

**History**  
of the  
**U.S. Food and Drug Administration**

**Interviewee:** Larry Pilot, Esquire

**Interviewer:** Suzanne W. Junod, Ph.D.

**Date:** December 21, 2004

**Place:** Rockville, MD



**GENERAL TOPIC OF INTERVIEW:** History of the Food and Drug Administration

**DATE:** December 21, 2004

**PLACE:** Rockville,MD

**LENGTH:** 120 Minutes

**CASSETTES:** 1 & 2

**INTERVIEWEE:**

**INTERVIEWER(S):**

**NAME:** Larry Pilot, Esquire  
1900 K Street NW  
Washington, DC 20006

**NAME:** Suzanne W. Junod, Ph.D.  
5600 Fishers Lane  
Rockville, MD 20857

**FDA SERVICE DATES:**

**FROM:** September 1969

**TO:** June 1979

**INDEX**

<b>Tape</b>	<b>Page</b>	<b>Subject</b>
<b>1-A</b>	<b>1</b>	<b>Early FDA employment interest &amp; educational background</b>
	<b>4</b>	<b>CPEHS (Consumer Protection &amp; Environmental Health Service)</b>
	<b>5</b>	<b>Upper FDA management changes</b>
	<b>8</b>	<b>FDA oral contraceptive safety (package inserts)</b>
	<b>10</b>	<b>Informed choice issue</b>
	<b>12</b>	<b>Consumer representative concerns re Charles Edwards &amp; Larry Pilot appointments Attorney Jim Turner</b>
	<b>14</b>	<b>Video record – Senator Gaylord Nelson’s hearings on the “pill”</b>
	<b>18 &amp; 27</b>	<b>Cooper Committee – composition &amp; accomplishments</b>
<b>1-B</b>	<b>20</b>	<b>David Link &amp; Larry Pilot survey initiatives re scope, categories &amp; products of device industry</b>
	<b>22</b>	<b>Device classification – advisory committees/panels</b>
	<b>23</b>	<b>Pivotal role of Dr. John Jennings in device program issues</b>
	<b>29</b>	<b>Diapulse device &amp; device packaging problems</b>
	<b>32</b>	<b>Cardiac &amp; intrauterine device problems</b>
	<b>34</b>	<b>Dalkon Shield, Manslin Spring &amp; Tatum T IUD investigations</b>
	<b>37</b>	<b>Lippes Loop IUD</b>
<b>39</b>	<b>Dalkon Shield wicking problem</b>	
<b>2-A</b>	<b>40</b>	<b>Senate staffer inquiry re alleged industry bribe</b>
	<b>42</b>	<b>Cordis investigation – injunctive relief hearing</b>
	<b>43</b>	<b>1976 Device Amendments – additional agency authority</b>
	<b>46</b>	<b>IDE (investigational device evaluation) regulation</b>

## INDEX

<b>Tape</b>	<b>Page</b>	<b>Subject</b>
<b>2-A</b>	<b>46</b>	<b>Delays &amp; excessive agency requests for data</b>
	<b>48</b>	<b>Working relationship with David Link</b>
	<b>51</b>	<b>Management styles of agency commissioners Edwards, Schmidt, Donald Kennedy</b>
	<b>52</b>	<b>Factors leading to interviewee's decision to leave agency</b>
	<b>53</b>	<b>Office of Small Business Assistance – need for function – personnel</b>
	<b>55</b>	<b>Infant formula issues</b>
	<b>58</b>	<b>Personal reflections on events leading to son's diagnosis of low potassium levels as result of infant formula feedings</b>
<b>2-B infant</b>	<b>62</b>	<b>Roles of Lynne Pilot, news reporter Lea Thompson, Carol Laskin, et al, in bringing the  formula problem to attention of the Congress 1980 enactment of Infant Formula Act</b>
	<b>65</b>	<b>Concluding remarks</b>

Interview with Larry Pilot

December 21, 2004

TAPE 1, SIDE A

SJ: Today is December 21<sup>st</sup>, 2004. We're here in Rockville, Maryland, in the FDA History Office, to interview Larry Pilot, who is one of the original employees and leaders of the device regulatory program. Dr. Suzanne W. Junod of the FDA History Office is conducting the interview with Mr. Pilot. How would you characterize that activity Larry, actually? I'll let you do it.

LP: Well, there was a component, when I joined the agency in late '69, that managed the activities associated with medical devices. So, actually, five people, three professionals and two secretaries. Joe Davis was the head of that group. And there were a couple of people in Compliance who were assigned to matters relating to medical devices. So when David Link joined the agency in late 1970, he and I partnered with assistance from two secretaries, to plan for the implementation of changes in the law brought about by the release of the Cooper Committee report, which was a departmental task force. In September of 1971, the Office of Medical Devices was formed. So that group, including Joe Davis, Bob Skufka, and Bob Kennedy and the two secretaries, were incorporated into it. Dave was the director of the Office of Medical Devices. I was in charge of compliance, and there were about twenty people who were part of that organization. I believe all of them came from the agency and were transferred into the

Office of Medical Devices.

SJ: At the top.

LP: Yes.

SJ: Okay.

Let's go back and talk a little bit about your education and where you came from and how you ended up there at that time, just a little informative agency background and training.

LP: My undergraduate degree is in pharmacy, and I moved to Washington in 1964 to work for the American Pharmaceutical Association. I had been in law school at the University of Detroit but dropped out to take the position at the APHA, and continued my studies at Catholic University Law School, where I graduated in 1967.

In 1966, I went from the APHA to the Pharmaceutical Manufacturers Association, where I worked at PMA from 1966 to '69, first in public relations, and then after I became a member of the bar, I worked on the legal staff at PMA.

I joined the Department of Health, Education and Welfare in August of 1969 as a special assistant to the Assistant Secretary for Health.

SJ: Who was . . .

LP: At that time, Roger Egberg had been appointed. He hadn't started in his position yet.

SJ: And how did you know him or how did you -- how did this come about? These kinds of positions don't just -- I know better.

LP: Okay. Well, I had worked on the Nixon-Agnew presidential campaign. Actually, I organized Pharmacists for Nixon-Agnew in 1968. As a result of that activity, and because my wife was working on Capitol Hill for one of the Republican congressmen, I thought I might apply for some kind of a position. I did get an appointment. I was a political appointee, Schedule C, and started at the Department of Health, Education and Welfare. Bob Finch was the Secretary, and Jim Cavanaugh was the Deputy Assistant Secretary for Health. It was actually Jim who I interviewed with to finalize the appointment.

Then I worked in the Secretary's office for several months, in particular on the reorganization of FDA and the Consumer Protection and Environmental Health Service, CPEHS; because FDA had been layered by the CPEHS organization, which was a product of the Johnson administration, the Johnson administration. The objective was to literally break up that organization so that the . . .

SJ: And what were its failures in your mind?

LP: What failures of the CPEHS organization? It was just a, it was a layer. It was a

political layer to provide positions for personnel who were aligned with the prior administration. Some of these people had been political appointees. It was an unnecessary layering, and so breaking that up was essential. People from that organization were reassigned to different positions in the Department.

And there's a history associated with that, too, when you talk about political issues, because some of the folks who were reassigned were unhappy about it, and there were some investigations relating to retaliation, one that I recall in particular. But, in any event, the organization didn't have any useful function.

Portions of the Public Health Service that related to environmental issues -- water and air -- ultimately became part of what is now the Environmental Protection Agency.

When I joined, I wasn't particularly pleased in the Secretary's office because the organization didn't, at least for me, provide a function that was useful.

SJ: Or easily identified, even.

LP: It was political, you know, special-assistant kind of thing. But once the establishment of, or the restoration, I should say, the restoration of the agency's line of communication to the Secretary's office was restored, and Charlie Edwards had been identified as the candidate to fill the Commissioner's position, I asked Charlie if I could go over to the FDA with him, and I did. It was two weeks after he started that I joined the agency.

SJ: Did you know him before in any capacity, or you just met him in the process of

getting him organized to come to FDA, or . . .

LP: I met him after he had been selected. But I, along with some other folks, were involved in the selection process, because there was a talent bank that had been set up by the Administration to gather resumes from people who were interested in coming into the government. Maybe my resume was in that pool; but, somehow or another, I was able to get an interview and to get the position.

