

**NUTRITION LABELING AND EDUCATION ACT (NLEA)
10TH ANNIVERSARY**

January 31, 2003

Speakers:

Joseph Levitt – Director, Center for Food Safety and Nutrition (CFSAN)

**Christine Taylor – Director, Office of Nutritional Products Labeling and
Dietary Supplements (ONPLUDS)**

**William Hubbard – Senior Associate Commissioner for Policy, Planning and
Legislation**

**William Rados – Director, Website Management Staff, Office of Public Affairs
(OPA)**

**F. Edward Scarborough, Ph.D., - U.S. Manager for Codex, United States Department
of Agriculture (USDA), Food Safety and Inspection Service (FSIS)**

**Michael R. Taylor – Senior Fellow and Director, Risk, Resource, and
Environmental Management Division, Resource for the Future (RFF)**

Maggie Glavin – Visiting Scholar, Resources for the Future (RFF)

**Bruce Silverglade – Legal Director, Center for Science and the Public Interest
(CPSI)**

Regina Hildwine – National Food Processors Association (NFPA)

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Joseph Levitt (Director, Center for Food Safety and Nutrition (CFSAN)): Thank you very much. It's a pleasure for me to be here, but I hope it's a pleasure for everyone to be here. I was talking to somebody just before and we said, you know, sometimes a good idea is like a good golf shot. You know, it doesn't come all that often, but when you hit it true and you know it and it feels so good. And the idea for this meeting came up several months ago when somebody said, "You know, we're coming up on the tenth-year anniversary of the NLEA regulations. We ought to do something to commemorate it." And this event kind of evolved out of that.

We had a lot of ideas on exactly how to celebrate this event, but we really thought the best way to do it and the most appropriate way was really to have what I call a class reunion. Invite everybody that was here ten years ago that worked on it. Reunion's keep us going. The nice thing about a reunion is there is always another one to go to. The point is to kind of relive the experience, enjoy the company, have some fun. There's no political agenda. There's no policy agenda. It really is recognition of the work, remembering some of it, and laughing about some of it. We won't comment about certain people's association with certain dogs in certain buildings, but I'm sure other memorable stories will come up. Sorry, I am getting ahead of the program a little. But that's the idea.

We're happy that so many different people have been able to come. In looking around the room, we've got colleagues from the whole landscape; people that work in the Center now; people that worked in the Center then; and people that are still working. We also have people that retired; people from different agencies, whether it's the United States Department of Agriculture (USDA), whether it's Federal Trade Commission,

whether it's Food Trade Associations, consumer groups, and people that work on the Hill, in conjunction with the Hill. This was all part of the package.

I think one thing everybody in this room will agree to, is that the food label is really one of the true landmark achievements of the FDA over the last decade, and it's something that certainly warrants this level of recognition.

I think with that opening, I will kindly turn the program over to Chris Taylor, who is the Director of our Office of Nutritional Products Labeling and Dietary Supplements, fondly referred to as ONPLUDS, something she would not have known about when these NLEA regulations were passed. They were passed by predecessor organizations, of course. But we have an all-star lineup of people, and I hope really for an afternoon that is something worth commemorating, worth enjoying, worth reliving and renewing some new acquaintances and old friends.

So with that, thank you very much for all of our participants and everybody in the audience. Please welcome Christine Taylor.

[Applause]

Christine Taylor (Director, Office of Nutritional Products Labeling and Dietary Supplements (ONPLUDS)): Thanks very much, Joe. And it's hard for most of us to realize that ten years ago, this month; we issued more than twenty-five separate regulations to implement the new and important statute. And for the time we have this afternoon, we want to tell our stories. It certainly seems to us, who were working on the development of the regulations, that it was a special time for the agency. And as Joe

said, some of the key players are here today, either on the podium or out in the audience. But it's fair to say that it was a special time for the world of nutrition and public health policy, and so we want to start our stories with one about what the milieu was like at the time NLEA passed, what happened and why. And there's probably no better person to do that for us than Bill Hubbard.

At the time of NLEA, Bill was the Associate Commissioner for Policy Coordination. It was an intense time. We had three years to get the proposals out, the comments taken care of, and the final rules published. And just as importantly, it was a very central initiative for our Commissioner, David Kessler. He took a very personal interest in the development of these regulations, and he spent considerable time on the nature of, and the process for the implementation. And as part of that interest Dr. Kessler created a cadre of staff that supported and advised him on NLEA, and Bill was one of them. We called them the *Parklawn Group*. That's how they were known to CFSAN. We also, as Bill is indicating, sometimes called them other names. But in any case, we shall call them—

William Hubbard (Senior Associate Commissioner for Policy, Planning and Legislation): You mean “that damned *Parklawn Group*”? [Laughter]

Christine Taylor (Director, ONPLUDS): This *Parklawn Group* would routinely on certain days of the week motor on down to FOB-8 from Parklawn, enter the building from the parking garage, push the elevator button for the sixth floor, and whoosh right up

there, where they spent the entire day in meetings, either with the staff or with themselves, all about NLEA.

Bill has an absolutely infectious laugh and was for us one of the most affable of the *Parklawn Group*. He certainly asked all the same tough questions that all of the other guys did, but we at CFSAN quickly learned that Bill, at least, could be diverted from the chase by asking him as soon as you could about the joys of bicycles and the mysteries of the [Washington] Redskins.

I think Bill's strongest skill set is his political savviness. He can get the most intransigent set of people to work it out, and in those days we really needed it. But in the end what I think we all treasured about Bill was that he really loved the idea of nutritional labeling. It just resonated with him. He saw it as something worth his time and really good for the country. So we're pleased that he's here today to talk about how it happened.

[Applause]

William Hubbard (Senior Associate Commissioner for Policy, Planning and Legislation): Unfortunately, as you can see, I've had too much nutrition since 1990. [Laughter] And when we did this, I didn't have to wear these things [id badges] when I talk to you guys, so fortunately—when Kessler came, he was thirty-nine and I was forty or something, you know. I could keep up with him. Now we've got another thirty-nine-year-old and I'm fifty-four. So it's tough.

One of my favorite stories and this is more of a lead-in to this as a story, about NLEA, as it is about regulations, but it refers to NLEA. Both Peter Hutt and Charlie Edwards once told me about when they did the original voluntary regulations in the seventies, they had the idea, General Counsel (GC) and the then Bureau, wrote up the regulations, gave them to the Commissioner, put them over in the corner of his desk for a few days while he went down and told the Secretary about it, and then gave them the go-ahead to publish them. And it was done. There were no meetings. There were no briefings. There was no Secretary signature and signoff. There was no Office of Management and Budget (OMB) clearance. Don't we wish we had those days back? [Laughter] It never will happen again, right?

But I had been in FDA for a few years and went downtown to work in the Assistant Secretary's office and the Secretary's office, and Joe asked me to come back to FDA in the mid-eighties. And one of the first things he handed me was a memo from OMB that questioned the validity of the 1970s regulations or the voluntary program. As you know, there was voluntarily labeling and then mandatory if you'd made a claim. We were actually worried at that point—this is, what, maybe '86—that we were going to be forced to revoke the existing nutritional labeling regulations, much less doing more. And there was actually a lot of anxiety about it, and I know that the Center folks were really concerned at the time, because they thought, not only were the regulations that had been done in the seventies a good thing, but that they should be expanded into mandatory nutrition labeling.

But I think an interesting thing happened in that period. First of all, California passed Proposition 65, which got the industry really thinking about uniformity of

labeling. And I think that was actually a good thing in the sense that while it was sort of a safety-related proposition, it did spill over a bit into the nutritional labeling. And then Dr. Young, I believe, got interested by both the industry's interest and by Center for Science in the Public Interest (CSPI), and the other consumer groups, saying, "This is really something we ought to do." So I think the groundwork got laid there in the 1986-1987 period for that with Dr. Young.

You know, if you recall, we did an Advance Notice of Proposed Rulemaking (ANPR), sort of asking questions about what we should hear. That was one of my proudest accomplishments, because Joe asked me to write the ANPR and I did, and of course, it was like five pages and a total piece of junk. And then I gave it to Ed Scarbrough, who saw this thing and said, "We can't publish this," and he completely rewrote it over a long weekend and then it was a great document. And so I was able to go back to Joe with a great document and say, "I accomplished my goal." And I probably got an award or something for it. Yes. [Laughter] So I'm very proud of that. And thank you, Ed, by the way.

