History

of the

U. S. Food and Drug Administration

Interviewee:	Michael R. Taylor
Interviewer:	Suzanne White Junod Ronald T. Ottes
Date:	December 23, 1992
Place:	Rockville, MD

DEED OF GIFT

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Michael R. Taylor

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INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by the Food and Drug Administration's History Office. The transcript is prepared following the *Chicago Manual of Style* (references to names and terms are capitalized, or not, accordingly.)

The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source, along with written and pictorial source materials, for present and future researchers. The tapes and transcripts are a part of the collection of the National Library of Medicine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBER(S) 1,2,3

GENERAL TOPIC OF INTERVIEW: Nutritional Labeling & Education Act

DATE: December 23, 1992 PLACE: Rockville, MD LENGTH: 150 min.

INTERVIEWEE	INTERVIEWER
NAME: Michael R. Taylor	NAME: Suzanne White Junod Ronald T. Ottes
ADDRESS: [redacted]	ADDRESS: Food and Drug Adm.
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FDA SERVICE DATES: FROM: 1991 TO: 1994

TITLE: Deputy Commissioner for Policy
(Last FDA position)

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Attachments (2)

RO: The Nutritional Labeling and Education Act was passed by Congress in November 1990. The act required that the Food and Drug Administration develop proposed regulations by November 1991 and final regulations a year later. On the way to the final regulations several differences on what should be included developed between FDA and the Department of Agriculture. The two agencies were unable to resolve their differences, so the dispute was elevated to Dr. Sullivan in the Department of Health and Human Services and Mr. Madigan in the Department of Agriculture. The two secretaries were unable to reach a compromise on the contested issues. This led to a White House meeting in an effort to end the impasse.

Today we are meeting with Mr. Michael Taylor, FDA's deputy commissioner for policy, who participated in that meeting to discuss the details of the impasse and how they were resolved. With Mr. Taylor is Mr. William Hubbard, associate commissioner for policy development and coordination. Also present from FDA's History office are Suzanne White and Ronald Ottes. The date is December 23, 1992.

Mike, we are interested in preserving a record of this presidential meeting for use by the agency and historians. Would you set the stage by reviewing the course the agency followed in preparing these regulations and then the specifics of the disputes and how they were resolved?

MT: I'll be glad to do that, Ron. I think it is important that such an extraordinary effort for decisions about FDA regulations and personal attention by the president be known. I think it is only by understanding what the situation was that one will understand why presidential involvement was necessary and why, in fact, it was beneficial to the agency in its goals.

You know, just to even go back before the enactment of NLEA in 1990, the department and the agency had been working on a food labeling reform initiative. It had been twenty years since the agency had seriously revised regulations governing the food label. In the early 1970s FDA promulgated rules that, among other things, set up a voluntary nutritional labeling program, so that if companies chose to provide

nutrition information they would have to do it in accordance with FDA's rules. Under these regulations, only if companies made a nutrition claim were they required to present the basic nutrition information that we see on the back of a lot of food packages today.

A lot has happened in nutrition science, obviously, over the course of the two decades since then. Perhaps the central development has been a recognition of the very, very powerful relationship between diet and health--between the intake particularly of various macronutrients like fat, saturated fat, cholesterol, and so forth, and health--and, indeed, the importance of maintaining a proper balance of these nutrients in order to prevent disease. Too much fat can cause heart disease and cancer. A properly balanced diet with respect to these nutrients can reduce the risk of heart disease and cancer.

As a result, the agency began a program to revise the food labels and, in particular, to require through regulation mandatory nutritional labeling for all food products so that consumers could have access on all food products to basic nutrition information that they could then use to construct a diet that responded to the new scientific insights about what constitutes a healthy diet. One of the benchmarks, of course, for a healthy diet that had emerged over the seventies and eighties was *The Dietary Guidelines for Americans*, a publication that was put out by both the Department of Health and Human Services and the Department of Agriculture and updated periodically over the years. It stated basic dietary guidance for Americans, including, for example, that consumers should seek to obtain 30 percent or fewer of their calories from total fat and 10 percent or fewer of their calories from saturated fat.

The question was, how could that information--that guidance--be made useful and practical to consumers in making food choices on a daily basis? Clearly the most direct way to do this was to provide relevant, useful information on the food label

that would enable consumers to select diets that would match up with the dietary guidelines.

Under Secretary Sullivan's initiative, the agency developed and published around the spring of 1990 a very large set of rulemaking proposals to require nutritional labeling, among other things.

WH: And in February of 1990 we had published regulations on health messages that had superseded some other health claims regulations that had been viewed as being overly lax.

MT: Right. The health messages phenomenon was, of course, one of the events of the mid-eighties that triggered the whole NLEA process, because companies wanted to promote their products as beneficial with respect to these newly recognized diet/disease relationships. The Kellogg All-Bran product was sort of the pioneer being promoted as a food high in fiber which could help reduce the risks of some forms of cancer. This was disturbing for the agency, because traditional FDA and food and drug law principles would say that if you make that kind of disease-related claim on a product, even if it's a food, that makes that product a drug. So we had a regulatory problem, of course, with Kellogg. But the important point is that the fiber promotion reflected the interest in the food industry in responding to the consumer desire for information about food products that could be used to construct healthier diets.

Bill refers to the fact that the agency in early 1990 published proposals that for the first time fundamentally shifted our regulatory approach to begin to allow, under some controlled circumstances these kinds of disease, prevention claims on food labels without going through the drug approval process.

Congress, of course, was watching all of this, and there was a lot of interest in the Congress in this whole area. Basically a decision was made on the Hill to go ahead and develop and enact legislation that would specifically authorize and indeed

direct FDA to address the health claims issue, to address the nutritional labeling issue, and also to clean up the confusion on the food label that Secretary Sullivan referred to as the Tower of Babel with respect to the very inconsistent use of nutrient descriptors that cropped up on food labels during the eighties--terms such as "low fat," "no cholesterol," "low sodium," "source of fiber"--came into vogue because consumers were demanding products that met these sorts of decisions. But these terms were used without definition and often in a way that was flatly false or misleading.

RO: Did FDA have any review and approval of those health claims?

MT: The concept that was built into the proposals we published for health claims per se, the disease claims, would have given FDA a role in reviewing those. But with respect to the nutrient descriptors that I just mentioned, under the existing law in the eighties, the companies were under no obligation to come and ask for our blessing, and we had no regulations defining these terms. So the companies were essentially on their own in using these terms with the burden on us to prove case-by-case if they were false or misleading. That's why it was important to do a rulemaking and why Congress in turn passed NLEA, which set up a requirement that these terms be defined by FDA and that they be used only in a manner consistent with FDA's definition. So the Congress gave us authority to approve in advance the use of these sorts of nutrient descriptors.

WH: Mike, I think an interesting historical footnote on this is that the Nutritional Labeling Act had been going through Congress throughout 1990, but there wasn't sufficient consensus at the time that the Congress was scheduled to recess for passage of it. The Medical Device Act was also before the Congress at the time and the FDA Revitalization Act. But there was a dispute over the budget, if you recall, in late October 1990, about the time Congress was to convene for the mid-term

elections. And that dispute over a budget arrangement forced the Congress to stay in session about three weeks longer than it had intended to.

While the budget negotiators were off at Boeing Air Force Base and elsewhere around town negotiating, the Congress remained in session waiting for them to come in with a compromise, and so they decided to pass legislation. And the Nutritional Labeling Act passed on November the eighth in that intervening time, only a day or two before Congress recessed, but after it normally would have. So if it hadn't been for that budget dispute, the act would not have passed in 1990, and what would have happened in 1991 is unknown. And as I said, the Medical Device Amendment was passed as well and the FDA Revitalization Act, all during that intervening period when they didn't have anything to do but wait for the budget negotiators to come back.

MT: So Congress passed the NLEA in 1990, in the fall, signed by the president on November 8, and addressing these three principal areas that I've mentioned--disease-related health claims, nutrient descriptors or content claims, and then mandatory nutritional labeling. Because this is where the dispute arose with USDA, I think we want to focus on the mandatory nutritional label aspect of it.

One of the important features . . .

RO: Mike, excuse me, would you mention here why Agriculture got involved in this, because the act specifically mandated FDA?

SW: Before you move into that can I ask one quick question about the NLEA? What was your insight into what was pushing this besides, I mean . . . Was it consumer groups? Was it FDA? Was it congressional leaders? Who were the major players?

MT: Let me give a few thoughts on that and Bill can add more. I think it was multiple things. One, of course, is that there was a real problem out there in the marketplace with the very inconsistent use of these terms, and I think consumer groups and the agency recognized the need to address this inconsistency. The people on the Hill who care about consumer protection and nutrition and health issues, obviously Congressman Waxman's staff and others, Senator Metzenbaum's staff, I think recognized the need to legislate. They had picked up on this and saw this as an important need to be addressed.

The food industry always plays an important role in the legislative process involving the food industry. I was not personally involved in that at all, but my observation was that the food industry motivation was centered around a concern that because of the proliferation of issues and problems out there in the marketplace, the states had begun to take a lot more initiative in enforcement and compliance with respect to food labeling.

And I think the food industry was getting very concerned about conflicting state approaches to food labeling issues, including the health claim issue. The state of Texas got very involved, and on other specific issues the states were getting involved. There was also Proposition 65 in California. And the food industry's sort of number one policy issue, I think, in the late eighties after Prop 65 was enacted in '86 was to get federal preemption of Proposition 65. I think the food industry saw food labeling legislation as a possible vehicle for national uniformity or preemption in this area, in respect to food labeling issues generally, but also the hope was to preempt Prop 65.

And of course, you can see the results of that industry angle in the statute, because it does set up preemption of most state-level food labeling requirements once we get our rules in place under NLEA. It also, of course, empowers the states in a very novel way. It empowers the states to enforce the NLEA rules in federal court, which is a new thing. The industry effort to get Prop 65 preempted failed, and

Congress specifically rejected preempting that sort of safety-related state level warning requirement.

WH: But they did get preemption of the nutritional label.

MT: Yes, right. My personal observation is that the industry tried to get something that would have been of significant value to them in the way of preemption, that is preemption of Prop 65. What they got as a practical matter was of very little value to them, because once the federal government sets consistent rules with respect to issues like mandatory nutritional labeling and most of what NLEA addresses, very few states are going to be interested in setting different standards. You had de facto uniformity or preemption, even without the preemption provision in the statute. So the industry in the end I think got very little out of it.

WH: I do think at the end the industry acquiescence was very, was critical in order to get that law passed.

MT: Right.

WH: I think of a couple of things. One minor thing that played in was credit. I mean, I think they saw Sullivan getting a lot of credit for doing this on his own, and I think that Congress had been working on this for a long time--it had a lot of oversight hearings on health claims--and I think they felt, "Hey, you know, we've been real players in this, too." But more importantly, I think that there was some suspicion that our ability to control health claims and nutrient content claims such as "low fat" or "light" were suspect. They didn't trust the administration, OMB and others, to let us set strict rules. They felt it was better to actually ban these claims and set up a system under which FDA had to affirmatively approve them, because there had been an earlier health claims proposal which had looked to them to be

very lax. And then I think even when we published our rules in February of 1990, and then later that spring on nutrient content claims, I think they were suspicious that we would have the real authority, and they felt that they needed to be on the books as an actual authority.

MT: Let me pick up with the discussion of the format issue, because in a very real way that, the mandatory nutritional labeling part of NLEA, was the heart of it. It's the core. It would assure that the core body of basic information about the nutritional composition of foods be present on virtually every food product in the country. You asked me to talk about Secretary Madigan or USDA's role. Let me do that and then I'll get to the substance of format.

RO: Sure.

MT: That is an important foundational point for discussing the dispute that later arose, because at the time NLEA was passed Secretary Madigan was a member of Congress from Illinois, was the ranking minority member on the Health and Environment Subcommittee of Energy and Commerce in the House.

WH: And was a cosponsor . . .

MT: And was a cosponsor of NLEA. I gather he was a very important player in getting it passed and participated directly in the ultimate passage. He then went over as secretary of Agriculture, and I don't know exactly when that happened. But sometime between the passage of NLEA in the fall of 1990 and the issuance of our proposals in the fall of '91 he became secretary.

WH: I can't remember either, but at the time that Secretary Sullivan announced that he was going to do a food labeling initiative in March of 1990 at a food policy

conference here in Washington, then-Secretary Clayton Yeuter of Agriculture spoke the next day. And while he didn't speak on this subject he was asked about it and suggested that his department was not going to follow that route, that such mandatory nutritional labeling was overregulatory. And he left shortly after that to become head of the Republican National Committee, and Congressman Madigan was tapped for that job. He had a very different view, and at the time that the law was passed was then prepared to, when he became Agriculture secretary, to say that the USDA would voluntarily do analogous nutritional labeling requirements even though the statute did not require them to do so.

SW: He was very supportive.

RO: Yes.

SW: I mean there's been a lot of press, as I remember, about differences between regulations enforced by the FDA and those enforced by USDA. Cheese pizzas are regulated by FDA and pizzas with meat toppings by USDA.