I met Charlie when he came in. He was a special assistant, I believe, to the Assistant Secretary, just as I was, and he had an office in HEW North, for which he was operating out of that office in anticipation of becoming the Commissioner. It was not public knowledge until the CPEHS group was broken up and it was announced that certain people were going to be reassigned, including some people from the FDA, because Herb Ley had been the Acting Commissioner, and Winston Rankin was Deputy Commissioner, and Kenneth Kirk was the Associate Commissioner for, I don't know if it was Regulatory Affairs or Compliance at the time. Each of those individuals were either reassigned or given an opportunity to retire. I think Winton Rankin did retire. Kirk may have retired. And then Herb Ley, who was Acting Commissioner, was assigned to the Secretary's office as some kind of special assistant. He was supergrade, etc. And I don't recall, my recollection is that he didn't stay very long in that position.

SJ: Was the atmosphere somewhat rancorous at the time?

LP: It must have been upsetting to a number of people in the agency to have their . . .



SJ: Their longstanding employees ceremoniously exited, exiting.

LP: Right.

SJ: Or unceremoniously exiting.

LP: Right. Well, you go to the trade press and the trade press will describe or did describe what the reaction of personnel was and what a shock this was.

As a matter of fact, Herb Ley was scheduled to speak at the Food and Drug Law Institute meeting in December of that year, and I believe that the day this reorganization was announced, he was to speak at the FDLI meeting, but he didn't show up. Fred Malek, I believe -- it's my recollection; you can check this out. But I believe Fred Malekallick appeared to explain what had taken place.

At that time, the Food and Drug Law Institute annual meeting was in December, and it was at the Twin Bridges Marriott Hotel, which is now gone.

SJ: Marriott.

LP: Marriott, right.

But that was quite a shock to the community that Herb Ley wasn't going to be speaking. He was somewhere else. There had been this reorganization, and there was to be a new Commissioner. I can't recall if Charlie Edwards had been named on that day.

This is just by recollection. Confirm it through the trade press.

SJ: Oh, yeah.

LP: But -- and, again, Fred Malek was the deputy undersecretary at the time, and I had worked with Fred as part of this "what do we do with the CPEHS organization," and are there personnel the Administration would like to have in key positions. Of course, Charlie was that person.

So that was a period of great activity inside the agency and outside the agency in December.

But, as I said, when I started, it was a week or two after Charlie, and my office was over in Crystal City, as was the Office of the Commissioner, because this building at 5600 Fishers Lane wasn't occupied yet.

SJ: It didn't exist.

LP: It existed, but it hadn't been occupied yet by FDA.

SJ: Oh, it existed?

LP: That occurred early in 1970. Folks moved over to this office with Charlie. The Commissioner's office is on the 14<sup>th</sup> floor. And, of course, I moved over here. I was on the 14<sup>th</sup> floor as well. And that began my tenure with the FDA as a special assistant to

the Commissioner. I worked on different things at the time.

SJ: Okay. Well, talk about those.

LP: Well, one issue that was very important to the agency at the time related to the safety of oral contraceptive drugs, and that was an activity that I got directly involved with because Congress was looking at the issue, and there were a couple of hearings that were scheduled, one of which was expected to be directly related to oral contraceptives.

Senator Gaylord Nelson chaired the committee -- I forget the exact title for the Senate side -- and Paul Rogers was chairman of the Health Subcommittee of the Commerce Committee. But over several weeks, from December to, I believe it was March, we were attempting to develop a position with regard to oral contraceptives and the safety of oral contraceptives. One issue related to a patient package insert, something that I supported. I believed that women, who were the beneficiaries of oral contraceptives, should have the information related to risks such as thromboembolic phenomena, TEP's. And my recollection is that, at the time, the data suggested one death in 30,000 users and one incident in 3,000 users relating to TEP, thromboembolic phenomena.

We worked on and finalized a draft of a patient package insert, and Charlie testified at Nelson's subcommittee hearing that he was going to require these patient package inserts. It was announced at the hearing that morning, and there was a great deal of publicity associated with that announcement that the FDA was going to require, through publication of a *Federal Register* notice, the transmission of this information to

women.

What I do recall are discussions that very morning with Charlie and Merv Silverman, who was a Public Health Service physician who had been there on a detail assignment. He and I were basically in charge of that activity, and we encouraged Charlie. I said, "Gotta do this, gotta do this." And Billy Goodrich was the general counsel then, and my recollection is that he supported this initiative as well.

But after it was announced . . .

SJ: Not much happened in the agency at that point without Billy Goodrich's support, from what I can tell.

LP: That's right. He was an excellent attorney, an excellent counselor. And of those people who were around before and after and could develop comparisons, there would probably be a consensus that he was certainly the most effective and most influential as a counselor and as a litigator, recognizing that the Justice Department has the actual litigation responsibility and authority. But his mind for litigation was very, very good.

In any event, because of the national publicity on this subject, there were some folks who were very unhappy about this, including the American Medical Association, who believed that the transmission of this information would interfere with the physician-patient relationship. They communicated with Secretary Finch, and his office communicated with Dr. Edwards. They were very unhappy because they didn't know that this announcement was going to be made.

It was the right thing to do, but, procedurally, it wasn't the proper method to

follow. But, nonetheless, when all the dust settled, the labeling was made available to patients. And I remember this experience vividly because I felt like I was kind of on the spot because of my advocacy for this position. And Charlie had to take a little bit of flak for it.

But it worked out very well in a number of different contexts, both with regard to the information that the patient, the consumer, the purchaser needed in order to make an informed decision, because this was not like a medication prescribed for some physiological abnormality. This was a demand item. Women went into a doctor's office, "Look, I want an oral contraceptive." They weren't interviewed by the physician or examined: "You know, I think you need to be on oral contraceptives." It's a demand item, so give the patient the information.

And it worked out very well because of the informed choice, but also in the context of product liability; because, if you look at the history of product liability claims with regard to oral contraceptives, you can appreciate that the number of lawsuits were rising up through the early '70s, and then after the implementation of this labeling requirement, they dropped precipitously. This was because women had the opportunity to make an informed choice.

So that was one of the first initiatives that I was involved with.

SJ: Do you remember working with Barbara Seaman or any of the female activists? Because, obviously, the women protested the Nelson hearings pretty -- they actually brought it to a halt at one point, calling themselves guinea pigs and those kind of things. My feeling was that some of this was in the works under Ley, and it sort of came to

fruition. But do you remember working directly or being influenced by these groups particularly?

LP: No. I don't recall being influenced at all by them. And Seaman. I remember that name, Barbara Seaman.

SJ: She wrote the book called *The Doctor's Case Against the Pill*.

LP: Right.

SJ: She and Morton Mintz, the *Washington Post* guy, were both highly critical of the pill.

LP: Yes. Well, Morton Mintz, I got to know him, had interacted with him during the years that I was with FDA, and even afterwards, in particular with regard to the intrauterine device, the Dalkon Shield, but on other issues as well. He's still alive. I don't know if you've interviewed him, but I spoke to him probably three or four years ago because he was doing something on the subject of infant formula.

But I don't recall any pressure.

I do recall that the consumer representatives, if you could characterize them that way, were very much upset by the appointment of Edwards, and my appointment as well, because Dr. Edwards came from the American Medical Association. He had been with Booz Allen Hamilton immediately prior to joining the FDA. And then I had been with

the Pharmaceutical Manufacturers, PMA. And I recall *The Chemical Feast*, a book that Jim Turner wrote, which was about to be published. I understand a page or two was inserted about these two pro-industry, pro-AMA physician guys who were going to go in there and a disaster was going to occur because of the appointment of these people. Since then I have met Jim, who practices downtown, and occasionally, we'd get together, with no hard feelings.

SJ: We do want to interview Jim Turner.

LP: Good. He's with the law firm of Turner and Swankin.

SJ: Keep going, I'm sorry.

LP: You asked me about whatever, oh, the reaction of -- you had asked me about the Barbara Seaman . . .

SJ: Yes, the reaction to you, yeah, to your appointment. But it turns out it was the perfect marriage in some respects.

LP: Oh, I thought . . .

SJ: You and Crawford turned out to be a wonderful team and . . . Not Crawford. I mean . . .

LP: Edwards. I know Crawford. You are talking about Les Crawford?

SJ: You and Edwards, Charlie.

LP: Yeah, Charlie Edwards. Have you interviewed him?

SJ: Yes. We'll let you see that interview transcript.

Anyway, tell a little about, you know, once you've tackled congressional hearings, which would have rattled almost anyone, but, actually, I have videotape of Edwards being a very calming influence during that and during those hearings. He came up with, he really injected some sanity into something that was rapidly becoming insane.

LP: I didn't know that you had those, a video of that.

