

History

of the

U. S. Food and Drug Administration

Interviewee: Linda A. Suydam, D.P.A.

Interviewer: Ronald T. Ottes
and
Robert A. Tucker

Date: July 24, 2002

Place: Washington, D.C.

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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Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBERS: 1 & 2

GENERAL TOPIC OF INTERVIEW: History of the Food & Drug Administration

DATE: July 24, 2002 PLACE: Washington, D.C. LENGTH: 90 minutes

INTERVIEWEE:

INTERVIEWER(S):

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FDA SERVICE DATES: FROM: 1978 TO: 1995
1998 2002

TITLE: Senior Associate Commissioner for Communications & Constituent Relations

(Last FDA Position)

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RO: This is another in a series of FDA oral history recordings. Today we are interviewing Dr. Linda Suydam, who held a number of key positions in the agency, the most recent being the senior associate commissioner for communications and constituent relations. The date is July 24, 2002.

Interviewing Dr. Suydam in her office in Washington, D.C., are Robert Tucker and Ronald Ottens. The transcript of this interview, together with the tapes, will be placed in the National Library of Medicine and become a part of the FDA oral history recordings.

Linda, can we start this by your giving a brief biographical sketch of where you were born, educated, and the background of what brought you to FDA.

LS: Okay. I was born and raised in New Jersey, and I graduated from the College of New Jersey. My first job was as a social worker with the state of New Jersey, which I did for six and a half years. During my social work career, I moved into administration, i.e., planning and budgeting. In 1977, I decided to move to Washington, D.C., and I worked for a year in a job in a career counseling firm. I began looking for a job in the federal government, because at that time, I wasn't ready to work in the private sector.

I heard that they were hiring in [Bureau of] Medical Devices, so I sent a letter to Bob Sauer, told him I was interested in working in Medical Devices, and got an interview with him. It took me maybe six or eight weeks to get an interview, Bob was a very busy guy even in those days. That was in March of '78.

As a result, I ended up working in the Bureau of Medical Devices. The office was the Planning and Budgeting office that was headed by Bob Sheridan. That began my career at FDA. It was a great place to start.

At the time, the Bureau of Medical Devices had only 135 people, and I can tell you that it's a lot more fun building an office and a program than it is having to reduce it or live in times of declining resources. We went from 135 people to 400 people, and that was in '82. 1982 was when we combined with the Radiological Health, and I was a key part of that combination.

John Villforth had decided to have seven task forces to actually bring the two programs together, Medical Devices and Radiological Health, and I chaired one of those task forces, which looked at what kind of planning system we would use in the new center. I then ended up being the planning and budgeting person for the entire combined organization.

RT: At what grade did you start?

LS: I started as a Grade 7, and I finished FDA as an SES-6 [Senior Executive Service], the highest non-political person in the FDA.

RT: Between the time of your degree from New Jersey and the time you came to FDA, were you involved in other kinds of professional work as well? I seem to recall in your *curriculum vitae* that you did something in education.

LS: While I was at Medical Devices, I taught at Prince Georges Community College, a course called Career Development and Life Planning. Before I came to FDA, I had finished a master's program in counseling at George Washington University. Then during my FDA tenure, I got a master's degree in public administration and a doctorate in public administration.

RO: At George Washington?

LS: No. At the University of Southern California, through their Washington center.

RT: Those were doctorate degrees?

LS: A doctoral degree, yes, in public administration. So I have two master's degrees and a doctoral degree.

RT: Thank you.

RO: Other than the planning in Medical Devices, were you involved in any of the Radiological Health activities?

LS: I wasn't, except from a planning perspective. This was post-Three Mile Island, and, of course, there was a radiological health expertise, but the medical device issues, for example, the Shiley Heart Valve, were the major issues. Shiley was one of the first,

actually, problem devices that John Villforth got involved in. I think the interesting side of that was that John Villforth was a very controlling kind of manager, and he liked to have things handled in a particular way. He found out that device issues were a lot messier than radiological health issues.

I remember sitting in the conference room in the Twinbrook Building, all of us, a whole gang of us, probably fifteen to twenty people, going through this whole issue with Shiley Heart Valves. They were breaking and causing some catastrophic injuries. And John being so frustrated, because he couldn't get a handle on how to fix this problem, and also the concern of not worrying unnecessarily people who had them, because they certainly weren't all breaking. And then what do you do if somebody has one? Do you tell them to get it explanted? An explantation operation is a huge surgery. So those were the tough kind of issues that started the whole medical device issue.

Then the other thing I remember in the early eighties is that we did something called the Criticism Task Forces. What we did was look at the whole medical device program and said, "What are the things that we can change administratively? What are the things we can change by regulation? And what are the things that we're going to need to change by changes in the law?"

Because, clearly, when Villforth and [Jim] Benson took over the management of the whole bureau, they recognized almost immediately that there weren't enough resources to do the job. And it's very clear now that almost all of the radiological program disappeared and is now consumed by Medical Devices. There's less than a hundred people doing radiological issues now, and the rest of the resources are involved with the medical device program.