WH: Well, it was noted, when we announced our regulations that meat and poultry were not covered, and then there were questions, editorials, and other news articles about why USDA wasn't doing the same thing.

MT: It's very hard for the public to figure out why it is that the federal government would have a situation in which a cheese pizza is subject to one set of labeling rules and a pepperoni pizza is subject to another set because it's under USDA's jurisdiction as a meat product. I think Secretary Madigan understood that point as well and, in a very bold and commendable way, shifted the department's position and announced that he would be proposing his own set of rules in parallel to ours with

the goal of having USDA's rules be as consistent as they could possibly be with FDA's rules on food labeling.

So as a result of that, in the fall, in November of '91, when we published our proposals to implement NLEA, Secretary Madigan published his own parallel set of proposals. We had a joint press conference, joint announcement. They were published simultaneously, as I recall.

WH: The deputy secretary of Agriculture joined Secretary Sullivan to make that announcement at the press conference.

MT: Right. And it was a very positive event. It was taken by the community, I think, as a real breakthrough in cooperation between the two departments.

RO: They were still going to be voluntary, though, for meat and poultry. Is that right?

MT: As I recall, their nutritional labeling would be voluntary for fresh meat, just as under NLEA, on a pilot basis, we are administering a voluntary nutritional labeling program for fresh fruits and vegetables. Under NLEA, our program becomes mandatory if we don't get substantial compliance with the voluntary program.

WH: They were doing it voluntarily, though; they were not doing it under Congressional mandate.

RO: Mandate, yes.

MT: USDA is under no statutory directive to do this, and thus does not indeed have the same statutory standards to satisfy that we've got. And let me get to that now and talk about format.

In the provisions of NLEA that deal with mandatory nutritional labeling we are required not only to provide certain information about the nutrients--certain nutrients have to be described--but we also were directed to present the nutrition information, the information about the amount of fat, and saturated fat, and vitamins, and minerals. We were directed to present that information so that the relative significance of those nutrients could be understood by the consumer in the context of the total daily diet. That is a pretty close paraphrase of what the statute said to the secretary of Health and Human Services.

RO: In fact, it was supposed to be educational, not just informational. Right?

MT: Well, this was the Nutritional Labeling and Education Act, and so there's clearly an educational component to the whole regime. There is a debate about--I mean, to some extent it gets semantical--about whether the label itself was intended to be merely informative or educational. I call that debate semantical because I don't find there to be much of a distinction between good information and education. And I'll try to explain that.

RO: OK.

MT: The statutory charge, again, was to provide the nutrition information so that its relative significance could be understood in the context of the total daily diet. The legislative history spells that out a little further by saying that this means that the significance of the nutrients should be understood in relation to available dietary guidance. What that said to Secretary Sullivan and to the FDA was that the purpose of the nutrition label was to present nutrition information so that consumers could

use it to construct a diet that would be consistent with the dietary guidelines. When you say, "understand relative significance in the context of the total daily diet," and then you have this legislative history specifically referring to dietary guidance, and you think about what's really going to be important to consumers, where the public health value will come, it's in having the nutritional label be an information tool that consumers can actually use at a practical level in selecting a diet that will meet the dietary guidelines if that's what they choose to do.

So we set out to implement the nutritional labeling requirement in a way that would meet that goal. And the question is, How do you present nutrition information so that it can be used in that way by consumers to meet that goal? And we, of course, had a certain amount of experience over the years with the existing nutrition format, but that format, which only provides the absolute amount of the nutrient--for example, 5 grams of fat per serving--was really not designed with this goal in mind. And it was pretty clear, I think, to the experts down at the Center for Food Safety that that way of presenting the information, just the absolute amounts, did not provide the kind of context that Congress called for and was not really useful to consumers if their purpose was to construct a diet over the course of a day that would meet the dietary guidelines. That format is perfectly useful for comparing the amount of fat in one product with the amount of fat in another, and that's valuable, but it didn't serve this public health goal of meeting the guidelines.

So in order to determine what would be the best way to go about that, the center did research and sponsored consumer surveys in which consumers were shown various different approaches to presenting the nutrition information in a way that would be most useful. And one of the tools that was used was the presentation of, in addition to the absolute amount of the nutrient, the presentation of the so-called daily value or a target figure for the amount of fat and these other nutrients that consumers should be shooting for over the course of a day. So in addition to presenting the amount of the nutrient in that serving, you'd get sort of a daily goal or a daily value presented.

And then another version that was tested was to present that daily value and then also present the percent of the daily value that was contributed by that particular serving of food. Now this was exactly the way, that is using the percent of a daily value, is exactly the way that vitamins and minerals have been depicted on the voluntary nutritional label for the last twenty years. We give simply the percent of the recommended daily allowance. So this was not a novel idea, but it was the first time it was considered to be applied to the macronutrients--fat, saturated fat, sodium, protein, carbohydrate, and so forth.

In the research it was very strongly determined that the information tool that worked best to meet the goal of the statute and the public health goal of an information tool the consumers could use to meet the dietary guidelines, was the percent daily value approach--that is, where the consumer would be given the absolute amount of the nutrient and then the percentage of the daily value contributed by that particular serving of food.

WH: Could I add that we looked at other possibilities, too, Mike. We looked at what other countries had done to provide that sort of information to their consumers. We listened to the consumer groups who wanted little symbols like happy faces or stop lights and stop signs and various kinds of other mechanisms. And we even tested some of those with real people. For instance, we tested formats that said high, medium, and low, and found generally that people didn't want simplistic things. They wanted real information; they wanted the numbers; and they also wanted this sort of percent value that Mike discussed that actually worked with real people. Even though a lot of people first thought it was cumbersome, when you tested it with real people it actually worked--they could make sense out of it.

(Interruption)

MT: So in the proposed rules that we published in November of '91, we proposed to require that the nutritional label include a daily value for the nutrients and a percent of the daily value for the nutrients. One of the most important issues in the whole debate about the nutritional label concerned the fact that the daily values for certain of the macronutrients--fat and saturated fat in particular--have to be based on some assumed calorie intake, because they are derived from the dietary guidance on fat and saturated fat which is articulated in terms of 30 percent of calories or less from total fat, 10 percent or less from saturated fats. So any one individual's daily value for fat and saturated fat will depend upon their own calorie intake. Calorie intakes obviously vary across the population depending upon your age, your sex, your level of activity, and other factors.

In the November '91 proposals, FDA proposed to base the daily values on a population weighted mean calorie intake of 2,350 calories. And the theory was that this would provide a reference, and any individual would have to make an adjustment in the daily value based on their own calorie intake. This would be achieved through education.

We received in comments on this proposal enormous criticism, frankly, from the public health community, which felt that, first of all, it was not realistic to expect that you could educate people off the food label to make that adjustment on a routine basis. The community felt that was asking too much of an educational effort for 250 million Americans; and that, to the extent consumers relied on daily values based on 2,350 calories, for a majority of the population, including virtually all women, the daily value resulting from an assumed intake of 2,350 calories would be too high, and that you would run the risk of misleading significant numbers of consumers to consume too much fat.

We got the message and arrived at a view--and I'll explain this in more detail in a minute--that 2,350 was not the right calorie intake and we have to come up with a lower figure. We ended up, of course, at 2,000 calories, which is what most of the

public health groups recommended. This became central to the debate between us and USDA.

The November '91 proposal addressed what the content of the nutritional label should be, but it did not address the format of the nutritional label--how the information would be organized on the label and presented so that it would be readily observable and understandable by the consumer. That was another requirement of the statute, that the information be readily observable and understandable to consumers. So we were obligated to publish a separate proposal laying out requirements for the format of the information.

WH: The reason we weren't ready then was that we needed to do some consumer research which was under way at the time of the November '91 proposals.

MT: Right.

RO: So there were really two proposals. Is that right?

MT: That's correct. We ended up publishing in July of '92 a separate proposal on format. And that's where we focused on, again, the organization of the information on the label. We reviewed all of the options in that document for how the context could be provided, including the kinds of options that Bill mentioned a while ago as well as the percent daily value option.

It was in getting that proposal published in July, though, that we basically discovered, or it became very clear, that we had a disagreement with the Department of Agriculture. The Department of Agriculture, of course, had to have its own parallel format requirement, so they were working on their own proposal. And we began to have discussions--and Bill can help fill in the details here--discussions during the spring of '92 with USDA about what the right format should be.

It was during the spring that our belief that we needed to move to a lower calorie intake began to emerge, became known to USDA, and obviously became a matter of great concern to the Department of Agriculture. That concern surfaced, and indeed, as a result of that, there were extensive meetings and discussions between the department and USDA aimed at trying to get some resolution of the format issue prior to publishing our format proposal. We had hoped to get our format proposal published in February or March of '92.

WH: Right.

MT: Because of these discussions, it didn't end up being published until July of '92. The discussions, which took place at both the staff level between the Center for Food Safety staff and the Food Safety and Inspection Service staff at Agriculture, also took place at a very senior level. The commissioner and I went over on more than one occasion and met with the USDA deputy secretary, Ann Veneman, as well as with Secretary Madigan's chief of staff, Bill O'Connor, in an attempt to try to find some common ground on these issues.

Those discussions did not lead to agreement, and indeed the decision was made to go ahead and publish our respective format proposals even though there was not agreement. The reason for doing that was that we all agreed on one thing, which is that we wanted to get our final rules done by November of '92, which was the statutory deadline for the regulations. And so the Office of Management and Budget and USDA basically went along with the decision for each agency to publish our own proposals on format even though they were different.

WH: Did you mention why . . . Did you mention the hammer?

RO: I was just going to ask that.

MT: I'm going to do that. An important part of the dynamic of the decision-making process was that Congress built into NLEA this so-called hammer provision as they did in the Medical Device Amendments that passed about the same time. It was sort of a newly discovered tool for the Congress to use to put pressure on the administration to get rules done promptly. I think the hammer tool was used both because Congress wanted in effect to give the NLEA rulemaking a high priority within the agency and the department, but also because there was distrust on the part of the Democratic Congress of the Republican White House and, in particular, the Office of Management and Budget, distrust that they would be an obstacle to getting these rules done at all.

WH: There was distrust about getting them done at all. And also I think there was a certain view that oversight hearings in the eighties had showed that FDA was very slow to get regs out. While clearly the ability to get regulations through the Office of Management and Budget was one of the big problems, there was also, I think, a perception that we just took our time, and they wanted to put our feet to the fire and make us do these rules expeditiously.

RO: You could go back to the middle eighties with the infant formula.

WH: Oh sure. And there were many oversight hearings during that period in which we'd be called up and some official at FDA would be chewed out by a particular committee of Congress who would say, "We told you to do something. You saw a health problem, and you knew regs were necessary, and you didn't do them or you took forever to do them."

RO: Yes.

MT: The hammer provision said in effect that one year after enactment of NLEA, FDA was obligated to publish proposals. Two years after enactment, FDA was to promulgate final regulations, and if the final regulations were not promulgated by the second anniversary of the statute, the proposals, by operation of law, would become the final rules.

RO: Regardless of how bad they were.

MT: Regardless of how bad they were or . . . Yes. This had the intended effect of putting enormous pressure on the administration to get these rules done. Because we published a set of proposals in November of '91 that were a very solid set of proposals; but as one would expect, we got 40,000 or more comments, many of which helped us in refining the rules and showing us how we could achieve the goals of the statute better than our proposals had. These were improvements and refinements that both industry and consumer groups supported and benefitted from. As a result, it became clear to everyone in the process that there was a big stake in getting improved regulations out by the November of '92 deadline, or else the less desirable proposals would become the final rules.

We used that argument and concern aggressively in trying to persuade the White House, the OMB, to clear our format proposal, because in order to meet the deadline of NLEA we needed to have a format rule. In order to get a format rule, we had to get a proposal published. Even so, it took a long time. And if you think about it, having published in July a proposal on a major issue like this on which you then need a final rule by November is a pretty late date to publish a proposal. I think a lot of people despaired that we could ever get a final rule with a proposal that late.

I think the Center for Food Safety has become so adept at doing the work, making decisions, and moving the process along on food labeling, and given that this was just one of a whole large number of regulations, they just figured that somehow,

some way it would get done. And I had personally, I have to say, complete confidence in the center. Their performance throughout was just Herculean and on a continuing basis they dazzled me with their ability to do massive amounts of quality work in a very short time frame.

SW: Were there any officials in particular at CFSAN who were involved in that?

MT: Well, there's a large number. Ed Scarbrough, of course, headed up the effort within the center. He had team leaders or group leaders assigned major parts of the regs. These included Virginia Wilkening on nutritional labeling, Betty Campbell on descriptors, the health claims was Beth Yetley, Vic Frattali, and Jim Taylor.

WH: Phil Derfler, of course, from GC was . . .

MT: I think everybody recognizes the absolutely indispensable role Phil played and he deserves enormous credit.

WH: And Fred Shank, the center director, made sure that this was a high priority with the center, the resources were committed, and the priorities were there for this.

MT: It was an institutional effort, but there are individuals who definitely deserve singling out, and we've named just a few of them. In any event, we published our format proposal in July. I don't think the USDA proposal published until August.

