -- a great time to be in the foods business. A year later, I say not only is it still a great time to be in the foods business, but it's getting better all the time. And it's getting better because, I think, there is a real recognition of the problems.

People are coming together to solve those problems and we're doing something valuable and critical for the American consumer. I'm delighted to be a part of that, but we know, again, our job is just beginning. Thank you very much for your attention to a talk that was probably a little too long. I thank you very much. We will have time later for questions.

What we're going to do now is Dr. David Armstrong, who is the research director at the Moffett

Center down the street, has a presentation which he promises you is shorter. And then we have a number of public presentations, people who came here prepared, wanting to give a presentation, also.

Please welcome Dr. Armstrong.

(Applause.)

DR. ARMSTRONG: I might say while we're waiting that I had no idea the Commissioner was going to mention the Moffett Center, in spite of what Mr. Levitt thinks. She did visit our Center a few months ago. She also visited the Chicago district. And I guess she was quite impressed with our operation.

I don't know if that's in focus. This is a picture of the facility. And it's located three miles west of Midway Airport in Bedford Park. And I'm sure those of you who are Chicagoans may have gone by this facility and thought it was part of the Corn Products Company, but it really isn't. The FDA part of this Center is located on the fourth floor here.

What is the National Center for Food Safety and Technology? It began about ten years ago as the Cooperative Research Consortium. And it was really, in my view, one of the first attempts -- first modern attempts of FDAMA by FDA in that we instigated to enhance FDA's food science

expertise, expand the FDA's food science research program, cope with emerging food production, processing and packaging technology and enhance FDA's scientific communication with industry.

Our goals were that we were the open lines of communications with our stakeholders. We wanted to foster and scientific and technical exchange among diverse segments of the food science community. We recognized we better needed to understand the science and engineering behind food safety. And we needed to conduct much more research promoting the safety and quality of the U.S. food supply.

And this is where we get into the concept of being a proactive Center within FDA in that once a food safety problem appears, we take the initiative. And now I'm going to show my diversity as far as multimedia and flip over to the transparency.

(Pause.)

DR. ARMSTRONG: I'm going to kill all my time with audio visuals. At the National Center is the Prevention and Intervention Program research program for FDA. And I -- as I said, it's really a proactive approach to FDA's mission to ensure food safety. Actually, we've had a long history in this program of responding to acknowledged food safety issues.

And we've done many collaborative projects and task forces in the past. Currently, we are responding to the president's Food Safety Initiative. As an example of the stakeholders we have involved at the National Center, we have, of course, CFSAN in Washington, who we are a part of. We have the National Center for Food Safety and Technology, which consists also of Illinois Institute of Technology, University of Illinois and also industry.

We have CFSAN-Dauphin Island. And then we have our various collaborations with USDA, particularly ARS. We have several universities that we do contract research with. We collaborate with the U.S. Army/Navy laboratories. And now we're beginning to collaborate with JIFSAN, our sister organization back in Washington. As well, we have extramural grants that CFSAN has given in this program.

Actually, we do three parts in this Prevention and Intervention Program. We do what's called a hazard reduction assessment. And some of you have heard about the five-log reduction that FDA is proposing for the juice regulation. Here we look at technologies to see if they're capable of actually doing a five-log reduction.

Besides that, we need to look at the critical control points in the process to assure us that we can measure that this reduction is being achieved. The next

part of the program is technology validation. What is it that we measure in the process that assures us that this reduction is achieved and can -- more importantly, can we deliver every time?

So do we have a valid technology that we can trust? And finally there, the par-market approval considerations for the technology -- during the process of doing this new technology, are there substances generated that might be fruit safety problems in themselves? I just wanted to give you here today some examples of the research that we're doing out at the National Center for Food Safety and Technology.

Number one, we're working on particularly alfalfa sprouts. Number two, we're working in the safety and assurance of unpasteurized juices. Three, we're working on the control of pathogenic organisms in seafood and four, on the survival of pathogens during the 60-day aging period for hard cheeses.

I might mention that this has recently been challenged because of some outbreaks that have occurred with hard cheeses from unpasteurized milk. And I should emphasize this -- unpasteurized milk and not pasteurized milk. Currently at the Moffett Center, we have a what we call pathogen pilot plant.

It's biocontainment pilot plant where we can actually inoculate E-Coli 015787, which is an organism some of you have heard about, directly into cheese and follow its growth in cheese. This is one of the few pathogen pilot plants in the United States. And we're just initiating that work at the Center.

I wanted to talk a little bit about another subject I'm sure some of you have read about, and that is the risk from sprouts. Recently, they've been linked to numerous outbreaks, Washington and California. We have found that the sprouting conditions really allow for pathogen growth. And probably the most interesting part or the most exacerbating part is that sprouts are consumed raw. There's no kill step involved.

What we have done at the National Center is to develop what we call a sprout task force. And we got together all the industry, the academia, USDA, other governmental agencies, if they were involved, and sit down with them and try to determine what we could do in terms of research to address this food safety problem.

And the research approach that we came up with was first, we're going to try to assess thermal, chemical, irradiation and other treatments that we might do for pathogen inactivation in seeds. Next, we're going to try to

conduct some commercial scale process evaluation in our biocontainment pilot plant.

