INTRODUCTION

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

DATE: May 1, 2001 PLACE: Rockville, MD LENGTH: 75 minutes

INTERVIEWEE:	INTERVIEWER(S):
NAME: Lois P. Adams	NAME: Robert A. Tucker
ADDRESS: [redacted]	ADDRESS: Ronald T. Ottes
[redacted]	Food & Drug Adm.

FDA SERVICE DATES: FROM: 1970 TO: February 2001

TITLE: Program Analysis Officer, Office of Legislation
(Last FDA Position)

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RT: This morning we're doing another in the series of FDA oral history interviews. This morning the interview is being conducted with Lois P. Adams, retired Program Analysis Officer with the Office of Legislation, FDA. The interview is being conducted at the Parklawn Building, and present in addition to Ms. Adams are Ronald Ottes and Robert Tucker. The date is May 1, 2001.

Lois, as we begin the interview, we would appreciate a brief résumé of where you were born, educated, and employment history prior to your joining FDA. So we could begin that way, if you would.

LA: Okay. I was born in Portales, New Mexico, in 1936. I give my age away immediately. [Laughter] Age tells anyway. I grew up moving around a lot all over New Mexico and Texas, West Texas primarily. I graduated from high school in Amarillo, Texas, and from college at West Texas State University in Canyon, Texas. I worked in a few jobs before coming to FDA. One of the more interesting, believe it or not, was working as a bookkeeper for a cattle trucking company and feed yard. Our offices were in the auction barn, and it was kind of noisy a lot of the time. It didn't always smell good either. Then I taught school in Alamogordo, New Mexico, for six years, and then I came to Washington [D.C.] as a management intern with the Department of the Army.

RT: When you graduated from college, was that an education degree curriculum?

LA: Yes, with a minor in math and a minor in science.

RT: You qualified for FDA?

LA: Yes. A minor in English, a lot of different things. In 1970 I came to work for FDA, primarily because the Department of the Army had a RIF [Reduction in Force], and the possibility of being able to continue to work there with little experience was very slim, and I needed something more permanent.

RT: When you were with DOD [Department of Defense], did you do any clerical work?

LA: No, I was a management intern initially. Then I worked in what then was called the Directorate of Cost Analysis, looking at the costs of various weapon systems.

RO: Where were you located?

LA: In the Pentagon primarily. Part of the time I was in an office in Alexandria [Virginia], but was primarily in the Pentagon.

RT: Did that require a security clearance at DOD?

LA: Yes, top secret.

RT: So that was a good prerequisite to FDA's security and so on, I assume.

LA: I think I had at that time a higher security clearance than FDA ever required of me.

RT: When you came to FDA, you came into what office?

LA: I came into the Division of Financial Management in the Office of Administration at that time.

RT: Was that under Ed Steffee?

LA: Yes, it was under Ed Steffee. There was a branch called the Operational Planning Branch under Conrad Horn. You may remember Conrad.

RT: Yes.

LA: And then for Jack Marcowitz before he left the agency.

RT: Was the work that you did at DOD, while not related to, but was it in any way helpful to what you did in FDA?

LA: I don't really think so.

RT: You went on an entirely different career track at the Food and Drug Administration?

LA: Yes. The cost analysis was strictly figuring out how much a weapon systems was projected to cost over its lifetime, and there's no comparable function here.

RO: What were some of the duties in your first job in FDA?

LA: This was when, I believe his name was Grant, Jim Grant, was the--

RO: Deputy commissioner.

LA: Yes. [Charles] Edwards was the commissioner. The idea of Management by Objectives had just surfaced, if you'll recall, and the unit that I was a member of worked in that area. Paul [L.] Coppinger eventually became the head of that activity. Paul and I came in primarily at the same time. There were a couple of other people as well. We were brought in to do and manage the Management by Objectives, the operational planning system for the agency. If you'll recall,

everybody had to set up objectives and milestones, and that had to be monitored and reported to the secretary periodically.