SJ: Thank you very much. I'll show you. I'm very proud of it. The broadcast news during that era was much better than it is now. Now it's just kind of canned and personality driven. In those days, they went after real stories, and so they actually have, in the Vanderbilt archives, broadcast media archives, whole sequences of the women protesting and shutting down the hearings, and the whole video of the Nelson hearings. And so what I did was a, CDRH [Center for Devices and Radiological Health] let me sit down with a video-editing machine, and I took pieces of all of this and strung it together. And I'll get you a copy.



LP: Oh, I'd like to have that, yes.

SJ: People who have seen it love it.

LP: When you mentioned this . . .

SJ: And it's not like I'm a good editor, but the material is so rich, you know, all you have to do is string it together.

LP: That's fascinating, because I do remember now. You stimulated the recollection. There was a lot of activity before that hearing, and Ron Nessen was with one of the networks and was trying to get to Edwards and did get to Edwards, and ultimately became part of the team in the agency.

But that morning, when we went down there, we were at FOB-8, so we went from FOB-8 only to the hearing and back. But now that you mention it, there was a lot of activity and a lot -- I remember it. But my memory could be better stimulated by looking at some of the video.

SJ: You'll have to look at the video, because I . . .

LP: Or pulling up from my clips from that time.

SJ: People really like . . . There's no way a historian could ever lecture and make anything as compelling as the actual footage from that whole era. And I started with the first mention of the pill on national broadcast media, had nothing to do with science, public health, pharmacy, anything. It was simply that Medicaid was going to start covering. It was an economic issue.

LP: What year was that? In the '60s, late '60s?

SJ: I was going to say, yes.

LP: Something like that.

SJ: Yes. Right before the safety stuff started hitting, hitting big-time anyway.

LP: Well, you know, my perspective on the subject, as I started to mention before, was in the interests of the user. The user should know what the risks are associated with their taking of a product like that. And with my pharmacy background . . .

SJ: And that's with your pharmacy background.

LP: Sure.

SJ: Exactly.

LP: Because the endocrine system is a very delicate system, and you sprinkle something into that system or you pour or you dump, and some bad things could happen. So let the user be aware, you know, *caveat emptor*.

But also from the perspective of product liability prevention. I believe that disclosure was essential to the manufacturer to reduce the risks that they encounter, and encounter now in the context of the aggressiveness of the plaintiffs' bar. So that's all worked out very well.

But I remember being a little bit, what, unhappy for a period of time because somebody had to be the -- I won't say the scapegoat, but Larry happened to be the guy! There were other people probably attacking, saying, look, you should have this and you should have that, because when Charlie became the Commissioner, of course, the bureaucrats within the agency quickly surround the new Commissioner or the new leader to demonstrate how effective they are, how conscientious, how they're not 9-to-5ers, things like that. And that's not bad if these are good people who are surrounding the Commissioner. If they're not necessarily good -- and by that I mean in the context of the function of an organization and the carrying out of a philosophy -- that can be harmful to the new executive, who doesn't know the agency and will have to take some time to learn about the agency, sometimes years. Then it's too late because the individual Commissioner term expires. "You know, this is integral to FDA. I didn't know that." At that time I believe there were about 3,000 people in the agency, something like that. Now, of course, it's over 10,000. So it's still a large agency, but relatively small as compared to some.

But during that period, I learned about what the departmental task force was doing under the leadership of Ted Cooper and became very interested in the medical device program. And I had actually submitted a proposal to Charlie about the reorganization of the activity, the device activity, because that's what I wanted to get into. And ultimately I did. But Dave Link came in, I think it was September of 1970, because he had an engineering background and some postgraduate work and consulting work. And he was a friend of Henry Simmons. That's how I believe he came in.

So Dave and I worked together and worked together very, very well with that, with the two secretaries, Maryann and Colleen.

SJ: Tell us a little about Ted Cooper. Did you know him?

LP: Oh, yes.

SJ: For such a historically significant piece of legislation, the paper trail on that commission, I swear, I think he just got people together on Friday afternoons at NIH and chatted, and then they wrote a three-page report almost as if, you know, almost in summary discussions or whatever. But there's not a rich paper trail on the Cooper Commission by any means. So we assume . . .

LP: This became known as the Cooper Committee.

SJ: Cooper Committee. You may be right.

LP: But I've got some of that. That committee -- Charlie was on that committee. Mark Novitoh was on it. I think Billy was on it. And there were representatives of the NIH and other components of the Department. But Ted Cooper, who was the Director of the Heart and Lung Institute at NIH -- was very well-organized, and he managed the task-force activity well, because he invited the public -- the industry, the health care community, consumers -- to present their views. And there was another activity separate from the Cooper Committee that coincided somewhat with that initiative, and that was directed by AAMI, the Association for Advancement of Medical Instrumentation. They had put together a group of people for the purpose of looking at what kind of legislative reform would be appropriate for devices, and in part because of the Supreme Court decision that was the backbone . . .

SJ: That was Unidisc.

LP: Bacto-Unidisc case, where something that everyone considered to be a diagnostic thing, a device, was now going to be subject to regulation as a drug, and a new drug. So the industry was beginning to react to all of this, as was the health care community.

So AAMI put out a report around that time. Maybe it was in 1969, and I have that publication somewhere.

But the Cooper Committee met in public and developed this report -- about a 15-page, double-spaced report -- that was literally under seal until about late 1970, when the word got out about the report, and then the report itself was released. I think something

had gotten to people beforehand. But the report made the recommendation that ultimately formed the basis for the legislative initiative, and which did survive through the '76 amendments; that is, the classification of devices system 1, 2, 3, and the use of advisory committees, etc.

So Dave Link and I, going back to 1970, took on the initiative to identify who was making what, because the FDA didn't know who was making what. We worked with the trade associations and professional groups to develop an identification of different categories of devices and to get from the trade associations, in particular, information about members, and also with regard to SIC codes to identify manufacturers. We established an inventory system and sent notices out to thousands of companies asking them to voluntarily give us information about their company and its devices.

SJ: Please tell me you have a copy of that.

LP: I've got some of that, sure.

SJ: I've been looking for that inventory -- I think that we're talking about the same thing. It was a survey type thing.

LP: Right.

SJ: I've been looking for it.

LP: I've got the original, and I think the letter that we sent out. I don't remember if it was under Charlie's signature or -- it might have been. But, yes, I have that.

SJ: Oh, thank you.

LP: Well, don't worry.

SJ: It is not in the archives. It is not there.

LP: And you mentioned the Cooper Committee. The attachments, the exhibits to the Cooper Committee, they were retained. I don't know what happened to them.

SJ: They're not there.

LP: Because I've got a couple of the exhibits. But Dave and I have talked about this a couple of times: what happened to the exhibits? I remember that he had them, and he was responsible for maintaining the exhibits.

SJ: Why don't we go ahead and cut it because it's going to cut off in a minute.

LP: Okay.

TAPE 1, SIDE B

LP: So Dave and I put together this industry survey, the form, the letter. And I remember the form. We had to go to OMB [Office of Management and Budget] to get the form approved. And we were in this building over on the 8<sup>th</sup> floor with Colleen and Maryann, who were the secretaries, Dave and I, and we were stuffing the envelopes. I think there were 3,000, something like that, that we sent out. And we got feedback which enabled us to put together a list of manufacturers and devices.

And because we were working off of the Cooper Committee Report, in anticipation of passage of that legislation, we formed two device advisory committees. These were to be used as a test of the classification scientific review process. So Dave had the cardiovascular, thoracic, and I had the orthopedic. We solicited names from the industry and consumer groups and identified the people who would participate in that activity. We also put together a format for them to test.

Those committees met at the Marriott Key Bridge in Rosslyn, Virginia, and, as I said, I had the orthopedic, and Harlan Amstutz was the chairman of that group. So we had a day or two meeting at the hotel to see how it worked and what advice they had, with suggestions.

As a result of those two test panels, we then formed panels for ten, fifteen disciplines, and those committees were approved by the Department and began the process of classifying devices. So, before the passage of the legislation, we had much of that work done.

Coincidental with that, since you mentioned GMP [Good Manufacturing Practices] when we were chatting before, I put together an advisory group with



representatives from industry, the health care community, trade associations, professional associations, and consumer groups to meet and discuss the concepts of Good Manufacturing Practices and the implementation of something that could become a regulation. This had to be around 1972 or '73, because the office was formed in '71. I remember we met over at that Rad Health Building on Twinbrook, and Sid Wolfe came to that meeting, just an open book. You know Sid. And we had that first meeting and then subsequent meetings with the industry to develop a draft. But Sidney didn't come to any more of the meetings. He was invited, he arrived, he participated somewhat, and then that was it, which was fine. But it was open door.