And finally, we're going to try to develop a rapid test method to detect pathogens in the sprout irrigation water. I don't know if many of you are familiar with the sprout-growing process, but these sprouts are grown in huge rotating drums. And generally, they grow -- you start with about 40 pounds of seeds which turns into about 800 pounds of sprouts.

But in the process, that takes from four to seven days. These -- this time period is an ideal incubation period for both microorganisms and pathogens. So we're looking at methods where we could, at the end of two or three days, test this irrigation water that's constantly being sprayed on these sprouts to determine if pathogens would exist in that water.

Therefore, the sprouters could make a determination at that time whether the sprouts were safe to distribute. Finally, I want to talk about who benefits from this approach. First off, the sprout growers benefit because in general, these are small -- very small companies, if you want to call them companies. They're usually individuals that have garage operations where they're growing sprouts.

And they do not have a lot of money to do the needed research in this area. So if we're going to have a sprout industry, much research needs to be done for prevention. For CFSAN, we can look at the guidance for HACCP and GMP implementation that we need to provide and we also need, perhaps, to incorporate into our regulatory programs.

Finally, when this all distills out, we need to provide guidance to the FDA field operations. And let me finish by saying that research is fine. And that if it's published -- and all of our research is published and we have great scientists, both in Washington and at the Center. But the most important part, I think, is the technology transfer part of it.

We need to get this technology out to the people who use it and out to the people who inspect it. And so that's my song and dance for today. Thank you very much.

MR. LEVITT: We now have three speakers that have asked to address us today. Before I announce them, I'm wondering if it would be well for everybody to stand up for just one minute in our places and take a stretch. You may not have realized you were coming to a double-header here.

If I could have everybody's attention, please. We have, as I mentioned, three people who have asked to make

a short presentation. Actually, two of them are here, and so we're not sure if the third one will be available. If not, we'll be happy to take their presentation and add it to the record of the proceedings.

But let me begin by introducing Joseph Doss, who is the senior vice president and director of public affairs at the Consumer Health Care Product Association. And we're going ask for each speaker to try to limit yourself to about ten minutes.

MR. DOSS: Thank you very much. I will be brief. I want to first thank Joe Levitt for the opportunity to be here. The Consumer Health Care Products Association thinks that this is a very important forum to encourage a dialog and sharing of information. It's helpful to FDA. It's helpful to the industry. And I think ultimately, it will be helpful to the consumer.

We have had participants at not only this location, but as you saw, we had someone in the Washington meeting, as well as the Philadelphia meeting. So we think these are very important, and we try to participate whenever possible. For those of you who may not know, the Consumer Health Care Products Association represents manufacturers of non-prescription medicines, as well as dietary supplements.

It's a relatively new name. We've been around

since 1881 -- over 118 years. But with our new name, we've only been around for about a month and a half. It's a new name. And we were formerly known as the Non-Prescription Drug Manufacturers Association. And we basically now represent over 200 companies involved in the manufacture and distribution of consumer health care products, primarily OTCs and dietary supplements.

My comments today will be just directed to dietary supplements. And I first want to say that we agree with the Agency's and CFSAN's objective of developing an overall strategy for dietary supplements, which is listed in that bible that Joe mentioned earlier, I think on page 10. And we'd like to offer a few thoughts on how the Agency might want to go about for developing this overall strategy.

We were first very interested in the Agency and CFSAN statement that they are seeking to set boundaries between a dietary supplement and a conventional food, between a dietary supplement and a drug and between a dietary supplement and a cosmetic.

And I just wanted to bring up the issue of -- as we've looked at that sort of terminology, boundaries, I wanted to talk a little bit about that, because we think that in some cases, some people might have a sense that that's a pejorative term, in the sense that it seems rather

limiting and doesn't seem to acknowledge that some of these could be more than -- fall into more than one category.

It may not have been the intent, but it was just sort of a reaction that some of our members had as they heard the word, boundaries. So we think terminology is important and would hope that as we move forward and discuss this that we start thinking about what dietary supplements are, rather than what they are not.

And if strict boundaries were to be set for particular classes of products, we think that it might have a tendency to box out other product classes. And, you know, it's obvious that there are certain examples of where products fall under more than one classes. Calcium products, for instance, are both -- they have health claims for osteoporosis, as well as making drug claims.

There are also psyllium products which are both dietary supplements and OTC drugs. As we're getting away from dietary supplements, you have the traditional antiperspirant deodorants which are categorized as cosmetics as well as OTC drugs. And there are certain OTC drugs which are also containing pesticides regulated by EPA.

So it's sort of -- there can be an overlap of product category, and we just wanted to begin thinking about that and to make sure that there was no unintentional sort

of activity that might exceed the current boundaries of DSHA [phonetic], and just wanted to have the opportunity as the Agency moved forward to talk to them about that and engage in a dialog on that.

Also mentioned in CFSAN's priority A list are dietary supplement good manufacturing practices and adverse even reporting. As for the GMPs, the Consumer Health Care Products Association, as well as the rest of the dietary supplement industry, have supported establishing GMPs for dietary supplements.

We have submitted comments to FDA. We're continuing to look at it and hope to further discuss it with the Agency as they move forward with the issue. On AERs, adverse event reporting, we heard a little bit of discussion about that today. As we go forward and we look at this issue for dietary supplements with regard to AERs, we wanted the Agency, and CFSAN particularly, to be aware of a couple of our thoughts.