RO: That's right.

WH: We might mention what USDA's concerns were. They thought daily values were inappropriate because there wasn't one value for everyone. They didn't like percents because they didn't think people could understand them, and even if daily

values were used, they didn't think 2,000 calories was the right amount. Other than that, of course . . . they loved it!

MT: Let's talk a little bit more about the substance of the debate, and Bill has identified really the key issues or key concerns, expressed by USDA about our format. The alternatives presented by USDA to our percent daily value approach included as their first preference to present the absolute amount of the nutrient--say, 8 grams of fat per serving--and then to provide a summary of the dietary guidance that was published in the pamphlets that HHS and USDA had put out. So you'd have the absolute amount of the nutrient, and then you'd have a diet with moderate sodium intake, 30 percent of calories or less from fat, 10 percent or less from saturated fat. Their fall back position was to present, instead of a percent of daily value, a range of daily values to take into account the fact that calorie intakes range from 1,600 to 2,800 calories roughly--rather than use a single daily value and a percent, simply give the absolute amount of the nutrient and then the range of daily values that cover this range of calorie intakes. I think for fat, then, you'd have a range of 53 to 90 as the daily values for fat that would be presented on the label next to the amount of fat in the particular serving of food.

SW: And they assumed the consumer would be able to sit down and figure this out without a calculator.

MT: Well, the argument was that consumers would need to figure out what their appropriate intake would be. And, rather than give a specific figure that would be wrong for some consumers, it would be better to give consumers information that they could then presumably use to calculate their own daily value.

We were puzzled at least and frankly disturbed at the USDA positions, because, of course, we were focusing again on this public health goal of providing a practical tool consumers could use in the grocery store and at home when they're

preparing meals, a practical information tool to select foods over the course of a day that would give them a diet meeting the dietary guidelines. We understood how our tool would achieve that objective. Research had shown that the percent daily value was a very effective tool for this. We could not for a moment see how the two USDA options would meet that objective.

Their first option, which would be just to repeat the dietary guidance, would have required consumers to go through a multi-step calculation to understand how the amount of fat in a particular serving fit with their diet. We gave them a ready reference--the percent of the daily value. They gave them raw information that would then have to be the basis for calculations by consumers. We didn't think that was practical.

The range-of-daily-value approach not only did not provide any specific guidance for consumers, but we were concerned would affirmatively mislead some consumers to believe--frankly, this was my take-away from the range approach, if I were coming at this as a lay person--that as long as you were within that range you're OK. Well, that range includes, intake levels based on 2,800 calories, which yields a daily value for fat, for example, that is very unhealthy for significant portions of the population. So we were concerned both that the USDA options did not provide the useful tool that we thought was needed, but that in the case of the ranges option would certainly be affirmatively misleading and detrimental to consumers.

USDA's complaint, of course, was that our reliance on a percent of daily value based on a 2,000 calorie intake would mislead some consumers to construct a diet based on a daily value for these macronutrients that was lower than was appropriate for them. And it is true that the daily value for fat of 65 grams that you derive from a 2,000 calorie diet is a lower daily value than is appropriate for, say, adult men whose calorie intake is above 2,500 and whose actual daily value is more like 75 or 80 or even possibly more if they're very active.

And here's where we made a basic public health judgment, which was that you could do no harm to any consumer by providing them a reference that would cause

them, if they took it literally, to shoot low on fat--that is, to consume less than they might ordinarily be able to consume to meet the guidelines. But you could do significant harm if you misled consumers to consume more fat than they ought to be consuming. And it was on that basis that we were persuaded to go to the 2,000 calories in the first place, to insist on that position in our discussions with USDA.

Let me make a couple of points about the internal process in the Department of Health and Human Services which became very important for the subsequent dispute and resolution of the dispute with USDA. Secretary Sullivan, of course, had been instrumental in food labeling reform from the very beginning, and he took a personal interest in the original proposals that we prepared prior to enactment of NLEA. He viewed this whole project as one of his highest public health priorities. He, of course, had as the centerpiece of his whole tenure as secretary a program called Healthy People 2000, which is built around the concepts of health promotion and disease prevention. Let's not just worry about investing in health care to fix people after they're sick, but let's try to help people be healthy and let's have a prevention strategy.

Diet and health--that link is one of the most important ones that can be built upon in the context of a health promotion/disease prevention program. Secretary Sullivan saw food labeling as an important vehicle for giving consumers information they could use to reduce the risk of disease and promote health. He saw it in a very broad public health context, and consequently, strongly supported the program and gave the rulemaking activity the priority that it needed for the department to get done on time. But he also was fundamentally oriented towards achieving the public health objectives of food labeling. And so he, from the beginning, was very supportive and immediately embraced the recommendations that the agency made to him for, in particular, the format, and the percent of daily values, and the decision to go to the 2,000 calorie assumption for calculating daily values.

I have to say something, as well, about the role that Dr. Kessler played, because he also saw this in broad public health terms. During the evaluation of the

comments after the November proposal, he focused particularly on the calorie issue and saw the need to go to 2,000 calories, a step that we all advised him would be a very desirable one from a public health standpoint, but also a very controversial one because of the anticipated USDA opposition and opposition possibly from some in the food industry. He was steadfast, though, and provided leadership on that issue that resulted in our making that recommendation to Secretary Sullivan. And as I said, Secretary Sullivan readily embraced it.

SW: Is that what got Dr. Kessler going on the children's nutrition issue? The fact that we were using 2,000 calories as our guide or baseline?

MT: No, that was separate. The children's initiative really flows from his experience as a pediatrician and the importance of getting kids started early in appreciating nutrition and appreciating the food label as a source of information about nutrition.

So I guess it's fair to say that by the summer we had Secretary Sullivan fully on board, although no final, formal decision had been made because the proposal was published in July and we had to go through the comment process. But you had Secretary Sullivan going strongly in this percent of daily value direction. You had Secretary Madigan taking this other approach and being strongly opposed to the percent of daily value approach. And you had discussions at a staff level that hadn't produced any particular agreement. The comments that we got on our July proposal very much ratified our belief that we had the right answer. They reflected very strong support in the public health community, among consumers and nutrition educators, for our approach to the format. So we just got continually reinforced that we had the right answer.

We continued during August to have discussions with USDA to see if there wasn't any way to accommodate their concerns in arriving at our final format decision. One thing that came out of that, and it was important, was our willingness

to allow the inclusion in a footnote to our basic nutrition label format, of information that would make it clear to consumers that 2,000 calories was not for everybody, that it was a reference, and that calorie intakes vary widely. Indeed daily values for some parts of the population would be higher than the daily values that we had adopted based on a 2,000 calorie diet.

We came up with a range of possible footnotes that would have been permissible under our rules for companies that wanted to provide that additional information, because it's a perfectly valid point. And if we can make it easier for those who have a 2,500 calorie diet, for example, to know what their particular daily value is, all to the good. We did believe strongly that you couldn't do all of that in the core of a nutrition label. You need a single, simple reference that could be reliably understood in a way that would be positive from a public health standpoint. But if additional information in a footnote was desirable, then that was fine with us. And we built that footnote into our draft final rule that we developed during August and early September.

As we moved into September we were facing a very troubling situation, which was that we had the November deadline looming; we had an unresolved dispute between two cabinet officers; and we needed to figure out somehow how to get that resolved, get decisions made so we could meet the deadline. We sent a decision memo to the secretary on September 24 which laid out the options and made our final recommendation.

We had a meeting with the secretary on October 9, in which he made his final decision. And we discussed in that meeting, since he had already largely resolved in his mind what the outcome was going to be, a strategy for dealing with Secretary Madigan in getting final closure on this issue within the administration.

It was agreed in that October 9 meeting that it would be necessary for Secretary Sullivan to deal personally and directly with Secretary Madigan. And indeed after that meeting, I'm told, phone calls were placed to Secretary Madigan's office in an attempt to arrange a meeting. There was preliminary conversation

between the two on the telephone, I think early the following week, that was not substantive but just sort of a recognition that they needed to get together on the issue. As a result there was a meeting scheduled for the afternoon of Friday, October 16 between the two secretaries.

The reason I remember the date and the time is that while this was intended to be a one-on-one meeting between the principals, the two secretaries, Secretary Sullivan asked me to come along with him in the event that substantive issues beyond his preparation would come up.

(Interruption)

MT: Before I go further in describing this meeting with Secretary Madigan I need to lay a little bit more of the sort of the foundation for how this thing got resolved.

We got real clear signals, I guess during August and September, from OMB that the OMB staff and other components of the White House staff tended to favor USDA's approach to the format. This was of concern because . . .

RO: Mike, excuse me, do you think that was really political?

MT: Well let me tell you what *I* think.

RO: OK.

MT: My personal view was, and I think this was reasonably widely shared within the agency, in FDA, is that the Department of Agriculture--because it is an agency that has as its primary mission fostering the agricultural economy--the Department of Agriculture views the industry as its constituency.

RO: Sure.

MT: And considers itself obligated to take account of the interests of that constituency. My personal belief is that, as a result, USDA was very concerned that our format, by clearly depicting the level of fat in servings of meat products in relation to an appropriate daily intake and indeed doing it in a way that did err on encouraging less consumption of fat rather than more, would discourage consumption of meat, which is obviously bad for the meat industry. USDA, during the course of this debate, steadfastly maintained that their position had nothing to do with the meat industry, that it simply reflected their view about how best to communicate nutrition information to consumers. I have a different belief, which I've just recited.

What motivated the OMB and the White House staff is not always easy to discern. Obviously there were components of the White House staff, the Council on Competitiveness, which viewed itself as and functioned principally as a conduit for industry views on issues into the White House decision process. Those views would then get at times conveyed to the OMB staff, who had the official responsibility for reviewing our regulations. So when you heard views expressed by OMB's staff, you never really knew whether they were speaking for themselves and motivated by some philosophical or analytical consideration, or whether they were passing along the views from others in the White House, which may have been originated with industry or from any other source. You never really knew for sure what was motivating the expressed OMB position.

Our concern was that if you had the Department of Agriculture and OMB lined up on one side of the issue and the Health Department in the government lined up on the other, those odds weren't quite as appealing as we might like our odds to be in any sort of discussion. And so we made a conscious decision. I sat down one day with the commissioner and expressed the view that--and this was no particularly novel insight--that as long as this issue were debated within the government behind closed doors, we stood a good chance of losing; but that if the

issue could be resolved within the government in a more public manner, with this public health issue being understood by the public for what it was, we stood a very good chance of winning. Because no one, I believe, or at least very few people can sit down over these various format options that were on the table--our percent of daily value versus the USDA options--and knowing what the goal of the statute is and what's at stake from a public health standpoint, very few people can sit down and tell you with a straight face that the USDA options are preferable.

We felt it was important to have this issue understood publicly. There was a lot of inherent media interest in this subject, because what you're talking about is the food label that every single American will see many times a day, just sort of a bread and butter consumer issue. We cooperated by providing them publicly available information about the debate and about the issues involved. They talked to USDA officials as well, so it's not as though this was some kind of exclusive little thing we were doing with the press. The whole point was that the issue got covered and the debate got played out to some very real extent in the pages of the *Washington Post*, *New York Times*, and to some extent, the *Wall Street Journal.*

SW: It was widely publicized.

MT: And then, yes, got picked up in the broader national media as well. It was addressed editorially with the *Times*, and the *Post*, and *USA Today*, and others editorializing on our side of the issue recommending that the outcome be the one that we were advocating. There were ads run in all the national papers by Phil Sokolof, the Heart Savers person out in Nebraska. So there was this very broad, public debate about the issue, or at least discussion of it in the press, I should say.

When Secretary Sullivan and I went over to USDA to see Secretary Madigan, I was first of all kind of stunned that we walked into the office and there was nobody there with Secretary Madigan and it was just Sullivan, and Madigan, and me sitting

at Secretary Madigan's conference table. It's clear that what was most on Madigan's mind in this meeting, a meeting in which Secretary Sullivan had wanted to go over and lay out his position and have a discussion with Madigan, was the public treatment of this issue and the press treatment of the issue. And he was mad because USDA had been made to look bad in the press, and he personally had been, he felt, been made to look bad in the press, although most of the press coverage had not been really aimed at him but at the issue, at the position.

SW: The one thing that wasn't in the articles was how Madigan had been instrumental in the beginning in trying to get support for NLEA at the beginning.

MT: Yes. Well, he, and of course he made that point very forcefully to Secretary Sullivan, that he felt that he had played a positive role in getting this going, that there wouldn't have been an NLEA without him, and that he didn't like being portrayed as the bad guy basically on this issue. And he was sufficiently angry, in fact, that he declined to discuss the substance of the issue with Secretary Sullivan. And as a result, the meeting ended and we left after we were there I guess forty-five minutes to an hour.

During the course of the meeting, Secretary Sullivan's response to Madigan saying that he found the HHS option not acceptable and preferred these other options was, "Well, I guess we just may be at an impasse here." And what that reflected was Secretary Sullivan's absolute commitment to his position. Even in the face of very rigid opposition from Secretary Madigan, he was simply not prepared to change his position.