I was the principal staff person on that task force, and we actually briefed the assistant secretary for health, Ed Brandt at the time. We, of course, briefed the commissioners. I think it was both Art Hayes and Frank Young. We went through the Hill, we talked to all the congressional staffers, and that really resulted in the Safe Medical Devices Act of 1990. Some of the things that we had initially talked about in those early days, in the mid-1980s, ended up in that legislation.

I think a lot of the innovations that happened in the device program were the result of that effort to explain to people that the law, the way it was characterized initially, perhaps needed some tweaking, and we needed to change some of the regulations that we had done, and those things happened over time.

RO: Did you get involved at all in the toxic shock syndrome?

LS: I did. I remember that as a major concern and issue, and trying to figure it all out. The science of it wasn't clear, if I remember. It wasn't an easy issue to resolve because of the variations in the products that were out on the market at the time, and the fact that no one knew exactly what was causing—I mean, they knew the toxin, but they didn't know why this product was causing that problem.

RO: Didn't that start with the more highly absorbent tampons?

LS: It did, and it ended up being the result, I think, of the higher absorbency products. So those, I think, were eventually taken off the market.

RO: It seems to me, at the time, the bureau was rather criticized for how long it took to get some suggested labeling for those.

LS: I think that also was the result of the fact that the science wasn't there. Nobody knew what was causing the problem, and I think that was indicative of a lot of the medical device issues. You weren't sure what was causing the problem of the day, whatever it was.

But it was an interesting place to work. I learned a lot in the device program. I learned a lot from working for John Villforth, too.

RO: Dave Link was involved in a leadership role back in the early days, too, wasn't he?

LS: He was the bureau director when I started at Devices, but he left pretty soon after I got there. I think he was gone in '81, and then Victor Zaffra had already come to the device program, and I worked for Vic a lot. At the time I was reporting directly to Bob Sauer, but Vic had a habit of coming in the office at six o'clock in the morning, and even though I'm a morning person and I would get there by 7:30, he had already—and, you know, of course, we weren't using e-mail at the time—dropped by and left things on my desk or on my chair, and they were projects that needed to be finished, particularly memos that needed to be written.

So Vic was there, and was the acting director of the Bureaus of Radiological Health and Devices when we'd combined.

RO: Did Vic leave after the combination?

LS: Yes. Vic ended up going out to Arizona State University, and then began a career in university administration. He was at ASU for a while, and then he was at the University of Illinois.

RT: Now, at one time, in the early days, there was a young fellow, Larry Pilot.

LS: I remember Larry Pilot. He was the head of compliance when I was there, and then he left before Dave Link left. I think he left in like 1979. It was interesting in the early days, because Bob Sauer and Bob Sheridan did not get along at all with Larry Pilot. It was like oil and water.

Dave Link recognized the value that Bob Sauer brought to his organization, but he also tended to philosophically agree with Larry. Both Dave and Larry were pretty anti-regulation.

LS: Yes. So that was an interesting dynamic, to watch the give and take, and to see who could win Dave Link's approval on any particular issue.

RT: Do you recall any reason why Dave left?

LS: Well, I know the rumor was that—and I don't know if it's a rumor and I don't know if you've ever talked to Jere [E.] Goyan, but Jere Goyan told me that he fired Dave Link. Those were Jere's words.

RT: Jere wasn't there very long, either.

LS: No, he wasn't. And the rumor on Vic Zaffra and why we got him was a very interesting rumor, too, and I know that partially this is true. Vic was the budget person at OMB [Office of Management and Budget], for the department budget. He was what they called a health director at OMB. Joe Califano was the secretary of Health and Human Services at the time, and Joe hated Victor Zaffra. So he evidently went to the head of OMB and said, "I want him out of there. I don't want him doing my budget."

So they said, "Okay, if you can find a job for him," and they found a job for him.

[Laughter] He became the deputy director and then acting director of the Bureau of Medical Devices.

Vic was a very smart guy, but a very critical person, and particularly edited everything. He had a manual that he carried around of English grammar, called Strunk & White, and if you didn't write from Strunk & White, you know, you learned what things he wanted. I probably still have one of those on my bookshelf.

RT: Do you use that kind of expressions today or is that just use of the wrong word?

LS: No. I think, actually, the grammar piece of it was good. I actually learned from him. But it irritated a lot of people that he edited everything that they wrote. I mean, that was his little quirk.

RT: He was a detail person?

LS: Yes, yes. He was a micromanager, yes, and sort of a nit-picker about things.

RO: While we're still on medical devices, FDA doesn't have user fees yet for medical devices.

LS: Right.

RO: But there's been some talk of getting user fees, but the manufacturers want third-party review. What's your view on that?

LS: Well, you know, there is already third-party review. It happened under FDAMA [FDA Modernization Act], but it was third-party review for limited classes of devices. And the really interesting thing about it is that manufacturers don't use it. They'd rather have FDA review their product than have a third party review it.

I think the agency needs user fees to adequately fund the medical device program, and I think once they get the user fees, then I think they'll be able to meet the time frames and the deadlines that industry needs to have. I think a third-party review is okay if it's

for limited classes of products, and if FDA has the final authority in the end to say yes or no as to whether it's approved or not.