Going back to the classification activity, during that several-year period, under the auspices of the Office of Medical Devices, we continued that activity and undertook some other initiatives. But with the formation of the Office of Medical Devices, to go back to that, this was September '71, and Dr. John Jennings was the Associate Commissioner for Medical Affairs. So we reported to John.

SJ: And he's still working. Or did he . . .

LP: He's deceased.

SJ: He's the one we missed, then.

LP: I'm really sorry you missed him because . . .

SJ: That was a big mistake. Yes.

LP: Because John and I were friends. We've been friends from the first uncomfortable moment I met him in Crystal City, and it was on a Saturday, because I think I was working with John on the oral-contraceptive issue.

John had literally been put on the shelf. He was director of the Bureau of Drugs, Bureau of Medicine, which became Bureau of Drugs. Henry Simmons went into that position. Because John was a supergrade, he was made an Associate Commissioner for Medical Affairs, which most people, as part of this organization -- I talked before, reorganization -- regarded as a shelf position. But John was brilliant, brilliant, brilliant, and very practical. And he and Charlie got to know one another and really like one another. Charlie relied heavily on John's good, great judgment.

So here, when I did meet him on a Saturday, he was kind of crusty, kind of crusty. You know, I'm from the outside. He's been with the FDA, etc., etc. But I liked him, and we got to be very, very good friends and maintained our personal friendship throughout the years.

But the Office of Medical Devices functioned under him, and he was a very good supporter and leader of that effort, and a great counselor to Charlie Edwards and, particularly later on, to Commissioner Mac Schmidt. It was Donald Kennedy who . . .

SJ: John Jennings got, anytime anything serious came up, John Jennings got it. He had a piece of it, either formally, informally, or otherwise. But other people recognized his genius, too, and I'm just sorry that . . .

LP: Genius is a nice word to apply to John.

SJ: He was sick. He was sick when we tried to interview him, and it just never worked out, but . . .

LP: Well, I'm sorry to hear that because, as I said, we were very good friends, very good friends indeed. I was the administrator of his estate, and he's just a good friend.

You know Sarah Kay?

SJ: Yes.

LP: Because Sarah Kay can tell you more about John.

SJ: I think I may talk to Sarah Kay and see if she can piece together some of it for me and see if he left any papers and that kind of thing. She's retired now, too, though, so . . .

LP: Oh, gosh.

SJ: Do you know how to get in touch with her?

LP: Yes.

SJ: Because she's retired now. I . . .

LP: She lives out on the farm in Woodstock.

SJ: Okay. Well, we'll get that later because I want to contact her.

LP: You know, when we were cleaning up the estate, there were a lot of papers, a lot of papers.

SJ: Please don't tell me you just pitched them.

LP: I didn't pitch them, and I don't know that Sarah would have. When I saw them, I thought they had usefulness as historical information. I have those. I don't know if Sarah has any of them. Check with Sarah. Okay?

SJ: Okay. We'll talk about that.

LP: But John and I . . .

SJ: Worked well together.

LP: Oh, yes. He was great, you know, brilliant. And it's too bad, as I said, that you didn't get a chance to interview him.

You had asked about Cooper and I started to tell you about Cooper. But Cooper was a fascinating guy, very bright and energetic, clever, creative, and responsible. He was a terrific servant of the public. He became Assistant Secretary for Health following Charlie Edwards. Then he went to Upjohn Pharmaceuticals. Well, he didn't go directly to Upjohn. He was a medical school administrator and then later joined Upjohn, where he was a very good executive, but died early, too early. He was 65, I think, something like that.

Connie Fouchey. That's the name I wanted to mention. Connie Fouchey, who was from Minnesota, worked with him on the report. She was the key staff person. I don't know if she might have saved these exhibits, because she was the person who did much of the work.

SJ: How do you spell it?

LP: It was F-o-u-c-h-e-y.

SJ: I'll find out.

LP: It's a name that's not unusual and maybe somewhat prominent in the Minneapolis-St. Paul area. But Constance Fouchey. She might still be in this area. I don't know. And I believe she has been employed on the Hill. And I don't know how she hooked up with Ted Cooper.

But during this period that, from '70 to '71 and a year or two after that, Dave and

I met a lot with Cooper -- I'd say frequently, not a lot -- to make sure that what we were doing was consistent with his vision of the kind of regulatory program that would be unique to devices as distinguished from drugs.

So '71 was the formation of the office. We had a division of, no, the office for compliance, called Division of Compliance, which was the major division. I think I had ten people working in Compliance, and then the other half, maybe another ten people, most of whom were in what was the Office of Device Evaluation or Scientific Review. I forget the title, but I probably have that somewhere. And Carl Bruck came in, and he managed that activity; then Bob Kennedy, a physicist.

Bob Kennedy is deceased. He's another guy you won't be able to interview. There are two Bob Kennedys. There was the Bob Kennedy that worked with Dr. Joe Davis, who had headed up that group that was interested primarily in quackery, the Diapulse device.

Well, I testified as an FDA witness in the criminal trial of Bern Siler and the other fellow, Forest Patterson, in New York. I don't know if you know who he is, but he was an attorney here and he was helping out the U.S. Attorney up in New York on that criminal prosecution.

Scientology and E-meter devices are two notable experiences.

SJ: I'll add it for another day. Yes, I'll put it for another day.

LP: Don't, when you get off the record, I'll tell you something else.

[Tape recorder turned off for a few seconds]

LP: We were talking about the classification of the Diapulse device. Bob Kennedy. It's two different Bob Kennedys.

But with the formation of the Office of Medical Devices, again, under the direction of John Jennings, we began to identify activities that we thought were important to the surveillance of the industry, compliance activities. So we wanted to survey the pacemaker industry, the heart-valve industry.

But one of the first issues that we got involved with related to pacemakers, cardiac pacemakers, and General Electric had a pacemaker that they recalled because of a flaw in the product. It actually had to do with dendritic growth. We learned about it from the press. I remember hearing either on the news or reading a newspaper article about General Electric pacemakers, so that's something we should look into. At the time, we began to look into this matter because they were undertaking a recall of a previously recalled pacemaker. So we inserted ourselves into the process even though we didn't have any legislative authority beyond the 1938 Act, and met with folks from GE and used what limited capabilities we had, analytical capabilities, to see if there wasn't something that we could work on together. And the issue did relate to dendritic growth and hermetic sealing of these pacemakers.

SJ: Like a Cordis device, or was it different?

LP: No. This was the GE. That's another story. But the General Electric device. GE

got out of the business shortly thereafter.

But at that time, there was also an issue with regard to use of microwave ovens and interference with pacemakers, and that's when we first began to interact with what was then the Bureau of Radiological Health, John Villforth's group, because someone had suggested that restaurants post a notice wherever there's a microwave oven, if you have a pacemaker, "Beware" kind of a thing, and we said, "That's not the way to go."

We began to meet with representatives of the industry, and one of the individuals we met with was Earl Bakken, who was the co-founder of Medtronic and who's still alive. We met with him. Medtronic was a very small company then. And there were possibly fifteen different pacemaker manufacturers at the time: Cordis, GE, American Technology. Maybe not fifteen, maybe ten, something like that. We met with Earl Bakken and other representatives of the industry to try and develop some approach that would be satisfactory to the industry and to the microwave industry, etc., etc.

And that goes off into another trail, because later on we have the issue with regard to Cordis.

But at that time, we were also looking at cardiac valves, and in particular because of an incident relating to one particular valve, and that was the Ball mitral valve, which you see here, because there were reports of fracture of the struts or the disk itself, but in any event, a disruption of the performance because of the breakage, which led to some deaths. This product was made by Travenol, Baxter Travenol and Art Ball. We had known Art Ball because he was very active in AAMI, and this valve was named after him. But we met with the company representatives to try and identify the problem.

One thing we discovered was that the method that they used to package this valve



wasn't even up to the level of amateur. It looked like a cheap cufflink box, plastic box, and then there was some foam at the bottom, and I don't recall at the top. This valve was placed in the box, and apparently in shipment through the postal system, because the pyrolyte carbon is very delicate, there was some damage to the pyrolytic carbon, and when the device was implanted, after a period of time there would be a fracture of the strut. The strut would break off and the disk would escape.

SJ: So it wasn't even necessarily the valve or the engineering or anything. It was more the packaging and shipping.