On the way back to the department, Secretary Sullivan asked me to prepare a letter for him to send promptly to Secretary Madigan putting in writing Secretary Sullivan's position and the basis for it and Secretary Sullivan's commitment to move forward in a timely way in issuing his regulations, basically leaving the message that we'd like you to join us in this, but if we can't agree, HHS would need to go forward

with its rules. You ought to have a copy of that letter. That letter, while it hasn't been widely reported, I know is public in the sense that people have it outside of the department, and I think you ought to have it for the record.

RO: Was there any suggestion that this would be elevated to the White House?

MT: It was not discussed there, but it was . . . We anticipated fully that there was only one other place to go and . . .

WH: There had already been involvement by Boyden Gray, the president's counsel, by the Competitiveness Council, by the Office of Management and Budget, and based on a meeting of the various industry groups the cabinet secretary had been involved. So there was a lot of White House involvement already.

MT: And indeed I think it had been the week just before the Sullivan/Madigan meeting--I think I have the timing right--Boyden Gray had called Secretary Sullivan to ask about the format issue and some other food labeling issues and to register some concern about the department's position. So, yes, the White House was already very involved at a senior political level. As White House counsel, you know, Boyden Gray was a fairly big force over there. So it was certainly recognized that there would be some further White House engagement. And indeed in addition to preparing a letter for Sullivan to send to Madigan, we also prepared a memo for Sullivan to send to Boyden Gray sort of stating where the secretary had come out in his commitment to go forward with these rules as he had prepared them.

SW: To make sure that I understand this, was there any insinuation at this point that the two of you could just simply publish separate regs and that would be it? Or was USDA at that point still committed so heavily to being in unison with FDA?

MT: Well, throughout this process everyone had agreed that there should be a consistent label. That was very much desirable for consumers and it was what the departments wanted. And I don't think at that stage, you know, immediately after the sixteenth, that the idea of going our separate ways had really surfaced as an option. It had certainly occurred to us. We had discussed internally that it was much more important for us to get our rule right than to compromise with USDA in the interest of getting something they could agree with. I mean, that discussion had taken place within the department, including with the secretary and his senior staff. It just hadn't surfaced in the administration as an option.

RO: Mike, at this meeting you were saying that the differences were on the format. There were also some descriptor differences. Was that at this meeting or before?

MT: There were, and again Secretary Madigan didn't want to discuss the substance at all. As I recall, he mentioned some other concerns that USDA had like the issue of "light in sodium," whether there should be a definition for "light in sodium" on foods that contained significant fat and calories. There was an issue about restaurants and whether the NLEA nutrient descriptor regime should apply in restaurants at all, and if so, how. There's also an issue concerning so-called "third-party endorsements," where, for example, the Heart Association would license its logo to foods that fell within the Heart Association diet plan with us taking the position that under the right circumstances this could be useful and lawful and USDA being categorically opposed to third-party endorsements. Again, the cynical view was that their products would so rarely fall within such diets that it would disadvantage their products to have endorsements out there in the marketplace.

USDA's staff were very frank about why the "light in sodium" issue was important, and they said it was because "their products"--and those were their choice of words--their products would rarely if ever qualify for a light descriptor based on fat and calories, and so they wanted their companies to have a light descriptor that

they could use for marketing purposes, and "light sodium" was the only one that they thought could be useful for this purpose. There are some processed meat products like bologna that, I gather, would be marketed as light bologna based on sodium reduction.

So there were these other issues. You know, it's interesting. The fact that there were these other issues I think played into the ultimate resolution by the president in a way that ended up helping us, and I'll mention that when I get to the end.

In any event, we had the meeting with Sullivan and Madigan on the sixteenth of October. There was clearly an impasse. Sullivan was determined to move forward, and we prepared a letter which was sent the following week to Madigan. We prepared a memorandum for Boyden Gray which was also sent, giving the secretary's position on the issues that Boyden Gray had raised.

What also happened that week though was that--and we're not exactly sure how this happened--the fact that there was a dispute between these two cabinet officials came to the attention of the Office of Cabinet Affairs within the White House. There's a staff there that manages the cabinet basically. And this came to their attention, and they alerted the Office of the Chief of Staff, Jim Baker. And this prompted a real concern in the White House, given that the election was a couple of weeks away, that here was a dispute between two cabinet officers on this consumer, public health issue, and they didn't want the dispute to pour out into the media any more than it had already out of a concern that it would just be a bad event for the administration.

The person involved at this stage was not, as we understand it, the chief of staff himself, Jim Baker, but rather his deputy, Deputy Chief of Staff to the President Bob Zoellick. And Mr. Zoellick charged Tom Sculley--who had been throughout the Bush administration a senior OMB official, had been the program assistant director, they're called, in charge of the part of the government that includes HHS and had been detailed, in effect, over to the Chief of Staff's Office during the fall campaign

so he could be involved in more political stuff--with conducting negotiations, discussions between the two departments to try to resolve these issues, to find a compromise, if you will.

So beginning that week . . . Let's see, I guess beginning with the week of the nineteenth or so of October--and we can fill in the dates I guess--but Tom Sculley convened in his office over in the old Executive Office Building a series of meetings that were attended by him as the chair, and USDA represented by Secretary Madigan's chief of staff, Bill O'Connor, and Mary McGrane, who had been on the staff of the subcommittee in the House that Secretary Madigan had been the ranking member on. She had worked on NLEA as his staff in effect, and she came to USDA in the spring of '92 to assist in completing the rulemaking. She was at these meetings as well for USDA. And then the department was represented by Robin Carle, who was Secretary Sullivan's chief of staff, and myself. And we had a series of meetings over the next ten days or so, probably five or six typically lengthy discussions of the format issue, the light issue, the restaurant issue, and the third-party endorsement issue.

The purpose of these discussions in addition to ideally reaching compromise was, of course, to keep the issues unresolved and sort of cooking, you know, within the government at least until after the election, just to keep the issue quiet as a public issue. And it worked for that purpose in the sense that we had lengthy discussions. The issues remained unresolved, but there was very little room for compromise. I think we agreed to some language in the preamble on third-party endorsements to the effect that we had no trouble with sort of expressing our reservations about it and our willingness to consider rulemaking to more closely regulate third-party endorsements. That was about the only issue though on which there was any sort of accommodation made between us.

And as a result, we entered November with the election on November 3; the NLEA hammer date coming on Sunday, November 8. We entered November with no resolution of these issues with a continuing recognition on our part, and at least

an acknowledgement at the White House of the desirability of getting the rules done by the hammer date, and we were still entertaining the hope that a definitive resolution would be made in time for us to meet the deadline. We were prepared for that in that we had completed all of the documents. They had all been signed by Secretary Sullivan. By the day or two after the election they had all been delivered to the *Federal Register* for preliminary processing but with the understanding that they would not be put on public display until we got official clearance.

So we were positioned, if we got the right decision, to go ahead and publish our rules immediately. But there we were with no decision and only a few days left. By this time, we had arrived at the view that the only way to get resolution and get us published on time would be for the departments to go their separate ways, for us to be clear to issue our rules and USDA be left free to do what they pleased, including issuing no rules, issuing rules consistent with ours, or issuing rules different from ours. We had concluded that the overriding need was for us to get our regulations out on time and in the proper form. And we began actively advocating that approach at the White House.

The next significant event occurred Thursday after the election, the fifth, I guess. And this was what at that point we assumed would be the summit meeting on this issue. This was Bob Zoellick deputy chief of staff to the president, calling in Secretary Sullivan and Secretary Madigan to hear them out on these issues and presumably arrive at some decision about what the government would do. Again, Madigan was accompanied by Bill O'Connor and Mary McGrane; I accompanied Secretary Sullivan along with Robin Carle. And then there were some White House staff there. This meeting was held in the Office of the Chief of Staff in the west wing of the White House. It was a meeting that I had expected to last a half an hour or so, and this fellow Bob Zoellick two days after the election was the senior guy on the job in the executive branch of the government. The president had just lost, was not at the White House and was not . . . I mean, he was paying attention to other things.

WH: He had gone fishing.

MT: He had gone fishing, right. Former-Secretary Baker, Chief of Staff Baker was hunting and was not present, and Bob Zoellick as the deputy chief of staff was basically the ranking guy in the executive branch. I assumed that neither he nor these two cabinet officers would spend more than a half an hour or an hour at the most on this issue.

We went in there, though, and to my surprise began a very detailed discussion of the substance of all of these issues that turned out to be three and a half hours long. And indeed Mr. Zoellick brought up issues beyond those that had been in dispute between the two departments, issues concerning other aspects of how the term "light" was to be defined, for example; issues about when you could present absolute amounts of nutrients on the front of the panel, when you could say 5 grams of fat on the front of a food label. In a meeting in which I thought the principal focus of discussion would be the format, we spent two hours discussing other issues before we even got to the format issue. So as I say, this meeting went on from noon until about 3:30 with no break and also with no progress, because neither Sullivan nor Madigan were prepared to yield an inch on the basic issues of the format as well as restaurants and the light issue.

It was in that meeting that Zoellick first raised the possibility of this matter being passed along to the president if no resolution could be reached. This sounded kind of like the twilight zone to me. (Laughter) I found that hard to imagine that the president of the United States would personally get involved in resolving these very technical, very substantive issues. But nevertheless, Zoellick surfaced that possibility in this meeting.

At the end of the meeting with no resolution but with the deadline looming and an apparent impasse such that it began to become clear that we were not going to be able to get resolution by the eighth, Zoellick called a meeting for the following morning without the cabinet officers but with the others there on their behalf to sort

of plan the strategy for how this would get resolved and what to do about the hammer.

That meeting was at 9:00 or 9:30 that Friday morning, and again Robin Carle and I went over there for the department. And it was at this meeting that Zoellick said, in effect, that he was prepared to let the hammer come down, that he was not prepared to impose a solution on either cabinet officer. He was also not prepared to let HHS go its own way when Madigan was still protesting that the HHS format was not the right format, and that he was going to give Madigan his day in court with the president. That's essentially what he said at that meeting. And he directed the OMB counsel, who was present at the meeting, a fellow named Bob Damus to begin to prepare an options paper for the president to decide these issues.

WH: This was what date again?

MT: This was Friday the sixth.

WH: Meanwhile, if I may interject, while Mike's off doing all of that negotiating, back in the agency, in hopes that that will result in a successful conclusion, we're scrambling to get the rules typed and coded--coded being a process for the *Federal Register*--final review by everyone that need to review it, and you know, 4,000 pages of regs, and the regulations management staff in the Office of Policy doing, you know, Herculean work, every weekend, long days to get all this paperwork done in hopes that Mike can say, "Go!" In fact, we even went so far as to submit them on the eighth, which was a Saturday.

MT: They were over there . . .

WH: No, the eighth was a Sunday, and we actually sent them over there that . . .

MT: They were over there before the eighth. I can't remember the date. I mentioned earlier that they were over there.

WH: We sent them over there, because the eighth was a Sunday, but for all practical purposes the next work day would be the day they needed to be published, which was the ninth. So they were there on Monday the ninth ready for that signal from wherever to publish them.

MT: And let me just say that we were pulling out all the stops to try to get them published. Despite what Zoellick was saying, the industry had a big stake in getting these rules published as they were--our format, everything. I'm talking about the non-meat food processing industry as represented by the Grocery Manufacturers and the National Food Processors Association. And as we saw this impasse looming, Wednesday after the election, Thursday after the election, we alerted the associations that it was beginning to look as though the hammer would come down unless there was some extraordinary reversal.

(Interruption)

MT: Sorry this is taking so long.

WH: I think this is what they want, isn't it?

MT: The industry was in an odd position, and in particular the GMA (Grocery Manufacturer's Association), because on the one hand they knew that it was in their interest to get these rules out, and on the other hand, they, up to the very last minute, the week before the election and even those few days after the election, were in there lobbying for changes in the rules, changes that we had told them we were not going to make because we didn't think they were right, changes that even if we

wanted to make it was too late as a mechanical matter to make at that stage of the game if we were going to meet the deadline, and that, therefore, those were just out of the question.

They, nevertheless, were in there lobbying Tom Sculley, other members of the White House staff with the dual message, "Get them out on time--get them out on November 8--but fix them before you get them out." Two fundamentally inconsistent messages. I think by Thursday, the day of the Sullivan, Madigan and Zoellick meeting, I think I finally convinced them that, the industry folks, that they needed to have a very simple message, and it needed to be, "Get them out the door." And I have every reason to think that they aggressively began to pressure the White House in that direction beginning Thursday, Thursday night, because Friday morning Boyden Gray, who had been one of the principal contacts for the industry on this issue, came into the Friday morning meeting with Zoellick very anxious about the need to get these regs out and was prepared to be very expedient about doing that. I mean, I think he was prepared to go with any solution that would have gotten the HHS regs out the door.

Zoellick would have none of it though. Zoellick was being very faithful to his view of the proper process, which is that if you have two cabinet officers in a dispute you have to give them a chance, if they feel they want to to go to the president, to have it resolved. So he was not prepared to respond to the industry pressure to get the regs out on time. So Zoellick, Friday the sixth, initiated the process of an options memo being produced. We were, Kessler and I, still active over the weekend trying to figure out ways to get messages into the White House to try to encourage a proper resolution of this.