RT: I forget the product classes, but tongue depressors and Band-Aids and things like that.

LS: Yes. Right. Most of the Class One products are already exempted. It would be mostly the Class Two products, and those are the ones that have to meet standards, current standards.

RO: In the drug area there are several issues I'm sure you've dealt with. I guess maybe one of the more recent ones might have been the off-label promotion idea. Is that something that you wish to speak to?

LS: No. Obviously, there was a lot of concern about off-label promotion, but it really is a difficult issue. I mean, it's a very difficult issue to deal with because FDA has been reluctant to take on the medical profession, and the medical profession continues to want that flexibility, to be able to say, "I know what's best for my patient." I think it will be impossible for FDA to take that one on in a way that doesn't offend the medical community, and I'm not sure it's a battle the agency wants to take on.

RT: Do you think that FDA has, though, interjected itself a little bit more in the practice of medicine than was done years ago?

LS: I think we have to a certain extent, and one of the reasons for that is because I think we've loosened up on allowing products that are riskier on the market, and I think rightly so. I think when you do that, you have to have more restrictions on how the products are used.

For example, the Lotrinex product. Lotrinex is a product that was approved by CDER [Center for Drug Evaluation and Research] for irritable bowel syndrome, and it was approved for women only. It was one of the few products that have been approved just for women, and it was misused, basically, given to a lot of people who shouldn't have it. And then there were many serious adverse events. As a result, FDA put pressure on them and the company withdrew it from the market.

But that product has a very wonderful effect for people who are suffering from that disease and who are able to use it successfully. So the agency is going to let it back on the market with a very restricted-use statement that says, "You can only use it under these conditions. It can only be prescribed by a gastroenterologist." Those kinds of things.

So in that case, we are interfering more with the practice of medicine. We're doing it more on things such as that when we approved thalidomide for limited use, because it is an effective product, we put a very restricted use on it, and those restrictions are necessary for the safe use of a product. I think in that way we are, in fact, doing more involving and engaging in the practice of medicine.

RO: Of course, there's an awful lot of concern by a lot of people that thalidomide has been approved..

LS: Right. But it's a very effective product. Very effective, necessary product. The same way with Acutane. Everybody knows that Acutane is a tetratogen, and it's only a product that's for acne. The agency has made a program, very restrictive. You know, you must be on birth control, you must sign a form that you're not going to get pregnant while you're taking it, and making sure that people have pregnancy tests before they actually start taking the product.

Well, those things are important, and that's the kind of program that the agency has put in place for Thalidomide as well. So, yes, we have interfered more with the practice of medicine.

RO: The agency has been involved in the middle of a lot of controversy over the so-called abortion drug, and then some of the other contraceptives. What's your view on that?

LS: Well, I was there when we approved RU 486, and I was very involved in it. It was an interesting process. Dr. [Jane E.] Henney made it very clear that the decision was going to be made on science, and science alone, and that it was not a political decision. It probably was the reason that Jane Henney was not kept as commissioner when the administration changed. She, I think, was told to leave at the last minute, as she expected she would be, because the anti-abortion people didn't want her to stay.

You know, you have to look at the law and the science, and those are the two things that Dr. Henney looked at. She looked at: Is it safe and effective for its intended use and does it meet the standards of the law, and the answer was, and, we had to say, yes to both of those questions. So, therefore, she didn't believe that there was no other choice to make but approve the product. And she was not about to make a decision based on politics.

I mean, one of the big things that Jane Henney did as commissioner was to depoliticize the commissioner's office. She wanted a non-political FDA. She wanted to go back to the days when there were no political appointees in the agency, and she did. I mean, she was successful. We went from fourteen political appointees when David [A.] Kessler was first commissioner to one when Jane Henney was commissioner.

And she fought for this ideal. I was with her when we went to the White House personnel office to tell them she wasn't going to take any political. The White House personnel director didn't like this idea at all, but she was able to win him over and say, "This is the way it's going to be. This is a non-political agency and we're not going to have political appointees in here."

RT: That's an interesting observation. I don't know that we've really learned that from anyone else, prior to your interview.

RO: Because we felt that FDA was really politicized back in the early nineties when the commissioner had to be confirmed by the Senate.

LS: Oh, yes. And it was, clearly, as soon as it had to be approved by the Senate. And David Kessler was a political animal. That was the thing I learned from him, was how to operate in a political environment. That's what he did best. He knew how to wheel and deal, and to succeed on the issues that he thought were important.

But Dr. Henney was not. I mean, Jane wanted the agency to be a neutral, science-based, regulatory agency. And she, I think, accomplished that in the two years.

Unfortunately, it slipped away pretty fast, because I know I was replaced by a political, the person who has part of my job. She doesn't have the whole thing, but she is a political appointee.

RT: That was one the things we'll ask you a little later, that is, why you left, and some other issues. Some of the other things we know you were dealing with was women's health problems and things like that in the agency. Can you give us some of the significant things that you—

LS: When the Office of Women's Health was established, I think that was a groundbreaking event in the agency, and it was really a recognition of the environment we were living in, and the fact that so many drugs had not been tested on women, just on white males only.