So then about that time the administration changed and Bush 41 had come in and there were a lot of questions about what we were doing here. They had an initial policy that only Commissioners could come to meetings on this. And so Joe and I knew that we had to brief Jim Benson, who by then was Acting Commissioner. And he would have to go down to the Secretary's office, where there would be a whole phalanx of the Secretary, the Deputy Secretary, the Assistant Secretary, and the General Counsel. All the staff was on one side of the table, and then the Commissioner on the other side by himself, explaining nutrition labeling. Of course, you could imagine the time that we had

to put into that. And of course, everybody wanted to be there and help, you know, pitch in and all that.

But I think that actually turned out to be a successful strategy, because over time it would be Jim and Joe and then it would be, you know, Jim and Joe and Fred, or it would be more people. And I think we, at the time, said to ourselves, “We need a Secretary involved in this. We need a Secretary who cares, because in the end we’re going to need him.” It turned out to be true, and we’ll say more about that later.

Then you may recall the Secretary made an announcement. This was, of course, the nutritional labeling that existed at the time. And you’ll recall that the Secretary made an announcement that we had urged him to make. The biggest announcement was on top of the front page of the *New York Times* and the *Washington Post*. That’s a big deal in the *New York Times* and *Washington Post*. And that really got the thing going, and the Secretary realized that this was something that’s important and needed to be done. And of course, there was a similar story in the *Times*.

So if you recall, then, we proposed regulations in mid-July of 1990 that sort of laid out a whole plan, but then Congress came along and passed NLEA in the fall and it sort of set us back. The interesting thing about that was, Congress was slated to go out because it was a mid-term election year. But if you recall, the President had dispatched his senior folks out to meet the senior congressional people at Boeing Air Force Base to cut a deal with the budget. That’s where President Bush reversed himself on his “Read my lips, no new taxes” pledge. And because they were all over at Boeing debating on the budget, Congress didn’t have anything to do. So they stayed around and passed NLEA. And that’s absolutely true. [Laughter]

Joseph Levitt (Director CFSAN): We believe you, Bill. We believe you.

William Hubbard (Senior Associate Commissioner for Policy, Planning and Legislation): But it would not have passed. And of course, at the same time USDA announced that they were going to do comparable regulations. And I think at that point our staff, the Center staff mostly, and the Food Safety Survey (FSS) staff were working well, although there were some issues, more at the senior levels.

Now I'm going to sort of basically stop here on the process. But one thing I did want to mention, there was a lot of interest, if you recall, in the format of the label, the look of it. And I think that the Center and the industry folks and the consumer groups knew that format was important, how you display the information. But that damn crowd in Parklawn didn't understand that. I feel like I was one of the people trying to say to Mike [Taylor], who kept saying, "Well, Hubbard, go off and you do your thing on format. You know, who cares?"

And you may recall that Dick Merrill's, Investigations Operations Manual (IOM) group had done a report before this that gave nutritional labeling a real impetus, I think, and we'd asked them to look at the format issues, but I think they realized after a while it was too much to sort of grapple in one report and so we didn't have a terrific start on format. But we were looking at a lot of things at the time. [Note from Richard A. Merrill: "I did chair a committee on nutrition labeling for the Institute of Medicine in the early 1980's. Mack Schmidt, former Commissioner, was a member. We produced a report that drew praise but Kessler decided to proceed with rulemaking before our report was turned in. I don't think we were asked to design formats but rather to recommend content and nomenclature."]

Remember some of these ideas that people were giving us at the time? This was actually a report by Gerson Associates that the Center had commissioned in the mid-eighties, and they'd been thinking about this way before anybody in the Commissioner's office. There were ideas for symbols. This was a real great one. And a pie chart. And of course, the old high, low, medium. And bar charts, graphics and little symbols for high, medium and low that illustrated certain things to avoid eating and eating enough of certain things.

Then people starting playing with shading. You may recall Jere Mann and others thought that was going to be a fun thing to do. [Laughter] And so there were lots of ideas about how to shade the label. Now, of course, most of these didn't take into account the fact that somebody had to really put it on real food, but it was still a lot of fun. And I don't know, there must have been two or three hundred of these, if you all recall, that were kicked around. And of course, we did end up with something that seemed to work.

I've got a couple things more when I come back, but I'm going to go to the next person now.

[Applause]

Christine Taylor (Director, ONPLUDS): Thank you, Bill. It's history like I never knew it. [Laughter] He was right about a lot of things; we know that now about Bill. Too bad we fought him as hard, at the time.

I'm going to now momentarily leap over a lot of things that actually happened, and turn now from the beginning to the 1993 outcome. While there were a number of components to what we call nutrition labeling, the nutrition content claims, serving sizes, health claims, as Bill has expressed, at the heart of nutrition labeling was the mandatory facts panel. At the time of the rollout in 1993, the first order of business was to get this facts panel out there and familiar to consumers, and media was the key.

So we're going to kick off our war stories with Bill Rados from the Office of Public Affairs. I'm just going to ask the rest of the war stories panel people to sit there, because I think being close to each other kind of offers a certain camaraderie that you might not get if you're sitting in the audience. [Laughter]

Bill, if you will just remain there. Bill remembers well those heavy days of getting the label rolled out as the New Public Health Initiative, and he has with him some of the more infamous media clips that we all came to know and love. So, Bill, the floor is yours.

William Rados (Director, Website Management Staff, OPA): Thanks, Chris. Everybody hear me okay? I appreciate being asked to come out for this celebration, because representing the PR folks, the communication folks, we weren't always in the thick of it, right in the trenches, like you regulation writers and scientists who were really doing battle on this stuff every day. We were busy, too, and mostly what we were busy with was bothering you folks while you were trying to write the regulations while we'd come down and say, "Take a look at this. Can we put this out?" You know, you saw all the various versions of the label that came out. I think we had a brochure prepared for

every one of those versions, and at the last minute we'd have to scuttle it and start over. It was an incredible undertaking, and it was a lot of fun. I keep telling myself that, and after ten years I'm starting to believe it. [Laughter]

I can't remember when we had a media campaign at FDA, and with all the many partners that we had, too, that involved different types of things, different widgets, than this campaign did over the years in the nineties. I mean, we did the usual things that we always did. We did brochures. We did FDA Consumer articles. We even did a special issue of FDA Consumer on the new food label. But we did videos, as you're going to see in just a minute, a variety of them, Public Service Announcements, video news releases, and we had a short educational video that we've used a lot. We also did posters.

We had to bring in extra help for something like this, as you know, because this is beyond the scope of what FDA usually dealt with. So we had folks like Sharon Natanblut, although I don't think there's anybody really like Sharon Natanblut. I don't know if Sharon's here today. There's Sharon. How are you? She came in and helped us with things like blimps. Who would have thought that we would be working with blimps on this? But we were. And we had, I think it was four or five different Goodyear blimps at that time that were flying over stadiums and other venues carrying the message about the new food label, "Check It Out." We had our message on the Jumbotron scoreboards in baseball parks. It was just amazing. Everywhere you turned this was popping up, not just in the grocery store. And these activities went on for a good long time.

These are the kinds of things that, looking back after ten years, you like to tell your children, these were growth experiences. At the time, I think they felt more like near-death experiences. But it looks better from this vantage point.

We're going to roll a tape in a moment that has some of these videos and it's by no means all of them, but these are ones that I think you'll really enjoy. And at the end I'd like to take a vote, an applause vote, to see which ones of these you like, the best now looking back, because you've got quite a variety here to pick from. We're going to start out with Curious George, our little buddy right here. I still carry him around with me everywhere I go. These PSAs were done with KidsNet. And we've got Curious George in the supermarket and then later on we've got Curious George in the kitchen. We've got English versions. We've got Spanish versions. Curious George, of course, being an immensely popular children's character that reached out to a lot of folks. It wasn't easy to get some of the talent that we used back then.

