History

of the

U. S. Food and Drug Administration

Interviewee: Philip Derfler

Interviewer: Robert A. Tucker

Date: October 28,1998

Place: Rockville, MD

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.

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Date: October 28, 1998 Place: Rockville, MD
FDA History Office

Interviewee(s): Philip Derfler

Address: [redacted]

Last FDA Position: Associate Chief Counsel for Foods
Center for Food Safety & Applied Nutrition

FDA Service Dates: July 2, 1979 - October 24, 1997

Interviewer(s): Robert A. Tucker

Number of Tapes: 2 Length: 100 minutes

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Phillip Derfler

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Chief, History of Medicine Division
National Library of Medicine

RT: This is another in the series of taped interviews in the FDA Oral History Program. Today, October 28, 1998, the interview is with Philip Derfler, a former associate chief counsel for Foods, Food and Drug Administration. The interview is being conducted in the Parklawn Building in Rockville, Maryland, and with Mr. Derfler is Robert Tucker of the History Office.

Phil, as we begin our interviews we like usually to have a brief resume or overview of your earlier experience, but really starting where you were born, educated, raised, and any particular relevant experience you had before coming to the Food and Drug Administration.

PD: OK. I was born in 1947 in New Jersey, and I grew up in a town called Fair Lawn, New Jersey, which is a small suburban town. It was a bedroom community where most of the people commuted to New York City. It was one of the towns that grew up after World War II in the New York metropolitan area.

After high school I went to Hamilton College in upstate New York. After that I spent a year in VISTA, which is Volunteers In Service to America, in Houston, Texas. I worked with poor people, black and Hispanic. When I started VISTA, the first thing that struck me was that as a white middle-class kid, I had nothing to bring to the poverty program at all. It became clear to me very quickly that if I really did want to contribute in some way to what was going on I would need a skill. So, since I never was particularly good in science, the skill that seemed most likely was that of a lawyer. So while I was in VISTA I applied to law school, and I got into New York University (NYU) Law School, which I entered in September of 1970, and I graduated from law school in June of 1973.

My fist job was with a legal services program in New Jersey, Passaic County Legal Aid Society, which is in Paterson, New Jersey. I was there approximately three and a half years until the end of 1976. I left in December 1976.

Then I went to New Orleans, Louisiana and worked for a place call the Louisiana Center for the Public Interest, where we were one of ten funded projects of the

Administration on Aging. We provided legal services to elderly people. It was there that I really became interested in health law. I did a lot of Medicaid and Medicare work, particularly in the nursing home context. In the Louisiana Legislature I drafted a bill that was ultimately passed that established a Nursing Home Patients' Bill of Rights. I thought it was fun.

So in 1979, in February of 1979, I left New Orleans and came to Washington to seek my fortune. I came without a job. I interviewed at a couple places, and I was offered a job at FDA, and it made all the difference, as they say. I was there for almost nineteen years, I guess.

RT: This Louisiana Center for Public Interest, that was a state-funded program?

PD: No, it was funded by the federal government. It was a grant from the federal Administration on Aging.

RT: I see. So were you a federal employee really at that time?

PD: No. The Louisiana Center was a private agency. I started at FDA on July 2, 1979, but actually my official start date is September of 1978, because they gave me 11 months credit for my time in VISTA, but that's all. Although legal services programs were funded by grants from OEO, and then ultimately by the Legal Services Corporation, which are both federal, and the Louisiana Center was funded by a grant from the Administration on Aging, I wasn't officially a federal employee until I came here.

RT: So you were then employed by the Food and Drug Administration.

PD: Right.

RT: And were you assigned to the Office of General Counsel?

PD: Right. Yes, I was hired into the Office of General Counsel. Bob Brady was handing hiring at the time. He was an attorney. And actually, I was the last person that Bob was allowed to hire. After that, Jeff Springer took over hiring, and he's done all the hiring since. Rich Cooper was the chief counsel. Jeff Springer was the deputy. My interviews were with Steve Terman, who was an attorney for a while, and Michael Peskos and Jess Stribling.

I came to work here on July 2, 1979. When I first came here, they needed an attorney who ultimately would do some administrative stuff. I wasn't hired as a litigator, even though I had litigation in my background. I did a lot of litigation when I worked for Legal Services, and quite frankly, I was just as happy to be done with litigation. I was tired of my stomach hurting every time I had to go to court. They were looking to hire somebody who would ultimately work in medical devices.

Rich Cooper was chief counsel until, I think, January of 1980, and then he left and Nancy Buc became the chief counsel. When Nancy came, by that time I knew enough about the agency that I knew that the Center for Foods (CFSAN--Center for Foods and Applied Nutrition) was downtown. So that was attractive to me, because I lived downtown. I lived in Adams Morgan. But Nancy wouldn't let me do it. She kept me for sort of special projects. I worked on the IRB regulations (Institutional Review Board regulations). I worked with Dr. John Petricianni. There was a department-wide effort to make the Patient Protection Regulations as consistent across the department as possible. So we worked with Dick Riseberg and some of the people from the office--Dr. McCarthy I think his name was--from the Office of Patient Protection at NIH (National Institutes of Health). The IRB regulations were adopted; they're Part 56 of FDA's regulations, and they're still pretty much in effect. They've been amended some since, but those are still

in effect. Patricia Harris, I think, signed them as one of the last things that she did as Secretary at the end of the Carter administration.

I also worked on prisoner regulations, which would have not allowed the use of prisoners in biomedical research. We were sued by Upjohn right after they were finalized, and when Arthur Hull Hayes came into office as commissioner he stayed their effect. I think they're still carried on FDA's books, but they've never been put into effect.

I also did some FOI (Freedom of Information) work. I did special assignments that came along, as well as and the basic seizures that are the staple of what OGC does. I mean, General Counsel in those days would break new attorneys in by giving you a lot of seizures, and then a criminal case, and an injunction. I told the general counsel when I came that I didn't want to do criminal work, but they made me do *one*, which was fine.

RT: I might ask you, when you first came in, Phil, do you recall who was the commissioner at the time?

PD: Yes. I started on a Monday, July 2, and Kennedy, Donald Kennedy had left the Friday before. His last day was, I guess, June whatever that would be, June 29. So he was gone. Sherwin Gardner was acting. Then Jere Goyan became commissioner for about a year. Then I'm not sure whether Sherwin acted when Goyan left or whether it was Mark Novich, but it probably was Mr. Gardner again.