There are issues that are clearly women's health issues, but one of the things that I think I felt good about in supervising the Office of Women's Health was that we used the money that we had to target problems which no one else would deal with. So in the last year I was there, we funded studies on pregnant women. No drug company wants to

study drugs in pregnant women, because they don't want to deal with the liability. But we are doing studies, they're doing studies now with three universities, looking at drugs that women have to take. You know, even if you're pregnant, if you have high blood pressure, you must take high blood pressure medication, even if you might not want to. The same way with diabetes. If you're a diabetic, you must take your medication when you're pregnant.

So the Office of Women's Health is doing these pregnancy studies that I think will, in the long run, give us the information we need to see what kind of effects these drugs have on pregnant women, and really to try to do some calculations as to what the right dosage is. So I think that was one of the best things.

The other things that the Office of Women's Health can do: One is, they can fund some projects in the agency that might not get funded, and this is internal to the FDA. They can fund some people in other parts of the agency, to get them started on projects so that they can then get money from other places that are relevant to the agency's mission, but might not be funded.

[Begin Tape 1, Side B]

RT: You were talking about funding.

LS: So the funding to the other parts of the agency then allow, say, the Center for Devices to see if this researcher can do this with a small amount of money, perhaps we can fund them with a little more and do a great deal more. And so some of the good studies

that have started at the Office of Women's Health have then been able to be funded in a greater extent by their programs and come up with, I think, some important breakthroughs.

The other thing about women's health that I think is important is their outreach effort. Clearly, the Take Time to Care Program was well established when I took over women's health. Sharon Holston had really started that when she was there. But it was, in fact, and is, continues to be an important program, because it's not the kind of thing that will be done by any other group if FDA doesn't do it.

One of the things in terms of consumer outreach that I found that's so important, and I mean consumers in the broad sense, everybody is looking to FDA for neutral, objective information about the products we regulate, and that's one of the things that we do, the FDA does, not as well as we do other things, because we always put it at the bottom of what we do. But people use our website. FDA has one of the best websites, and we get so many hits on it that hundreds of thousands of people are going to the FDA website, looking for information about the products we regulate. And we really, as an agency, need to do more.

RT: About the outreach now, is that targeted? Is there a constituent relations element in the Office of Special Health Issues?

LS: Constituent relations included the Office of Special Health Issues, it included Orphan [Drug] Products, it included the Office of Public Affairs, and I loved running the Office of Public Affairs. That was one of my favorite offices, and I think one of the offices

that's done the best for FDA. We have a very well-run media program. The FDA consumer magazine is a premiere government publication; in fact, a premiere publication in general.

So, yes, I think in terms of constituent relations activities, we are talking about the general consumer, the specialized consumer, like the women's health would be, special populations groups, like the cancer patients, the AIDS patients, and the Office of Orphan Products. And even the industry, because the Office of the Ombudsman reported to me for over three years, and so I had an awful lot of industry people who came in to talk about issues that they had when they were having problems with particular centers.

RO: In what regard? In regard to getting products approved?

LS: Yes, or even compliance issues. For example, Abbott Laboratories came in, after the consent decree was signed, and would say, "Here are the problems we're facing. Can you help us?"

So I did an awful lot of that. When two companies were having a dispute over should a product be considered designated an orphan or not, those issues all came to me.

RO: I can understand that, but I would think that on some of the regulatory issues, they would have gone to Regulatory Affairs, for example, to complain.

LS: Often they'd go to Regulatory Affairs and then they'd come to me after that, because they didn't feel like they got their answers.

RO: Because they didn't get the right answer from Regulatory Affairs?

LS: Right, absolutely.

RT: And I think in the information that we received about some of your career activities, you made mention of orphan drug development. What was happening there in the agency when you were—

LS: Well, you know, the Office of Orphan Products, or Orphan Drug Development, is one of the great success stories at FDA.

RT: Does it take a special incentive from the agency to the industry to interest them in pursuing these things that may not have big-market returns?

LS: Well, it doesn't take a special incentive from the agency; it takes a special incentive by law. And because they get orphan exclusivity, then they can be on the market and no one else can. And that really is the reason that I think the program has been a success. But, you know, the designation of orphan products, people come into the agency and they asked to be designated as an orphan, and then therefore they're treated somewhat differently, although they still have to go through the same review process as a regular drug or a regular biologic. They still have to go through that review process, but they get an orphan designation and then when they're approved, they get exclusivity for a period of

time. I think it's 180 days, six-month exclusivity. In fact, it may be longer than six months. I'll have to go back and look at that. No one else can market that same product.

And the other thing that happens with orphan products is that the office has a grants program, and the grants program is about \$12 million now and has funded hundreds of small studies to get orphans on the market. There are now twenty-five products that have been approved that were funded by FDA in some of their initial trials. It's a fantastic program and it helps people who would never get the drugs they need if it didn't exist, because there's no commercial viability on many of these products.