LP: It was the packaging, and the company agreed and developed a package that could be used in sterilization -- I think it was ethylene oxide that was used -- and then could be used for shipping purposes as well. They had done a great job, because this package was such that the valve was secure in the package, and you could literally take that package and throw it up against a wall. It was a plastic container. And the valve would remain intact, without any damage. So they went from this cheap cufflink box to a very secure packaging system.

I still have one of those, so I can show you that.

SJ: Please let us get pictures.

LP: Yes.

And there was no further problem with the valve. The performance of the valve

was fine.

We also had other valves that we looked into, one of which was a, I think it might have been the Smeloff-Cutter valve. And the company, Starr-Edwards, made the product.

SJ: My uncle worked with Dr. Smeloff.

LP: Okay. And I think it might have been the Magna Cromy. Whatever it was. But the ball itself was of a plastic material. I recall the company coming in to meet with us because they were having some problems. Their analysis of the problem revealed that through the method of sterilization, the ball became distorted and was responsible for the kind of problems that they had. There was a “recall” of the product, but not from the patient. The company discontinued use, made a modification, etc. And, again, this is all before or around the time of the '76 amendments.

We had encouraged manufacturers to come in and talk to us if they had an issue to determine whether or not we could be helpful in any way, and, I believe, for the most part, people who were in the industry or the health care community at the time respected what we did and agreed that we were trying to be helpful and practical about our responsibility and their responsibility to the public.

So we had the major pacemaker recall issue and some subsequent hearings and the investigations, FDA, FBI investigations. I remember that.

SJ: FBI?

LP: Oh, yes, because allegations of some kind of wrongdoing by us, favoritism to GE. Senator Ribicoff was chairman of the Senate committee, and there was an investigation of our performance, my performance, because of the allegations by some former disgruntled employee, whistleblower type -- none of which was supportable.

But the same thing happened with the intrauterine device, an investigation of our performance and our conduct, and an allegation that I'd taken lots of money from A.H. Robbins Company to smooth everything over, all of which was false.

And so we had the heart valve, the cardiac valve matter; we had the GE and subsequent pacemaker industry issues; and the intrauterine device.

The intrauterine device was a big, huge matter, and John Jennings chaired public hearings that we had on that subject. That occurred during Mac Schmidt's tenure as Commissioner.

Those issues were evolving, developing, giving greater visibility to the office and focus on the importance of legislation, in particular the Dalkon Shield.

The Dalkon Shield was a very interesting investigation on the part of the agency, because there was no question that there were significant reports of mid-trimester septic abortions. But what the significance of those reports were in the context of an epidemiological exercise was uncertain. We pulled together the existing ob-gyn device committee and the existing drug committee, put them together as a panel, and had a couple of days of public hearings; and we invited experts from, literally, around the world, from the U.S., in particular someone from the U.K. who was an author-investigator-analyst-physician. Snowden, I think was his name. The FDA had had, on

the drug side, I believe, two published IUD reports. Well, I have these two FDA reports. I recall two reports on intrauterine devices but it may have been one report. But all of this is background to what ultimately was the completion of this advisory committee process to determine the “safety” status of the Dalkon Shield. A.H. Robins had decided during this process to discontinue the distribution of the intrauterine device. And we worked with the Robins folks. We had limited access to facilities and documents because FDA’s authority was limited. But the Robins Company appeared to be cooperative. When they discontinued the distribution, we characterized that activity as a withdrawal, not a recall, never a recall. The reason that it wasn’t characterized as a recall is because the data just didn’t support any allegation that this was a hazard to health, one for which it would be appropriate to characterize it as a recall, and a Class I recall. But that didn’t prevent us previously from seizing another intrauterine device, the Masslin spring, which we believed was a danger to health. And the Masslin spring was like a series of paperclips so that it compressed when inserted into the uterus and then the spring would expand. The problem was . . .

SJ: Getting it out.

LP: Well, that might have been a greater problem. But the configuration of this spring was such that it didn’t conform to the design of the uterus, and you had pressure on the lower end, which would cause perforations and then drift on the device into the abdominal cavity. I recall that a member of the FDA advisory committee on intrauterine devices had these devices in his practice and was using these devices in his practice, and

apparently had a large store of them, which we had discovered from distribution records of the company that was out of business. We wanted to get those IUD's out of commercial distribution.

I called this physician -- his name doesn't come to mind immediately -- in the evening, and I said to him that we'd like him to turn these over to us. We would appreciate his cooperation. He said, "No, I use these," and da-da-da, "I'm a member of the advisory committee," and all this kind of stuff. But he would not voluntarily release these. So we did arrange to send in the U.S. marshal possibly the next day, but very shortly thereafter, to seize these, and he didn't contest the seizure. But we were asking for his cooperation and he wouldn't give it to us, and we had an opinion from the chairman of the drug advisory committee, who was at Johns Hopkins, that these were in fact a danger to health. So we had an expert opinion to support our reaction. If there was a contested seizure, we had an expert opinion that said, "Look, these are not safe." So those were seized.

But the Dalkon Shield was a different story because the company was cooperative and did what they considered to be the right thing. The issue, I believe, related to the multifilament tail because of a possible wicking phenomena. Dr. Tatum appeared at that advisory committee meeting, and he had some slides to show how this wicking phenomena could have occurred. He had a dye that was used, and he had a very impressive presentation. I thought it was very good. However, the difficulty was he did not disclose that he had any IND that was under review then in the Bureau of Drugs. It was the Tatum T device; a copper-containing device -- which I think should have been revealed, and for which under circumstances today, would have been revealed: "Look,

I'm here to present this evidence, but I've got to let you know that I've got a device that I developed and it's under review." "Okay, fine."

SJ: The same thing happened in the Nelson hearings, the guy that developed . . .

LP: The Dalkon Shield.

SJ: Yes.

LP: Yes, Dalkon Shield.

SJ: Of course the pill's highly dangerous if you've got this alternative out there that you're trying to market.

LP: Well, that was Davis. You're talking about Davis on the . . . Yes, oh, yes. That hearing, that was the same hearing at which Charlie spoke. It propelled the IUD in particular, the Dalkon Shield, into the best marketing form that you could ask for.

SJ: That's right.

LP: Front-page news.

So docs and women flocked to the IUD. It was a very good device because it did not have the expulsion rate of others, and it could be removed, not like the Masslin

spring.

So Robins, which had bought the rights to this IND and marketed it, they just zoomed. There were literally millions of these devices being implanted. So it was not unusual that there were a large number of reports, a large number of reports about the safety in these mid-trimester septic abortions. But when you flatten it all out, it was no different than the other devices, like the Lippes loop. I remember the Lippes loop, Jack Lippes did appear at that hearing to talk about the Lippes loop, and I won't say the virtues, but you can go back to the transcripts. I hope the transcripts exist of that hearing.

SJ: Congress keeps their records, unlike certain Food and Drug officials.

LP: I'm talking about FDA, that FDA . . . Those were all tape recorded.

SJ: If they're hearings, they're probably there.

LP: Okay.

So with the Lippes loop, Jack Lippes testified to his evaluation of that device. I remember when we put that display -- Joe Mamana was responsible for putting this together.

SJ: He was working on an exhibit we distributed to the field, I think, to show them about IUD's.

LP: Yes. This was done when I was . . .

SJ: Oh, you did it.

LP: As I said, Joe Mamana, who worked in my office, I think was responsible for this.

But another interesting thing about the Lippes loop was from one of our employees in Compliance. I learned after the hearing that she had been a patient of Jack Lippes' when he was investigating the Lippes loop. She told me that, after the insertion, she was uncomfortable. She went back. She was still uncomfortable. And she went back again. And his advice was reassurance. You know, "This is fine." She finally went to another physician to have . . .

SJ: To remove.

LP: Removed. So that gets into, well, what was the quality of that data to support the claims for effectiveness and safety of the Lippes loop when you question the luck to follow-up because the investigator, who's the named party, is saying, "Oh, it's okay, it's okay"? That's not a good study; that's not a way . . . If it's not, if a patient's having discomfort, well, then you have to take it out and you mark it down there as an adverse reaction. So there was some skepticism, certainly on my part, with regard to this marketplace on intrauterine devices because folks had their personal interests, competitive interests, financial interests in all of this.

But the Dalkon Shield was a good device. What was the problem, as we learned



later on, was that there was a somewhat alert employee in the manufacturing facility at Chapstick, where I recall they made the intrauterine device, who was curious about what he thought was lines for fishhooks -- and I don't know why he did this; I have to go back into the book that Mintz wrote. But he discovered that this phenomena, this wicking phenomena, and he apparently told his supervisor, who told him, "Forget it. Get out of here," something like that. But that message apparently had been known to the company at the time, but not known to us. I learned this after I left the agency.