RT: I think it was.

PD: And then Arthur Hull Hayes came in.

RT: Yes, well that kind of establishes the time frame in which you were doing these things.

PD: OK. So Nancy Buc stayed until the election, and when the Democrats lost the election, Nancy left. Jeff Springer was acting chief counsel for I think four or five months, and then Tom Scarlett became chief counsel. Bob Brady became Hayes' special assistant, so there was an opening among the foods attorneys. So I asked to be a foods attorney, and they chose me, and I started being a foods attorney. The other foods attorney at the time was Dave Weeda who left right at that time. Same time that Brady went upstairs to work for Hayes, Weeda left the agency and joined the firm of Olson & Frank, which is now Olson, Frank & Weeda.

When I started there was what was called the provisional list of color additives. The Color Additive Amendments of 1960 essentially set up a transition period when all color additives then in use had to be reviewed for safety by the agency. The agency at first tried to use that authority to regulate cosmetics. A color additive is anything that imparts color to various things including the human body. So the agency argued that rouge, lipstick, eye shadow, everything like that was a color additive and therefore had to be approved by the agency before it could be used. There was long litigation about that. Ultimately, the agency lost, in I think it was *Toilet Goods vs. Finch* or some case like that. So, anyway, the agency lost, so it was not until 1968 that that litigation was resolved. Consequently, the agency really didn't start working on its review of color additives until eight years after the legislation had passed.

Then, in the mid-seventies, FDA started running into problems with the Delaney Clause with a number of the color additives. So FDA kept extending the provisional list for those additives. In the mid-seventies a whole lot of them were dealt with, but by the time I came there were like thirty, I think, thirty colors left on the provisional list, and just about all of them raised Delaney Clause concerns. So the provisional list was set to expire in January of 1981, except then the agency decided to extend it. FDA would periodically extend it for two or three years or something like that.

Reagan came in and put his moratorium on regulations, so the provisional list got put in limbo for three or four months. So one of the things that I first worked on when I started working on foods was sorting out the status of the provisional list in the wake of Reagan's moratorium on new regulations, which obviously had the unintended consequence of depriving the industry potentially of the color additives that they wanted to use.

Then we got sued on the provisional list by Public Citizens, actually by Bill Schultz, who is now deputy commissioner for policy. He's a lawyer on the other side. So I worked on the defense of the provisional list at that time with Jeff Gibbs, who was another GC attorney. Then ultimately I worked on the documents by which the agency winnowed down the provisional list till the end.

RT: So during this time . . .

PD: I could walk through that if you're interested, if you want.

RT: OK. Well, it might be helpful to do that. Now during this period you were doing this for the Center for Foods, were you really assigned at the location of Foods or . . .

PD: No. My office was here (Parklawn). What I started doing was--and part because it was convenient to me, but in part because the center wanted it--I would have office days, at least one day a week, at the center and the other four days I would work here. Then I'd be at the center as necessary, and there were times when the press of business, the press of getting regulations out or a problem with a lawsuit or a congressional hearing coming up, would require that I spend the whole week at CFSAN, but basically I would be at CFSAN one day a week and the rest of the time here.

RT: Let's see, who was the director?

PD: Sandy Miller was director of the center, and Dick Ronk was the deputy director. Taylor Quinn was head of the Office of Compliance and the person with whom I had the most direct contact.

RT: OK, I wanted to establish the persons involved there. Do you want to expand a little further then on the . . .

PD: On the provisional list?

RT: Yes.

PD: Sure. Well, the provisional list . . . I guess, well, let's do it this way. There were some of the colors that we were dealing with that ultimately we decided were carcinogens. There were questions at the time as to whether the animal studies that we required were reasonable. I mean, that was when all the talk started about how you feed fifty rats twenty times or fifty times what anybody would ever eat, or five hundred times, and then because three of them get tumors, the stuff is a carcinogen. So there's all these questions.

But ultimately, we got the list down to fifteen color additives. Most of these colors were for cosmetics, so they were for external application--although the agency had a precedent that if there was any skin penetration of the color additive, then it would be treated as though it were an ingested color.

Industry, Peter Hutt, and CTFA (Cosmetic, Toiletries & Fragrance Association), first came in with the idea of de minimis. Joe Rodericks from Environ, who had previously worked in the FDA during the seventies, came in with Peter Hutt, and

Cavanaugh was the guy who was the head of CTFA. They made this big presentation about why the risks from some of the color additives were so small as to be de minimis.

So that started us on two tracks. The first was the de minimis track, that there were some risks that were so small as to be of no regulatory significance, even if they were carcinogenic risks, and that the Delaney Clause admitted to that. Ultimately that resulted in litigation that dragged on until, I think, 1988 with *Public Citizen vs. Young*, in which the court said, "No, the Delaney Clause is written in such a way as to admit no exceptions, even a de minimis exception." Therefore, the court rejected the agency's argument. The agency had listed six color additives, I think, on the basis of a de minimis theory. *De minimis non curat lex* ("the law takes no account of trifles") is the legal principle. All those listings were thrown out.

The other tack that we took was we did the constituents policy, in which we argued that in the testing of a color additive, if the color additive itself did not produce a carcinogenic response, it would not be considered to be a carcinogen subject to Delaney. Some of the color additives on the provisional list met this test. If the color additive itself did not produce a carcinogenic response in testing, even if we knew that it contained a carcinogenic constituent, it could be listed; because we argued that if it was not the color additive itself that was causing a problem, then we could use risk assessment to look at the risk presented by the constituents.

So the first one we used the constituents policy with was Green 6, and I wrote the relevant parts of the Green 6 document. It had a constituent in it called para-toluidine, and when CFSAN did a risk assessment, the risk from the para-toluidine in the Green 6 was very low, I mean 10^{-7}, somewhere in that range. We had a benchmark number of 10^{-6}, although we never enunciated it.

RT: I was going to say, I think you have described the constituents policy, but in a very succinct way, how would define that term then for someone that wouldn't be familiar with it.

PD: The constituents policy is as follows: Since it's impossible to have a chemical reaction, or at least this is what the scientists told us at the time, it's impossible to have a chemical reaction that's complete; there's always going to be some residue of the starting materials. So you're going to have a color additive that was made using some substances that are carcinogens, and there would be some residue of these substances in the finished color additive.