RT: Ironically, I suppose, the Management by Objective concept emanated from the Department of Defense, didn't it? Mr. [Robert S.] McNamara?

LA: I think that was one of the roots. I think there was a management professional named Drucker, Peter Drucker--

RT: Oh yes. Sure.

LA: --who actually wrote some books on that subject, and that concept was adopted by many companies in the private sector. It was a profit-based concept, really, and it had to be adapted to a nonprofit organization. So the objectives were never quite as easily stated as they would be for a business.

RO: That didn't last very long, did it?

LA: It lasted about four or five years. It was a good concept in some respects, but with changes in administrations, all of those things fall eventually, you know. I think in some respects we still have remnants of it, or did when I left a couple of months ago.

RT: It was under a different name.

LA: Yes. Oh, definitely. A new concept for everybody.

RT: There was an issue not entirely parallel to this that also came in, and that was zero defect performance.

LA: Yes.

RT: That came from a retired military person who came back to the agency after having a military career.

LA: And that concept, when I went to DOD, was kind of at the apex of its existence and was really beginning to decline, because it's an unachievable goal, and I think even they finally figured it out. So it was an interesting concept, but not very practical.

RO: We don't want to jump too far, but I know some time in the course of our discussion we'd like to get into the areas where you were liaison for the agency with the Congressional Investigating Unit, GAO [General Accounting Office] and others. Was that a little further on in your experience?

LA: Well, not that much further. Within a couple of years after I came here, I guess actually in 1974, I spent a year on detail, more or less, as the executive officer in the newly created Parklawn Computer Center. Two units, one from HSA [Health Services Administration] and one from FDA, were put together to form that unit. The management was given to FDA, but the funding came through HHS [Health and Human Services]. So all of the mechanisms for paying the bills and keeping the place operating had to be devised because there was nothing similar to work on, and I did that. So it was kind of a challenge.

RO: When did FDA end the partnership? Because FDA got its own computer center.

LA: Actually, that continued until almost everybody had desktop computers. It was a fee-for-service organization, so they serviced all of the [U.S.] Public Health Service agencies, with the exception of NIH [National Institutes of Health]. NIH had their own. They also sold services to Social Security and the Department of Commerce and other federal agencies. It was always within the government.

RT: Was the hardware located here in Parklawn Building?

LA: Yes, it was, primarily. There was some down in FB8 [Federal Building 8], but primarily it was here in the Parklawn Building. I believe for a while there were some computer elements

across the street in the Park Building, too.

RO: That was the period of development in computer technology where there were rather large, massive units.

LA: Yes. Mainframes, as they were called. That gradually phased out, however I couldn't give you a date for that. I don't remember. I was no longer there, but it was, I would say, in the mid-eighties, probably, when that just kind of died.

RT: You were only on detail.

LA: Yes. I was there for a year. Then it was after that when the GAO function, the liaison function, was put in the Office of Operational Planning.

RT: Was that located in Financial Management?

LA: Yes. I guess Jack Marcowitz had been there for a while. It was about that time, I believe, when Paul Coppinger became the head of that.

RT: Before you personally were involved or the immediate office you worked with was involved, how was liaison with the GAO handled?

LA: Essentially it wasn't.

RO: Maybe I could give a little history on that. One of the early GAO studies was on sanitation in the food industry. Since that study dealt primarily with the inspection cycle in the food industry by the FDA field staff, I was designated the agency liaison. You may recall the study concluded that FDA did not have sufficient staff to fulfill its responsibilities and this led to Project Hire. Following that study, GAO started looking at other FDA activities and it was decided there was a need for a central agency liaison.

LA: Well, partially. There had been only one or two studies done on FDA prior to 1974, and at that time they began to do more extensive work in FDA. That was essentially left to each bureau at the time, or the field headquarters, as to how they would manage it. There was no effort at a central control on that.