#### TAPE 2, SIDE A

LP: I was saying that the disclosure of that information was disappointing to me because I believe that if the representatives of Robins would have advised us of this, assuming that they knew it at the time they were dealing with us, I believe our recommendation -- I know my recommendation to them would have been, "Look, if this is a possibility and a reason, a likely reason for these septic abortions or the infections, the PID's, you should advise physicians who use the device so that they can advise the patient."

Now, the patient could have made her own choice as to whether or not she wanted the device removed, because the device was labeled very well. The instructions for use were superb, much better than the Lippes loop or the Safety coil. It was very good labeling; it was terrific labeling.

But we didn't know that. And I felt that if I'd have known that, I would have recommended they notify the patient. They could have kept their device on the market

with the monofilament rather than the multifilament. That ultimately is what got them into, the product's liability, a death hole, the fact that this was viewed as a smoking pistol. Somebody knew about this in the company and nobody did anything about it. Ultimately, of course, they did advise recall, that is, physical removal of the device. But it was too bad.

That issue was investigated by a Senate committee, and Walter Sheridan interviewed me. Walter Sheridan was Bobby Kennedy's kind of right-hand person. You know who he is?

SJ: Mm-hmm, I've heard of him.

LP: Right. Well, he went after Hoffa. He was the leader of the team that went after Hoffa. Bobby Kennedy wanted Hoffa. And so Walter Sheridan, who wrote a book on that -- and the name escapes me now, but I did read the book. In any event, he interviewed me, and he said something about a rumor that I had taken money, because I knew the Robins folks. I knew them very well from my PMA days, E. Claiborne Robbins, the chairman, and Skip Forrest, the attorney.

And I said, "Well, what was this all about?" I asked Sheridan.

He said, "Well, we understand you took \$200,000."

This was about 1975.

I said, "Two hundred thousand dollars?"

He says, "That's right."

I said, "Boy, if I took \$200,000," I said, "I wouldn't be here speaking to you."

I didn't take any money. There was nothing. Everything was open book with regard to the communications, etc., etc.

So that was the Dalkon Shield issue before the passage of the '76 amendment. That gets treated in the House report. That wasn't what prompted the change in legislation, such as thalidomide with the '62 amendments and other incidents.

But the pacemaker industry continued to be an industry for which we had undertaken surveillance activities, and for which Cordis began to have some issues, and those issues related to some recalled devices, an investigation by us, a determination that their manufacturing practices were not what we considered to be state-of-the-art, and for which the FDA Orlando district office recommended injunction, injunctive relief. So we looked at this, and I thought that the evidence wasn't sufficient, and suggested another inspection.

That inspection was performed by a fellow by the name of Fred Hooten, who was in EDRO at the time, and the evidence was somewhat persuasive. I can't remember whether it was two or three inspections, but if there was a third one, it was the third one that was undertaken to confirm that the objectionable observations that we made before continued. The observations related to, for example, production workers having English instructions when their native language was Spanish, and they had no idea as to what the words in English said or meant. That was one that I remember. In any event, we were convinced that it was appropriate to go forward with a recommendation for injunctive relief. There was some tension between headquarters and the district then, too, because the district was angry at us for my refusal of the recommendation, because I didn't believe that the evidence was adequate or contemporaneous. It was kind of stale.

And, ultimately, we did file the complaint for injunctive relief, and that resulted in a hearing by a Master, appointed by the Federal Court, for which ultimately the matter was resolved amicably. The Master wrote a report that basically satisfied both the FDA and the company, and the company learned from the process and continued.

SJ: Is that Judge Davidson?

LP: No. He's the administrative law judge. No. There was a special master. His name was Heinz, Bill Heinz, who was on the faculty of the Georgia Institute of Technology.

SJ: Georgia Tech.

LP: Georgia Tech, that's right, Georgia Tech. And he was appointed as a special master because of his knowledge of quality control, etc. He didn't have any experience in the medical device industry, but he knew the principles of quality control, quality assurance, and as to how they should relate to something as sensitive as a pacemaker, a lifesaving, life-supporting device.

So those were some of the major regulatory initiatives that we were involved in prior to the passage of the '76 amendments.

Then, with the '76 amendments, we now had the authority to implement the activities that we had been pursuing voluntarily: the classification of the devices, the Good Manufacturing Practice regulations, pre-market notification, administrative

detention, banning devices. The regulations that I had an interest in and had the responsibility for: GMP, banning, administrative, 510(k), registration listing, we had a head start on those. We were ready at the passage of the legislation and were able to complete those final regulations.

SJ: All this with a staff of five people?

LP: Well, we were up . . .

SJ: Six?

LP: No. We actually became a Bureau of Medical Devices around '74, '75. It was the Bureau of Medical Devices and Diagnostic Products, and then it became the Bureau of Medical Devices, because the diagnostic-product activity was previously in the Bureau of Drugs, and that created some administrative problems because some of those products were drug-like and others were clearly devices under the definition of the term "device."

So the component that was the diagnostic-products component moved over to the Office of Medical Devices, and maybe it was that move that prompted the creation of the Bureau of Medical Devices and Diagnostic Products. Eloise Evanson was the woman who was responsible for that activity.

So we had both of those activities, and the organization grew from about 20 in 1971 to maybe 100, got up to a couple hundred. At the time I left, it was several hundred. I left in '79. Dave left in, I think, '80 or '81. But it was in the several

hundreds, because when I left we had over 100 people in Compliance.

I do remember I was offered more positions, and I declined to take them. There were maybe five positions. I said, "No. Everybody is busy. They're not wasting their time. I don't know what I would do with five more positions because people are handling the load now and handling it well." When you get extra positions, people start to look for things to do to create justification for their jobs, and that happens in the agency. It happened then, and it's still happening. So you get into mischief-making then. That isn't going to be very productive in the context of the mission. That's another subject I could talk about.

I felt that we had a good staff. The supervisors agreed with me. There were three divisions in that Office of Compliance at the time. And the people seemed to be very happy in their work, as Mao Zedong would say, "happy in their work," because it was productive and the activities were well managed. I believe those who had the responsibilities recognized that there was a job that was important and for which they could take pride in being part of that process.

So I left in '79, but whatever you want to know between that period of time, '70 and '79, I'm happy to answer any other questions that you have.

SJ: Well, is there anything else on heart valves that you recall, having worked on particular problems?

LP: Well, I recall at the time that I left that the St. Jude valve was being investigated, clinically investigated, and that clinical investigation was widespread, to the extent that --

it wasn't a clinical investigation. It was a marketed device. And shortly after I left, the company was subject, I believe, to a regulatory letter in the context of their promotion of the device, and then there was some back-and-forth that I was involved in initially when I left the agency but did not continue lest there be any interest or concern about a conflict.

But, yes, that was a major issue because the investigational device regulation had not been finalized. That's my recollection. We started with the IDE regulation, and the first effort was rejected by the industry and the health care community, and for good reason, since we literally rushed it out. I remember that. And I anticipated there would be some reaction.

Well, that initiative resulted in the republication of a proposal, and then the ultimate finalization which came -- I can't remember -- '79, '80. It might have been '80, because the pre-market approval regulation followed that. I believe it was finalized when Frank Young was the Commissioner. So we had the IDE activity.

The 510(k) process was underway, and that was being managed, I thought, very well and was not overly burdensome . . .

SJ: That's always been the key to the device field in some respects. Don't you think?

LP: Pre-market notification.

SJ: Yes. The way that part is managed, because then the key to the success of it overall.

LP: The way it was managed.

SJ: Right.

LP: The way it was managed from '76 to the early '80s, and then it literally spun out of control. It became a surrogate pre-market-approval process, which was not helpful.

And that's another story, which I approach from a different perspective because I'm in practice now and witnessing the performance of the agency with regard to delays and requests for data that are excessive and not at all consistent with what Ted Cooper and his committee had in mind as we executed our responsibility from '76 to '80, when Dave was still there. It was not intended to function as a pre-market approval, and that was because of the classification process itself.

Those devices which required some thorough review of clinical data primarily to establish safety and effectiveness were in the Class III category. Those were the devices that were to be subject to scrutiny that was appropriate for the nature of the device, not all the I and the II categories.

Then I approach it, as I said, from another perspective because I thought that the management of the program was out of control and harmful to the industry, very harmful to the industry.

When I say the industry, I mean this in the context of the public as beneficiaries of what we expect from those who manufacture and regulate. So it was a disaster after that. Some of the flaws still exist today, unfortunately.

But I'm here only to discuss up to 1979. Right?