I don't know if you all know this, but we actually had to offer Curious George a full-time position with the Food and Drug Administration. And as it turned out, he was one of the many Deputy Commissioners that Dr. Kessler had back then. [Laughter]

William Hubbard (Senior Associate Commissioner for Policy, Planning and Legislation): And no doubt a better one than Mike Taylor. [Laughter]

William Rados (Director, Website Management Staff, OPA): You said that. I think he was planning to go to Yale with Dr. Kessler, but that didn't work out, so I think he burrowed into the bureaucracy and he's a lab director in the Center for Veterinary Medicine (CVM) these days, if I'm not mistaken. [Laughter]

But besides *Curious George*, we've also got the original *American Idol*, David Kessler himself, doing some of these things in the supermarket and making

announcements. It was hard to get Dr. Kessler in front of a camera, as you probably remember, but once we succeeded, it worked out pretty well. In fact, pay special attention to the first video with Dr. Kessler, where he's making the announcement about the new food label, because if you watch closely, he's got this kind of smirk on his face, and you can't help but think that he's thinking, "If you think this food label is something, wait until you see what I'm going to do about tobacco." [Laughter] And Dr. Kessler will appear again later in these videos as one of the earliest examples of reality TV where he's in the supermarket talking to someone about how fascinating the food label really is. [Laughter]

We've got professional baseball players, some of whom are still playing, incredibly enough. Roger Clemens is pitching, not with the same Boston Red Sox, but with the Yankees. Juan Gonzalez doing a Spanish version with Donna Shalala. I remember being in her office trying to get that take down pat, because she was not only catching a baseball, but trying to say "Check It Out" in Spanish, at the same time, and we did go through a few takes on that until we got it right.

But with all that let's roll the video if we can, please, and just sit back and enjoy some of these moments.

[Video played.]

William Rados (Director, Website Management Staff, OPA): This next one is the "Check It Out" PSA and we did this with the American Heart Association.

[Video played.]

William Rados (Director, Website Management Staff, OPA): And here's the reality TV segment ten years before its time.

[Video played.]

William Rados (Director, Website Management Staff, OPA): These were done with major league baseball players.

[Video played.]

William Rados (Director, Website Management Staff, OPA): I can never quite understand the logic of doing Spanish PSAs for a label that's in English, but it seemed like the right thing at the time.

[Video played.]

William Rados (Director, Website Management Staff, OPA): And these are the last two with *Curious George*.

[Video played.]

William Rados (Director, Website Management Staff, OPA): All right. That's it.

[Applause]

William Rados (Director, Website Management Staff, OPA): Let's take a vote. After ten years which of those PSAs do you feel held up the best? How about major league baseball? How about applause for whoever thinks that was the best?

[Applause]

William Rados (Director, Website Management Staff, OPA): And how about "The Fat that Jack Eats?"

[Applause]

William Rados (Director, Website Management Staff, OPA): One soul. Did you produce that one, sir? [Laughter] And then we got "Check It Out" with the people in front of the label and all that.

[Applause]

William Rados (Director, Website Management Staff, OPA): How about *Curious George?*

[Applause]

William Rados (Director, Website Management Staff, OPA): Thank you all very much. Oh, I thought that went without saying.

Christine Taylor (Director, ONPLUDS): Thanks very much, Bill. We really appreciated that. We're now going to really launch into our storytelling, and I guess the place to start is kind of where Bill left off. The Nutrition Facts Panel now is a familiar image, but for its time it was really quite remarkable. Certainly, the development of the label required all kinds of things from thinking about what its public health message was and how it should be connected to label claims and how to sell it appropriately as policy. But there really was an important question of design. And as Bill has pointed out it was multi-faceted, the Center worked on it, outside experts came in, and there were several key players from Parklawn, the *Parklawn Group*. All converged happily and at times unhappily to get this panel designed. And it really does represent an incredible piece of agency work and I have to say we amazed ourselves. On the day it was introduced it received a lot of media attention. It was front page on both the *New York Times* and the *Washington Post*.

And now if Mike would help me, I'm going to illustrate a little bit how important it was in the American lexicon through its presence in comic strips. Comic strips at the time really do show how striking and memorable it was to the world at large. This is one from *Fasttracks*. The last panel says, "What's this?"

And she says, "FDA law. Every comic strip has to have this." [Laughter] And it's a series of amusement facts.

This is the infamous *Sally Forth*, and it shows a lot of children in the supermarket lying around in shopping carts, and she says, “You don’t look very comfortable.” And she says, “They should put cots in supermarkets so kids can lie down while their parents take a look at the labels.” [Laughter]

We do have a vote from our canine friends. [Laughter] I like that one.

And then the proverbial *Blondie and Dagwood*. He says, “Let’s see what’s in here.”

And she says, “Take a look at the nutrition label.”

He says, “Sodium, sugar, fat. That’s just what I want.” [Laughter]

Now, it’s also important to realize that this label did become iconic. The Department of Energy has admonished electrical appliance manufacturers to try and communicate in the same clear way that FDA does with its nutrition facts panel.

The Drugs Facts Panel took a cue from us. And perhaps one of the highest compliments that we received was in 1994, The President Award for Design. If you look at the top, this is part of the judges’ decision and their criteria, “It’s a superlative example of design.” And then down at the bottom, “FDA’s research, testing, and scrutiny have refined them into a structure so logical and so sturdy as to give the label an almost iconic quality.” We amazed ourselves. We were glad that the President figured it out.

Perhaps the highest compliment, though, and testimony to its iconic nature is that it’s used in advertising. We’ve got two very interesting examples. One is from a box of Puffs. These are facial tissue facts. Perfume, 0 percent; ink, 0 percent; dyes. And then my all time favorite, Joe Boxer. The nutrition facts there are really quite seductive in their own way. The nutrition serving size is one classic brief. Servings per container,

three. Freshness, 100 units. Goodness, 100 units. And then the percent daily value of total fun, saturated fun, quality, nice fit, and comfort.

William Hubbard (Senior Associate Commissioner for Policy, Planning and Legislation): I find this kind of embarrassing, myself. [Laughter]

Christine Taylor (Director, ONPLUDS): And on that note we're going to turn from Joe Boxer to Ed Scarbrough. We're going to go just slightly out of order with the agenda and turn back now to the substance and the process of getting those regulations developed and to Ed Scarbrough. Getting these things written down and logical was a Herculean task that took a lot of people doing a lot of different things, and there were certain people who were central, and Ed was one of the most, if not, in my opinion, the most central of these.

Taking the statute and turning it into twenty-some implementing regulations is mind-boggling even now that we know it happened, and it was definitely very daunting then. A lot had to happen at a lot of levels. The Center's expertise and thinking had to be married to the policy thinkers at Parklawn, at the agency level. And the agency decisions had to be pushed through and vetted at the department level. Stakeholders had to be dialogued with. And of course, somebody had to sit down and write the regulations. And as I said, that responsibility fell squarely, and I'm sure he'd say heavily, onto the shoulders of Ed Scarbrough. This task had to have taken the patience of Job, especially at the beginning when most of the people who had been conscripted to serve him had the alarming opening question of, "What's a regulation?"

We were fortunate in Ed in that he is one of the best writers, at least I've ever known, and possesses the invaluable skill of being able to take a half-baked, rambling document, like most of us would probably plop onto his desk, and make it into something useable, logical, and at times Ed even made the document sing, to the extent that any preamble can sing. He also had the remarkable skill of tracking a whole bunch of those developing tones and making sure they didn't run in different directions.

Ed obviously had to sit through endless meetings, both with the droning staff and anxious stakeholders. For example, I remember one very interesting meeting with the Pickle Packers Association, who were having great trouble packing their pickles in ways that allowed for standard serving sizes. But Ed had a mechanism for dealing with the potential for unending meetings that to this day I don't know if it was just fortuitous or actually planned. He had the hottest office in the building. [Laughter] It was the kind of heat that after about thirty or forty minutes you had a headache and your sinuses became like the Sahara Desert. I think in any other office we could have gone on and debated and debated, but in Ed's office you just wanted to end it. [Laughter] And so the meetings were perhaps much shorter than ordinarily would have happened in a regulatory setting. And my belief is that it is this fact that kept Ed from going off the deep end. Years later I looked all over that office to see if there was a thermostat he could have manipulated, but there was not. I think he just had a few NLEA gods looking out for him.

Ed has now moved to USDA, but he has graciously come back, at a busy time for him, so he can share his recollections. Ed.