The first one I got involved with was on adverse reactions right at the end of that GAO study, when the draft report was all ready and people were called together for whatever reason to review it and comment on it. It was a disaster. That function was given to the office I was in, and someone else had the responsibility. I think it probably is better not to name the person, because that person really didn't do anything. The agency kept being surprised by what was coming. So that was then given to me to do, among other things.

RT: When was it, Lois, that you came under the aegis of the Office of Legislation?

LA: That didn't happen until 1986, and there's a long history of why that happened. From 1974 until '86, it was in the Office of Management. At that time it was primarily under Gerry Meyer.

RT: When the General Accounting Office was planning to do a study, did they notify the agency of that fact?

LA: At that time they didn't. They would just show up, and at that time they could get in the building any way they chose. We didn't have much security. They primarily would come in, get a telephone directory, and would find the name of somebody at really a very low level who they believed might have something to do with the subject.

They would call a person, and it always scared people to death, because at that time there was very little experience with GAO, and when you're being investigated, particularly the first time, it's kind of a scary thing, so they kind of threw their weight around. They maybe would not make threats, but certainly would imply that they had authority to look into everything and ask all kinds of questions. Instead of coming in at the top of the organization, they'd come in at the bottom, get all these bits and pieces of information that may or may not have been coming from the right person, and certainly it was disjointed, and didn't make a full picture.

One of the things that I did after getting involved in this was to say, "You can't come in the back door." It took a little bit of doing to convince anybody in FDA that they were not to talk

to GAO unless GAO had talked to me, but they had to let me know that they were coming, and then I could let the proper higher authorities know so we could arrange for an entrance conference, this was my concept. "You come in, you talk to the top people in the agency about this, get the perspective of the management on it, what it's supposed to do and how it all fits together. We'll tell you who you should talk to, and we'll go along to be sure that you talk to the right people and so forth."

That always irritated GAO, because they prefer to come in and be able just to wander around and talk to whomever they please. What I found was that agency people will talk about anything, whether they know anything about the subject or not. So you'd have fairly high-level people in the agency involved in this. As an example, someone at a high level in Drugs talking about the field organization as though they knew anything about it, when in reality they didn't, and making statements about other people's programs that then would appear in a report.

On a couple of occasions we even went so far as to write letters to GAO saying, "This particular person does not speak for the agency on this subject," and they were high-level people, because they were talking about a subject that they knew nothing about and therefore they were giving misinformation.

Part of the whole thrust of the GAO liaison when I was here was to be sure that GAO got the right information, not sanitized information, but that they went to the right sources for it.

RT: Did you sit in on all the interviews?

LA: Not initially. It was still somewhat loosely managed, but there was a central point where people in the agency could go for support. We usually, almost always, had an entrance conference that would set the stage, as I said, and then the center would manage that. I've forgotten the exact dates, but sometime in the mid-seventies, or maybe it was 1980, anyway, somewhere in that time frame, Congress changed GAO's statute and gave them more explicit authority to look at programs and not just financial management.

As a result of that--and Paul Coppinger had moved on to other things--I recommended to--in fact, it was Ron Chesemore at the time, if you'll recall. Gerry Meyer left the agency for almost a year and then he came back. So I recommended to Ron that we go to a more proactive management of GAO because of the nature of the change in their law. There were some conflicts between their law and ours. So that's what happened.

RT: I recall in one instance when I was still working, GAO was here in the agency doing some kind of a study, and they got a lead--by interviewing a state official up in Philadelphia District--on the state contract program. They then wanted to come down here, and I recall your advising them the agency wouldn't entertain two concurrent investigations and you advised them to work it out so if it was ever done, it would not be done at the same time something else was being studied.

LA: We tried that, and it worked pretty successfully for a while, because they were just driving the agency crazy. At one time we had five different studies on pesticides going on

simultaneously, and I did say, "Look, we can't manage this and do our jobs. So pull your teams together, and we'll talk to you once, but we can't have multiple studies of the same subject at the same time." That was at a time when the agency and the department were more willing to stand up for their rights. I don't think that would happen today.