I was fairly shameless myself. I felt that anything we could do to get this resolved would be in our interest. I even . . . A friend of mine who was the secretary of the navy in the Reagan administration ran the legislative operation at the White House for a while under Reagan, a guy named Will Ball, who is now president of the Soft Drink Association. I called him and said, "Will, how can we get

to Jim Baker?" because to this date Baker had not participated at all. We had hoped that maybe he would see the logic. And so we made a contact there to try to have Baker get involved.

In any event, right up until the end of the day Monday--I mean, I think we were still hoping for a reversal . . .

WH: With the rules sitting at the *Register* . . .

MT: With the rules sitting at the *Register.*

WH: . . . waiting to be published the next day.

MT: So, you know, with every minute that went by the chances of getting cleared obviously reduced, but it wasn't until the *Register* closed on Monday the ninth that we finally and completely gave up on getting them published on time.

WH: We had a staffer posted down there literally waiting, babysitting them, with the message to move them into the publication process. They had been typeset, had a GPO, they were ready to go, and that person was called at 5:15 and said, "Put them in your car and bring them back."

MT: Yes.

WH: It came down to that last minute. We were still hopeful a call might come.

MT: The commissioner was concerned that something strange might happen to the rules, you know, so he specifically directed Bill to find a safe to put them in.

WH: Was that the night that we met down at the hotel in Bethesda? That Monday night?

MT: Yes, I guess it was.

WH: Mike, and I, and the commissioner, and a couple of other deputy commissioners met down there to strategize on what to do next at the hotel restaurant in Bethesda. And that's when he was worried about the safety of the rules.

MT: In any event, the hammer went down. Peter Hutt opined publicly that you may think the hammer went down, but he articulated a theory whereby the hammer really didn't go down.

RO: Really didn't go down, right.

SW: I was going to ask you about that.

MT: His theory was that we had not actually published the proposals in the *Federal Register* until November 27. The deadline in the statute was November 8. We of course had completed the rules by the eighth and made them publicly available. But Peter's theory was that because we hadn't literally met the deadline for the proposals that the hammer somehow didn't operate, was not valid. We got some pleasure out of finding in the files a letter that Peter had written to Fred Shank when we got the proposals published congratulating the agency on its efforts and specifically congratulating us on getting the proposals done on time.

WH: And "meeting the deadline."

MT: "Meeting the deadline." (Laughter) So Peter spun that theory, but the hammer in our minds had come down. And indeed it was important for us that that be understood, because that was part of what would keep the pressure on the process to get the rules done. Because as long as the hammer had come down, we had final rules as of the eighth, but they were the rules that had been published in proposals the year before.

The process at the White House of preparing an options memo went on. I think it was the middle of that following week after, and I actually wrote these dates down somewhere.

WH: We're to about November the 12th now.

MT: Somewhere in there Robin Carle and I were invited over the Bob Damus's office to review a draft of an options memo. We provided extensive oral comments. We were not allowed to take the document with us. We were also told that we probably wouldn't see the final version. The options memo needed a lot of work, because it was taking all these issues out of context, and it did not present them in a balanced way, frankly, and we provided comments that we hoped would improve it. I think Bob Damus was operating in good faith. I don't quarrel with his efforts to be straightforward, but it did not come out as a fair depiction of the issue, certainly in the first draft, and I went back and saw a second draft the following week which was better, but still, you can't possibly extract these issues from this very complicated statute and this long, lengthy process and present them in a succinct form and give them the credit they deserve.

My personal feeling as I was reviewing this options memo is that it still seemed ridiculous to think the president would actually get involved. I kept expecting something to happen to resolve this short of the president personally being involved. But that event never seemed to come.

SW: Is there really anything but a gentleman's agreement preventing us from going ahead and publishing this at the *Federal Register* or am I missing something major here?

MT: Well, Zoellick had been very clear to Sullivan that . . .

SW: I mean, if Congress ordered us to do this, could we not have published them and said we were following Congress's orders?

MT: As a legal matter, there's a good argument that we have legal authority to do that. But Zoellick, on behalf of the president, was telling Sullivan, "Don't do that until we present this to the president." And it just would have been inappropriate for Sullivan . . .

SW: Right, but the legal . . .

MT: Yes.

SW: I just wanted to make sure we had the legal . . .

MT: Right.

WH: But it wasn't . . . It's just a couple of years ago when Clayton Yeuter was at Agriculture when they first did their advance notice of proposal, on this subject as a matter of fact, on nutritional labeling. They couldn't get OMB clearance, and Yeuter just published them anyway. And he had the authority to do that, but, you know, a cabinet officer does that at some risk.

SW: At some risk.

WH: And OMB admits that they'll sort of pay them back later. So one of the unresolved issues is executive power, I guess.

MT: In any event, we went through the next couple of weeks following the week of the election watching this options memo develop, being told that there would need to be a meeting with the president. Sullivan I know was out of the country some of this time. Finally, though, I guess it was the Tuesday or Wednesday before Thanksgiving we got word that a meeting was scheduled for the thirtieth of November with the president and with the two cabinet officers to resolve the issues. That was Monday the thirtieth.

At that point I began to acknowledge in my own mind that there was going to be a meeting with the president. It had been scheduled. We . . .

WH: May I interject, in the intervening time between the time the hammer fell and that event, there was a lot of interest. There was a cascade of newspaper articles, editorials, as you mentioned earlier. The style section over Thanksgiving in the *Post*, in a little sort of current events thing for people and personalities, ran a thing showing a little button that a Washington law firm had prepared called "Free the Hostage Rules." So there was a lot of interest. It remained visible. And presumably the president was seeing these things in the paper as well as were his staff.

RO: Let me ask you this, though. The hammer theoretically had fallen. But really it was stayed in some manner or wasn't it stayed?

MT: Let me fill that in.

WH: Part of what Carle . . .

MT: Yes, part of what I spent time on during those two weeks was working on the *Federal Register* notice the statute requires us to publish in the event the hammer goes down. The statute says, "The department shall promptly publish a notice announcing the new status of the proposals as final rules." So we began preparing that notice and went through a clearance process with the OMB. Well, really it was more with the White House, the White House counsel's staff. Boyden Gray's staff got involved in reviewing that, because they had heard about Peter's argument. I think we convinced them--we did convince them--that in fact legally the hammer had gone down, and finally they cleared a *Federal Register* notice announcing that fact which published in the *Register* on the Friday after Thanksgiving, as I recall. So the hammer did go down. It was officially announced in the *Register* that the hammer went down, and so final rules were in place.

WH: And major food companies were frantically calling saying, "What does it mean? Do we start changing our label based on the hammer rules? Are you going to have new final rules? Are you going to repropose? What's going on?" And we were at a loss to give them a definitive answer at that point.

MT: Having heard that there was going to be this meeting at the White House, we began fairly intensely getting ready to get Secretary Sullivan ready, and we put together . . . Bill really look the lead and put together a fantastic briefing book for Sullivan. He had asked for lots of details, lots of materials. He was already very conversant with the issues, but he was determined to take this meeting with the president as an opportunity to substantively lay out his position and persuade the president what the right thing to do would be. And we provided him with materials that would enable him to do that.

Dr. Kessler and I went over to Secretary Sullivan's residence Sunday evening, the twenty-ninth, as a pre-meeting essentially for the meeting with the president. We had intended not only to go over substance with Secretary Sullivan, but also we wanted Secretary Sullivan to know and to deal in his own mind with the sort of harsh reality of the situation we were in--that is, that we were about to meet with the president; there was some risk the president would side with Madigan and in effect direct the secretary to adopt a format that we at FDA were not prepared to adopt and that the secretary had made it clear he was not prepared to adopt.

The commissioner and I had talked about this a great deal, and so how would we handle this, because you can't just disobey an order from the president. And it was clear in our minds that the only way we could deal with that as political appointees was to leave. I mean, there's just no way either of us for our own part or the institution, for its part, could be fairly expected to adopt the USDA format. It was just wrong. And so we went over there wanting to be sure that the secretary had confronted this. I knew, from talking to his chief of staff, that he was well aware of that. And I think he, well, I don't know everything that was in his mind, but I think he viewed it as an issue that could conceivably lead to that outcome for him as well. Because, again, he viewed this as a very major part of his public health legacy.

So we had a little bit of discussion of that issue, but most of the time that Sunday night was spent on the substance, because again he was boning up. He had faith that if he could sit down with the president and lay this out that he could persuade the president to do the right thing. He said that he had had conversations with the president specifically about Healthy People 2000 and how important it was, and that the president was very supportive of that. So he was optimistic that he could convince the president.

The meeting, again, was intended to be Sullivan and Madigan. Sunday night the secretary asked if I could accompany him again, to go over there, and not to be

in the room but in case questions came up. I said, "Yes, I can work that into my schedule." (Laughter) And the meeting was scheduled for 9:00, I guess.

WH: No, 10:00.

MT: It was at 10:00, yes.

WH: Because you met at 8:30 with the secretary in the secretary's office.

MT: Right. It was scheduled for 10:00 that Monday morning, yes. We had another planned session, which we went over to the secretary's office at 8:30 and just reviewed a couple of issues. Interestingly and importantly, I think, we heard around 9:00 or so that Marlin Fitzwater's office had called over to the Public Affairs Office at the department and had asked for the recent news articles on the subject of nutritional labeling. And so we sent them over a packet that included not only the recent news articles but the editorials and so forth that had laid this issue out for the public.

WH: Almost all of which had sided with us.

MT: Yes. I took that as an encouraging sign because of our theory that if this issue were understood in public terms it would be hard for us to lose. If it were dealt with as a private dispute between us, Agriculture, and OMB, it might not be so hard for us to lose. So that was an encouraging sign. The secretary and I left the department about 9:45. I was astounded that he was cutting it very close for this meeting. I was concerned we'd be late. But it doesn't take any time to get over there. We got over there in five minutes basically and pulled into that driveway between the west wing and the old Executive Office Building. Got out of the car. You know, the press hangs out up on the front of the west wing, and they come over to the fence. They

sort of looked down to this entrance into the lower level of the west wing. And they were up there with cameras sort of waving and trying to get Sullivan's attention to come talk to them, which he wouldn't do.

We went into the west wing and were greeted. At this point I was taken to an office in the old Executive Office Building to wait in case I was needed and Sullivan went up to the meeting. I sat there in this office for ten minutes or so. And the fellow whose office I was in was there. And the phone rang, and he talked to somebody for a second and then got up and came over to me and said, "You've been called to the Oval Office." I said, "Well . . ." (Laughter) "Let's go, I guess." So we headed on over there, down the hall and across that driveway and into the lower level of the east wing and up to the main level where the west wing lobby is and then . . . You actually get into the Oval Office going through a little office adjoining the Oval Office where the president's personal secretary sits.

And I was ushered through that office to the door into the Oval Office. You see the pictures of the presidents sitting next to some chief of state, you know, foreign dignitary in these two chairs in front of a fireplace with their backs to the fireplace. And then there are two couches in front of them. And the president's desk is at the other end of the Oval Office. The president was sitting in one of those chairs in front of the fireplace with his back to the fireplace. He was in the chair on the left. And the door I came in was just over his left shoulder, sort of behind him. So I was ushered in the door.

As I've said to people many times, my first impression, with the door opening and there's the Oval Office, which I had never laid eyes on before, but you know, it's one of the most famous sights in the world. I walked in, and there's the Oval Office, and there are all these figures sitting there. There's President Bush, there's Vice President Quayle, Jim Baker up at the other end of the couch is sitting in a chair. And my first impression was that I was walking into a wax museum, that this could not be real--this was some kind of set. But the president immediately disabused me

of that by getting up and very graciously extending his hand. We shook hands, and he asked me to come in, said that they had some questions for the expert.

So I walked around to the far end of the couches, and there were two chairs sitting opposite that end, so opposite of the chairs that the president and vice president were in, and Jim Baker was in one chair and I was given the other chair. The other people in the meeting were Secretary Madigan on one couch, with Marlin Fitzwater sitting next to him, and then Secretary Sullivan on the other couch, with Bob Zoellick, the deputy chief of staff, sitting next to him.

And the issue that had come up in the meeting apparently was the question of what it would take for the department to implement a decision to adopt the USDA format. You know, we had been telling the White House staff that in addition to the fact that we didn't think the USDA format was right, we also had said that our administrative record would not support the USDA format legally, and that in order for us to adopt the USDA format, even if Sullivan were willing to do that, we would have to reopen the administrative record, and it would take a significant amount of time.

Well, apparently the secretary had said, in going through the issue, that it would take six to eight months at least to go through the process required to adopt the USDA format. And this apparently stopped the conversation, because that was not what they wanted to hear. It was not acceptable, because they wanted this issue resolved on the president's watch. So it was to address that issue of why it was that it would take that amount of time that I was called into address.