So it's a great program. Marlene Haffner is a fantastic champion for that program. She's well recognized across the world for her expertise in helping to establish orphan programs throughout the world, and it was a pleasure having her work for me. She also runs a really good staff. We made awards to probably thirty companies a year with the grant money.

RT: She has been in there almost since its inception.

LS: Marion Finkel was there for a short period of time. Marlene started in the medical device program with me. She came to the device program in 1980, and I think she came to Orphan Products in '82.

RO: How about the generic drug problem? That was kind of an unfortunate incident.

LS: It was in unfortunate incident. And I had very little involvement in that. I was in the device program at the time, but one of the things I was asked to do by Jim Benson, who was acting commissioner, was to review two of the cases of administrative actions against the two employees. It was not the people who were in the generic program, but it was the supervisory level.

The cases there were for general mismanagement of the program, of the office. So I had reviewed stacks of documentation, and then met with Jim Benson, who was the acting commissioner at the time, to make a recommendation.

RO: You were surely in the agency during the tobacco issue.

LS: Yes. I missed some of it, because I was in New Mexico for three years, but the interesting point is that when I came back, I had the tobacco program report to me, and so I was there for the end. I was there for the beginning and I was there for the end. In the beginning, when David Kessler started to talk about regulating tobacco, and he did it because he was interested in what public health issue can we take on that will have the greatest impact.

Jane Henney was working for him then as the deputy commissioner, and being a cancer specialist herself, she said to him, "Well, David, if you want to really do something that would improve public health, you ought to figure out a way to get people to stop smoking."

And so that was the beginning of the idea, and then he took off with it and started looking at the whole legal framework. At one point, Dr. Henney left and then I was acting

deputy commissioner for eighteen months. During that time period, there was a lot of secrecy about what was going on with tobacco. Nobody was talking. There were all these investigations and we had people working on a special task force. I remember saying to David Kessler, "What's happening with tobacco?"

And he said, "Well, don't worry about tobacco, Linda. You worry about everything else. I'll deal with tobacco."

So that was the deal we struck. And then when I came back, I think FDA had actually put together a really good tobacco program. I think the compliance checks at the retailers was a good idea. We had a really good computer system that tracked violations and that got fines. Civil penalties were coming into the agency at a really good rate. And we had a good advertising program that was hopefully limiting smoking.

But, of course, the Supreme Court ruled that the program was unconstitutional or was not in FDA's purview and it was unconstitutional. And so I had to supervise the shutting down of the program. We had at the time about thirteen people in the tobacco program. It took a year to really close it down completely, and it's still not closed down completely. There's one person still working on providing documents for the Justice Department suit against the tobacco companies.

We had to archive all the records, we had to make sure that all the civil penalties in the bill were taken care of, everybody had been paid. And then we just started placing people throughout the agency.

RT: What's your personal view on that? Do you think that the agency really had the authority to do anything?

LS: Well, I'm not a lawyer, and think it's probably very iffy, but should the agency have authority to regulate tobacco? Yes, I think they should. Somebody should. It's a drug. I mean, there is no doubt about it, it's a drug. Nicotine is a drug. We regulate it in other ways. And, in fact, it's strange that we regulate the nicotine replacement programs with such rigor.

RT: Well, it's perhaps somewhat of a unique product, since in the Department of Agriculture there are some subsidies for growing and marketing the product, contrasted to the regulatory side. So maybe that dichotomy needs to be resolved.

LS: Yes, yes, absolutely. There's no doubt about it. But I think it put a terrible burden on the agency, and I'll tell you why. I think choosing to take it on was actually a good public health decision. I think Dr. Kessler was well motivated by that, but actually taking it on was very detrimental to the Food and Drug Administration. The agency suffered for a long time. I remember coming back to the agency in '98, having been gone for three years, and had to go down on the Hill to meet with the Senate appropriations staff. Rebecca Davies was the staff director for Thad Cochran, and Rebecca was so hostile to FDA. She didn't believe anything we said, and I was taken aback by this attitude. And then, of course, people explained to me, "Well, she's still angry because David Kessler lied to her about tobacco."

And that's the reason the agency's budget did not get increased, and she was micromanaging the Office of the Commissioner, how much money is spent in each area. I

think the whole program was very detrimental to the FDA and it cost the agency money in the long run. Our budget in the nineties went down because Dr. Kessler chose to regulate tobacco. But it was the right public health decision.

RO: How is the agency faring in these congressional hearings now?

LS: Well, I think it depends on the hearing. The thing about congressional hearings is that it depends on the member, it depends on what their motivation is, and it also depends on how much the agency can deflect an issue or divert an issue away.

I did a number of congressional hearings when I was there, and they weren't always pleasant. I actually staffed, for Vic Zaffra, the very first medical device oversight hearing, which was in 1982, before the merger, and that was an experience. I mean, it was just an attack on the device program.

I did a hearing with Congressman [Dan] Burton on vaccines, and Congressman Burton is a Republican from Indiana. He got reelected last year, with 75 percent of the vote. He hates regulation, he doesn't like the FDA, but he also doesn't like drug companies and doesn't particularly trust them. And so he was very angry at the vaccine manufacturers, because he felt that his grandchild had gotten autism from having taken a vaccination. But what he was attacking the agency on and what he was taking me to task for was that we had advisory committee members who had what he considered conflicts of interest.