RT: Was there an exit interview? You said there was an entrance interview to lay out the parameters of their studies. Was there then an exit interview when they felt that they concluded it?

LA: That evolved, yes, and I don't remember specifically whether this was their initiative or not. I think it was probably theirs. I know on the entrance conference that was my initiative, and they had never done that before in any agency. Now it's common practice throughout the government.

RO: When GAO completed their study and sent a copy back to the agency for comment, did you coordinate the agency's response?

LA: Yes.

RO: Did that go through the department?

LA: Most of the time then it did, yes. If you'll recall, we were under the Public Health Service.

It would go from us to the Public Health Service, and from the Public Health Service to the department, and most of the comments were signed by the secretary. After the Public Health Service demise, that changed somewhat, and when I left the agency, most of the reports were signed by the commissioner and did not go through the department.

RO: Have the number of GAO studies diminished over the years?

LA: No. That was always kind of an up and down thing, but two or three things happened. One, GAO didn't diminish their work in FDA. Sometimes we'd have as many as forty active studies going on, although that was rare. Once in a while it would get down to eight or ten, but that was even rarer.

GAO began to impose a very strict time frame on their auditors or evaluators, for getting a job finished. When I left, they had to make a commitment at the beginning as to when that report would be given to the requester, and they were committed to meeting that commitment within that time frame. So the amount of time given to the agency to comment was drastically reduced, and the studies became compressed in time from as much as two or three years down to six or eight months.

RT: For the record, Lois, would you describe how these studies were initiated?

LA: Well, there are two ways that they're basically initiated. The primary way is for a member of

the Congress or a committee chair to detail the specifics of what they want studied.

[Begin Tape 1, Side 2]

LA: In addition to the studies that are initiated by a member of Congress or a committee chair, GAO does self-initiated work that they decide they need to do. Now, because in FDA there are strict limits on what we can give them, depending on whether it's a member of Congress or a committee chairman or they've initiated the study themselves, even if it's one they're initiating themselves, they will seek to get a committee chair to sign on to it, because we have to limit what FDA can give them.

When a study is going on, the rules are they cannot have information to any trade-secret information unless it's a committee chair, and if it's just a member of Congress, they're treated like any member of the public, which means basically anything that we wouldn't make public will not be given to GAO. So they can't even get our deliberations.

The conditions we imposed--and I have no idea of what's going on now--but we did not give GAO access to the deliberative process, in other words, drafts or any minutes of meetings that would be explicit enough to say really what's being contemplated. And, of course, trade-secret information, personal identifiers, any information like that, they were not allowed to get. While this put a burden on GAO, it also puts a burden on the agency, because we couldn't deny them access to all of the records just because it might have a trade secret in it. Therefore, somebody had to purge it before GAO could see it.

RT: Is it pretty well governed under the Freedom of Information Act?

LA: No, they're exempt from it, but our law was so explicit, the 301(j), until 1990, I believe, GAO couldn't even see 301(j) information, and while there isn't all that much of it, that's a matter of interpretation. At that time, 1990, the mere existence an IND [Investigational New Drug] or an NDA [New Drug Application] that hadn't yet been approved was considered to be a trade secret. So they were excluded from seeing a lot of information that their requestors began to want to see, because the requestors, you have to remember, are political animals and they often represent the perspective of a drug manufacturer or someone with an ax to grind, and they want to see what FDA is doing with a particular drug or what have you.

RO: You said the chair of a committee was entitled to certain information.

LA: They are now. That came about in 1990 when the law was changed.

RT: We're speaking now of the FD&C, the Food, Drug and Cosmetic Act.

LA: Yes, section 301(j) dealing with the disclosure of trade secret information.

RT: As the information and data are accumulated through these investigative teams, those bits of

information, perhaps, are used by congressional oversight committees to stimulate a particular response from the agency?