The president himself asked the question, in fact. He said, "I'm a little puzzled here that I'm being told that I can't just make a decision here and have it promptly executed, that the department can't just salute smartly," he said, "and go execute whatever decision I make. And why is that?" And I basically gave him as a discussion of only about eight or nine minutes the whole thing at that stage. But I explained to him that we were operating under a specific statutory charge and pursuing specific public health goals that the secretary had given us, and that we had

to follow the Administrative Procedures Act, we had a big administrative record, and there was not support in the administrative record for the USDA position. And so in order, if we were going to change position, we would have to reopen the record and so forth.

Mr. Zoellick challenged that a bit by saying that, wasn't that simply an arbitrary, capricious standard that we were operating under, and as long as we had any support in the record couldn't we arrive at the USDA format? And the vice president sort of chimed in on that theme as well, kind of challenging the assertion. I just went through again that the industry--and they alluded specifically to the industry comments as having presumably supported the USDA option. I had to explain how it is that the industry comments were supporting an option that did not address our statutory charge and our public health goals. So there was industry support for another option but not one that could be reconciled with our expressed objectives and our statutory goal. And that's why you'd have to go back and redefine the goals in the first place and then try to build an administrative record to support a format along those lines.

At one point in the discussion I used the metaphor addressing the president that in response to his concern that we couldn't just salute and go do it, that we could promptly begin turning the wheel on the ship, but that it takes time for the ship to turn and that that was the situation we were in. Obviously, the secretary and I did not want to be seen as in any way being disrespectful to the president's authority. On the other hand, they needed to know that there were real constraints on what we were able to do. And that's what that discussion was about. It probably lasted, again, I don't know, eight or nine minutes, at which point I excused myself and I went back out the door.

And then figuring that maybe they would have some further need of me, I decided to ask that instead of going back to the old Executive Office Building that I just wait in that office, which they said was fine. You may have heard the joke at

the center that the reason we got the right result is because Ranger, the president's dog, liked me. It turns out . . .

SW: I thought the White House dog was Millie?

WH: The first lady's dog is Millie. Ranger is the president's dog.

MT: When I walked back out into this little office, sitting . . . There was . . . The secretary's desk sort of sits there just outside the door to the Oval Office. She's sitting with her back to that door, and then opposite in this fairly small office is a nice antique dresser, and on each side of that two nice old chairs. Sitting in the chair closest to the window sort of gazing out into the rose garden was this dog. I thought it was Millie, to be perfectly honest--looked like Millie. But it turns out the president has his own dog named Ranger, and Millie is the first lady's dog. And this was Ranger sitting there just sort of passing time. And I sat there for about a half an hour in the other chair waiting, and, you know, Ranger got up and at one point walked over and offered me his head to pat, and I patted his head. And then Ranger later on asked to be let out, and the secretary let him out, and that was it.

So in any event, I sat there for about a half an hour in this little office. Real interesting to me was as I was sitting there was this was a meeting with the president that had started at 10:00, was scheduled to end at 10:50, and I began to hear as 10:50 rolled around this discussion between the secretary and the staff assistant--there was another little office there--about the fact that they're expecting a phone call for the president and that they were worried that the food labeling meeting would go on too long. And the call was from Boris Yeltsin, the president of Russia.

I found it to be a very kind of strange juxtaposition of topics that, you know, the president was in there, as it turns out, talking about by that stage of the meeting, some very detailed and frankly minor issues in the scheme of things about food labeling. They by that time were talking about light in sodium and how the absolute

amount of nutrients could be depicted on the front panel, and here was this call coming in from a major world leader. Brent Scowcroft, the president's national security advisor, by this time had come into this little office and was pacing nervously, kind of worried that the call would come in, and they'd have to interrupt the president, and things weren't going to go right here, because the food labeling meeting was going on too long.

Around 11:00 or so I got called back in. They had another question, and it was on the "absolute amounts" issue, again with some misunderstanding on Zoellick's part about what our position actually was. I came in and explained it. And that was sort of the last issue of the day.

It's interesting. I came back in and saw that there were papers spread all over the coffee table between the couches. We had provided Sullivan with some props to use for this meeting, and the most interesting one I think involved the 2,000 calorie issue. The commissioner had discovered at a McDonald's up in New Jersey when he was on vacation last year that McDonald's has these tray liners that give nutrition information, including daily values for macronutrients. And McDonald's uses the 2,000 calorie figure as the assumed calorie intake for calculating their daily values for fat and saturated fat. And the commissioner thought that this would be a great rhetorical tool . . .

(Interruption)

MT: When I came back in the room that second time, these menus as well as some other props we had given the secretary were strewn all over the table. And the secretary told me in the car going back that the issue had come up and he was able to explain the position on 2,000 calories as not only what he felt was right from a public health standpoint and what the comments from the public health community had supported, but that McDonald's was using 2,000 calories as the basis for selecting daily values. He said that when he laid that out on the table in the meeting, that

captured everybody's attention for a minute or two, and he couldn't even get their attention again because they were so fascinated by these McDonald's tray liners.

In any event, that closed the meeting. We left with no clear sense of when a decision would come except that they said that it would be soon.

WH: Meanwhile, while you were over there and coming back, I was with the commissioner over at FOB 8 in great anticipation of wondering what was . . . I won't elaborate, but the commissioner was waiting for Mike and the secretary to return.

MT: Well, I guess it was after . . . It got to be about 11:30 by the time we were coming back to the department, and I knew the commissioner would be waiting. But the secretary said, "Come up to my office just for five minutes. We'll tell Robin Carle, the chief of staff, what happened." And so I, of course, followed along. (Laughter) I went up to his office, we sat down there, and instead of it being five minutes we spent twenty-five or thirty minutes sort of briefing Robin. Because the secretary came out very pumped up, very much feeling that he had made his points, that he had won the substantive argument, and feeling very good about how it had gone. So we spent, you know, close to a half an hour filling Robin in. Well, it began to dawn on me that the commissioner must be going nuts trying to figure out what was happening, because for all he knew there had been a decision on the spot. And he was sitting over there. Bill was with him.

WH: Well we were watching out the window when the secretary's limousine came back with Mike in the back seat. And they go in, and we think, "Well, any minute they'll walk in." And a half hour passed, and no Mike, and no call, and you know, what's going on?

MT: Well, I began to feel awful, but I couldn't just get up and walk out on the secretary. Finally we broke, and I did go to a phone just outside the secretary's

office and call over and say I was on my way and went over and filled the commissioner in about the meeting: it had been a good meeting, but there was no decision, and you know, we'd have to see what happened.

WH: That was Monday.

MT: Yes. Right. Let me . . .

WH: The secretary was going to leave town for Rome, if I recall, and hoped to get a decision.

MT: Yes. Let me correct something I said earlier. I mentioned getting, trying to get Baker involved. That really . . . That occurred not the weekend the hammer went down, but it occurred the weekend leading up to the meeting with the president. And the basic message we were trying to get to Baker was the message that, "Look, the only resolution of this is to let the two cabinet officers go their own way. They're not going to compromise. The president should not insert himself in the middle of this and impose the wrong answer on Secretary Sullivan." And we just didn't imagine, frankly, that he would impose our format on Secretary Madigan, so we were basically making the argument that he ought to let the secretaries go their own way. And we would do our thing and Madigan could do his thing. And so that's what the Baker contact was about. And we don't know whether . . . I know calls were placed to Baker, and we have no idea whether we got a substantive message through to him or not.

RO: Do you have any idea, Mike, why it appeared that they were leaning towards Madigan rather than HHS?

MT: Well, there was nothing about the meeting with the president that gave us any feeling about how he was leaning. It's just that Zoellick, who was staffing this with the president, and all of the White House staff were against us. For whatever reason, they were against us. They were clearly leaning towards USDA.

SW: And you presented the articles that they wanted?

MT: Well, but that's why . . . I mean, Fitzwater, you know, he doesn't get involved in this sort of stuff until it gets to be time to deal with the press in the president's public image. So, yes, I don't include him in that. But that's why it was a positive sign that the morning of the meeting Fitzwater asked for the clips and that he was in the meeting.

So there was the meeting. We left, didn't know what the answer was going to be, complete state of suspense really. Tuesday night I got a call at home from Robin saying that the secretary had been called over the next morning, Wednesday morning, to meet with Zoellick to hear the decision, to go through the president's decisions on these issues. I remember vividly anticipating the worst--driving in that morning, sort of composing what one says or if one resigns over issues like this--and went over with the secretary. The secretary asked me to come again--that's why Robin had called--to sort of hear the decision and deal with any substantive issues.

WH: Plus you had been told there would be a subsequent meeting with OMB general counsel on implementation. And obviously if implementation was "We approve your rules, go with them," why would we need an implementation meeting? So the signs were bad and . . .

MT: Yes, that's right. Yes, exactly. There was a meeting with OMB and the Justice Department to talk about implementation. We took that as a bad sign. Anyway, we went over there. This was 9:30, I think. Went into Zoellick's office,

which is in the west wing, part of a suite with the Chief of Staff's office, and went in there. Zoellick was there, and Fitzwater was there. Zoellick sort of opened it by saying that, "I asked Marlin to come because we want to go ahead and announce these decisions this afternoon." We still didn't know what the decisions were. And he said, "First, I want to talk about the format decision." And he had some papers in his hands which included the options memo which had had attached to it our format plus the USDA options.

WH: Our format and its modifications, its possible modifications.

MT: Right. And I was convinced, sitting there, that he was ruffling through it to find the ranges format, the so-called compromise format, and again, expecting the worst. He ruffled through, and he pulled out this piece of paper and said, "This is the president's decision," and handed it to us. And it was our format. It was a specific version of our format that included everything we cared about and also had as a footnote one of the footnote options that we had said was acceptable. It's the footnote option that involves stating the daily values based on both a 2,000 calorie diet and a 2,500 calorie diet, basically the concept presumably being, "We side with Secretary Sullivan on the basic elements, but we will require provision of information that addresses USDA's concern about no calorie level being appropriate for any one consumer."

Well I was aghast and thrilled and indeed personally felt that the president had selected--if space limitations were of no concern, because this footnote takes a lot of space--had selected the ideal format in terms of having a good clean format that gives the percent of the daily value and then puts the daily value information and all of its detail down at the bottom. I felt it was the perfect format. And we subsequently went through a discussion of the other issues.

Secretary Sullivan was wonderful, because there was a very difficult and delicate issue concerning the restaurant issue. And one of the options being

considered was exempting menus from the scope of the NLEA regime. And this was a very tough issue for us, because menus are labeling under our statute. There's no legal principle we can think of that would keep menus from being labeling without undermining very basic principles that we rely on in all of our work for drugs and devices and everything. And our concern was that we would be ordered to exempt menus and declare them not to be labeling.

Well, we got to the discussion of menus and, you know, they announced that the president was going to, had decided to exempt menus. And we had a good, close discussion in which the secretary, despite having gotten all this good news about format, which was clearly a major win for us, was still as an advocate for this agency sort of holding tough on the issue of, "Well, we can exempt menus but we can't say that they're not labeling." And it was very impressive that this guy was holding firm on these basic principles that we had schooled him in during this process. Fortunately, the president's decision, as articulated by Zoellick was, exempt menus but don't do it in a way that will undermine FDA's other programs. And so we have exempted menus and we've been silent on the legal theory. If it comes time to defend it, we will defend it on some ground other than that menus are not labeling. The Justice Department has said it can defend it legally. We'll see what happens there. But it was just impressive to me that Sullivan, who could, having won on format, just sort of taken it and run, hung in there looking out for the agency's best interest.

In any event, we went through the decisions. The president sided with us on the definition of "light," requiring a minimum of 50 percent fat reduction if you're a high fat food, siding with the USDA on "light in sodium," but in a way that we can live with.

WH: Absolute amounts.

MT: And the "absolute amounts" issue, which again, we had said we could do the way the White House wanted us to do it if it were legally possible. The Justice Department had said it was legally possible, so that was not a problem. The issues we cared about--preserving the labeling principle, format, and the basic definition of light--were resolved all in our favor.

But what was the most traumatic aspect of this--and let me just come back to this--is not just that Zoellick pulled our format out of the pile, but the president's decision was that this would be *the* format on all food packaging, all food labeling, both USDA's products and our products, so that there would be a consistent label. So what took an hour or so to sink in was just how significant it was that we had really achieved the results. The president had imposed a result that was beyond what our realistic expectations had been. Again, our fondest hope at that stage was to get our format on the products we regulate and worry about consistency and the USDA products later. But the president, the only person in town who had the power to achieve this result, had decided that he was going to adopt our format for all products.

And I think I know why he did it. I mean, to me anyway the reasons why he did it are clear, and there are two basic reasons. One is that--and I got this from the secretary in the car coming back from the Oval Office meeting--is that the secretary had made the presentation that he had said he was going to make, that this was a big public health issue, getting this format decision right was a big public health issue, and that the USDA format options, he told the president to his face in front of Madigan, were simply unacceptable. And that was sort of the bottom line word he used--USDA formats are unacceptable. And I think that had a big impact on the president.

I think the other factor, quite frankly, was that Marlin Fitzwater read the clips and saw that, "Mr. President, you can . . . " And I'm making this up here; I don't know what he told the president. But I can imagine him telling the president, "You

can either be a good guy or you can be a bad guy on this issue." You can either follow Secretary Sullivan's health instincts or you can follow whatever instincts are governing Madigan. But it's real clear that the next article is going to be on how you will play on this. That had to have had some influence, I think, on the process.