If the color additive as a whole tested out negative, then the fact that there was reason to believe that there would be some residue of a carcinogen in it would not necessarily prevent the listing of the color additive, or the food additive for that matter. When a risk assessment is done on the levels that this carcinogen is likely to be present as a constituent--that is, as a contaminant--in the color additives, if the risk assessment finds that the risk would be lower than our benchmark of 10^{-6}, although we never really announced that formally in any kind of rule-making, the color additive can be listed. Since we never established a level of risk, we took whatever the risk was, and we argued that that risk was de minimis, and we argued why it was so low as to be of no concern.

The idea had actually been around in the agency for a while. I know that I had seen some papers when I was doing research for it. I found some paper that Peter Hutt had written in which he kind of played with the idea but then basically rejected it. So when we came out with it in the *Federal Register*, Peter Hutt attacked the idea as being inconsistent with the act. That's Peter's quirk, and somebody else can deal with that. I had also seen a memo from Michael Taylor when he was a staff attorney at FDA to Rich Cooper in which he thought about it this concept, but they never decided to go forward with it.

I think there were two things that allowed us to go forward. First of all, I went to the hearing clerk one day and I found some old documents. Actually, Jenny Butler found them for me. Jenny Butler was in the hearing clerk's office; now they're called the Dockets Management Branch. Jenny Butler found for me some old, old, old paper. It wasn't a preamble, but it was notes that somebody in the agency had made right around the time that the Color Additive Amendments were passed. They were kind of explanatory notes for what was intended for each provision. The relevant discussion played into our idea of a constituents policy. I found some stuff in there, and it's quoted in the *Federal Register* in the preamble to the Green 6 document. So that was real helpful.

Then we found some language in the statute itself that lended itself to the interpretation that we gave it. So we cited those things, and we published our document, and we were sued by a guy named Glenn W. Scott, who had actually been an agency gadfly for a number of years. I think when he was in law school he sued the agency on the provisional list, and his law suit, I think in the late seventies, was the trigger that caused the agency--and I'm kind of digressing here because something I missed is coming back to me as I talk--but his lawsuit caused the agency to establish a schedule under which it would get rid of the provisional list, and that was the schedule that had expired in 1980 and that I alluded to when I started this discussion.

So he sued us again on this. He sued us in the Sixth Circuit, and we actually won. It's a reported case, *Scott vs. FDA*, upholding the constituents policy. After that we were never challenged again, and we used it. It became a regular part of the things that the Office of Food and Color Additives in the Center for Food Safety used in listing color additives.

RT: Mr. Scott, when he was . . .

PD: He became a doctor. He's a physician, I think, now. He's a doctor and a lawyer.

RT: I was just wondering, his second legal action, was that in behalf of any industry or anyone else?

PD: No, himself.

RT: Just himself.

PD: As an interested consumer, he sued claiming standing because he would be hurt if he ate this carcinogenic color additive or was exposed to it. And the court found that he had standing. We really didn't challenge it because at one time FDA had a procedural regulation that said the agency wouldn't challenge standing in litigation. The Department of Justice ultimately became more aggressive, and basically that regulation is now ignored by the agency. At one time, there were really big fights between the General Counsel's Office and Justice as to whether or not we would raise standing as a defense. But we didn't challenge Scott's standing, so he had it because he was an interested consumer.

RT: Very good.

PD: So that's the story of the constituents policy.

RT: Well that's given some information that many people would not be aware of, so I appreciate your elaboration on it.

PD: Actually, the only name that I didn't mention that deserves mention is Terry Troxell, whom I worked on the constituents policy with. Terry is still at the Center for

Food Safety. He did the scientific work on the constituents policy, and I did the legal work, and it wound up being a pretty good document.

RT: OK. That pretty well covers that area. Now nutritional labeling. I don't know if we're getting these in the order . . .

PD: Sure. No, you can do anything you want to do.

RT: . . . of occurrence, but that again was a rather large undertaking, and I'm sure you did a lot of work in that area, if you'd care to cover it.

PD: Actually, I started working on labeling in 1988. Fred Degnan, who had been a lawyer in GC for a year--actually he predated me, I think, by a year or two, and he's now at King and Spalding--Fred had been doing the food labeling, and I was working on food additives and color additives and GRAS (generally recognized as safe) substances. But with his leaving, there was a hole there, so I started working on it. Food labeling during the 1980s had basically been ignored by the agency. As the agency's resources had dwindled during the Reagan years, the decision was made that we needed to focus our attention on safety issues. I mean, to the extent we had any resources to bring to bear at all, we'd worry about food safety and we wouldn't worry about labeling.

So in 1984 you had Kellogg's coming out with an All Bran box on which they had a message on the back from the National Cancer Institute (NCI) about the importance of fiber in your diet. This was the first time that a discussion of a disease appeared on a food label, because the agency's traditional approach had been that if you mention a disease on a food label, it's a drug and we'd go after you. Well, Kellogg's was kind of crafty about how they approached it. They had gone to the National Cancer Institute and gotten their sign-off on putting the information on the package, and they'd also gotten clearance

through their general counsel's office. So when this box appeared, FDA's first response was to say, "We've got to do something about this. There's this drug out on the market." Secretary Heckler said, "No, you're not."

So essentially, we got backed down, and that started a whole health claims debate. It created a whole new category of things called "health claims" or "health messages." The question was, what should we do about health messages? As a result of Kellogg's action, various other things started appearing on the food label: calcium claims became real popular; fiber claims became real popular.

To make food look healthier--people were really health conscious in the eighties--to make food look healthier, Sara Lee, for example, came out with a famous "light cheesecake" which was made lighter. That is, it's calories were reduced by the fact that they based their nutrition information on a smaller piece of cheesecake, and they did nothing to reduce the calories or fat or anything. And FDA basically did nothing about it. Paul Hile issued a statement, I think in 1986. In 1987, before I started doing this, FDA issued a health claims proposal that essentially licensed anything. OMB made the agency do it, and so essentially it said, "Any claim that you want to make is probably going to be legal, even drug claims." I mean, there were no such thing as drug claims under this proposal.