LA: Yes. Initially, when I started working on this, while FDA was having a lot of hearings, they didn't really involve GAO that much. Then, over time, both political parties have finally realized that they have a tool there at their disposal. So over the years, the studies more and more generated hearings or the study was generated by a chairman's desire to have a hearing. Very few of those studies, when I left FDA, were done at the request of individual members, and almost none are being done now at GAO's own initiation. They don't have the time. Their staff was cut by a third or more a few years ago when the Republicans took over the Congress, before they realized that they, too, could use GAO because GAO works for whomever pays the bills. They take on the persona, the perspectives of their requestors.

RO: When you retired, was this liaison turned over to another group, or is it just kind of in limbo?

LA: That's a good question, Ron. When I retired, this was, as I said, a function in the Office of Legislation, which had, maybe a year and a half ago, been combined under Bill Hubbard in the Office of Policy, Planning and Legislation. Bill debated what to do with this function, knowing I was retiring, and I think he debated too long, because only a month before I left did they even get a detailee in to work on it, and because they were in a hurry at that time and didn't go through the

proper personnel procedures, they ended up with a short-term--well, it had to have been not more than sixty days--detail. That was Jean Metz. She is no longer there.

Bill also moved the function from Legislation to the Office of Planning, so there has been no continuity whatsoever since I left. I have no idea what's going on, but there was no continuity vided for.

RO: After the number of years that you worked on that, you kind of get saturated with those studies, don't you?

LA: Yes. You can tell I still remember a lot of them. I'm not regretful at all of being out of it. [Laughter] The good part of this job is that you get into everything the agency does, and that made it interesting for all those years.

RT: How successful was the agency in altering the final tone of their final reports, because they did come back for review and comment? A lot of them were very critical of the agency.

LA: Well, it really varied all over the place. On a couple of occasions, we were successful in that the reports were withdrawn and completely reworked or were never issued. That was rare. In other instances we were able to change the wording so it was more neutral in tone. One of the big problems with the early GAO reports was they were all accusatory and pejorative. They really used unnecessarily harsh tones.

One example comes to mind--and please don't ask me which report, because I don't remember--but in this particular instance the statement was made in the report that FDA only did ten inspections during a year, and what was missing from the report was that there were only ten plants to be inspected. There's a big difference between saying FDA inspected all ten of the plants and saying we only did ten. That's the kind of change which was necessary. You can't change the facts. You don't even really want to change the facts. But the tone is really where we had the most impact over time in getting them to be more factual in their statements and less judgmental.

RO: My experience with the group from GAO was the tone of the report depended an awful lot on the individuals doing it. Some of them, I found, were easier to work with than others.

LA: That's very true. Yes, very true.

RO: You did other interesting things in the agency besides GAO.

LA: Well, yes. For twenty years I was on the Research on Human Subjects Committee.

RO: That's interesting. I didn't realize that the agency had a committee.

LA: This committee was formed probably in 1969, which was before I came to the agency. Do you recall John Jennings?

RO: Yes.

LA: He was one of the--not just a member. I think he was the chair of the committee when I first came to it. Frances Kelsey?

RO: Yes.

LA: Those are the two names that stand out in my mind. Joanne Sisk, you may recall her. But it was established, in essence, to implement the Helsinki Agreement on the rights of human subjects. It was designed primarily and really exclusively to look at the research done either in-house or under FDA contract. It wasn't to look at the regulated industry or their research, from a perspective of the efforts involved, but whether or not it would be ethical to do a particular study.

Part of that determination had to do with whether it would be ethical for the federal government to spend public money to do it, and, of course, part of the decision had to do with whether the particular study, in and of itself, could be ethically done. A third element was whether the science that was being used for the particular study was adequate, was appropriate to the study, and would do what the study purported to be doing.

RO: You had reviewed this before the study was undertaken.

LA: That's correct, yes. I had a continuing role in any that was done in-house. If it was done under contract, eventually that would have been turned over to people at NIH and other places.

RO: How many in-house studies of that nature does FDA do?