One of my jobs at FDA was reviewing every conflict-of-interest document and signing off on it, for every advisory committee. So I looked at every one of them and my

name was on there. It said, "We can waive this conflict." And you really have to do that, because otherwise you would not have any experts. Congressman Burton's point of view was, you could just take any doctor off the street, put him on this committee, and ask him the questions you wanted to ask about a vaccine. My contention was that this was not possible. You needed to have a person who actually knew what vaccines were all about.

So he actually had asked for all of the financial disclosure statements for all of the vaccine committee members, and then he had them blown up and shown on a slide on a screen, and then would say, "Look, Professor So-and-so has \$5,000 worth of Merck stock. Don't you think that makes her ineligible to sit on the panel?"

I was in a tough spot, because I actually couldn't talk about their finances because of confidentiality, the Privacy Act. So he didn't care that he was violating the Privacy Act, but I did, and I didn't want to be in violation of that law. So I would say, "I'm sorry, Mr. Burton. There's not much I can say about that, because I'm not going to address the specifics of Dr. So-and-so's holdings."

But in the end, that hearing actually came out fairly well. He could be really nasty, but he kind of backed down a little bit.

But the last couple of hearings, I did both of the FDAMA, the FDA Modernization Implementation Act hearings, in '99 and 2000. Those were almost like love-ins. I mean, we had a lot to report, we could tell them all the things we were doing, and with a few exceptions, all of the congressmen were very supportive.

RO: That was kind of welcomed after all the other controversial ones.

LS: Yes, absolutely, absolutely.

RT: Several reorganizations have happened in the commissioner's office, especially under Dr. Kessler, and you were involved in some of them. What is your reaction, in regard to how the commissioner's office was constituted?

LS: Well, this is my theory. Dr. Kessler wanted to bring his own people in. He didn't want to fire any of the people that were there, so he just put another layer in above them. And I think that actually created a lot of conflict. I mean, having five deputies was really, in my way of thinking, a stupid idea. You have one deputy. That's what you should have.

It caused a lot of conflict with the centers. They didn't know who they were supposed to be dealing with. You know, one deputy would tell them one thing and another one would tell them something else, and they just didn't know who should they be listening to.

When Dr. Henney came in, she actually did interviews with all the center directors, with all her direct reports, and then we eliminated all the deputies and went back to more of a structure similar to what it was before Dr. Kessler came. Unfortunately, I think Dr. [Lester] Crawford is already changing that, so it didn't last very long, and that's unfortunate.

RT: Dr. Henney, before she left the first time, was the deputy for operations, and the center directors reported to her.

LS: And her view was that the center directors should always report to the commissioner, and she wanted that to happen and it did happen when she came back.

RT: Now, I guess your role would have been to coordinate all the concerns of all the five operating centers, and I suppose with the Office of Regulatory Affairs as well, and coalesce them for the commissioner's right decisions.

LS: That's correct, yes. And that was okay. I mean, in essence, you have to remember, Dr. Kessler was an issue commissioner. He liked issues. He didn't like to run the organization. He didn't like the day-to-day stuff. And so it was a good thing that someone like Dr. Henney or myself was there to really run the place, because that had to be done, to resolve conflicts between and among the center directors, and ORA and the centers, and somebody needed to do that.

RT: I think you went with or followed Dr. Henney to the University of New Mexico. Was there a particular motivation for you to serve at the university level at that time?

LS: I'm one of these people who likes change, and so I felt I was ready for a change. I happened to like working for Jane Henney. I thought she was the best manager I have ever worked for. She was offering me an opportunity to come out there, and I always thought I wanted to work at a university. So I thought, "Well, this will give me a chance to do it."

My husband and I were willing to move. We think it's an adventure to go live different places, so we were willing to go and live in the Southwest, and we really liked it a lot. I enjoyed New Mexico. But I found out I didn't want to work in a university. It was far too slow a pace for me. There was far too much politics. There's nothing like a university in terms of politics. It's the political professors.

RO: Not as we think of politics, though.

LS: Not the politics of Democrats and Republicans, but the politics of how things get done. The politics with a small *p* is incredibly political. You know, is this department better than that department? Should the nursing school have anything to do with the medical school? All of those kinds of issues.

The deans of the schools were like little kings in their own kingdom and they didn't like it when people tried to tell them how to do things in a different way. And it's very slow. It's a very slow process. Not the same kind of issues and not the same pace.

RT: Too relaxing for you.

LS: Yes, far too relaxing.

RT: So you were attracted to return to FDA after that.

LS: Yes. And I also missed the East Coast and I missed Washington, and my family and friends are here. I found out how hard it was to get back and forth between the two places. So I'm happy to be back in Washington, and I was happy to come back to FDA, knowing that Jane was going to come back as commissioner.

RO: You and Dr. Henney didn't come back at the same time?