F. Edward Scarborough, Ph.D., (U.S. Manager for Codex, USDA, FSIS): Thank you very much, Chris.

[Applause]

F. Edward Scarborough, Ph.D., (U.S. Manager for Codex, USDA, FSIS): The introduction was too kind, but then you started off with boxer advertisements. I don't know what the connection was, although I noticed that they were made in Thailand and I'm now in the international area. It's interesting that many countries look at the U.S. label. The U.S. model really served for the Canadian label regulations that have come out just recently. I notice Ann McKenzie from Canada is here. The Canadian regulations seem to be working just like the United States' regulations, because they published a study within the last couple of months that obesity is on the decline there, as well, as the United States. It had the effect, and not quite the effect we wanted, but it does seem to have a universal effect.

I hate to contradict Chris, but I really didn't write the regulations, and I have to start off with a nod to the person who really did write the regulations, and that's Virginia Wilkening.

[Applause]

F. Edward Scarborough, Ph.D., (U.S. Manager for Codex, USDA, FSIS): Virginia and I worked long and hard together on this. But we did actually go around the world on

NLEA. We went around on the Department of Commerce. Started out through Frankfurt and went to Singapore and Malaysia, Vietnam, Thailand, Indonesia, Hong Kong, and back through Chicago, circled around the world, a great trip.

There's a story, though, that I told when I left FDA, and I'm convinced it's true, although I can't find the evidence for it now. We were working late one night. We'd been working twelve, fourteen hours and reading the regulations, and we came upon a sentence, and I said, "What does this sentence really mean?"

And Virginia said, "I have no idea. I don't know what it means."

We kicked it around for a while, we wanted to go home, and we said, "Well, Phil Derfler will catch it." And we shipped the regulation out to Phil, and he never caught it. So, somewhere hidden in those twenty-five regulations is a sentence that is just incomprehensible. [Laughter] I still don't know quite what it meant, but now I can't go back and pull it out and put it up there.

But talking of Phil, I guess that's the other person we should acknowledge for who really wrote the regulations.

[Applause]

F. Edward Scarborough, Ph.D., (U.S. Manager for Codex, USDA, FSIS): I'm sorry Phil wasn't able to be with us today. But he is responsible for a new word coming into the English language, and that word is "Derflerizing." And it doesn't mean just to edit, and it also doesn't mean just to edit and re-edit to put back into the document the material that was there to begin with. It also means to do it with an unsharpened pencil while

riding on the Metro, so that you can hardly read what it is. I mean, somebody ought to give that boy remedial computer lessons or something. [Laughter] It's so much easier with Word and tracking, etc. But he still insists, and he's now down at the Department of Agriculture inflicting "Derflerizing" on USDA, as well, and I hear some of the same complaints that I heard before.

Speaking of USDA, we've got Maggie Glavin with us. At USDA they really know how to work. They harmonized their regulations by copying what we had written, and then they got bonuses that were larger than the bonuses we got for writing them to begin with. [Laughter] They had a smaller pool in the bonus pool because when it came time to hand out bonuses there were people coming out of the woodwork at Parklawn I had never seen. [Laughter]

William Hubbard (Senior Associate Commissioner for Policy, Planning and Legislation): Some of Mike's staff, no doubt. [Laughter]

F. Edward Scarborough, Ph.D., (U.S. Manager for Codex, USDA, FSIS): But seriously I think one of the real accomplishments of the NLEA is that a number of regulations were put out at the same time and there is an internal coherency. They hang together. And we really did spend a lot of time thinking about "If you change this, what does this do over here?" kind of analysis. So that we tried to keep it a very consistent set of regulations. I think it would be a good model for Maggie to take back to USDA and look at their policy book. Whatever you want to do, you can find it in the policy book somewhere. The consistency needs to be looked into a little bit there, I think.

And then, of course, mentioning Parklawn, Mike Taylor, of course, was out there. I did go out and buy a copy of David Kessler's book when it came out, and it was a different regulation he was talking about in that book. Jere Mann really didn't write that much of it. [Laughter]

I requested of Chris that I go on before Regina [Hildwine], because I learned a valuable lesson while we were in the midst of this. Regina and I were on the same program, it was an industry-sponsored program, and she got up and she was vicious. I mean, it tore the regulations, FDA. I mean, it was almost an ad hominem attack on the idiots who wrote these regulations. And when she finished, she came back, sat down, cheery, and we're chatting as if nothing had happened. [Laughter] I'm sitting here saying, "From now on, get on before Regina and take your shots first." At least, you know, you have a chance that way, otherwise you don't have a chance.

I was going to say some funny things about serving size, but maybe that's just a joke enough in itself, because—

William Rados (Director, Website Management Staff, OPA): I'm going to take care of that for you.

F. Edward Scarborough, Ph.D., (U.S. Manager for Codex, USDA, FSIS): That was one part of the regulations I always wanted to go back and really straighten out, but never had the energy to do. But if you want a laugh, just go look at ice cream, or some of the serving sizes.

But really, finishing up with a true, absolutely true story, and I'm glad to see Steve Steinbourne because he'll probably verify it for me, I hope. But when I was in the position of Director of the Office of Food Labeling, on Sunday morning I would get up very early and go to the Giant to get a bagel or muffin for breakfast, and I would literally spend an hour, hour and a half, in the Giant reading labels, going up and down the aisle, seeing what the various companies were doing, what were the mistakes being made, how was information being presented.

There was one day I sort of turned to backtrack and ran straight into Steve, and he was right behind me looking at the labels I was picking up. [Laughter] And, you know, I thought, "Oh, no, here's the ultimate form of label ambulance chasing." [Laughter] "If FDA frowns, there may be a client there.."

William Hubbard (Senior Associate Commissioner for Policy, Planning and Legislation): It's a good idea.

F. Edward Scarborough, Ph.D., (U.S. Manager for Codex, USDA, FSIS): And finally, just a story. I'm from Tennessee, from back in the hills of Tennessee, and when I went to visit my parents, ten, fifteen years ago, one of the real entertainments since there wasn't much to do, was on Saturday afternoon go down to a store called Big Lots. Big Lots had a couple of entertainments going on. First, the clientele. I mean, some of those guys look like they came out of trailers back in the hills of Tennessee. You know, there's always some underlying truth in a stereotype, and here was an underlying truth of the stereotype of hillbillies.

But also they had a fairly large food selection of lots that had been salvaged, and the labels on there were just amazing. You could just go through and see label after label with mistakes, misspellings, illegal, and incorrectly done. They had lots of food for sale with labels that were not even intended for the U.S. market, in foreign languages. And the people were in there buying these large quantities of these labels. So that was good entertainment on a Saturday afternoon.

This summer I was back in Tennessee, and I went to Big Lots to see the labels, and actually the labels were much better. I found very few that I thought were completely off the wall. A few minor mistakes here and there. The store itself, they tried to make upscale as well as the clientele. It was very interesting, because in the store with me were a couple of guys who I guess were Vietnamese. And then there was a large Hispanic family going through the aisles, buying food. I followed them out into the parking lot and they got into cars with the local license plates. I'm saying the world has really changed when that kind of ethnic diversity is getting back into the hills of Tennessee. That's great. I mean, we're seeing a real change in the United States, and I think we did change the United States, as well, with the label, because it is everywhere.

Just to end up, I also had a cartoon from last Sunday's paper with the nutrition label on fish. It's still showing up. But my favorite is the glass with the nutrition labeling for beer on the back. So that really is the basics.

Thank you very much.

[Applause]

Christine Taylor (Director, ONPLUDS): Thank you, Ed. We're now going to turn to Mike Taylor. Mike was Deputy Commissioner for Policy at the time. David Kessler brought him into FDA in mid-1991 for the specific purpose of helping with the implementation of NLEA. His primary job, which few of us at the Center actually got to see him do, was to escort these regulations through the department into a final reality. He was one of the Parklawn group, and we'd see him come into the building and whoosh up to the sixth floor just like everybody else, and yet he was definitely the one who was called in when there was a knotty issue, and he had the remarkable ability to bring calm and order to a completely chaotic discussion fast going the way of either a shouting match or *Saturday Night Wrestling*.