So there was the decision that day, that morning. Fitzwater was there, because they wanted to announce the decisions. We agreed on the spot that we would do a press conference that afternoon, which ended up going at 2:00. A lot of the work preparing for a press conference had already been done in terms of a basic press release and so forth, but it was the most hastily put together press conference I've ever been involved in. But it probably could not have gone any better, because Sullivan and Kessler, who were the principal presenters were so versed in the subject they really didn't need preparation. And the media showed up in spades, both print and television. I think it was . . .

WH: Fourteen TV cameras.

RO: And Madigan wasn't there.

MT: And Madigan was not there. I just have to relate that, after getting the result, we came back to the department that Wednesday, and this time I had the foresight to have them call the commissioner and have him come over. I guess I called. Somebody called.

WH: Yes, and then he called, and more of us came over.

MT: Well, the commissioner came over to the secretary's suite, and we went in and sat with the secretary, Robin, and Jackie White, who's the executive secretary of the department, and basically, the purpose was to plan for the press conference and look at the statement, the press release and all of that. And we spent, I have to admit,

several minutes with just the secretary being in this wonderfully exuberant frame of mind. He was kind of telling the war story a little bit for David and Robin and Jackie. Then we got to the press release. He had used this phrase, "the Tower of Babel." And we got to that point in the press release where "the Tower of Babel" was mentioned in a not particularly striking way. And he said, "I want it to say, "The Tower of Babel has come down." So that got written into the press release at his instigation. And that was the sound bite that was most prominent in the evening news that night.

SW: That was Bev Corey's speech line. She had written a draft speech for Dr. Sullivan much earlier, but had no idea it would be used verbatim. We were in the office when she was writing the speech, and we had been teasing her about a couple of the lines she was using. She had been listening to a preacher or something.

MT: Yes.

RO: When are these regulations going to issue?

MT: Since that day we've been working on making revisions in the documents that were needed to execute the decisions. One thing we've done, which will be of some historical importance I think, is some substantive work on the format itself, not only looking at the basic organization of the format, but also at the kind of enhanced graphics that would make it more readable. The posters you've seen of the format include the enhanced graphics.

As we had originally written the final rules, some of those graphic elements were mandatory and some weren't--some were optional. The commissioner was very tuned into the need to be sure that the format as it appeared on labels would be as consistent and readable as possible. So we took advantage, frankly, of the president having selected a specific format. We went back and looked at our rule and spent

a number of days' effort in seeing how we could build a little bit more specificity into the details of the format rule itself so that the actual legally required format would look as much like the one that Zoellick had pulled out of his sheaf of papers as possible. Because those graphic enhancements had been designed to assure that the format was as readable as possible.

We've finally got all those changes made. We've been in the process the last several days of getting final clearance, and just yesterday we were authorized by OMB to send the final rules to the *Federal Register.* They're at the *Federal Register.* We're hoping that they will be displayed, put on public display tomorrow, Christmas Eve, and then they'll publish in the *Register* maybe next week--if not, early the following week.

RO: Let me ask you, Mike, though, the hammer has fallen. So theoretically there are the proposed regulations that are legal. Right?

MT: Actually, they are actually, right, in place today.

RO: Now isn't it illegal to issue another set of regulations?

MT: No. The lawyers have scrutinized thoroughly, obviously, what process we have to go through to remove or revoke the hammered rules and put the new rules in place. If you look at the hammer and its purposes, look at the Administrative Procedure Act and its purposes, and look at the process we've gone through, we are really on secure ground legally in revoking the hammered rules without notice and comment and putting in place the improved final rules based on the extensive administrative record that we've developed. Really the final rules were developed through the administrative process and are just superseding the hammered rules.

Procedurally we're issuing our final rules as final rules. We're revoking the hammered rules without going through full notice and comment, but we are giving an opportunity for comment after the fact, if anybody wants to raise any technical issue about the final rules or any other issue. We're giving an opportunity for comment, but comment on final rules, so that we're not obligated--unless we're persuaded to make some change--to go through the full review and the full blown process.

RO: What's the comment period on that? Thirty days?

MT: It's thirty days. We are going to review the comments obviously, and if we find any errors or any adjustments we want to make, we'll make them. Otherwise we will probably publish a notice sixty days from now or so in which we say that we've got final rules; we're making whatever adjustments we're making, or we're not making any adjustments; and you can now begin compliance.

RO: Do you think, Mike, there's any possibility at all that the new administration will reopen this whole matter?

MT: By and large not. I mean, I know I think that they will have no interest in reopening the great body of these rules. No, I'm not concerned about that. I think we have satisfied the statute. I think the staff on the Hill who are most important on this have been very congratulatory of the way we came out. Whether on specific issues the next administration will take a look, nobody can rule out.

RO: I'm sure right now they've got higher priorities.

MT: Yes, I think that's right.

SW: The pressure's really on USDA to bring their rules into line as quickly as possible.

MT: Well, they're going to be publishing their rules conforming to ours simultaneously. It's really a remarkable event, as you think about it, because I think I could fairly say nothing will have as lasting or visible legacy. This format will be on food packages a long time. Twenty years from now we'll be walking through supermarkets seeing this. I also personally think that as a public health matter, this is as important as anything we've done. Even if only a small percentage of the population makes use of this format and the other information that's going to be on the label, if only a small portion of the population seriously uses it to construct healthier diets, that will still have great public health impact.

RO: I think it's really interesting though to think that here's two cabinet officers that just threw down the gauntlet, and you've got to go to the president of the United States to resolve a problem.

MT: You know, I said to Damus, the OMB counsel at one point, I said, "This just seems bizarre to me that these issues are going to be laid in front of the president." And he said, "Well, that's what he does for a living. He makes decisions." I don't think he typically makes decisions on these kinds of issues.

RO: No, I don't.

MT: But nevertheless . . .

SW: He's a health-conscious individual himself, and he may literally have chosen what made sense to him personally.

MT: Yes, I think that's part of what the secretary was relying on. And I think his instincts were in our direction. I think it was the staff over there that had to be fought through. And again, the issue got to the right guy with the right power and he did the right thing.

RO: Mike, we really appreciate your devoting two and a half hours to . . .

MT: Well, I had no idea it would take this time. I'm happy to have done it.

SW: I think this was one of the most exciting histories. (Laughter)

RO: We'll close this interview.

(Interruption)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 19, 1992

NOTE TO JACKIE WHITE

Attached are the materials we discussed on Friday: (1) a draft letter to Secretary Madigan along the lines requested by Secretary Sullivan; and (2) a memorandum to Boyden Gray stating the need for closure on food labeling this week and transmitting (a) information on the three issues he raised with the Secretary, and (b) a summary of FDA's movement on the nearly two dozen "major" policy issues.

At the Secretary's request, I spoke with Mary McGrane twice over the weekend. We had pleasant conversations that cleared the air at a personal level but did not yield any movement substantively. One "compromise" USDA seeks is for us to allow the range approach on FDA-regulated foods. I told her that ranges had been thoroughly debated within HHS, sharply criticized in comments, and rejected by the Secretary on consumer confusion and public health grounds.

I am available all day today if anything comes up.

Michael R. Taylor

cc: Ms. Eleanor Kerr

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

The Honorable Edward R. Madigan
Secretary of Agriculture
14th St. and Independence Ave., S.W.
Washington, D.C. 20250

Dear Ed:

I am writing to follow up on our meeting last week on the format for the new food label. Our discussion confirmed in my mind how strongly we share a commitment to improved food labeling and to a format for the new nutrition label that works for American consumers.

Since our meeting, FDA officials have had further conversations with your staff on what I seek to accomplish under the Nutrition Labeling and Education Act and what I have concluded are the key elements of the nutrition label format. Let me also reinforce some of the points I made in last week's meeting. First, we have made a number of modifications in our format to address the concerns raised by your staff and others who have commented on our proposals:

1) For food producers who believe that the Daily Values prominently displayed at the top of the label are inappropriate for their customers, we will permit the Daily Values to be moved to a footnote at the bottom of the label;

2) We have strengthened an explanatory statement on the label that the 2000 calorie diet shown as an example is only a reference and may not be appropriate for the individual consumer. Further elaboration of that message can be provided at the producer's discretion;

3) Producers who favor value ranges or otherwise believe that Daily Values based on other calorie levels should be considered may add those ranges or calorie levels to the bottom of the label as well;

4) We have adopted your staff's suggestion that additional dietary guidance--derived from the food pyramid or Dietary Guidelines--be permitted as part of the nutrition label; and

5) If a reference to detailed dietary guidance is considered necessary, a producer can refer the consumer to the U.S. Dietary Guidelines and describe how to write or telephone for them.

The second point I want to make is that we have attempted to carefully test a variety of formats so that our policy decisions could be supported by factual information about how real consumers will be able to use the new label. We first presented alternative labels to a series of "focus groups," then used those results to conduct two rounds of formal testing around the country with hundreds of food shoppers. We tested formats, for example, that told consumers that foods were "high," "medium," or "low" in nutrients and that highlighted certain nutrients. All of the alternatives we tested were compared with the current format that was first created in the early 1970s.

Our study results were convincing on several points. First, the current format performed poorly in helping consumers build a better total diet, a task that is at the heart of our whole NLEA labeling reform. Second, consumers wanted more information than the current format provides. And third, the format we have proposed (percents with Daily Values) was clearly the best performer in the most critical tasks (choosing a variety of foods for constructing a healthy diet). In fact, you may be interested to know that we found that this format portrays meat and poultry products in a more favorable light than the current format (by reducing the emphasis on the grams/milligrams of fat/cholesterol and concentrating more on a given food's contribution to a total daily diet, in which meat and poultry clearly have an important part in contributing protein, iron, B-vitamins, and zinc).

Third, I insisted that FDA identify a format that can be understood and used by less educated Americans who are not familiar with the Dietary Guidelines and the principles of sound nutrition. The format we have proposed does that well. Simply put, our research shows that consumers who do not know grams of fiber from milligrams of sodium can understand how percents of a daily value can be applied to building a diet.

Lastly, you should know what advice we have gotten from public health groups around the country. The American Medical Association, the American Heart Association, and numerous other health groups--as well as several food producers--strongly support the format we have chosen and have told us it will provide a real public health benefit to the nation's consumers in the coming years. It will complement the work of the food pyramid in helping Americans understand that a variety of foods comprise the best diet and that all foods are good for you if consumed in appropriate balance.

In closing, it is clear to me that the format we have chosen will meet the three goals we established for our food labeling program--to clear up confusion, to help families choose healthy diets, and to encourage product innovation. I regret any reservations you may still have about the utility of our format for USDA-regulated products but, as we discussed, I am compelled by the strict statutory deadline in the NLEA to forward our regulations to the Federal Register by the end of this week or early next week. I plan to do so. I will support any decision you make about the USDA rules, but I hope you will be able to join me in announcing our new food labeling rules to the American public. They are an achievement of which we can all be proud.

Sincerely,

Louis W. Sullivan, M.D.
Secretary of Health and
Human Services

POLICY REVISIONS ON THREE FOOD LABELING ISSUES

RESTAURANTS

- The Nutrition Labeling and Education Act exempted restaurants from several of its provisions (e.g., mandatory nutrition labeling) but included restaurants in two areas:
  - If a restaurant chooses to use a nutrient descriptor (e.g., "low fat"), it must adhere to the FDA definition for that term; and
  - If a restaurant makes a health claim (e.g., "fiber rich foods reduce the risk of cancer"), it must be a claim approved by FDA, as instructed by the statute.
- HHS has examined whether a further administrative exemption from those two provisions is appropriate and feasible. The Department has determined that an exemption should not be granted, for two reasons:
  - HHS's General Counsel advises that an exemption would stand at best a 10-20% chance of being sustained legally.
  - As a policy matter, it is inappropriate to exempt restaurants because as much as 45% of the consumer food dollar is spent in such settings; an exemption would perpetuate the "Tower of Babel" HHS has promised to correct by allowing "low fat" to mean one thing in the supermarket and something else in a restaurant.
- However, the Department has determined that two significant steps can be taken to ensure that restaurants are able to comply realistically with these requirements and are not deterred from providing useful information:
  1) FDA's final rules will permit restaurants to achieve compliance with the regulations without performing costly analysis of their food if they make a good faith effort to have a "reasonable basis" for their claim, utilizing available information sources such as government publications about nutrient levels in foods, cookbooks, nutrition labeling on ingredients used in restaurants, or any reliable data base. The National Restaurant Association says its members, which include small restaurants and large chains, can comply with this flexible approach; and

FDA REVISIONS TO FOOD LABELING PROPOSALS

When Congress passed the Nutrition Labeling and Education Act in 1990, it included a somewhat unique provision that FDA must propose implementing regulations within one year, and that those proposals would automatically become final rules unless FDA promulgated final regulations within an additional year (November 8, 1992).