LS: I came back before she did. I came back in June, and she was not named commissioner until October. But we knew that she was probably going to be nominated. It wasn't a sure thing, but we knew it was probably going to happen. In fact, Mike Freidman brought me back when he was the acting commissioner, and Mike offered me a position to come back as the associate commissioner for strategic management, and to run the FDA Modernization implementation. So I did that until Jane came back, and then I was basically her chief of staff and coordinated all the activities of the Office of the Commissioner.

RT: Not to regress too much, but there were a couple of other products or issues in the pharmaceutical area that maybe we could touch on. One of them was Ephedra for weight control. What, if anything, would you care to comment about that issue?

LS: Well, it's interesting, because Ephedra is one of the products that one of the companies I represent now still makes, so I've seen it from a different point of view. Obviously, the concerns that were being raised in 1995 about Ephedra were over the

number of adverse events. That is, healthy individuals who were taking Ephedra and then having adverse effects.

I think Ephedra is an issue that's still being resolved. It hasn't been resolved yet. The secretary has gotten involved in it now, seven years later. Tommy Thompson issues a statement, "We're going to have a study to look at Ephedra."

Well, this is the problem with not having the right science in dealing with a product.

RO: What is the relationship between the FDA and the Department and the White House? There's rumors that it's a lot different than it used to be.

LS: Yes. I saw a big change in this administration. When this [George W. Bush] administration came in, there was a total lack of trust about the careerist, and that's really unfortunate. There is a terrible thing. And so there was total second-guessing of FDA decisions. I mean, talk about micromanagement. You know, approving every person who travels internationally. Anytime you have more than five people to go to one meeting, you have to get approval from the department. I mean, that's crazy. It's really not helpful at all to getting the job done at the FDA. I think it's unfortunate.

I don't know if it will get better. I mean, I don't think it has gotten better, even with Dr. Crawford being there. You know, Dr. Bern [Bernard] Schwetz was the acting commissioner, and he did everything he could to make the agency continue to run well. But it didn't matter to the department what we were doing. It wasn't enough, because

they just didn't trust anybody who had been there before. And that's unfortunate, because the careerist basically doesn't care what party is in office. They just want to do their job.

RO: Just be left alone.

LS: Right.

[Begin Tape 2, Side A]

RO: When we were changing tapes, I had asked if there was a layer of bureaucracy imposed in this administration between the department and the agency, and I think you were about to respond.

LS: Yes. There's not another layer of bureaucracy, but, in fact, it's more in terms of processes that have been put in place that require the department to know more. For example, one of the things that I did was the significant activities report that went to the department by e-mail every Friday morning at noon. It had to be submitted by noon. And it was amazing the kind of things they needed to know: every meeting that was being held with outside people; any media event that was going to be done; any congressional hearing; any travel by your senior people. All of these things have to be reported on a weekly basis, and updated.

RO: In former times, I know they had staff meetings with all the member agencies of the department. I assume those are continuing, and if they are, does FDA have stature in those discussions?

LS: Yes, yes. That happened when Donna Shalala was the secretary. She changed the reporting structure, and FDA reported directly to her. And so did all of the other agencies—NIH [National Institutes of Health], CDC [Centers for Disease Control and Protection]. That all happened with her.

What this secretary does is have weekly luncheon meetings and to get the agency heads together. That's where he does his staff meetings.

RO: So does the commissioner, or would you, as his representative, attend those meetings?

LS: I never went to any of those meetings. Only the principal can go. So if your principal is out of town, you can't go.

RT: But then the agency isn't represented.

LS: That's correct.

RT: Well, years ago, I know that oftentimes the principal interest in FDA at the department staff meetings related primarily to matters that were something sensitive, but

otherwise some of the larger department components seemed to dominate those discussions. Perhaps that's been corrected now.

LS: I'm not sure it's been corrected. I think it changes with every administration. I think Donna Shalala was a very enlightened manager. She had run a big university; she came from the University of Wisconsin, a huge university, and knew how to run big organizations. And she had her own issues, the things that she thought were important. I mean, she was a real advocate for children, but she also knew that each of her agencies were valuable and made a contribution to public health and welfare. I think she really recognized the value of each of the organizations that reported to her.

Secretary Thompson is really interested in FDA issues, and so are his people, but they're not so interested in terms of making a change or of the public health social good. They're interested because of the kind of publicity that they'll get from the activity, whether it's good or bad.

RT: I was just going to observe that was what I meant in the recent reference. The department was very interested whenever the agency was in some controversial issue that would be publicized in the media.

LS: Right. And that's true. Secretary Thompson doesn't like to have anything show up in the paper that he doesn't know about.

RO: I was just going to wrap both of these in together, and probably can be our finale here. You've mentioned two of the commissioners so far, in depth, Dr. Henney and Dr. Kessler. You were also in the agency with Dr. Young, Dr. Hayes, and Dr. Goyan.

LS: And Don [Donald] Kennedy.

RO: And Don Kennedy. Would you care to comment about them?

LS: They're all different. It was an interesting experience, getting to know all of them. I think I didn't have much experience with Don Kennedy, because I came in as a GS-7, and when you're a GS-7, you don't get much contact with the commissioner. But he was an incredibly smart man and I think the agency certainly was able to take advantage of that intellect.