He used to scare us because he got to the heart of the matter so fast. We'd all be prepared for a long, drawn-out explanation of why something was the way it was, and before we could get it out, he'd state the bottom line more clearly than we could. A supreme compliment was paid to him from the highest possible authority on regulations briefing, Virginia Wilkening. Once recently in a conversation when Mike's name came up, Virginia got a very dreamy look in her eyes and said, "Ahh, Mike. He was such an easy brief." [Laughter]

Michael R. Taylor (Senior Fellow and Director, Risk, Resource, and Environmental Management Division, Resources For The Future (RFF)): We'll have a drink later, Virginia. [Laughter]

Christine Taylor (Director, ONPLUDS): Now, on a personal note, despite the fact that Mike and I have a close relationship now, we were definitely not close at the time. Mike and I had one conversation—one conversation—during the entire NLEA development process. It lasted less than two minutes. I'd been told to present to him a particular problem and get him to weigh in. The issue, the specifics of which I've long forgotten, involved some type of declaration for a nutrient that was best illustrated by a box of Maypo cereal. I remember dutifully approaching Deputy Commissioner Taylor during one of these sixth-floor meetings and launching into whatever the problem was, holding up my box of Maypo.

About thirty seconds into the conversation I looked over at his face—I'd been focusing on my box of Maypo—and it was clear that he thought he was dealing with a deranged person. I tried all the harder to explain the issue, waving the box all the more, and he definitely took a step back. At that point, realizing that I didn't even know what I was talking about anymore, I decided to retreat with some dignity and said, "Well, I'd better go back to my office and figure this out."

Mike said, "That would be a very good idea." [Laughter]

Knowing that I had humiliated myself beyond any acceptable standards, I avoided the man like the plague for the rest of the entire NLEA project. Only recently did I learn that he has absolutely no recollection of that at all. But he's here today to talk about the things that he does remember, and I'm glad our Maypo conversation is not one of them.

Michael R. Taylor (Director, RREMD, RFF): Thank you, Chris.

[Applause]

Michael R. Taylor (Director, RREMD, RFF): Louise and I don't remember, I should say, that Maypo conversation, in addition to the mesmerizing effect of being talked to by then Dr. Lewis. I think it was because my brain was completely consumed and obsessed by trying to understand the jelly bean rule, which I still don't understand. I wonder whether anybody understands the jelly bean rule. But it was one of many that was challenging.

It is really good to be back with this group, and I particularly think of Ed, Mr. Substance, and Bill, Mr. Process. You know, Ed, in all of the complexity of these rules and the difficulty of the substantive issues, really was the person who had his arms around the whole thing. And it's striking that you kind of emphasize, Ed, this notion of logic that it all hangs together. That was exactly the metaphor to such a compelling internal logic of these rules, which as I'll suggest in a few minutes, was critically important to everything that happened after they left the Center. That was compelling.

Bill, on the other hand, Mr. Process, you know, I really didn't realize it when I actually talked to Joe Levitt when I first arrived at FDA trying to set up an office. Bill had been working for Joe in the Office of Executive Operations and I talked to Joe about Bill. I didn't really know him that well. And you know, what could he bring to the Office of Policy? Joe said, "Well, he's a process genius." Little did I know that that translated into Bill being a guy who would never read a regulation. [Laughter] You know, this is a conviction with Bill. He always managed to arrange things so there was always somebody at the Center or somebody above him in the Commissioner's Office

who would read the regulations. And as it turned out, that fell to me. He assigned me that task since Kessler was signing off on the regulations for the *Federal Register*, along with [Louis] Sullivan, but neither Lou nor David, I can assure you, read the regulations. So I felt obligated.

But that was a very critically important experience for me because it equipped me to deal with the issues that came later. I thought that it might be instructive just to illustrate the internal logic of the regulations, and really to show Bill what he missed in not reading these regulations. Read a few excerpts from the serving size, the preamble to the final rule on serving sizes. And there are several here. Stop me when you've had too much. I could go on with this for quite a while, but these illustrate various important points.

The first comment that I'll read here illustrates that there really were big interagency issues and not just with USDA. According to the preamble, there's a comment from an unnamed federal agency stating that there should be a products category for gelatin salad. I assumed this was the Army, from my mess-hall experiences. But let me just read to you quickly. In the 1991 serving size proposal, this is FDA's response to the comment, "All gelatin products were included in the custards, gelatin, or pudding category under desserts. Because some gelatin products are served as salads, rather than desserts, FDA agrees with the comment that it would be desirable to have a separate category for gelatin salads. Accordingly, a new category, gelatin salad had been added to Table 2 in new Section 101.12(b)."

This is a key point here. “Following the general principles and the procedure described in the 1991 serving size proposal, FDA has determined the referenced amount for the category to be 120 grams, which is equivalent to a half cup.”

Now, this, to me, is a striking example of the fact that lots flowed from common principles, which Ed established and was the guardian of. But comments, of course, came from industry to a great extent, and there’s a comment here that I think captures both the essence of some of the critical issues and also the active mind that was at work at FDA in dealing with these comments. This is Comment Number 34 in the preamble to the final rule. An industry comment, according to this, requested that FDA add—quote—“crumb cakes and similar products”—close quote—to the “coffeecakes” category under bakery products. The FDA seriously engaged this comment.

Bear with me to follow the logic from this and the exquisite attention to detail. “FDA advises that because crumb cakes are similar to coffeecakes in their nutrient content and use in the diet, governing principle, coffeecakes and crumb cakes are included in the same food code in the National Food Consumption Survey. Consequently, crumb cakes were included in the coffeecake group in determining the customarily consumed amount of coffeecakes. Therefore, the agency agrees with the comment that it is appropriate to include crumb cakes in the name of the coffeecake category. However, the agency finds that it would not be appropriate or desirable to add a term such as ‘similar products’ to the product category name because such a term could be interpreted differently by different companies and may result in inappropriate classification of a product.”

And this is where we get to the kind of nub of the matter. “For example, because apple crisp has a crumb topping, like crumb cakes, it could be misclassified as belonging to the coffeecakes category. However, apple crisp belongs in the pies, cobblers category, not the coffeecakes category, because apple crisp resembles products in the pie, cobblers category in nutrient content governing principles. And in use in the diet as indicated by being listed in the same food group as cobblers in the National Food for Consumption Survey. Therefore, FDA has modified the name for the coffeecakes category to read Coffeecakes, crumb cakes.”

And finally for clarity, it says, “For clarity, FDA has also modified the name for ‘pies, cobblers’ category to read, ‘pies, cobblers, fruit crisp.’”

William Hubbard (Senior Associate Commissioner for Policy, Planning and Legislation): Mike, may I mention that my signature is not on that, but yours is.
[Laughter]

Michael R. Taylor (Director, RREMD, RFF): Here’s another one where I think the old folks got a little carried away, and this is a comment from a manufacturer requesting that FDA not use the term “Popsicle” as part of the product category name because it is a trademark owned by a particular company.

The FDA response is that, “FDA has deleted Popsicle from the product category name. The new name for the product category is ‘frozen flavored and sweetened ice and pops, frozen fruit juices: all types, bulk and novelty (e.g. bars, cups).’”

There’s more. There’s a good one here on pickle relish, but we’ll just skip right over that.

This version of the regulations before it went to the *Federal Registry*; actually, the pile of documents you see on the floor here is actually all of the documents as they were prepared for sending to the Office of Management and Budget (OMB). And Bill, these are for you. It's never too late to read a regulation. Maybe you could get someone to read them for you. You know, maybe Les Crawford would like to read them.

William Hubbard (Senior Associate Commissioner for Policy, Planning and Legislation): Mike, they got a new invention now, it's called a paper shredder.

Michael R. Taylor (Director, RREMD, RFF): Yes. As Chris said, my principal role in the process was to shepherd the regulations through the Department and through OMB. I had a very clear assignment, which really arose from the internal logic of the documents, but also from David Kessler's expectations, which was basically not to let anybody change anything relative to the Department or OMB. That was sort of my mission, and that actually made it fairly simple because you didn't have to think a lot; you just had to not agree to their ideas.