And first of all, one is that there are currently several sources of information that are available to obtain dietary supplement adverse event reporting information. You've got Med Watch, Dawn [phonetic], spontaneous reports from consumers, the toxic exposure surveillance at the Poison Control Center, the published literature and other

sources, as well. So it's important to take a look at that.

Also, let's talk about the website and putting up of adverse event reports on the website. Clearly, the web is an important tool to get information out to consumers. However, we have some reservations about, I guess, the way it's currently being done in terms of putting things up there that might not have had the proper filter to make sure that they're accurate reports about a specific scientific concern.

And in keeping with the thought of today in trying to get input from groups like ours, we think that it's important to think about the kind of approach that would allow the education of the public about the concept of balancing the risks and the benefits, but without unnecessarily alarming them, because it might not have been an accurate report or you just don't know what the source was.

So we, again, welcome the opportunity to be a part of that discussion. As to the -- how the Agency can enhance its outreach efforts, these are great meetings -- stakeholder meetings. Dr. Soller, who was at the Washington meeting, mentioned that perhaps that the Agency should take a look -- or CFSAN should take a look at having a meetings manual policies and procedures.

I don't think you have one. As Bill mentioned, that's something that you might consider. We worked with CEDER [phonetic] to develop that. And it set forth procedures for scheduling meetings and conducting the meetings with outside groups. It describes, among other things, the maximum time after request for a meeting to be scheduled, the need for prompt preparation and sharing of minutes from the meeting and for a summary of the major points that take place during the meetings.

And we found them very successful and would encourage such procedural documents be prepared within CFSAN. So in sum, I just want to thank Joe and Ray for the opportunity to be here to share our thoughts, and look forward to working with the Department, with the Center as they move forward.

Also, just one procedural matter: We'd hope that maybe the record could be kept open for a week or so. I know that you're going to be accepting more questions, but we may have some follow-up process as a result of some of the things that were said today. Okay. Thank you very much.

MR. LEVITT: Thank you.

Our next speaker is Ms. Karen Truskowski, multiple chemical sensitivity health and environment.

She's here.

MS. TRUSKOWSKI: I'm going to discuss the problems with fragrances. A person easily uses a dozen or more fragranced products in a day. Many of these products are applied directly to the skin. The users of these products assume the safety of the materials used in them and the final product has been established. It has never occurred to most people that this is not the case.

Fragranced products such perfumes, colognes and personal care products come under the jurisdiction of the FDA. However, due to the trade secret status of fragrances -- or fragrance formulas, the fragrance industry is basically self-regulated. The ingredients used in fragrance formulas do not have to be disclosed to anyone, even the FDA.

Increasingly, fragranced products are cited as triggering or causing health problems. Though the industry has in place procedures for establishing the safety of fragrance materials, these measures are not adequate. The industry has been slow to address the issues involved. The answers provided by the industry need closer examination.

The industry says fragrance materials have a long history of relatively safe use. It is true that fragrances have been used for centuries. However, until late the late

1860s, virtually all fragrance materials were obtained from plant and animal sources. And the concentrations were pretty close to found in nature.

No one chemical was found in isolation. Companion chemicals found together often had synergistic and modifying effects. The majority of modern fragrances materials are synthesized from petroleum products. Many are not found in nature. There is no long history of use. The material that are obtained from plant materials are often extracted as isolates.

This means individual chemicals, rather than the complex mixtures found in nature, are used. History of use of -- history of use no longer applies, as the action of individual chemicals may be far different than in mixtures. Okay. Industry also says compounds are used at such low levels that they are not a health risk.

The current trend in fragrance formulation is toward using powerful long-lasting synthetics at higher levels. One material may make up as much as 25 percent of the formula. It is not unusual for four or five materials to make up 80 percent of the formula.

Industry also says fragrance materials are safety tested. The Research Institute for Fragrance Materials safety tests fragrance materials. Only about 1,300 of the

more than 5,000 materials used in fragrances have been tested for safety. The testing that is done is generally limited to acute oral and dermal toxicity, irritation and dermal sensitization and phototoxicity.

Testing is limited to individual materials. There is little effort to address synergistic and modifying effects of materials in combination through the -- though the IF -- RIFM is aware they do occur. Early on in testing, it was found that when similar materials were tested together, more positive sensitization reactions occurred than when the materials were tested individually.

Testing procedures were changed so only unrelated materials were used in a testing sequence. Most chemical data sheets and the MSDS information on fragrance materials plainly states, "The chemical, physical and toxicological properties have not been thoroughly investigated.

And they say -- industry also says present testing is adequate. Musk ambrette was found to have neurotoxic properties. This was first discovered in 1967 when mice were fed varying levels of musk ambrette. Since dietary consumption of musk ambrette is generally very low, the impact was discounted and no assessment was made of exposures from fragranced products.

In 1985, after studies were published on the

neurotoxic effect and it was determined that the musk ambrette was readily absorbed through the skin, the IFRA recommended that musk ambrette not be used in direct skin contact products. Musk ambrette had been used in fragranced products before the 1920s.

Versalide had been used in the fragrance industry since the 1950s. In the mid-'70s, it was discovered that -- by accident that this material was severely neurotoxic and caused the internal organs of mice to turn blue. Perfumes and fragrances were recognized as triggers for asthma by the American Lung Association and other organizations concerned about respiratory health.