Because of this statutory "hammer" and concerns raised about unnecessary requirements in the proposed regulations, FDA committed to identifying--and resolving--the key policy issues in June, before the "hammer's" effective date. Nearly two dozen such issues were identified, and in each case FDA has made modifications to increase the flow of useful information, while still achieving the goals of the NLEA. These include the following examples:

DESCRIPTORS (the use of terms such as "low fat" and "light")

- **Scope of Regulation**--The NLEA dictated that any "nutrient" descriptor terms be banned on food labels unless defined. FDA has defined the obvious ones, such as "low fat," "high fiber," and "light" and announced that many other terms (such as "nutritious") are not covered by NLEA and thus need no definition. One term remains at issue ("healthy"); FDA will draft a new proposal to determine a definition.

- **"Light"**--FDA proposed a stringent definition of "light" (1/3 less calories and 1/2 less fat), but has now changed that to either 1/3 less calories or 1/2 less fat (except for high fat foods, which must reduce fat by 1/2 with or without a change in calories). This change is supported by most food companies and fairly reflects what companies are now achieving in the marketplace.

- **Label Clutter**--Concerns were expressed that too many front panel disclosures were being required. Of the 13 such cases at issue, FDA has dropped or moved eight. Also, the NLEA required that disclosures accompany descriptors if a claim being made was counterbalanced by a negative characteristic (e.g., a "high fiber" claim on a muffin containing high fat). FDA raised the original "thresholds" for such high amounts of fat, cholesterol and sodium to levels that eliminate the disclosure for many foods. Moreover, FDA has reduced the type size requirements for the remaining disclosures where the agency has the discretion to do so.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MEMORANDUM FOR C. BOYDEN GRAY

Subject: Publication of Final Food Labeling Regulations

When we spoke last week, I said that I would provide brief written comment on the three food labeling issues we discussed. That information is attached at Tab A.

As you know, we are operating under an extraordinary statutory deadline that requires final food labeling rules to be published in the Federal Register no later than November 8, or else the proposals we published in November 1991 become the final rules. Having that statutory "hammer" operate in this manner would be an unacceptable failure to perform on our part and would yield an adverse result for the public and the food industry, since we have significantly improved our rules based on public comments--improvements overwhelmingly in the direction of providing a greater flow of useful information under more flexible rules.

We have also been in dialogue with OMB since June on the major policy issues. Based on public comment and consistent with the goals of the Nutrition Labeling and Education Act, we have moved substantially on virtually every issue. This movement is summarized in Tab B.

I am deeply committed to these rules and to the successful completion of the food labeling initiative. This is an issue on which my Department and the Administration took leadership before Congress acted. It is one of our most important public health initiatives. The announcement of our proposals last year was received very favorably by the public health community, the general public and the media. We can expect the same this year.

To meet the statutory deadline, our documents must be delivered to the Federal Register this week, ~~or early next week.~~ I will appreciate your support in this important public health endeavor.

Louis W. Sullivan, M.D.
Secretary of Health and
Human Services

Attachments

2) FDA will announce in its final rules that it will defer implementation of the NLEA requirements for most restaurants (all but large chains) for an additional year (so that they will have until 1995 to comply). The HHS General Counsel advises that this approach has some legal risks but can be justified to provide maximum flexibility to restaurants.

COMPARATIVE CLAIMS

- The issue is whether to allow "reduced," "less" (or "fewer") claims for nutrient reductions of less than 25 percent. NLEA requires that FDA define such terms.

- FDA originally defined "reduced" as a decrease of at least 50% in a nutrient and "less" as a decrease of at least 25%, and required a minimum absolute reduction (e.g., at least 3 grams of fat, 140 mg. of sodium).

- Responding to concerns of industry, consumers and OMB, FDA revised its proposal so that only a meaningful reduction (25%) need be made for either term, and dropped the minimum absolute reduction entirely.

- OMB would like FDA to go further and provide manufacturers the option of choosing either the 25% minimum reduction or the minimum absolute reduction.

- HHS has rejected OMB's proposal to allow only a minimum absolute reduction because it would allow foods with large amounts of sodium, calories, fat or other nutrients to make a trivial reduction (e.g., 600 calories down to 550) yet still suggest to consumers that it had been significantly "reduced."

- Moreover, food processors tell HHS that a 25% reduction is usually readily feasible. Thus, OMB's approach would not encourage product innovation toward healthier foods; it would merely allow comparative claims without meaningful differences in nutrient levels.

DECLARATION OF AMOUNT AND DISCLAIMERS

- Concerns have been raised about the requirement that declarations of the absolute amount of a nutrient (e.g., "100 calories per serving") must in some cases be accompanied by a disclaimer (e.g., "not a low calorie food").

- This is a very technical issue driven by the NLEA; FDA believes it is being as flexible as the law allows.

- NLEA provides that declarations of the absolute amount of a nutrient other than in the nutrition label (e.g., a popcorn package declaring on the front panel "100 calories per serving") are permitted only if the declaration is "consistent with" a defined descriptor.

- The drafters of the NLEA included this provision because of the concern that such front panel declarations ("100 calories," "contains only 5 grams of saturated fat") could easily mislead a consumer to believe that a food has a desirably low level of a nutrient when, in fact, the level was fairly high.

- FDA originally proposed that such declarations of nutrients be permitted only if consistent with the definition of "low." In response to comments, FDA agreed to allow such declarations, without any disclaimer, if they meet the definitions of any descriptor (e.g., "less"). Thus, the "100 calorie" declaration can be made on popcorn without a disclaimer if the popcorn is merely "reduced" or contains "fewer" calories.

- Moreover, FDA went even further to provide maximum flexibility by allowing the declarations of amount on products that are not literally consistent with a defined descriptor (e.g., the popcorn that is not low calorie or "reduced" in calories). It is only in this case that the accompanying disclaimer (e.g., "not a low calorie food") is required to satisfy the statute.

- **Nutrient Density**--FDA originally proposed to require foods to make descriptor claims based both on their standard serving size as well as "per 100 grams" (so as to keep small serving size foods from being inaccurately compared with most foods). Because many lightweight foods appropriate for descriptor claims, such as breads and cereals, were then disqualified, FDA has halved that requirement to "per 50 grams," thus resolving the problem for almost all foods.

- **Comparative Claims**--FDA proposed separate definitions for "reduced" (50% reduction) and "less" (25% reduction) and specified a minimum absolute reduction (e.g., 3 grams of fat). FDA has dropped the minimum absolute reduction entirely, and determined that only a meaningful reduction (25%) need be made to use either term.

- **Front-of-the-Package Statements of Amount**--FDA proposed to allow only nutrients meeting the definition of "low" to give the amount on the front panel (e.g., "contains 2 grams of fat"). That has been changed to allow the disclosure if any definition is met (e.g., "low," "less," "source of", etc. (The NLEA requires that such front panel declarations be "consistent with" a defined term.) FDA went even further, allowing such a declaration that did not meet a defined term if the manufacturer discloses that fact (e.g., "contains 200 mg. of sodium, not a low sodium food").

- **Meal-Type Products**--Food producers were concerned that FDA's proposed definitions of microwave dinners and similar dishes would be so restrictive that they couldn't make "low fat" and other such claims. The final rules have been made more flexible to allow many more such claims in appropriate cases.

- **Lean, Extra Lean**--USDA was concerned that FDA would adopt a different definition than USDA had for meat and poultry. FDA has adopted the USDA definition for meat-like products it regulates (seafood and game meats).

- **Brand to Brand Comparisons**--The FDA proposed regulation raised questions about the propriety of such comparisons (e.g., "our peanut butter has less sodium than their peanut butter"). The final rules clarify that such comparisons can be made.

HEALTH CLAIMS (claims linking nutrients and disease reduction)

- **Dietary Guidance**--Concerns were raised that appropriate dietary guidance (e.g., "eat lots of fruits/vegetables high in fiber") might be regulated under NLEA. FDA has clarified that they will not be.

- **3rd Party Endorsements**--Concerns were raised that FDA might ban or require prior FDA approval of such endorsements (e.g., "this food meets the American Heart Association's recommendations as part of a heart healthy diet"). Such endorsements will be permitted by FDA, if truthful and nonmisleading; and FDA preapproval is not required.

- **Wordiness**--The original proposal was read by many as allowing only long, cumbersome health claims, thus creating label clutter and deterring food producers from making useful claims. The final rules clarify that brief, concise statements on the front of the package suffice.

- **Extent & Number of Allowed Claims**--The NLEA allows only health claims approved by FDA, thus raising concerns that FDA would impose an overly strict standard. Of the ten health links Congress listed for FDA review, FDA is agreeing that a link exists for eight, including two of great public interest--fiber and cancer and fiber and heart disease.

- **Outside Advice**--Concerns were raised that the FDA process for approving health claims would exclude advice from outside experts. The final rules make clear that such advice is sought and will help form final decisions.

OTHER ISSUES

- **Restaurants**--Concerns about the ability of restaurants to comply with the rules prompted the Secretary to examine whether they could: 1) be subject to a less stringent standard and 2) be exempted or have their coverage deferred. FDA's final rules will do both--a "reasonable basis" standard for compliance will be adopted that requires far less specificity than for food packagers, and the rules will be deferred for non-chain restaurants until 1995 to give them ample time to comply.

- **Percent Juice**--FDA's proposal required producers of juice blends to label both the percent of total juice (e.g., 40% juice, 60% water) and the percent of each juice (e.g., 10% strawberry, 50% apple, 40% grape). In response to industry comments, percent declaration of each juice has been dropped. However, if the name and flavor of a product (e.g., "Country Strawberry") highlight one juice when most of the product consists of other juices (e.g., grape and pear), the contribution of the named juice must be disclosed by either declaring its percent or calling the product, in this case, "strawberry flavored."

- **Type Size Requirements**--Food producers complained that FDA was unnecessarily limiting the size allowed on the label of such terms as "light." FDA's final rules were changed to accommodate their concerns (i.e., the terms can be twice as large as the name of the food).

- **Sweeteners**--Food producers objected to FDA's proposal to require sugars to be grouped on the ingredient label [e.g., "sweeteners (sugar, fructose, corn syrup)"]. The requirement has been dropped in the final rules. Further, the definition of sugar was changed to allow more "sugar free" claims.

- **Label Format**--FDA proposed a new nutrition label that received virtually universal praise from health and consumer groups but was disliked by industry. The agency has developed some optional modifications that address those concerns, particularly USDA's, while retaining the key elements so critical to the health community's public support.

- **Serving Sizes: Volume vs. Weight**--FDA's proposal permitted serving sizes to be based only on weight (grams, milligrams, etc.). The final rule will allow volume-based serving sizes, when appropriate, as many food manufacturers requested.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D. C. 20201

NOV 9 1992

MEMORANDUM FOR THE CHIEF OF STAFF TO THE PRESIDENT

Re: Food Labeling Regulations

As you know, Secretary Madigan and I have met with Bob Zoellick to discuss differences Ed and I have over food labeling regulations. Based on those discussions, I am convinced our differences are not resolvable. While it would be desirable for our Departments to simultaneously issue consistent regulations, we are under no legal duty to do so. To the contrary, I am under a statutory mandate to have issued final food labeling regulations by November 8. If I do not act today, rules that we proposed last year take effect. These rules are strenuously opposed by industry and are more costly and regulatory than the rules I want to issue today. Furthermore, if I ~~fail~~ to act, our Administration will, as a practical matter, have forfeited this issue to the next Administration.

I initiated food labeling reform in 1990 by proposing regulations to require basic nutrition information on food labels, define such terms as "light" and "low fat", and permit claims linking diet with disease prevention benefits. In November 1990, President Bush signed the Nutrition Labeling and Education Act, which confirmed the general direction of my initiative and mandated promulgation by my Department of the detailed regulations now in dispute. Secretary Madigan issued a parallel set of labeling proposals covering meat and poultry products, but without a specific statutory mandate or deadline for final rules.

Food labeling reform is an integral part of Healthy People 2000 -- our landmark disease prevention and health promotion initiative. We have learned over the past two decades that the incidence of heart disease and cancer in our country are strongly influenced by what we eat and can be significantly reduced if the intake of fat, saturated fat, cholesterol and sodium is brought within recommended dietary guidelines and fiber intake is increased.

My Department has developed final regulations that will provide consumers with reliable information they can use to select healthier diets. Our regulations are based on our specific statutory mandate, extensive research, and over 40,000 comments from consumers, industry and the public health community. It is not possible to please everyone in an undertaking of this complexity, but, on the key issues in dispute, our rules have broad public support. On the most important issue -- the nutrition label format -- the public health and nutrition communities strongly support our approach.

These rules are important to the public health and of fundamental importance to me as the Nation's chief public health officer. It is imperative I issue them immediately. My failure to do so places me in violation of my statutory responsibility, will cause enormous hardship for the food industry, and will likely mean that the final rules will be controlled by the next Administration. I simply must act. Secretary Madigan should be free to make his own decision about USDA's rules when he is ready to do so.

I genuinely believe the issuance of those regulations will be a proud and important legacy for the President and his Administration.

Louis W. Sullivan

Louis W. Sullivan, M.D.

cc: Mr. Robert Zoellick

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D. C. 20201

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