The Department part of the process was a lot of work, and I think it's fair to say folks, who were involved in that, and I know Ed and Chris and Betty and Virginia, a lot of folks went over and had lots of meetings with staff at the Department. They put us through the hoops at a staff level, but Secretary Sullivan was not a problem, and he got it instantly, as Bill said. I mean, he was completely there on the public health importance of this, and so the sort of saving mantra to ourselves, "As long as we get to Secretary Sullivan, as long as we get around that conference table in his suite, we'll be okay." And

that's really the way it worked out. I think the documents that went to OMB were essentially clearly the documents that FDA had developed.

I think it's fair to say that the Office of Management and Budget and the other White House staff offices posed a somewhat different challenge. OMB, as now, is populated with some incredibly bright, incredibly young people who ask very hard questions and are charged with doing that. That's their job. So we went through an enormous grilling on the substance of the regulations. And in all seriousness, the thing that made it possible to sort of go through that was the internal logic of the documents. You could not play here because you had a little problem with this regulation, without considering all the things that would happen over here. Ed could come in, in an elegant way, and just explain that and sort of relentlessly go through the reasoning. And I think, frankly, we basically wore them down.

There were other components in the White House, of course, besides OMB, who were involved in the process. At that time Vice President [Dan] Quayle, had a staff and an operation called the Competitiveness Council, I think it was called that. He also had an interest in regulations. And so there was kind of a parallel sort of shadow review going on of the regulations. So in addition to the front door review at OMB, there was this sort of back door review at the Competitiveness Council.

I remember one late night meeting, Michael J. Calhoun, who was then Lou Sullivan's Chief of Staff, and I were over there with two of the staffers in the Quayle operation, and we really thought we were getting close to the finish line, wanted to get these regulations cleared, needed that office, obviously, to sign off. And of course,

Michael J. Calhoun was representing Dr. Sullivan's public health perspective on these, and all the reasons why we needed to get these regulations out.

Finally, at one point, the senior person on the Quayle staff, who later served in Congress, if you know who I'm talking about, you know, looked us in the eye and simply said, "We don't think the way you do." And that's when I knew that we had a little problem here.

I think as everybody knows, ultimately the real debate and the controversy around these regulations arose from some differences between the two departments, USDA and Health and Human Services (HHS), over format, principally, and a couple of other issues. I stress, when I think about this, and talk about this point that Pat Jensen made, but it's a really important thing to remember that, in fact, USDA didn't have a statute and didn't have a requirement to do this. And Secretary [Edward] Madigan, who'd been involved in NLEA's adoption on the Hill when he was a member of Congress, made a commitment that USDA would issue regulations and that they would be consistent with the HHS regulations, and that's an enormous big deal. You probably shouldn't complain so much if USDA is conforming its regulations to FDA's, that's not all bad.

Although when I did mention this sort of collaborative thing and said what I thought what was a good model for interaction between the agencies, I mentioned this to Bill Hubbard yesterday, in thinking about this, and he looked me in the eye and said, "Once an Aggie always an Aggie." [Laughter] I don't know what he meant by that.

So there was a lot of back and forth, as everybody knows, between USDA and HHS, and essentially reached an impasse, particularly on the critical issue of the format of the label, and what it had to do with the use of daily values. Also, the question of what

daily calorie intake to assume for purposes of calculating the daily values (DV's), which would, affect the percent daily values, which would affect the way products look, particularly in relation to fat.

If you recall, this debate was going on leading up to the statutory deadline, the so-called hammer date, for the regulations. This was on the second anniversary of the passage of NLEA, which was a couple of days after the '92 election, which was when the hammer would fall. And this became a somewhat sensitive conflict politically just because I think the White House didn't like the idea of having two cabinet officers at loggerheads around election time.

So the solution to that was to lock the agencies up in the office of Tom Scully. Tom is now the head of the Medicare and Medicaid Services Center down at HHS, but then was a senior OMB guy. So I was essentially locked up in his office with Bill Connor and some other folks. Maggie, I don't know if you were forced to sit through those. But they got the politicals in the room and basically told us to behave until the elections were over.

And then essentially the White House took charge of getting this issue resolved. I'll never forget the first time I was told by the General Counsel of OMB that the White House had decided that the President was going to have to resolve this impasse. And to me it was surreal to think that the President of the United States, particularly at that point, a lame-duck President, would be asked to resolve this issue, that there wouldn't be some other way that it would get resolved. But he said, "That's what he does; he resolves disputes."

I said, "Well, okay."

So we set about working with him to prepare a decision memo for the President, which was a document that the two departments agreed to, so it was an objective presentation of the issues, and it went up through the system. And we were told that a meeting that was to be scheduled with President Bush and the two cabinet officers Monday, November 31st, just three or four weeks after the election, a few weeks after the hammer date had gone down. So we were kind of in legal limbo. And so the President was going to be asked to decide on these issues that separated the agencies.

This was obviously a big deal for FDA and for the regulations. Secretary Sullivan obviously regarded it as a big deal, as well, so we put a lot of effort into prepping him and trying to give him props that would help convey what we were talking about. And so we obviously had a whole bunch of the alternative formats that we prepared and sent over to try to show the differences between the format ideas.

But also there was an issue, as I mentioned, about the calories that would go into calculating daily values, and we discovered that McDonald's was providing nutritional information in its tray liners. At that point, McDonalds had adopted a similar sort of approach in terms of daily values, and had used a 2,000-calorie diet, which was the FDA preferred approach in calculating their value. So we had collected some samples of these tray liners and the night before the meeting with the President, David and I went over to Sullivan's apartment and we briefed him on what was going on, and gave him these tray liners. Thinking they would be a nice illustration, you know, at least for him, of what was going on and what the issue was, and if it was good enough for McDonald's, you know, wouldn't it be good enough for USDA? [Laughter]

So, Monday morning this meeting was on the schedule and I was asked to go with Sullivan. The fact of the matter is, Dr. Kessler seemed to get under their skin a little bit at the White House, and that's really the reason, I think, that I was asked to go over and be in on a lot of these meetings. So it was left to me to ride over to the White House with Dr. Sullivan, but I was sort of to be held in reserve. I wasn't going to actually be in the meeting, necessarily. So I was put in an office over the Old Executive Office Building while the meeting started. And I was sitting there wondering what was going on, when someone came in and said, "You're wanted in the Oval Office."

I said, "Well, okay," without knowing what it was. Let me just say, as a tourist or anything else, I'd never been in the Oval Office, so this was kind of a critical moment in my young career. So we walked over and walked in through the little room where the President's secretary on *West Wing* sits. It's very authentically done. And into that door it's sort of right over the shoulder of the President when he's sitting in that chair in front of the fireplace. I'll just never forget, they opened the door and I looked in there, and I thought I was walking into a wax museum, because sitting in the chairs were all these figures that I had not had a lot of personal dealing with except Dr. Sullivan—you know, the President in his chair and Vice President Quayle in his chair, and Jim Baker in his chair, sitting at the opposite end of the couches. Secretary Madigan, Secretary Sullivan on the couches, Marlin Fitzwater on the couch, and there was an empty chair, again, at the far end of the couches.

So I walked in and, again, I thought I was in a wax museum until President Bush stood up and walked over and very graciously shook my hand and said, "Come in. We have some questions for you." And the question they had been debating was whether at

this stage of the administration if the President had wanted to arrive at a different decision on format that FDA had arrived at through its rule making, could he do that? Could he basically decide to adopt a different format that had come out of our rule making process? And so he asked me this question, he says, “If I want to pick a format that’s different, why can’t FDA just salute smartly and go implement that?”

You know, the only thing that came to my mind was a nautical reference, and I’m not sure why. He got the military involved with this snappy salute way of putting it. I forgot he’d been a pilot in the military and not a naval skipper. But the only thing I could think of to say was, “It’s like turning an aircraft carrier, Mr. President. You can start turning the wheel, but it takes a long time to turn the boat around,” and basically in not so many words, “you don’t have enough time.”

I was really referring to the fact that this format had come out of this incredible rule making, you know, with thousands of comments, all these public hearings, and this is what Secretary Sullivan had decided the law required to implement it faithfully, and there was this whole record behind it. And if you wanted to change that, you’d have to go back through the rule making process and open it up and get a record essentially that would support a fundamentally different outcome.