So finally, this was becoming a really big embarrassment to the agency. The state attorney generals, using their own laws, were bringing actions against food companies, and the food companies were, quite frankly, making concessions and stopping using claims and stuff like that. But the food companies said, "Wait a minute. We don't want to be exposed to this harassment by the states." So the time was right. We were getting interested in it. Commissioner Young actually was embarrassed by the situation. Industry was interested, so the time was right for Congress to act. Before Congress did in 1988, right after Fred Degnan left, Commissioner Young decided that he wanted to take one last shot at seizing the initiative, so he asked Tom Scarlett, and then Tom Scarlett in turn

asked me, to develop a strategy for how we were going to resurrect FDA's control over the food labeling.

(Interruption)

PD: OK. So in 1988 Scarlett asked me, and I developed a strategy that talked about first publishing an ANPR (Advanced Notice of Proposed Rule-Making) that described a general strategy and asked for comment on it, then having a series of public meetings on the ANPR, and then ultimately doing rule-making. We did that. The ANPR, I think, laid out four or five major areas. That published in 1988, and then we had four meetings around the country to get public comment.

Now, the interesting thing about this is during the time that we were having the public meetings, Commissioner Young was removed, and Jim Benson became acting. And also during those meetings, Tom Scarlett was removed, and he was replaced by Margaret Jane Porter. That was in 1989. But we started the meetings like in November or December in 1988 and they went over into January, February 1989.

We got all these comments, and we listened to them. You know, ideas about nutrition labeling, and health claims, and nutrient content claims--those are some of the big things. And food standards was another topic. As a result of those hearings, in the summer of 1990, FDA published a series of proposals. Nutrition labeling had been required since 1972 or 1973 if a manufacturer made a nutrient content claim, or if they added a nutrient to their food product. I developed a legal theory for why we could require nutrition labeling of all foods under sections 701(a), 403(a), and 201(n) of the Food, Drug and Cosmetic Act. That's all explained in the preamble to a proposed rule that the agency published in 1998. We also developed a set of ideas about what nutrients should be included in the nutrition label, and we published a proposal on health claims.

On December 13, 1989, I think, we had withdrawn the 1987 health claims proposal that was causing so much trouble.

In conjunction with our publication in the ANPR and the beginning of the public meetings, not only did Scarlett change and Young change, but the president had changed. George Bush had become president, and his secretary of Health and Human Services was Dr. Louis Sullivan. Dr. Sullivan was very interested in food labeling. I don't think we ever would have gotten as far as we did without his support. I mean, he really was instrumental. Sullivan held a press conference--that's how significant this issue had become--at which he talked about the supermarket shelves having become the Tower of Babel. So that really gave the whole effort a big boost.

So we published our proposals. I think they came out in July of 1990. However, as I said, there was a growing pressure from industry and from the states and from us by our actions, for legislative change, so Congress started really looking seriously at nutrition labeling and reforming the food label. In November of 1990, after our proposal was published, but not our final rules, Congress passed the Nutritional Labeling and Education Act (NLEA) of 1990. We had been trying to head that off in what we did, and because of that the agency made a conscious decision not to be at the table when they negotiated the NLEA, although in all honesty, Bill Schultz and I had backdoor conversations--he would ask me questions, but I was only providing technical assistance.

So the NLEA passed. It made nutrition labeling mandatory. It gave FDA authority over nutrient content claims. It gave us authority over health claims. It significantly modified the rule-making procedure for food standards. It did a number of really wonderful things for the agency, if you're interested in food labeling and think that the food label can be an important public health communications tool. So all of us were kind of tired after doing the 1990 proposals. I mean, we had been working since '88 under a lot of pressure, but we hadn't seen any pressure yet.

By this time we had a new commissioner named David Kessler. Kessler had come in with a bang on food labeling matters. The first thing he took on was "fresh." Ragu had canned pasta sauce that they put in a jar called Ragu "Fresh" Italian. The agency had been talking about doing something about it and talking about doing something about it, and then Citrus Hill came out with a "fresh" orange juice from concentrate. And Kessler just came in and said, "Enough talk. Let's do something." So he said, "I want you to go to court." So we took action against Citrus Hill first, and we seized their orange juice in Minnesota. Denise Zavagno was the lawyer in that case, and the day after, Proctor and Gamble caved. Then we went after Ragu pasta sauce, and Ragu caved.

David Kessler became a folk hero by this point, and then he went after "fat free" claims, actually saturated fat free. It was saturated fat free on oils that were 100 percent fat. You know, that was misbranding, so Proctor and Gamble again came in and signed a consent decree that they would change the claims that they were making. So Kessler came in, made a really big splash, and made his name doing something about food labeling.

So the first thing, there was never any doubt in anybody's mind that what we were going to do is meet the time frames set in the law. The NLEA had mandated the proposals be out within one year of passage, by November something, 1991, and that the final rules be out one year after that, November 27, or something like that, 1992. CFSAN--the Center for Food Safety--has never been so motivated in its life. There were literally tens of people thrown into the task of drafting regulations. I was the lawyer assigned to it, and I did all the legal work on it.

We published the set of proposals, I think, on November 27, 1991. There had been some noise in the system involving voluntary labeling of raw fruits and vegetables. But we published the set of proposals on November 27, 1991, and then we took comments, and then we published the final rules, but before the final rules could be published . . . USDA (United States Department of Agriculture) at this point had sort of

gotten into the act and decided that they were going to have nutrition labeling. They had been involved. They had been in all the hearings that we had held going back to 1988, but they hadn't really done anything. In 1991, they decided that based on their existing authority--which I now understand, but didn't then--their existing authority to approve labels, they would only approve food labels, meat labels, other than raw, single ingredient product, if it were nutrition labeled. That's what their regs say.

So they got into the act, and they were going along with us, but then as we got to the eleventh hour, USDA and FDA split on about six or seven issues: whether restaurant menus ought to be subject to the health claim provisions of the act and the nutrient content claim provisions of the act, and various others. The dispute was never settled between the two agencies, and it went up to President Bush.

RT: Was it the Department of Agriculture who was pro on the nutritional menu, nutritional informational menu, or FDA?

PD: No, Agriculture did not want menus to be subject to the health claim regime, and we said that there was legislative history that required it, and there clearly was. There were other things: how the nutrition label was going to look. Kessler did some real ground breaking. You know the whole Percent DV (Daily Value) column now, which I think is probably the most accessible part of the nutrition label, that was developed through Jerry Mande and David Kessler. That was really key in helping people understand. And Agriculture was reluctant to go along with that, I think.

RT: Was their reluctance predicated on the premise that this would be a very voluminous menu that would be passed out to customers or what?