In spite of legitimate concerns, the industry does not include testing for neurological and respiratory effects of fragrance materials. The industry also says the industry can adequately regulate itself to ensure safety of fragranced products. The International Fragrance Association takes the information obtained from the RIFM materials and establishes guidelines for use -- safe use of fragrance materials.

These guidelines are not binding and there is no enforcement by the industry. In 1985, the IFRA recommended that musk ambrette not be used in direct skin contact products. In 1991, the FDA still found musk ambrette in

skin contact products. Musk xylol is found in waterways and aquatic life. It is being found in human adipose tissue and breast mill.

In spite of this, the IFRA has made no restrictions or recommendations concerning its use. The industry also says only a small segment of the population has adverse effects from fragrances. One to 2 percent of the population has skin allergies to fragrances. Fragrance is one of the most common causes of adverse reactions to cosmetics.

Asthma rates have doubled in the past 20 years. In 1994, there were 14 million asthmatics. Perfumes and colognes trigger 72 percent of asthmatics. Each year, over 35 million people suffer from sinusitis. Fragrances are general irritants that contribute to the incidence of sinus problems. For some, they are the primary triggers for upper and lower respiratory illnesses.

Migraines affect as many as 25 million people. Fragrances are known triggers for migraine headaches. Many of these health conditions are adversely affected by fragrances. Those with chronic lung diseases find exposure to fragrances exacerbate their condition. Those receiving chemotherapy for treatment of cancer often find exposures nauseating.

Okay. Okay. The attempt to regulate fragrances is not an isolated incident. In Massachusetts, there was an effort to regulate fragrance inserts in magazines. One possible solution may be to require odorless sealed packets for fragrance samples. Resolving this issue may well involved the U.S. Postal Service, because it regulates the use of such inserts.

Okay. In light of the fragrance industry's unwillingness to adequately address this issue of fragrance safety, it is time for the FDA to intervene. Though FDA resources are limited, there are cost-effective means of acting and ensuring the safety of public's health. Programs and resources already in place can be utilized to more effectively monitor the safety of fragranced products.

Make available fact sheets that acknowledge exposure to fragrances can exacerbate or trigger asthma, sinus or upper respiratory problems, migraines and other disorders. It is important that consumers are aware that the FDA does not require pre-market testing of products. Many patients with asthmatic children are not aware that the products they use may be contributing to the their child's illness.

Such education would also increase the awareness that second-hand fragrance can cause problems for others.

Many parents are unaware of the general consensus among pediatricians that fragranced products should not be used in infants.

Expand the Cosmetic Adverse Reaction Monitoring so that complaints can be registered via the FDA website. This would make it easier to file complaints. Data could be used to pinpoint specific products that are problematic. The National Center for Toxicological Research can be utilized to analyze fragrances that are problematic.

The results can be examined to determine if there are substances or formulations that common in the -- that are common in the products that complaints have been filed. Further, the results of analysis can be examined to make sure that materials banned, voluntarily or by law, are not present. Also, any lack of compliance with the IFRA recommendations for restricted materials should be noted.

The product should also be examined for proper labeling, et cetera. The vast numbers of materials used in fragrances makes the task of ensuring safety of each and every substance beyond the scope of the FDA's resources. However, by closer examination, several reasonable points to start can be determined. The fragrance mix patch test is diagnostics for the majority of skin allergies to fragrances.

These materials would be a good place to start in determining if fragrance materials can be -- also act as respiratory sensitizers. More complaints are registered concerning fragrance formulated since the mid-'80s. Examination of these products may prove clues to why these formulations are frequently cited as causing problems. Material -- some materials may have been used on a limited basis previously, but newer information increased their use.

For example, in the late '70s, it was found that amylcinnamaldehyde and hexylcinnamaldehyde have the ability to hold the scent, even after washing and rinsing. Though both of these materials have been used for some time, usage in products with a wet application increased.

Materials introduced in the past several decades need to be closely monitored, as they have no history of use. This is especially true of the newer products that are used at relatively high levels in modern fragrance formulas. Fragrance materials are not the only things that need examining. Newer technologies, such as the use of cyclodextrins, also need to be examined to determine if the use of such materials add to the health risks.

Though health risks from an individual fragrance may seem insignificant, the sheer numbers of fragranced products used make them a concern. Further bioaccumulation

of fragrance materials increases the concern. Presence of fragrance chemicals in fat tissue and breast milk raise the issue of effects on the fetus and nursing infants. These are health concerns that should not be ignored.

Increases in asthma and other respiratory problems triggered by fragrance exposure raises concerns over effects on the airways and the lungs. These and other concerns need to be addressed by the FDA and fragrance industry. Thank you.

MR. LEVITT: I believe that the third speaker who requested to speak was not able to be here. So what we will do instead is we will go to the last segment of the program -- baseball terms, the ninth inning. And we'll invite up to this table Mr. Mlecko, Dr. Johnson [sic] and myself. And we won't make you fax your questions up.

We will invite you to just walk up to that nice little microphone over there and raise what you would like to within the context of either the Dr. Henney-Linda Suydam teleconference from the first segment of the program, or issues that were raised by any of our presentations or by the programs that we administer.