I think some of the commissioners were sort of out of their depth, and didn't really have an understanding of the full scope of what it was they were doing. I think in some ways, and I'm biased, I know, but I think Dr. Henney was the ideal commissioner because of a lot of things. One, she's very smart. She's an M.D., but she knows how to run organizations and she's been a manager for a long time. And the greatest part was that when she came to FDA as commissioner, she had already been there. She had been there for two and a half years as the deputy, and the transition was so easy. It was really easy, because she didn't have to learn all the things about the agency.

Transitions to new commissioners are very difficult, very difficult, and especially when they come in not knowing anything about an agency. I remember the Frank Young

transition was very hard, because Dr. Young wasn't used to running a large organization, and it took him a long time to understand the complexity of FDA.

Dr. Kessler was difficult because he didn't like to manage anything. He was not a manager. That wasn't his forte and he didn't want to be bothered with that, and so it made things very difficult.

Jere Goyan I just like as a person. I mean, he's been a friend since the eighties, and I've continued to stay in touch with him. I think he's a real special person. But, of course, he wasn't there very long, either, as a commissioner.

RT: For how long?

LS: Eighteen months.

RT: He was a nice fellow.

LS: He's a very nice. He's a great guy. So, you know, I think the commissioner needs to be a very special person and be a person who has both medical and scientific understanding, as well as being a person with experience in running complex organizations, because this is a complex organization.

RO: You do think being an M.D. should be a requirement?

LS: I think an M.D. is preferable, although Don Kennedy was not an M.D., and neither was Jere, and they both did fine. But I think the world has changed a lot, and I think so many of the issues the FDA deals with now have so much clinical significance that I think it's helpful to have an M.D.

RO: What's your take on the future of the agency?

LS: Well, I think the agency's future is pretty good because of the recent user fees. You didn't ask me about the user fee negotiations, because that was the latest thing I did. I did the last user fee negotiations. That was my program. I didn't sit there at the table, but I was the person who developed the strategy. I think that's been helpful to the agency. It's given the drug program the resources it needs to do its job. And, of course, all the bioterrorism money will help the agency bring on new inspectors, which we need desperately, to replace the people who have left.

My hope is that we'll get a permanent commissioner, and that the permanent commissioner will respect the civil servant. And, frankly, I don't think that's happening right now. I think that there's a lot of disrespect for civil servants, the careerist, and that's unfortunate. It's a very political environment right now.

RT: USDA and FDA, as far as the food oversight is concerned---

LS: Combined?

RT: Well, they've been matched for some time, and now, in view of all the meat recalls, they're again talking about consolidation.

LS: Right. I truly believe there should be a single food agency, but I think it should be in the FDA. And I don't think you should tear the FDA apart and make a food part and a drug part. I think you ought to have one FDA and you ought to have all the food regulation in it. But I don't think that will happen, because I think the agriculture lobby is too strong, much too strong.

RT: Since you are now not in the FDA, per se, but in a health care association, do you see the agency in a different light than when you were in it?

LS: I do somewhat. I was surprised. I went to my very first advisory committee meeting after I left the FDA, and it was on the issue of switching the drug Prilosec, which is for heartburn, from prescription to over-the-counter. And, of course, one of my companies, Proctor & Gamble, is going to have the over-the-counter product. I was surprised at the medical officer for drugs who presented the data, and I thought he was arrogant. I really did. I'm not sure I would have thought that, although I may have, if I was still at FDA. It was just so apparent that he was so arrogant, and I thought that was funny. I really did.

RO: The position you have now, I didn't realize there were a lot of companies that you represented.

LS: Yes. I'm the same position as Jim Cope was in. Do you remember Jim Cope?

RO: Yes, sure.

LS: Non-prescription drug manufacturers. That's what I do. I'm the president of that organization, and we have sixty-eight companies that make over-the-counter products, and then we have about 200 other members who are suppliers to our over-the-counter manufacturers, as associate members.

RO: Just, so I understand it, drugs?

LS: Over-the-counter drugs. It used to be the Proprietary Association.

RT: Is this an outgrowth of the Proprietary Association?

LS: We are the Proprietary Association. We're the new name. That's the new name.

RO: That clarifies it for us. And was it Jim Cope who used to be in this association?

LS: He was the president, yes.

RT: I remember him when I worked in the legislation office of FDA.

LS: Yes. And it had another name change in between. It was called the Non-Prescription Drug Manufacturers. It went from the PA to the Non-Prescription Drug Manufacturers, to the Consumer Health Care Products Association, and that just happened in '99.

RT: With that "consumer" in front of this, I was really misled.

RO: I didn't recognize it as the Proprietary Association either. Interesting. Glad you clarified that for us.

LS: Well, I'm representing the industry, happily.

RO: Linda, thank you.

LS: Well, thank you for coming down. I really appreciate it.

RO: We'll have this transcribed and give you a copy for your editing, which we trust you will return.

LS: I'll get back to you as quickly as possible. I'm very good about that.

[End of interview]