PD: No, I don't think so. I don't really want to speculate about what their motives were, because I probably would libel them if I did. (Laughter)

So there were like seven or eight issues that went up to President Bush, and there was a meeting. Secretary Madigan went; Secretary Sullivan went. It was cabinet level, and Mike Taylor was there for the agency. President Bush sided with us in almost every respect. We had to change our rules slightly, but in January of 1993--January 6, 1993--the final rules went out. I think there's some really fabulous stuff in it. I mean, it's probably the thing I'm most proud of in my entire government career. There's a whole lot of people who deserve a whole lot of credit for it. I guess as the food label is now, five, six, seven years old, and people are having second guesses about it. I think the nutrition label has changed how people eat. I guess their fat intake is sort of creeping back up; however, the label had a really big initial impact, and now it's creeping back up.

RT: Certainly you see consumers in the stores looking at these nutritional panels, whereas before it certainly was not as obvious to them.

PD: The label is now reliable. Under the old rule was industry could establish its own serving size. So in the case of Sara Lee, they wanted to have less fat, so they made the serving size smaller. If they wanted to make their vitamin content higher, they would have a bigger serving size. We established 136, I think, categories of serving sizes, and every food must fit into one and get its serving size. We have this whole regime of RACCs (Reference Amount Customarily Consumed).

Could we break for a second?

RT: Certainly.

PD: I need to get a drink. My throat's . . .

(Interruption)

RT: OK, Phil.

PD: We had Yung Me Park, who is a woman at CFSAN, who analyzed all these data bases to come up with the various serving sizes--one of the most amazing feats I've ever observed in my whole life. But, I mean, there are just hundreds of people--well, maybe not hundreds, but many, many people at CFSAN who did extraordinary yeoman work.

I guess what I'd like to talk about a little bit is how it went into effect. We published the final rule on January 6, and the regs were supposed to go into effect, they'd be legally binding one year after that. No, I think they had eighteen months after that. It was supposed to be in June. Yes, June in 1994 is when they were supposed to go into effect. We got sued for a TRO (temporary restraining order) right before they were supposed to go into effect. We got sued by can manufacturers. They were generic packers, so they were worried about how many different labels they were going to have to do. They sued us in front of Judge Sporkin in D.C., and it was probably the most unfortunate choice that we could have gotten, because the question was never *whether* he was going to give them an injunction; it was for how long. He entered a TRO. The second time we went back in front of him it became clear that Congress was considering and actually passed legislation that extended the effective date ninety days, I think, from May, either May or June, to August 8, 1994. So Judge Sporkin seized on that and extended. So it was sort of a disappointment that we didn't get to do it on exactly the day that we had planned, but because Congress changed the law anyway, it was no harm, no foul.

The other thing that was an underlying theme that developed pretty strongly during the NLEA implementation period was dietary supplements. Dietary supplements have been a long-standing issue for the agency. The question was whether or not they were

going to be subject to nutrition labeling. Bill Schultz is probably the best source for this, because he was on Congressman Waxman's staff at the time that the NLEA was passed, so he would know exactly what happened. As I said, we weren't at the table, but my understanding from him is that at the last minute the dietary supplement industry put in some stuff about health claims for dietary supplements and nutrition labeling of dietary supplements, making dietary supplements subject to the NLEA. So when we did the proposal, we included dietary supplements in the coverage of the regulations.

Before the final rules were done, PDUFA was passed--the Prescription Drug Users Fee Act. I order to get PDUFA passed, Senator Orrin Hatch insisted that FDA had to re-propose our regulations on dietary supplements. PDUFA established a new schedule under which we would re-do rule-making on dietary supplements. By the time this all happened--this was in October 1992--so even before we knew that there was going to be the train wreck with USDA that led to the White House, we had to scramble in the last couple of weeks to pull out dietary supplements, because we were obviously done. A lot of the documents were done, and we had to pull out all the references to dietary supplements.

RT: Now L-tryptophan was an item that was significant in this process, wasn't it?

PD: Actually, no. L-tryptophan was something different. L-tryptophan had occurred in 1989. This involved Showa Denko, a Japanese company that manufactured L-tryptophan for the U.S. market and supplied a lot of U.S. dietary supplement manufacturers. Sometime in 1988 or 1989 they changed their manufacturing process. As a result of that, they apparently introduced something into their L-tryptophan that in 1989 led to a significant outbreak of Eosinophilia Myalgia Syndrome, EMS, associated with people taking L-tryptophan. I can't quite say that it was definitely what the chemical company did, because apparently, as we found out when the problem started, there had

been problems associated with the use of L-tryptophan prior to this whole outbreak of illnesses. So it may be something inherent in the L-tryptophan. Nobody has really ever exactly found out what it was. But as a result of this there were like 1,500 people who became ill, and thirty or forty died. CFSAN did a major recall, because the product was unfit for food. We had a congressional hearing in front of Congressman Patsy Mink in which a number of people who had gotten sick from L-tryptophan were there and sort of attacked the agency for not protecting them better.

RT: What kind of food or product was this item in?

PD: L-tryptophan is an amino acid. It's an essential amino acid. The agency had some history in the late 1970s of trying to take action against dietary supplements that contained L-tryptophan and losing because at one time L-tryptophan had appeared on the GRAS (generally recognized as safe) List as a nutrient supplement. In the early seventies the agency tried to take it off the GRAS list. But in 1977 when it published the CFR, the Code of Federal Regulations, there was a snafu, and L-tryptophan accidentally appeared as still being GRAS, so the judge in New Jersey threw out our case. So the agency had long-standing concerns about L-tryptophan, but it had never really been successful in doing anything. As a result of the 1989 outbreak, however, we banned all use of L-tryptophan in dietary supplements and in a lot of other protein products and stuff like that.

I guess there's continuing pressure to get it back in products. People tended to take L-tryptophan products because it helped them to sleep, or they said they thought it did. Actually, there was a whole cluster of illnesses in South Carolina around a psychiatrist or psychologist who was telling his patients to take it because he thought it would help them with their sleep. Once we recalled it, that basically ended the problem, although, like I say, there's continuing and ongoing pressure for the agency to allow it back on the market.

RT: How about infant formulas? Did you get into some work with that with CFSAN?