I think that our original goal was to try and finish around 4:00. But I think we will stay longer if there is interest and questions, because you come out to a

meeting and we want to be responsive to that. I'm going to now walk over there.

The other thing I've learned is some of these microphones are so you can hear me and some of these microphones are so this lady who's recording can hear me. This is the one that you can hear me with. Good. I think I got it. If you could please introduce yourself before you ask your questions.

Yes. Nancy Donley.

MS. DONLEY: I'm Nancy Donley, and I'm president S.T.O.P. -- Safe Tables are Our Priority. We're a foodborne illness victims' organization. We are a national organization comprised of families who have lost loved ones to foodborne illness, who have been victims themselves and who are just consumed -- concerned consumers everywhere nationwide.

We are very active in policy advocacy, public education and as well as victim assistance and support. That said, I have -- and I -- this is to the third question that has been brought up with the purpose of this meeting today. And it has to do with communicating with consumers and as an educational type of component. It's the -- what actions do you propose for educating the public about the concept of balancing risk against benefits in public health

decision-making?

I want to start off by saying, first of all, I'm going to make a couple comments, and I am going to ask a question, as well: One being that I think that enough cannot be said for the usefulness and the necessary component of just being truthful in disclosing all of the facts available. That means no sugar-coating of messages.

Too often, consumers are hearing conflicting information. When, on the one hand, we have the safest food supply in the world, but on the other hand, we're also being told is, You better treat it -- treat all your food as toxic waste, because it's up to you to make sure that if it's unsafe, it's your fault. We're getting conflicting information.

And that's why I want to really bring up a couple things, because it was brought up by Janice Oliver earlier today, and that is the fight back campaign. And I just picked up this book and kind of leafed through it that was left on the back table. And here is just another instance. And I would also say we offer S.T.O.P.'s assistance in producing any consumer information, if you'd like, because we're starting out right here with a "keep your food safe" message.

And that's in the fight back campaign. If you

really stop and think about, we're not keeping food safe; we're keeping people safe from unsafe food. So we have an implicit -- an implied message here that if something goes wrong and you get sick, Mr. or Ms. Consumer, it's your fault. No.

We're dealing -- what we have to be aware of is we're dealing with our safety and how to work with it and decontaminate it, if you will, or practice safe food handling practices or not to take -- cross-contaminate safe food with unsafe food. This year's fight back educational message is a -- is going to be a really, really tough one for FDA and the consortium that is dealing with it.

And I think you're really going to be challenged here. This year's education focus is on the cook it component of the fight back four areas of -- that they position. We have -- and the cook it -- and these are kind of outdated in here, is another thing you might want to know. We have a real problem here in this particular quadrant of the fight back campaign where we're going to -- we have mixed messages and conflicting information that is going out to the public.

On the one hand -- let me give you two examples. On the one hand, both industry and government has acknowledged that the only safe hamburger to eat is one that

is cooked to 160 degrees internal temperature verified by the thermometer -- that color is not a reliable indicator and that you must -- the only way to ensure that it's safe is to use a thermometer.

Yet you can walk into just about a restaurant anywhere across the United States and order your burger any way you want to. Now, the National Restaurant Association is part of the Food Safety Consortium, as well as public health departments. And this is a real problem. Another example is eggs. You -- the only way -- safe way to eat eggs is -- as acknowledged, is to make sure that they are cooked thoroughly and that all whites and yolk is firm.

But you still get -- ask routinely anywhere you walk into the -- into restaurants, How do you want your eggs prepared? That's conflicting information. We can't be a "do as a say, not as I do" society and expect any changes in consumer behavior. And that's the key here. It's not consumer education; it's behavior modification we should be after.

And we cannot achieve that if we are sending out conflicting information to the public. That said, I think what this points out is kind of an overall larger problem that I hope FDA is going to -- and CFSAN, in particular, is going to recognize the need for further federal regulations

throughout the food industry, and that we cannot have -- and the Food Code is a great example of this.

In the Food Code, it's because municipalities can adopt any portion that they want to of it. They can take -- they look at the Food Code as a menu and say, I'll take this part and this part and this part, but I don't want this part or I -- and I'll modify this part. We cannot have a patchwork safety system for food throughout the United States.

Public shouldn't be more protected in one area or one state or one county or one city -- more protected there than they are anywhere else. And where we -- this is where we, the public, are looking to the federal government to establish food safety standards that must be utilized evenly throughout the United States. And I can't emphasize that enough.

It's once you get strong federal regulations that you build a good base to develop these partnerships that you are talking about on the state and local level. And once you have national regulations, national performance standards, then you can branch out and develop your partnerships. And I think then you will probably have a very even system across the country.

You then stand a chance of really developing

something good and something wonderful. But it has to be based on a national framework and a level playing field throughout. So I guess that said -- I'm sorry I'm taking so much time up here -- I do -- I really feel we have this coming up in September -- this education -- I'm going to end with the education component here of this fight back campaign.

And I'm -- I am very, very concerned as a president of an organization who -- we are routinely giving out information to people who ask it -- of what we should do. And then these same people are hearing other things back or just viewing other things -- getting wrong, wrong, unsafe information coming back to them from industry. Thank you.