In response to that, Vice President Quayle sort of protested mildly, “Is that really the case?” And I don’t think necessarily trusting me on the issue. And very fortunately, Jim Baker, who’s a lawyer, as well, jumped in, in support of this basic administrative law concept. And I think that was a critical kind of resolution of an issue that had clearly stymied them enough and had been important enough in that conversation to justify bringing the staff, me, into the discussion.

I then went out and sat in that little office outside the room. Kessler's fixating on this fact that one of the President's dogs was hanging around in that room and it was, like, sitting on the floor by me. And it's true. It was not the biggest thing on my mind at the moment, but David tells this story repeatedly. She's a nice dog. But I was sitting there not knowing whether I was going to be called back in or not, so I was not focusing on the dog. And they did call me back in. I think there was an issue about "lite."

It was just so striking because, you know, here an issue that we'd been laboring on in the trenches for so long, it was so in our professional lives, to walk in there and see this set of folks working on it, to see the McDonald's tray liner and these various draft formats that Bill showed, strewn all over the coffee table in the Oval Office, you know, as these guys were really grappling with it, it was quite a striking kind of experience.

So the meeting ended, and we went back to the department and basically were told that the President would get back to us. Well, two days later on Wednesday, December 2nd, we were called back over to the White House. And so Dr. Sullivan and I went back together in the car. And by that stage of the administration, Bob Zellick, who is now the U.S. Trade Representative, was the Acting Chief of Staff. Baker had left officially, and so it was Bob Zellick who actually rendered the decision. He brought us into the office and he sat us down in his little office there in the west wing and said, "The President has made a decision." He said, "He's selected label 2C."

And I wasn't sure right away what that meant and I sort of shuffled through my little stack of formats and, you know, by golly, it was the label that we had recommended, but with an interesting kind of compromise, and there is a compromise in that label. The reason you've got the column of 2,000 and 2,500, you know, the

nutrients—you know what I'm talking about. I forgot. But where we show the daily value of fat and other nutrients under a 2,000- and 2,500-calorie scenario is, I believe, the President or the staff knew a way of cutting the baby with USDA. Because critical to USDA was this concern about 2,000 being too few calories for the average person, and overstating the fat content of products. So there were a couple of other issues. We won, I think, on "lite." We lost on restaurants.

But Dr. Sullivan, when we got in the car and went back, I mean, he was just exuberant at the outcome of this, as was I. So we went back over to the department and we went up to his office. I, of course, didn't have a cell phone at the time. I had no way to call Dr. Kessler and tell him what was going on. Bill can tell the story about him and David sitting up in that office on the sixth floor wondering what was going on here. I was swept along with the Secretary and went up to his office, because we'd been told to announce the rules that afternoon. So we went up, went into his office, and finally somebody called and David came over.

But the vivid memory for me is sitting at that little table in Dr. Sullivan's office and working on a press release. I think there had been something drafted that, you know, a sort of perfunctory sort of release in anticipation of this outcome. But Dr. Sullivan took a pen to that draft and he spoke the words that he wanted to say. I have the press release here, and he says—quote—"The Tower of Babel in food labels has come down, and American consumers are the winners." Secretary Sullivan said, "For the first time consumers will be able to use a single format for virtually all processed foods to compare nutrition values and make healthy choices." And that's the way the regulations were announced.

My view is that it is a good thing to have worked on and to have accomplished. And I've got to say, and it's a running joke with my daughter, but I've never stopped being proud of being involved in that effort and pointing it out to her and saying, "I worked on that." And she's tired of it, but I'm not. [Laughter] And again, it was a truly formative and fabulous experience for me. I'm delighted that we're back here and can reminisce a bit.

Thank you, Dr. Taylor.

[Applause]

Christine Taylor (Director, ONPLUDS): Thank you. We've finished the part of Mr. Inside and Mr. Outside, and we're now going to turn very quickly to three other people who had a significant impact upon the rules or represented groups that had an impact. The very next is USDA. The representation by Maggie Glavin, I think, is a very good one. As we've all heard, NLEA was targeted and meant for the foods that were regulated by the FDA, but notably USDA also had foods. At the time in the early nineties USDA recognized the desirability of coordinating their efforts, and while that's an easy statement to make now, as you've heard, it was not the easiest thing to accomplish. But we did work closely with the staff and developed many important relationships and friendships with them that have held over time. And I would say from my vantage point of the director of the office that does deal with food labeling, we have a flawless, seamless, and very good relationship with USDA.

Maggie Glavin, if I have your title right, you were Deputy Administrator at the time of NLEA. She is here to share her memories with us. Maggie.

Maggie Glavin (Visiting Scholar, Resources For The Future (RFF)): Thank you. Who knew you were having so much fun at FDA? [Laughter] Honest to God, we thought we were working hard. It's not easy to copy harmonized regulations. We'd be working late, and occasionally eight o'clock at night on the Metro Center platform I'd run into Ed, and we'd sort of commiserate about how hard it was. And now I know he was going home to write another change that we'd have to harmonize and then do again. And the Phil Derfler corrections. Oh, my god. Terrible. Absolutely terrible.

You know, it was really tough at USDA. First of all, you know, this was all supposed to have improved Americans' diets. And I don't know about FDA, but at USDA you got coffee for breakfast, chips for lunch, and a takeout pizza for dinner. So our diets were just absolutely shot. And in between times you had to be in Bill O'Connor's office, where he chain-smoked. So, bad health from NLEA.

However, one of the things I remember is that the lunches of chips and Reese's Peanut Butter Cups and all those good things did lead to a lot of interesting discussions about why certain foods should not be labeled. And to this day I really believe that things like chips and Reese's Peanut Butter Cups should not be labeled. When you eat them, you know you're eating things that are bad for you. You don't need to be reminded. But I don't know. My vision didn't prevail.

However, you know, for all the fun you were having, immediately after NLEA, you all came over to USDA. [Laughter] I don't know.

William Hubbard (Senior Associate Commissioner for Policy, Planning and Legislation): When they got there they copied our Hiring rules. [Laughter and applause]

Unidentified: That's rough. That's rough.

Maggie Glavin (Visiting Scholar, (RFF): You know, history is being rewritten as we sit here. [Laughter] When Mike came over, he said, well, he really wanted to bring some FDA talent over with him. Phil and Ed were begging, begging, to get out of FDA. I mean, I'm not saying there's a connection here, but it is absolutely God's honest truth that their paperwork to come to USDA was not finalized until the day a large shipment was delivered to the Administrator's office consisting of many cases of Diet Coke. [Laughter] Well, I don't know.

Anyway, I do think that despite all of the hard work and the late nights and the bad food and some of the hiring shenanigans that went on in its wake, the nutrition labeling regulations really are a tribute to regulatory agencies putting aside differences, albeit with difficulty and with some blood on the floor at times, but putting aside differences in the interest of serving the consuming public. And I do think it's really fun to be here for the celebration of that.

[Applause]

Christine Taylor (Director, ONPLUDS): Now I'm going to turn to Bruce Silverglade and his Center for Science and the Public Interest, and from our perspective they speak for the consumer. We have Regina Hildwine here with us for the industry and Bruce is here to speak for the consumer.

Bruce and the CSPI staff took their responsibility during NLEA very serious and they did their jobs well. Bruce was one of the strong and always present players during the process of developing the regulations, but he was also key in getting NLEA written into law. He worked tirelessly to organize consumer and professional groups and to harness their power into a single voice that helped to push NLEA towards enactment. The agency itself, as you've heard, had begun a labeling process, but when NLEA came, it gave incredible impetus and validity to what we were trying to do. He faced difficult and complicated work, and Bruce never stopped. There was no issue too big or too small for CSPI to tackle.

What stands out in my mind and what I remember most was Bruce's willingness to listen. He'd listen to our issue very carefully and intently. You could almost see the energy it was taking to listen to what we were saying. He'd go back to his office and think it through, and then offer creative solutions. It's a quality that's highly valued during the process of developing regulations, and Bruce offered it.

I suppose you could say we never knew what Bruce thought about us, but his apparent delight in being asked to come and share in our celebration today suggests that maybe he remembers the times with some pleasure. And we know he surely has some stories to tell, and I take pleasure in introducing you, Bruce. Thanks.