PD: Yes, I had kind of minimal contact. The Infant Formula Act passed in 1980. Then in 1986, Senator Metzenbaum did amendments to the Infant Formula Act that significantly changed it, actually. The agency was very, very, very slow in responding to the 1986 Infant Formula Act, implementing it. FDA decided to implement it on a piecemeal basis. So by the time I started working on infant formula, which was like in the late eighties, there had been regulations in place that were adopted under the 1980 amendments, but they had never been amended to reflect the 1986 amendments. So finally in the mid-nineties, about '93-'94, I worked with the people in the Office of Special Nutritionals at CFSAN, and we developed a comprehensive proposal to amend the regs to fully reflect the new provisions of the infant formula act. I think they're in the process of trying to finalize that proposal now. I did not stay around long enough to see it all the way through. There were a lot of fits and starts.

The biggest problem in infant formula when I was here, I think to a certain extent, since our regs never were in place, there was a certain amount of holding our breath. But there were three, I guess, sort of specific incidents that I guess I'd point to.

One was Carnation Good Start. Carnation came out with a new infant formula, and under the 1986 amendments, they're required to give us ninety day notification. At the end of the ninety days we had concerns, so we wrote them a letter telling them not to go to the market. They were really upset because they hadn't heard anything from us. So there was this big meeting at CFSAN which Bob Lake attended. The representative of Carnation told us that the train had left the station. This was in like 1988, I think. Bob Lake said, "You better pull the train back." As a result of that, they did. They ultimately submitted the data they needed, and it got put on the market.

The second thing is we had a really big problem with counterfeiting of infant formula. What people would do would be to buy infant formula as a loss leader at K-

Mart or Wal-Mart, or someplace like that where it is sold real cheap, and these people would then resell it. The problem was, as a result of that, there was a lot of mixed lots, and it was impossible to tell, to know really the conditions under which the infant formula had been kept, and whether or not it had been abused in any way, because obviously it had been subjected to various temperatures and conditions. So that was always the concern, but the act never really gave us a terrific handle on this problem.

I guess the last thing of interest--I'm trying to remember--was exempt infant formulas. There is a fair amount of abuse of exempt infant formulas. The act really was not very well written. Exempt infant formulas are infant formulas that are exempt from all the premarket review requirements that apply to normal infant formulas because they're for a population that has special dietary needs. Trying to get a handle on that type of product was a major job, and we made a decision to amend our regs to try and deal with it better. The problem is that we never did.

So those are the major problems with infant formula.

RT: Now, during all or part of this time, you served as a liaison person with other agencies--I think EPA and USDA. Is that correct?

PD: Well, the liaison activities that I did were not on an ongoing basis. It was more on an issue by issue. For example, we had problems with salmonella enteritidis in eggs in the late 1980s, so we tried to work closely with USDA to try and solve the problem. Actually, it didn't work. Salmonella enteritidis was a problem we started dealing with then; it was a problem confined to the Northeast, and now it's a national problem, because USDA basically didn't want to do anything. But I worked at it on an ongoing basis. I don't have any particularly terrific experiences.

RT: How about EPA then? Was that something you did with them?

PD: I worked with them a little bit on pesticides. It was really not a major focus of mine. Where I worked closest with EPA was in the wake of a case called *CNI vs. Young*, which said that in order to do action levels, if they were going to be binding, even if it was only binding on the agency, the agency had to do rule-making. So it significantly changed how the agency provided guidance, did guidance documents and stuff like that. It is still a problem. That case directly affected EPA, because it put at issue our action levels; the action levels that we use to try and protect people against pesticides in many instances. So I worked with them on that.

There was a major recall involving Cheerios in 1994 and 1995 because there was an illegal pesticide. I think it's chlorpyrophos was applied to the Cheerios, that is, the oats that were going to be used for Cheerios while they were in storage. There were two related pesticides; one of them was registered and the other wasn't. The one that wasn't was cheaper, so the General Mills' contractor used it to make a little extra money. That was like a really major recall, about five million boxes, I think, of Cheerios.

So there have been specific instances over the years where I had contact with them, but it was not really in any sense a direct liaison.

(Interruption)

RT: OK, Phil, I think we're on board again.

PD: All right. The area I guess I sort of wanted to follow up on a little bit was after we got out dietary supplement regs in place . . . The nutrition labeling regs for dietary supplements didn't get into place until I think last year, but for health claims, they were in effect since 1994, I believe. We got sued thirteen times by dietary supplement companies challenging our health claim regs on the grounds that they were unconstitutional and a violation of the First Amendment.

So there were cases in Utah, the Tenth Circuit, the Ninth Circuit, Utah District Court, New York, Eastern District of New York, and then in Washington, D.C., in the D.C. District Court. So we wound up defending all those cases with the Justice Department. A woman named Susan Strahn at Justice, and in New York Southern District there was a local U.S. attorney whose name I don't really remember. But the First Amendment challenges were fairly significant and it took a lot of work, but at least until now we have won. Actually, a couple of the cases are still on appeal. One, they're seeking a writ of certiorari in the Supreme Court, and one is I think on appeal to the D.C. Circuit Court. But either by getting the cases dismissed because of a lack of standing--that issue--or lack of ripeness, or ultimately on the merits themselves, we have prevailed. We had a couple decisions, one I think in Second Circuit and one by the D.C. District Court, that upheld our regulations as being consistent with the First Amendment. They used the Central Hudson analysis and found that the regs are consistent under all the prongs. And all those cases are reported, but that was really a major development.

I guess the other thing that I did that isn't reflected here is I did work on tobacco. I worked on two aspects of it. First of all, whether cigarettes could be a restricted device, and I wrote the preamble to the *Federal Register* on that. Ultimately we didn't win on that in the district court, and obviously in the court of appeals it has gone even worse. And then I wrote the sections of the document on the First Amendment and why our regulation of advertising would be consistent with the First Amendment--again going through the full analysis under Central Hudson. I guess the agency has requested that there be rehearing in banc in the Fourth Circuit. I guess we'll see how that turns out.

So that was another major activity of mine. I'm trying to think what other . . . That was basically it.

One more area I ought to mention is that the first thing I really worked on when I started at CFSAN and being the CFSAN counsel was the GRAS Review. In 1969 one of the chemical companies was testing a mixture of I think cyclamate and saccharin, and

they found that the mixture caused carcinogenic tumors in rats. So they figured it couldn't have been the saccharin, because saccharin of course was safe, although later scientific evidence raised questions about that, so it had to be cyclamates. Cyclamates and saccharin were both on the agency's GRAS List (Generally Recognized as Safe List).