MR. LEVITT: Thank you very much. I'm not going to try and respond to every point made, but I will highlight a couple of items. One, I want to begin by commending you and your whole organization for the important advocacy you're arguing in the area of food safety.

As Ms. Donley mentioned, she and -- I don't know -- all -- most -- many members of your organization have really seen the dangers of food safety as -- firsthand and had members of their families become very sick or even die as a result of foodborne illness. And to me, there is

nobody who comes with more credibility than that.

In fact, when I first saw -- I've never said this, but when I first saw the name of your group, Safe Tables are Our Priority, I thought it stood for -- as S.T.O.P., Stamp Out Pathogens. Maybe that's a -- and so let me begin with that. The issue of cooking: You're right. We will be challenged.

We -- I mentioned that we're -- are coming forward, in addition to the fight back campaign, with a proposed regulation on egg safety, one component of which is safe handling practices for consumers, which will include both refrigeration and cooking thoroughly. But you're right. The hard thing to explain to people is, Wait a minute. I grew up on this. I've had this all my life.

You know, how do we convey how the world has really changed? And, you know, any help as we go through developing the materials, you know, we welcome. We can put on labels that say, Cook thoroughly. Or as you say, in meat, even if that's regulated by USDA, you know, cook to a certain degree level.

It's different from making it happen. I will give you just a couple of anecdotes that I've just experienced. And they're only anecdotes. You know, they do have now the little disposable -- I'll put in a plug for

USDA products. There is now a little disposable thermometer that you just put in your hamburger, hold it for six seconds, pull it out.

And if it's white, it's -- you have to cook it more. And if it's black, it's heated to the proper temperature. And I can tell you I put it in and it's still white, so I have to close the oven again. But, I mean, they do work and they are reasonably priced. And people need to understand that's something we need to do.

But you're right -- behavior modification. I think you're exactly right. I also -- good news -- I was up at a New England state over vacation, and it was on a border. So I'm honestly not sure if it was in Massachusetts or if it was in Connecticut, because it was right on that border. But the people at the next table ordered a rare -- a hamburger medium rare. And the waitress said, I'm sorry. We can't serve it to you that way.

So there is -- the message is starting to get out. But clearly, more needs to be done. The last point I wanted to address is the issue of federal standards. And we are, I think, coming to understand that in a real way. We have had, as I mentioned, a number of meetings with state and local officials about how to expand food safety coverage in an appropriate way.

And one of the first themes that we had -- we had a list of criteria. One of the first themes was uniform minimum standards. And what we found was, number one, that was very much misinterpreted. I found that common uniform minimum standards became common minimal standards -- became exactly what you suggest as allowing or even encouraging a patchwork.

And at least within our internal discussions -- and you'll see in the response that the administration gave to the Academy, you know, that the first criteria is strong national standards so that we do have a level playing field across the country, you know, where we can do that. I think, you know, the HACCP regulations from either Agency are a major step in that direction.

The last thing is the Food Code. I would just invite any of our state and local health officials here, if you would like to comment at all on the Food Code, on implementation efforts, on how that is seen from the receiving end, because we do see it as a critical component to the whole food safety effort.

MS. BOHM: My name is Shirley Bohm, and I'm the food program manager with the Division of Food, Drugs and Dairies, Illinois Department of Public Health. We are, in Illinois, very strong proponents of the FDA Food Code. In

1996, in January, we adopted critical portions of the Food Code into Illinois rules. And the majority of the local health departments in Illinois have those as their -- part of their legal base.

We felt at the time that our director, and basically the entire department -- all of the food program -- felt that it was a very large document and it would be very difficult to make that changeover with the -- with so much material. So we started with step one by incorporated critical sections -- all the time temperature control and consumer advisory and hand contact with ready-to-eat food and a number other -- of other issues.

We're at the stage now of finishing up a review -- continued review of the Food Code, and we expect to share a draft with our stakeholders here in the state later this summer and then propose it for -- the entire Food Code for adoption. I would like to make one recommendation to FDA. I think this might help you, and certainly would help us.

The two-year cycle that you have where you come out with a new Food Code every two years is very difficult for the recipients. Rulemaking is a long and sometimes difficult project. And we can't keep up with you. And CFSAN can't -- I don't think -- I don't see how you have

enough time to continue doing that two-year cycle.

I think now we've resolved a lot of the issues with the conference for food protection and a lot of input from the industry and regulatory agencies, as well. So perhaps it won't be so difficult now for you to maybe go on a four-year or six-year cycle that would correspond with the conference for food protection, because I know you take a lot of input from the conference.

So that was a recommendation, I think, from a lot of people I've talked to, and certainly would make my life a lot easier. Thank you.

MR. LEVITT: Wait. Before you -- could you help us? If you look ahead four years from now -- let's assume FDA hasn't revised it in the next four years. We'll try and think about it in that way. Do you see -- knowing how it's viewed in your state, knowing how your state counterparts are, do you foresee the result being broad in uniform adoption, or do you perceive the result being a patchwork approach as was suggested with a degree of worry a few moments ago?

MS. BOHM: With the present system where it's a recommended document -- a model document that's made available for everyone to adopt as they will, certainly every jurisdiction, whether it's a state or a local level,

will have the opportunity, then, to tweak it as they will or as they want in response to local situations, to local lobbyists, to whoever makes comment.