[Applause]

Bruce Silverglade (Legal Director, Center for Science and the Public Interest (CPSI)): Thank you very much, Chris, and it is a delight to be here. We've kind of been going in reverse chronological order talking about how the regulations were developed. Of course, these regulations were mandated by a law passed by Congress. I'd like to give you a little bit of behind-the-scenes history of how that law got passed.

I came to CSPI in the 1980s, and Mike Jacobson, CSPI's Executive Director, would come to me with packages like this, Sara Lee "lite" cheesecake that had more fat and calories per serving than Sara Lee's regular cheesecake, and he'd say, "Do something about this." And I would, I would write a complaint or a petition to FDA and meet with Bob Lake and Bob Lake would say, "Well, Bruce, you know, these "lite" claims are kind of a light issue. I don't think we have the resources for this."

So anyway, in my naivete, I sat down at my desk and decided, well, we need to pass a new law, because this case-by-case approach obviously isn't working. So we met with Scott Balen from the American Heart Association, and Ellen Haus from Public Voice for Food and Health Policy, and the three of us wrote a new law, essentially. We took it to Mr. Waxman, who chaired the Health Committee, and we said, "We'd like this introduced." And he said he's busy.

So we decided to form a broader coalition. It became clear to us that nutrition labeling wasn't just a consumer right-to-know issue; it was an essential public health measure. And we began contacting the leading health and medical and public health groups across the country and formed a coalition called the Food Nutrition Labeling

Group of about twenty-five such groups, including the American Cancer Society, Nancy Helfern, extremely helpful, played a very valuable role. Larry White from the American Association of Retired Persons should be recognized.

We formed a nationwide coalition, and we went back to Mr. Waxman's office, and they actually wouldn't open the envelope. We delivered the draft bill in a CSPI envelope, and I called Bill Core, Mr. Waxman's staff agent, and I said, "Have you looked at this yet?"

He said, "Bruce, I haven't had a chance to open the envelope."

And I said, "Just open the envelope," because we had this nice new coalition letterhead. Instead of just one group, it had twenty-five groups on it.

And when Bill Core opened the envelope and he looked at the letterhead, he said, "Let me call you back on this." And that's what started it off.

I think Bill Core with Mr. Waxman's office, Bill Schultz, Joel Johnson and Senator Metzenbaum's office, if they're not here, should definitely be recognized for picking this up and getting this legislation through Congress. It's what they call a staff-drafted bill, meaning that the changes that were made after that were drafted by staff. The only time I ever saw Senator Hatch was at the reception after the law had been passed, and he came by for a photo with me and kind of grabbed me like this and hugged me, and I was kind of like this [gestures]. I'm scared the picture is floating around the Internet somewhere. [Laughter] Senator Kennedy showed up for some shrimp that I think the National Food Processors Association (NFPA) paid for.

But anyway, it was a staff-drafted bill, but I think it was a good piece of legislation. Apparently, we made everyone work incredibly hard, though, and I apologize for that. We had no idea how much work it was going to cause everybody else.

Canada, Australia, and New Zealand have adopted nutrition labeling since the United States has adopted it. The European Union is now engaged in a joint program with the FDA to develop a nutrition labeling program for Europe. I think it's no coincidence that Ed Scarbrough and I both started working on international issues and Codex issues, because after dealing with this, you've got to get out town for a while, I'll tell you. [Laughter]

We need to still improve the label. There's still work to be done, and I think this is a good moment in time to think about that. We need transfatty acids listed on the label with the daily value. We need added sugars listed on the label with the daily value. We need nutrition labeling of fresh meat at USDA. I can't turn to you anymore, but I'll turn to somebody. We need percentage ingredient labeling of key ingredients. Here's a Birdseye frozen fish product and the label says 50 percent fish on the ingredient list. And this one, this store-brand fish product, frozen fish, says 70 percent fish. Of course, these products are from Australia. You can't get that information in the United States. And so there's more to be done with food labeling. We need an allergen bill passed through Congress this year. Let's have some applause for that. Let's get that bill through Congress.

[Applause]

The Commissioner's behind it. I think what we've seen here with nutrition labeling is that this is an illustration—we're living in an era of supposedly what government can't do, but this is really an illustration of what government can do. And so thank you.

[Applause]

Christine Taylor (Director, ONPLUDS): Thank you, Bruce. A key perspective important to this whole process was the view of the food industry. At the time that NLEA was passed, a number of the food industries had lined up solidly behind mandatory labeling. And because the industry was the ones who had to actually deal with the label and live with it on a daily basis, they understandably had thoughts and opinions about what we should do to implement the statute. When it was clear that the NLEA train was leaving the station, the legislation was passed, and it was going to happen in three years, I think the U.S. food industry did an amazing job of rallying itself to provide input into the process and to make sure that the input was appropriately targeted, timely, and comprehensive.

When I think back to that time, Regina Hildwine from the National Food Processors Association simply rises to the top as one of the most remarkable spokeswomen for the industry. She was a whirling dervish of activity. She canvassed her members, she thought through issues, and in the best sense of the word, Regina was always in our face. She did at times frighten the heck out of us because she seemed to

know our proposals better than we did. And as Ed said, this was always most evident when we were on a public platform with her.

In truth, unbeknownst to her, I'm sure, we paid her the highest compliment a regulator could ever pay a regulatee, because in those days if we were worried about something, especially something highly technical or subtle or complicated, we reassured ourselves that we're probably okay because Regina hadn't pointed it out. [Laughter] She worked hard, she got her members organized, and she did them and us a true service. Regina, we'd like to hear from you.

[Applause]

Regina Hildwine National Food Processors Association (NFPA): Thanks, Chris. I'm almost speechless, but not quite. My name is Regina Hildwine and I work for the National Food Processors Association. The NLEA has been very, very good to me. I was able, through the NLEA, to turn some project work into I think what we'd all now recognize is a—well, a career. I wish a happy tenth anniversary to the NLEA rules.

Crunch time started for me when CFSAN published the rules, in the food industry. We had commented, we had said our words, but it was the food industry, after all, that got us from food labeling rules to food labels, and we had to implement them. For me, a happy tenth anniversary will be August 2004. That's the tenth anniversary of when the food industry completed its transition to the nutrition facts labels, and those of you who worked on the original rules and remember writing May 8th, 1994, you're

forgetting the four-month congressional extension that happened at the last minute. Well, okay, 2004, August, but I don't think we'll be having a party. [Laughter]

Today we're sharing war stories about the good old NLEA rule making days, war stories like veterans tell after the war is over. So the war is over? Really? I didn't get the memo, and I think it's too soon to tell.

Now, shortly after the NLEA rules were published, I was wandering around the wilds of Ottawa, Canada. I was there for the meeting of the Codex Committee on Food Labeling and I noticed the Chair of the Committee, now Dr. McKenzie, is with us today. But I'm wandering around Ottawa doing some shopping, I think, and ahead of me I spied a teeshirt that said, "I survived the NLEA." A CFSAN staff member was wearing this teeshirt. Now, in Canada, I don't know how this message played in 1993, '94, but I guess in Canada we'll soon find out whether those regulators survived mandatory nutrition labeling. There were a lot of these teeshirts going around, and I think that those people that have them should flaunt them. Who's got a teeshirt? No, no. Who's got a teeshirt? There's one. There's one. Give those people money. [Laughter] Ed's got his on! [Laughter and applause]

Well, you know, just remind yourself of this message from time to time, because I'm not sure yet that we have survived the NLEA, because it's too soon to tell. We're still at it. And you know, I don't continue to be active on labeling issues just because I am belligerent. [Laughter]

Now, there's a lot of NLEA veterans here today. From our perspective down here, this is a blast from the past, ladies and gentlemen. There are a lot of people who moved on from labeling, others who are still in the trenches. But some of the people who

worked on the NLEA moved on pretty much immediately after the rules were published. I believe it was approximately fifteen minutes after the rules were published, CFSAN reorganized. Some that are here today remember that and others have blocked it from their memories. That's when the Office of Food Labeling was created, by the way.

Now, while traumatic enough for the CFSAN staff, that reorganization threw those of us outside of FDA into a tizzy. The reorganization meant that several CFSAN people who had worked on the rules were no longer at the phone numbers published for them in the *Federal Register*. The *Federal Register* with the final rule said, "For information contact—" Yeah, lots of luck.

[End of tape one, side B; tape two is blank.]