So as a result of that, President Nixon ordered the agency to undertake a GRAS Review, a review of all the substances that were listed as generally recognized as safe in Part 182 of our regulations--21 CFR (Code of Federal Regulations), Part 182. And there was this long process where the National Academy of Sciences developed principles, and then committees--I forget who the committees were--but there were committees that reviewed each substance that was on the GRAS List in 1970 and did a report. Those reports ultimately went back to the agency, and then the agency did rule-making to affirm substances as GRAS, and when a substance was affirmed as GRAS, it was put on the list in Part 184 of our regulations.

By the time I came to the agency and started working on foods in 1981, the GRAS Review was still ongoing, but it was not the sexiest activity. So when I started, there was a backlog of ninety documents, ninety GRAS Review documents in the Office of General Counsel. I started looking at those and gradually worked down those documents. I caught up, and we finished the GRAS Review, I think in 1985 or 1986. So we finished something that had been pending for a really long time. So there was that.

RT: Now during this period of counseling the Center for Foods, were you involved in congressional hearings or preparations for hearings of that unit.

PD: Yes, periodically. I talked before about the de minimis policy in the agency. There was a big congressional hearing in I think 1984 or 1985 in which the agency put forward this whole de minimis theory as to how it was going to show that these color additives were in fact safe. Actually, in all honesty, I had written a memo to Tom Scarlett

in which I said that I thought that de minimis was a lot of bunk and that it was inconsistent with the statute.

It was intended to be a strictly internal document to provide advice to him. I wrote the memo, and I knew it was fairly charged politically, so I only made one copy of it. I gave the original to Tom Scarlett, and I gave a copy of it to somebody in Foods, since they were the client. I asked them to destroy it after they read it. Well, apparently they forgot to destroy it. It wound up in their records. The records were subpoenaed by a congressional committee, and low and behold, they found this wonderful memo. So my first contact with a congressional hearing was to be quoted and cited by committee staff as, "Here's your lawyer, your prime color additives lawyer, saying that your whole policy is illegal." So I think there's a congressional report where I'm quoted at length, which was not exactly the best way to advance my career, I guess.

Other than that, I was involved in a number of hearings on food labeling. There were periodic hearings on dietary supplements over the years. And that's basically it. None of them were terribly dramatic or memorable. I guess the most memorable was the day before we had one of our public hearings--I think in Atlanta we had a hearing--Congressman Weiss of New York, who was at that time head of the Oversight Committee, had questions about . . . I don't even remember the questions anymore, but he had questions about our labeling policies.

Again, they had one of my memos. Actually, Mitch Zeller, who is at the agency now also, was the staffer for Congressman Weiss, and he found a memo in which they felt that I had sort of made a major concession or something. So they kept quoting to me what I had written. I write little marginal notes on documents, and they kept reading them to me, and I really didn't mean what I had written the way they wanted me to have intended to say it. I was really saying something different. It was totally innocent. But they kept reading it to me, and I kept trying to explain it, and they didn't understand, and they kept reading it to me, and I'd try to explain it and they didn't understand.

So as a result of all this, I was really depressed, because I figured, I'm so inarticulate I can't get my point across. But after the hearing, Frank Young came up to me and started shaking my hand and said, "Great job. Great job." He said, "You've completely confused them. It was wonderful. Wonderful work!" (Laughter) And I just said, "Oh. Oh, thank you, I guess." So that's my only . . .

RT: Well, Congressman Weiss, he was pretty probing as I recall, so you apparently performed well for the agency.

PD: I don't know if I did, but in Frank Young's eyes I sure did. So that's my only congressional hearing story.

RT: You said at the outset, I think, that you were not personally involved in litigation or regulatory . . .

PD: No, I was involved in a fair amount of litigation, but it was mostly in a defensive posture. I didn't handle a lot of seizures. Most of my seizures won by default. I was real lucky in that way. But I did all the defensive work on the health claims litigation. My first case, my first big case, was an FOI (Freedom of Information) case involving interocular lenses. When I was given the case, I was told that there were nine documents at issue, and it wound up being 350 documents. So I wound up doing a Vaughn Index on 350 documents, and my Vaughn Index was 350 pages long. So I did that, and that actually resulted in a couple of reported decisions.

My involvement in litigation was as defensive litigation, and there's been some over the years, but the highlights were the FOI litigation with which I started and the First Amendment litigation which I described before.

RT: You have, of course, served under several commissioners and a number of different general counsels. Do you have any particular impressions or observations in terms of how it was as a staffer in the Office of General Counsel in these different periods?

PD: I'll give my reactions, although probably they . . . I'll be candid, although I should probably be careful. (Laughter)

I think Goyan had virtually no influence on the agency that I was aware of. He was here for about a year, and didn't bring any particular policy stamp or anything like that.

My only reaction to Hayes was that I didn't think he respected the people who worked in the agency. I'm not sure he did a bad job. He obviously ran into trouble, because there were questions about his ethics and who he let pay for trips for him and stuff like that. But whenever I was in a meeting with him and he would ask a question to the general counsel or whoever was representing--you know, Jeff Springer, who was the acting general counsel--Hayes would ask the question to Springer. Springer would turn to me; I'd answer the question; and Hayes, if he had a follow-up question, wouldn't ask it to me, he'd ask it to the general counsel again. It's sort of like he only had to talk to the people who were higher up in the agency.

I thought Frank Young, I guess personally I had problems with him. I did a lot of stuff during his tenure. I thought that he gave away the store. In his negotiations with OMB, I think he consistently gave away the store. I think what he deserves credit for is finally realizing toward the end of his tenure, and I don't think he thought it was the end of his tenure, but toward the end of his tenure he realized that things really needed improvement, and he started us on the upward path on food labeling, and I think he deserves credit for that. I think he made a lot of mistakes, and I don't agree with a lot of the stuff that he did, but I think that he deserves some credit for that.