Without changing a system so that there's a -- oh, I don't want to use that M word for mandatory -- but without changing the system that you will end up with some local differences at the -- at whatever level -- whatever jurisdictional level. And without something to sweeten the pot, let's say, to encourage state and local agencies to adopt as is -- for example, a model code as is -- perhaps funding or whatever -- I can't see -- I can't foresee that situation changing, really.

MR. LEVITT: Okay. But you just gave me one idea.

MS. BOHM: Good.

MR. LEVITT: And I'll take that -- your idea. My impression on the Food Code -- I'm not a long-term expert. My impression is that this year was viewed as a breakthrough year and that there had been a lot of opposition to some key points.

And with basically an agreement reached at the conference of food protection last -- about a year ago by now -- as basically ratified in the Food Code that came out in January or February -- January, I guess -- that this

really should become the code we are trying to get implemented.

And it is probably not useful as people in the process of implementing for us to keep moving the target a little bit. So I certainly will take that -- to make that suggestion back and the other idea back, too.

MR. MLECKO: Shirley, you mentioned "sweeten the pot." How can we sweeten the pot?

MS. BOHM: Well, I can use the USDA setup -- USDA and State Department of Agriculture setup with meat and poultry inspection. That's one possibility where USDA requires state agriculture departments to basically adopt, as is, federal regulations, make their program equivalent or identical to the federal program and, therefore, they also get -- I believe it's 50 percent of the program funded by the feds.

That's a possibility. Certainly that's one setup. I, you know, don't know enough about how it could work. There may be other alternatives. But that's one possibility of having some federal funding tied to that uniform adoption.

MR. LEVITT: Thank you very much.

Who else has a question? Yes. Please.

MS. SOSA: My name is Merle Sosa, and I'm manager

of food safety programs for Food Animal Concerns Trust, or FACT. And my question has to do with the announced notice of public rulemaking that was done in May of last year for *Salmonella enteritidis* in shell eggs. And you mentioned a few things in your presentation about things you've got coming up for eggs, But none of those related to anything on-farm.

I should mention that our group is involved -- the group that I represent -- what we advocate is more humane -- using animal husbandry systems to improve the safety of milk, meat and eggs. So one of the things that we're concerned with is the fact that there doesn't seem to be any regulation on the horizon that would relate to systems on the farm.

So what you're doing is implementing programs that will be -- I think you mentioned refrigeration and transportation and things like that. But our group feels that the best chance for trying to prevent SE in eggs is right on the farm. And we do have model farms. We have 14 in Pennsylvania where we use extensive SE testing programs to try and prevent SC.

So what we don't understand is what happened in the interim process. There were comments made. We tried to find out more information on the comments and what the whole

process is going to be, but there hasn't been anything that's come out since comments were made in August. So my questions are: Number one, is there going to be anything on the horizon concerning regulations for on-farm pathogen protection programs with regard to SC.

And number two, my question -- my second question relates to communication. Once comments are submitted, you're kind of left with: Where are things going? And so one thing that we've tried to do is we've tried to contact FDA officials to check on the status. And we have received no response whatsoever.

Whereas, when we contacted the USDA for their part of this whole joint process, we received very, very prompt response. So my take on the FDAMA modernization act was: We want to communicate. We want two-way communication with the stakeholders and we want to communicate with you. So those are my two questions.

MR. LEVITT: Okay. Thank you. Number one, if you'll leave me a card or something, I'll be sure that somebody more specifically knowledgeable than me will call you back. But in general, let me kind of give you broad brush. Number one, we recognize that the first steps I outlined we're doing because they're the clearest and most direct that can be done -- if you will, the easiest -- and

so we ought to get them done.

The refrigeration will limit further growth of *Salmonella enteritidis*, and that's important. And the safe handling practices -- refrigeration will do the same and the cooking will kill the bacteria. We do not want a system, however, where we're relying on the consumer to be the principal checkpoint. You are right. We've got to go back to the farm.

There have been some successful farm quality assurance programs in Pennsylvania. We have within the priorities documents -- you'll see it -- it is on the B list -- to continue to foster those. I am not an expert in this area myself, but the discussions I've had on it so far have at least convinced me that it is a -- it's a hard problem to try to figure how to solve.

That doesn't mean we shouldn't try to solve it. I said when I was up there, you know, eggs -- *Salmonella enteritidis* is one of the big food safety challenges we have. I'm not sure that the comments in totality gave us a clear direction. But, you know, we will try to get done this year what we've laid out and come back and follow that more intensely in the future.

I don't know if that answer is fully satisfactory to you, but it's at least truthful and honest.

MS. SOSA: Right. We appreciate that.

MR. LEVITT: And did I hit both of your questions, or did I --

MS. SOSA: Well, I'd like you to address -- well, I guess one of things I have about the communication issues is there -- I guess my question is, is there a directive to the FDA personnel? I guess what I'm trying to say is some people feel that regulatory agencies are insular and are hard to communicate with. And I think that the FDAMA, as a document, is trying to change that impression.

And so I guess what my question would be is, is there going to be some work within the FDA to try and make FDA personnel more accessible and have some responsibility for them to -- if people do reach out to them, that they'll come back and at least respond either by e-mail or some other kind of communication?