SJ: Not necessarily, no.

Tell me a little bit about Dr. [David] Link. How was he to work with? We've got an interview with him as well, but we'd like to get a feel for some of the personalities and some of the people, especially in this area, merging of devices and radiological health programs, because you formed the core of what was divisive.

LP: There's no question about it. We were . . .

SJ: It has been said that if it hadn't been for John Villforth, we wouldn't have been able to merge the two fields because he recognized that devices would ultimately have to prevail. So to bring the Radiological Health folks in and allow them -- I'm putting words in people's mouths. But the device field was always the stronger field.

LP: Yes.

SJ: But the leadership that came after you in devices was not as strong as the leadership strength within Rad Health.

LP: It was a disaster. When I say disaster, it did not work well because -- although, personally, I thought that . . .

SJ: Well, let's discuss you and David Link first.

LP: Sure. Well, Dave and I started in September '70. That's when I met him, and we worked together, actually, under, well, under John Jennings' direction, because we, although we reported directly to Edwards, John's influence was very important to the process. That's why one year later, when that Office of Medical Devices was formed, John was responsible for the management of that office until the formation of the bureau.

So Dave and I worked very well together, very well indeed. Dave's a very bright guy, very articulate and positive, not at all reluctant to make decisions, tough decisions. So he and I got along very, very well.

There were times when Dave disagreed with me, and I probably disagreed with him. But for the most part, we had a very congenial and professional relationship, and personal too, because I've kept up my relationship with Dave.

But one thing I remember, when I left the agency -- and I announced my resignation several months before I planned to leave and issued a statement at the time, which you can get, because I described what my experience was and the expectation, and the importance of the revolving door, because I believe that it's good for people from industry to come into government, it's good for people from the agency to go into industry, it's good to move that and keep the process dynamic.

But I was the object of a surprise party because I didn't want any party. But I walked into what I thought was a meeting on contact lenses, and it wasn't.

And while I was there, Dave made some very nice remarks. And one of the remarks that he made, he said, "Larry and I," and da-da-da-da, "and I've always valued his advice, even though I didn't agree with it and later regretted it." And one of the smart

guys there said, “Well, why are you waiting now to tell him that?” And Dave remembers that.

But we got along very, very, very well, and I believe the success of the program was in large measure due to our respect of personalities and willingness to be creative and outside the box.

But, again, Dave was very decisive and he had good judgment, too. I mean, we . .

.

SJ: Yes, but coming across in the paperwork.

LP: I believe that . . .

SJ: The paperwork shows you being very much on top of the issues, the technicalities, the ramifications of things, and him not being, not afraid to make a decision and ultimately move in a particular direction.

LP: But also to complement the Commissioner, because Charlie Edwards was a very .

..

SJ: I was going to say, of all the people to work under . . .

LP: He was great because he identified the subordinate supervisors, and he recognized

that their delegated responsibility was to discharge consistent with his philosophy, his management style, and to have uppermost in the mind of the manager the public, as well as the need to function as an agency which would not be embarrassed. So he was great. He delegated. He didn't have to be out there in front of everything. As a matter of fact, on some of those hearings, he declined to go to some of those hearings: "No. I'm going to send Henry" to Congressman Fountain's hearing -- and there were a lot of hearings. But Charlie was very good as a manager.

Mac Schmidt was a different type of personality, much different, but a good fellow. A different kind of a manager, though.

Then Donald Kennedy came in, who was another type of manager, and that's when John Jennings left. He and Kennedy couldn't, they weren't compatible.

Then I left at that time, not because of any reluctance on my part with regard to Commissioner Kennedy's commitment to the program, because I thought he was very good. The only problem was, we didn't have a deputy in the organization. When Dave was out, I would function as the director. But for political reasons, another person came in as deputy, and that created some problems. And in part, that was a motivation for me to say, "Look, I think my time here has been long enough."

SJ: Who was that?

LP: Victor Zafra.

SJ: Vic Zafra. He alienated a lot of people, actually, I think.

LP: Yes. Well, he came -- he was from OMB. He was at OMB, and apparently Secretary Califano didn't have, for whatever reason, the stories that I heard were that Califano had some difficulty with Zafra, but that Kennedy knew him and Zafra wanted, maybe wanted to get a spot in FDA, and there was no deputy. Dave didn't want a deputy. I can understand that. Zafra was put in there, and he had no choice over that. That kind of bothered me because Zafra was not a very, very good -- well, he wasn't a manager, and he knew nothing about the programs. So he comes in and he's got ideas and wants to make a name for himself, an image, but it wasn't very good. He lasted for about a year or two.

So then you go into the, you know, my departure, because all I can say about our relationship, to summarize it, Dave and I got along very well and did a lot of things together. There were occasions when he didn't agree with my advice and later regretted it, in a jocular way. But we worked together very well. We identified some very good people to function as subordinate supervisors.

So I left. Certainly, in Compliance, I felt very comfortable that I had three individuals running the three components of the organization.

SJ: You can name them.

LP: Yes. Well, there was Harry Butts, who was responsible for the Compliance operations; Layton Hansel did the management of the registration listing those kinds of things, program development; and Ed McDonald, who was responsible for the

implementation of training programs, public relations activities, and Good Manufacturing Practices.

I had initially the responsibility for the Office of Small Manufacturer Assistance, and there were some who were unhappy about that office being a part of Compliance. I felt it was important, but, then again, you have different managers, different styles, because the office functioned very well under us, but it was taken out. I believe it reported directly to Dave just shortly after or just before I left. I believe in the importance of small manufacturer assistance and that function. I think it's been relegated to kind of a back-door operation now, which is a shame because it's a statutory requirement. And the industry still is composed primarily, in numbers anyway, of entrepreneurs, small manufacturers.

Medtronic was a small manufacturer. You know, Bakken came in a couple times. He was active in AAMI. You look at their goal. What is now Boston Scientific Corporation. John Abele at Cooper, when it was Cooper something or another, he started that company and then, with Pete Nicholas in 1980, or the '70s, formed the Boston Scientific Corporation. So there are a number of different organizations today that were very small businesses and still have an entrepreneurial spirit.

But going back to my departure in '79, the organization that I left was a good organization with good people, not just in that division, three divisions, but within the divisions, the structure was very good. People were very, very good. Some came from the outside; some developed within the agency at headquarters; others developed through their experience in the field. Steve Needleman was part of that office and spent many years in Compliance. Who's left? There are a few people, but a lot of people have

retired.

Did you know Sharon Kalokeroin? Well, Sharon K. started to work for me as a secretary, and she was terrific, great. Then she moved into a professional position.

Diana [unclear]. Oh, Patty Kuntze, who started as a GS-4, I think it was, maybe a GS-2 secretary, and I remember her hiring, because I didn't interview all the people, but any professional that was to be hired by a subordinate supervisor, I interviewed them. For the most part, I agreed with the recommendation of the subordinate superior. There were some occasions where I didn't agree and we didn't hire the person.

But Patty started out early. I may have interviewed her. You'll have to ask Patty if I did, but she was a remarkable talent, and you see where she's worked her way through the organization. Her husband, I understand, is back, Ed Kuntze. I don't know if you know him.

SJ: I don't know him.

LP: Yes. Well, there's another story there. I can't say it's a love story, but it's a nice story, because they met while working for the Office and were married, to my surprise. They've been married for a long time, and they have two adopted children from Russia.

SJ: Oh, I know that. I remember how she was doing that when I came.

LP: Is that right?

SJ: Yeah.

LP: Terrific.

Who else was, who else started and is still here?

SJ: Well, tell me a little about what your perceptions are.

What I thought we'd do is we'll, since you do have to get back, why don't we stop with the devices stuff, and then we'll start again when we can meet again to do infant formula and all that.

LP: Yes, I'd love to do that one with you.

SJ: Because that one is one that I'm not as familiar with, and I want you to figure out how you want to do that for the record, to try to get in the oral history.

LP: I'll bring my wife Lynne with me on that one, or Carol Laskin.

SJ: Wonderful.

LP: If you want to interview the mothers who are behind this . . .

SJ: Let's do it.



LP: Well, Carol Laskin and . . .

SJ: We'll take what we can get.

LP: That brings me to something else.

Lea Thompson did a major piece on infant formula.

SJ: The investigative reporter.

LP: Yes.

SJ: Yes, okay.

LP: Well, it launched her career.

SJ: Okay.

LP: We have the tape. But Lynne had my son borrow it, and we haven't gotten it back. How can we get a copy of that tape? I'm sure that Lea Thompson would have it, or NBC, the local NBC. It was a great piece.