I thought David Kessler was a godsend. There was one day that we were in Minnesota after the Schwann's Ice Cream outbreak. I'm not sure you're aware of that. Schwann's made ice cream that's distributed probably throughout the Midwest, and I guess they actually sell some in Maryland, too. There was a tank truck that brought in pasteurized ice cream mix to their plant that had previously transported unpasteurized eggs. The truck was not adequately cleaned, and there was some small amount of egg that was left inside the tanker. The egg residue contained salmonella enteritidis, and it spread throughout the ice cream mix. Since the ice cream mix was theoretically pasteurized, when it did come to Schwann's, they never repasteurized it. So they made all this ice cream that was contaminated with salmonella enteritidis, and there were 200,000 people that became sick throughout the Midwest.

So in the wake of that huge outbreak, Kessler took a small group of us and went out to the Minnesota District Office and tried to reassure the people that FDA was working and CDC (Communicable Disease Center) was working and stuff like that. This was right after he had begun the tobacco initiative. The local U.S. attorney, who was involved with tobacco--the state of Minnesota obviously had a suit, and the local U.S. attorney was interested--but anyway, he came in to meet with Kessler, sort of a courtesy visit. Sitting there in the course of that meeting it struck me that I was in the presence of a great man--that's David Kessler--and probably he was the only great man I ever really met in my whole life.

I think Kessler's legacy is being eroded significantly. I mean, the loss that we've suffered with tobacco and breast implants, I'm not sure he winds up looking all that good. And everybody makes fun of "fresh." So I think really what his lasting legacy is becoming is the food labeling and what he pushed us to. I think it's really too bad, because he is a visionary in a lot of ways, but I guess his vision is really not standing the test of time, which is too bad. But I would have to say, of all the commissioners I worked for, he was the one that I liked and respected and enjoyed working for the most.

RT: Now, in the immediate Office of the General Counsel you were also serving under several folks there, too. Let's see, Peter Hutt, was he before you?

PD: He was before my time. Peter Hutt and Dick Merrill. I came during Rich Cooper.

RT: Right. So are there any particular experiences you have there that you care to share?

PD: Sure. Well, I'll talk about the general counsels I served under. I think Rich Cooper was probably the smartest guy I ever worked for. Just to be in his presence was to be intimidated by him. And now he obviously is representing the tobacco companies and won their law suit. But he's really smart. I just really enjoyed working for him. It gave you a sense of confidence that if you made a mistake, he was going to figure it out and find it. (Laughter)

Nancy Buc was a completely different person. I don't know that she was as smart as Rich, but she brought a sense of reality. She would ask what made common sense? Just sort of down to earth. Did it make sense? That was really the question she asked over and over. You know, "I don't care what the law is. Does it make sense to do that? What are you doing?" I think I learned a lot from that perspective.

Tom Scarlett was, again, a really, really smart guy. He had been in the general counsel's office as a staff attorney and moved up and became one of the deputy chief counsels and then went out in private practice and came back as general counsel. Really smart, really penetrating in his analysis. He too represents the tobacco companies now.

I think he insulated the office from the political pressures that the agency and particularly the chief counsel's office was under during the Reagan administration. As a result of that, I don't think the staff attorneys really appreciated what was going on in the world around. He allowed us to continue to function and he took the heat. It was sort of

interesting. When he was there, everybody sort of grumbled about Tom, because I don't know that he had a whole lot of moral courage. But then, when he left, and under the circumstances in which he was sort of forced out, he became a hero. Sort of interesting.

Then Margaret. Margaret Porter has been chief counsel now I guess almost a decade. Margaret's kind of in the middle of all of them. Her approach is as practical as Nancy, although maybe not quite as practical, but she emphasizes practical. She's not quite as smart as Rich or Tom, but she's smart. She's converted the office, I think, from an office that liked to think that it was a law office that happened to be in the government to a government office that happens to do law. And maybe in the long run that's necessary as the office became part of the agency. I think there's still a sense of esprit de corps, but it's not as strong as it was when I first got there. But in a lot of ways her doing that was necessary for the office to prosper and to continue to grow. I mean, she's really increased the size of the office, and probably with that has come increased responsibility and increased role in the agency, really. So I think that's to her credit.

RT: Very good. We've covered a rather broad range of activities. Are there any other thoughts you have that we might want to include in the interview?

PD: Not really. The only thing I'd say is that I grew up here. I was here for nineteen years. I met my wife here. I had my children here. My wife worked for the agency. I met her at a meeting in CFSAN. So I don't work here anymore, but it's more than just a place to work. The thing that really strikes me, now working for another agency, is that there's a real esprit de corps in FDA. I think the people are united in the sense that they're working for the public health. Even in the really bad times of the Reagan administration and stuff like that, it was always there. There was always that sense. I don't have that sense at USDA. I mean, I like USDA and I think I'm being treated well and having a fun

time and everything like that, but there is not the same strong sense of camaraderie and esprit de corps that I felt here.

RT: USDA, though, on the other hand, I guess, is a much larger body of programs.

PD: Yes. Well, I'm talking about FSIS (Food Safety Inspection Service), which really isn't . . . I mean, FSIS has a very big field force. It has like 7,500 people in the plants and only about 500 people in headquarters. So it's about 8,000 people. I guess that's more than FDA.

RT: Yes, I'm not sure currently either.

PD: Both agencies have a food safety mission, and not that people at FSIS don't take it seriously or aren't strongly committed to it and stuff like that, but there's not that feeling at FSIS. The union is very strong there, and that may have something to do with it. I don't know. All I know is I'm really proud to have worked at FDA.

RT: Now when you were here, I'm sure you were recognized for your efforts at various times. Are there any particular awards or accolades that you recall receiving while serving FDA?

PD: I got a few. I don't know.

RT: Well, I know you may feel humble and so on, but I think they might be worthwhile mentioning.

PD: I got a fair number of group awards. I really don't know how many--about twenty or thirty. I'm not exactly sure. I got the Award of Merit three times, the Commendable Service Award once. I got the Public Health Service Distinguished Service Award once and the Departmental Distinguished Service Award twice.

RT: Those group awards, of course, were indicative of good teamwork abilities, I'm sure, too.

Well, Phil, we really are pleased that you have given us this interview for the History Program. You are now in the Department of Agriculture Food Safety and Inspection Service as general counsel there?

PD: No, actually, I'm not. I am the associate deputy director of the Office of Policy, Program Development & Evaluation, and the general counsel there reminds me on a daily basis that I don't do law anymore.

RT: Well, I'm sure that the law background and experience you have is useful in your work now.

PD: If it's not, I'm bringing nothing else to the table. (Laughter)

RT: Well, thank you very much, Phil, for the interview.

PD: Sure.