MR. LEVITT: Okay. I think -- let me address this first in the case of a rulemaking proceeding, which is different from a lot of other things. One of the issues in rulemaking is what's called ex parte contacts with the idea that the process is, I'm afraid, kind of an arms-length process. That's why I tend to like these public meetings, because it gives you a chance to get more give and take than just read the document, summarize the comments and figure

where to go from there.

And we're doing -- you know, we've done workshops in a number of areas. But actually, it's not exactly the case here for people to extrapolate. When we issue a proposed rule, we really are not supposed to be talking to people outside of the process, because that creates an elements of unfairness. I'm talking to you now. I'm talking to somebody else. Who called? Who didn't call?

So it unfortunately does put you at a feeling like: I'm in the dark. And I don't -- I mean, the best solution to that is speed. When we did the juice labeling rule, we went from proposal to final in less than 60 days. It might have been less than 30 days. It was so fast, we can't even -- can't count them all.

But that was unusual. We had a particular time element we had to hit for the fall -- apple season. And I've tried to say to people and staff who literally worked all day, all night, all weekend for about a month or a month-and-a-half on that, we will reserve that for when there is not just importance, but time certain urgency where we'll bring out our staff so fast that they won't be here to do the next one.

But part of it also is, when you think of my boulders and pebbles, is how many of these can we

systematically address well at once, including follow through. We're working on following through on seafood. We're working on follow through on the fresh foods and produce, both domestically and internationally. And so part of it is how many of these major areas can we take on at once?

And I wanted to be sure the ones we do take on are -- we can do right and thoroughly and not have everything neutralize it out. So I think it's a combination of how much we know, how clear the comments were, what its priority is against other things. But yes. We know it's a real problem. We've got to get to it.

MS. SOSA: I guess in a situation like the SC regs when they've basically gone on for this long -- I mean, it's been -- what -- eight months since the comments were received. Then in that situation, I guess, as stakeholders, what we want is at least perhaps some status report that's put onto the web that says, you know, We're working on this, or, you know, We foresee in the horizon X regs.

And that way, at least we're -- we feel like we're part of the loop and we can -- and if there's something that we want to address, we could at least file more comments or do something. But we feel like there's -- we're just in this black abyss. And I understand. I, too,

am an attorney, also.

And so I understand the concept of ex parte communication and things like that and how that would be a problem. But once it gets so lengthy, there has to be at least something that we can have.

MR. LEVITT: Okay. That's a valid point. Thank you.

Other questions or comments? Yes?

While he's walking up there, I'll welcome Ken Moore, who's executive director of the Interstate Shellfish Sanitation Commission. I think maybe he wins the award for the person who travelled the furthest today.

Okay. We'll let you introduce yourself, though, for the record.

MR. MOORE: I'm Ken Moore, and I am with the Interstate Shellfish Sanitation Com. I really want to comment, not so much a question. Regarding the Food Code, our organization, quite frankly, provided the blueprint that the Conference for Food Protection used when they developed their organization. And quite frankly, we copied ours from the milk conference.

Ours is -- the Interstate Shellfish Sanitation Conference is a little different in the fact that we deal with interstate shipments of shellfish. Therefore, when our

organization adopts a requirement, every state is expected to go home and adopt the requirement in their entirety. There are no choices regarding whether -- you know, whether you can adopt a portion or not, because not only is FDA, but the states, as well, expect reciprocity in programs.

I'm going to tell you with the Food Code, if every state was required to adopt the Food Code in its entirety, it would look different today. One of the reasons you have the adoption of the document that you have or the ratification by the states is they recognize the fact that they would have options when they return home. You have a unique talent if you expect every state to adopt the Food Code as it is presently written.

I see difficult issues before our conference -- issues of things like particular situations in shellfish which affect immuno-compromised individuals. Those issue are debated over years. The organization has, quite frankly, found themselves in situations where certain public health officials felt differently about the right of choice the consumers had.

Those issues become very difficult if you're in a process in which the results of the discussion will result in every state having to adopt each requirement in its entirety. So I only want to suggest that you do have a

challenge if your purpose is to develop a Food Code in which every state is going to adopt it. I mean, I recognize what Shirley said, as well, when she said that we'll sweeten the pot.

Well, quite frankly, if you look at democracy, and that's what the country's all about, everyone supposedly has their own process. And when you're looking at food, you're looking at situations that aren't necessarily interstate shipments of food. They're intrastate shipments. Quite frankly, the states have that choice as to how they plan to regulate it.

You find different opinions in different parts of the country. You find different cultures in different parts of the country. Again, you have some unique challenges. Thank you.

MR. LEVITT: Thank you. If I was Mark Barnett, I'd be at the point that I'd say we have time for one more question. And seeing none, let me again thank all of you for coming, thank the presenters, again thank the staff both in Chicago and from back in Washington.

Mr. Mlecko, thank you for your hospitality --

MR. MLECKO: You're welcome.

MR. LEVITT: -- as host of the meeting, and Dr. Armstrong from the Moffett Center. And we'll continue to

work on this issue. So we wish you all a safe trip back home. This will conclude the meeting.

(Whereupon, at 4:25 p.m., the hearing was concluded.)

REPORTER'S CERTIFICATE

IN RE: Chicago District Video Teleconference

DATE: April 28, 1999

LOCATION: Chicago, Illinois

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the Food and Drug Administration.

Date: May 7, 1999

Official Reporter