SJ: We may. Well, I'll get my assistant to check on it.

LP: Okay. You might even have a copy of it here. Then I can get a copy.

SJ: It was too early, probably, but we can probably get one.

LP: Nineteen seventy-nine?

SJ: Yes.

LP: Well, NBC -- I'm sure that . . .

SJ: If we could locate it, do you have a budget to pay for it to be duplicated?

LP: Sure, oh, yes. Sure, I'd be happy to. Yes, no problem.

SJ: We have no budget yet, so . . .

LP: Oh, no. I'd be happy to do that.

But contact Lea Thompson. She's still -- she's on network, but . . .

SJ: That shouldn't be a problem.

LP: But Lynne Pilot and Carol Laskin were the two mothers who bird-dogged that issue. Al Gore chaired the hearings, did a good job. Later on, the Senate, and so did

Senator Metzenbaum, Schweiker. But Lynne and Carol did a magnificent job.

You know how this all came about. This is an aside, a quick aside.

SJ: Go ahead.

LP: I left the end of June in 1979, and I didn't take vacations. I had lots of vacation time, and I lost a lot of vacation time. I had a thousand hours of sick leave that, you know, I never took sick leave. One day, and the only time I took sick leave was because I thought I had strep throat and I didn't want to come in and infect people. I didn't have strep, though.

But we did go on vacation when I left the FDA. Lynne's from Cleveland, I'm from Detroit. Our son Bradley had been born in February. So as we traveled to Cleveland, Lynne was apprehensive about Bradley's not sleeping well, this and that, and she's a very conscientious parent. You can appreciate that as a parent.

So we take Bradley to Rainbow Children's Hospital in Cleveland, affiliated with the Cleveland Clinic, and they look at him and can't figure out anything. Teething? I don't know what it is. So we go to Detroit, and he's still displaying the same symptoms: not eating and . . .

SJ: In an infant, that's not good.

LP: Yes. So we go to Detroit, and I call a friend of mine who's an ophthalmologist: "Well, who do you know? I need to get to see somebody." Well, he knew the chief of

pediatrics at Children's Hospital in Detroit, so we get squeezed into his schedule and we see him. His name I'll remember. But I remember him from Wayne State University, when I was in school. He was my organic chemistry instructor. So, small-world kind of thing, not real small. But he couldn't figure it out.

And we get back to Detroit, and Bradley is not doing well. It was a very uncomfortable period.

So Lynne checks with our physician, and he can't . . .

#### TAPE 2, SIDE B

LP: So our physician suggested that we go to Children's Hospital, because he couldn't figure it out.

So how to get him into Children's Hospital right away. This is where Dave Link comes in, too, because Dave lived next door to the administrator of Children's Hospital. So I call Dave, and Dave lets the administrator know, and I call the development office at Children's Hospital, because when I left, rather than have any kind of a party, I said, "Look, if people want to come to a party, they can come to Chalet de la Paix," which is a restaurant that I started with three other people when I was with FDA. One of my law school classmates worked at the Mayflower and had grown up in the business, and he had this idea. So in '71, we opened Chalet de la Paix. Initially I was involved in the management of that, taking care of the books and stuff like that, but somebody complained that that's a conflict of interest.

SJ: With FDA?

LP: Yes. And Peter was no help on that one either.

SJ: Peter Hutt?

LP: Yes. So I gave up the active interest. I prepared a blind-trust agreement, sent it up to the Secretary's office. It's still there. But I withdrew from the active role -- and when I say "active," it was part time. It was in the evenings, on the weekend, taking care of the books, stuff like that, because I wasn't going to be down there working and all that.

But, in any event, we had a Sunday function at the restaurant where anybody who wanted to come could come, but all I asked was that they make a donation to Children's Hospital. And it wasn't that we had any great interest in Children's Hospital other than that it was a good charity, and Wally Werble, who was the founder of the "Pink Sheet," was on the board, and I thought, "Well, that's a good . . ."

So I took all the money that people donated, and I told them, "Write checks to Children's Hospital," and I gave it to Children's Hospital, maybe \$2,000 or something, which wasn't a lot but a good amount at the time. I paid for all the food, and the restaurant just, you know, they -- Werner and Lou, my partners, they took care of everything. We had a wonderful event.

But I called the fellow who was in development, and we did get Bradley in like the next day, I think it was.

In the meanwhile, I had suggested to Lynne, "You know, the constants and the

variables? What about the infant formula? Maybe we should put him on another infant formula,” and Lynne said, “No, no, no.”

So she takes Brad to the hospital. In the meanwhile, there’s an article in the *New York Times* on B<sub>2</sub> or B<sub>6</sub> about Syntex recalling their infant formula. And Lynne’s friend called her and said, “Lynne, did you see this?” “No.” So Lynne gets this information. She calls FDA and I think she spoke to a Dr. Chopra. “Salt, it needs salt in it.” So then Lynn apparently was putting salt in the formula or on the nipple, and she called me about this and I said, “Well, don’t do that. Go in there and let’s have a diagnosis because you might compromise the result. It might be something else.” But it was the absence of chloride in the formula.

The sad thing is, Lynne had been nursing for four months, and Brad was a big, healthy kid, 16 pounds, but he’s dropped down to 14 pounds over the 10 days that we were gone. And he went on that formula, because all of our kids are lactose intolerant, and Bradley had been on Enfamil -- that’s the soy preparation -- and he was not taking it very well.

I was on Capitol Hill at some function and talking to somebody who had been in our parent-and-child class, and they said, “You should try this new Neo Mull-Soy.” So I stopped off at what was the People’s Drug then in Arlington, and I look at it. “Oh, it’s Syntex Laboratories. I know Syntex. That’s a pharmaceutical manufacturer.” I knew the general counsel and president. So I bring it home and Lynne says, “Oh, Bradley seems to be doing fine.”

Well, what we didn’t know was over that six-week period of time that he was on it, he’s going downhill. If he had continued for a few more days, he would have

definitely had a heart attack because his potassium level was drifting so low.

That's what began the interest and the odyssey that led to the passage of the Infant Formula Act, because Carol Laskin went to the same pediatrician that Lea Thompson was going to and said something to the doc, who then put Carol in touch with Lea Thompson. And by telephone, Lea Thompson was getting this information from Carol, Lynne, and me, you know, providing information about the status of infant formula, etc.

She indicated to us that this program was going to appear at six o'clock, and da-da-da-da. We figured it was about a three-minute piece. It went on for about 10-15 minutes. It was a major piece. Al Gore, of course, was part of this because of the hearings. Lynne and Carol met one another by vision through the television. That was the first time. They called one another and they said, "Oh, that's what you look like," and everything. That led to their continued pressure on Congress to pass the bill.

So they're the women behind it, and the husbands. Carol is a management-consultant type, and her husband was with one of the -- Touche Ross.

SJ: Carol. What's her last name?

LP: Carol Laskin, L-a-s-k-i-n.

SJ: Yes. I've seen her.

LP: So if you see the -- get [unclear].

SJ: And your wife's name is Lynne?

LP: Lynne, yes, Lynne.

SJ: What's her maiden name?

LP: Widlitz. She's from Cleveland. And Lynne had worked up on the Hill before our first was born, and she has -- she's an attorney.

SJ: And Bradley is okay now?

LP: Bradley is, he graduated from the University of Virginia, as did our other two children, and he graduated with a master's degree in sports medicine. He works for Gold's Gym, and has since he was a teenager. He was always a slight kid, strong but slight. Now he's a mountain. He's a little taller than I am, but he's a big kid. And he works in corporate at Gold's.

And Benjamin is the Laskin child who is in his last year of medical school and probably is going to specialize in pediatric nephrology. It was the physician at Children's Hospital, the nephrologist, Jose Salcedo, who put Lynne and Carol together, because he had treated these children and diagnosed them as having metabolic alkalosis before any connection with Syntex Laboratories between defective formula. He expressed to each, "You know, you should meet this other parent." He was responsible



for getting them together, and that's how they literally began their quest to lobby Congress for a change in the law. President Jimmy Carter signed the bill into law on September 22, 1980, and he was very gracious. Geraldo Rivera had done a couple of "20/20" pieces, was at the house. But Carter was very gracious. And Lea Thompson, so . . . I'll tell you another story about that.

SJ: Okay. Well, we're going to stop right now and pick it up again later.

LP: Okay, sure.

SJ: This is because you've got to go now. This has been a wonderful interview so far. I had no idea you would have so much information. We'll pick up again later when it can be arranged.

LP: Yes.

END OF INTERVIEW