LA: Well, at the time, there were quite a few, particularly in biologics and medical devices. There was quite a bit of research involving human subjects, and at the time there were quite a few contracts. Certainly FDA never had a budget that allowed for a tremendous amount, but you may recall, around the time we were doing the DESI, Drug Efficacy Study Implementation, we were also beginning to look at generic drugs--I think we called them "me too" drugs--and how they related to the innovator drug.

There were studies going on in foods, particularly fortified foods, and how they affected people, whether the fortification of foods would help the nutritional value of the food and how people would react to that, things of that sort.

So it was a pretty busy committee. We met once a month, I believe, and at certain times, particularly around the end of the fiscal year, we would meet more frequently in order to be able to get all of the reviews done in time for the contract procedures.

RO: Did some of the studies FDA did itself involve human subjects?

LA: Yes.

RO: Where did they get the subjects?

LA: Some of them were FDA employees, some of them were, I guess, recruited on the campus at NIH. Most of the ones done in-house were not under contract and were done by the then Bureau of Biologics.

RT: I guess that clientele didn't include persons incarcerated in penal institutions?

LA: Some of them did initially. Those were primarily done under contract, but even though it was a contract, if FDA was paying for it or any part of it, it was reviewed by the Research on Human Subjects Committee.

RO: Did any of those get turned down because they didn't meet requirements?

LA: Primarily no. There were a couple that did, and we'll get into those, but primarily the reason they were not turned down is because the committee would work with the sponsor to change whatever was necessary, the human protection side, and to get it ironed out enough so it could proceed ethically. We didn't primarily turn things down, but worked to improve the quality.

RT: You mentioned that John Jennings was the original chairman.

LA: Yes.

RT: Now, who chaired that committee later on?

LA: Stuart Nightingale. I believe Mark Movitch was between the two. In fact, I know he was.

RT: So the center for that activity was set up in Health Affairs at that time.

LA: Yes.

RT: I think you were also involved in women's health issues. Was there a committee on that?

LA: Yes. It was a Commissioner's Committee on Women's Health, and I was on the committee for three or four years. I really have no idea how long.

RO: What commissioner was in place when that was started, do you recall?

LA: I believe it was Frank [E.] Young.

RO: Dr. Young?

LA: Yes.

RO: And what were they primarily looking into?

LA: This was at a time when allegations began to surface that women were under-represented in health care, particularly in research and things of this sort, and that drugs and things of this sort have not been studied in women. I really had some problems. That was not my favorite committee. Part of what was looked at was the question of studying drugs in pregnant or lactating women, and one of the issues we got into was daycare centers. I never felt that was an appropriate use of FDA time or money. However, I probably was wrong, because the real issue there wasn't the daycare center, although that's a lot of where the focus turned out, but it was the spread of disease through daycare centers. And even that is questionable as to whether that's an FDA responsibility--in my mind it was questionable. We had a number of younger women who were mothers of young children on the committee, and instead of focusing on women's health, they really were focusing on children's health.

RT: Would that be a general area of interest to the CDC, the Centers for Disease Control in Atlanta?

LA: Yes, at NIH more than FDA. Certainly there now has been a lot of study about daycare

centers and the spread of disease and things of that sort, but it really wasn't an FDA issue, in my opinion at the time, and I argued vigorously against it, but I didn't prevail.

RO: You were a minority.

LA: [Laughter] Yes. I was too old already.

RO: You've worked for several commissioners. Do you have any reflections on ones who were particularly forward-thinking on some of these issues or otherwise noteworthy in their way of administering programs you worked on?

LA: Well, I think Dr. Edwards was probably forward-thinking in initiating the Research on Human Subjects Committee, which, by the way, is still active. He had some good people there in Dr. Jennings and Dr. Kelsey and other people who brought that activity to a good point and gave some strength to it. Dr. [Alexander M.] Schmidt, I think was too tied up on other issues and really wasn't involved in that. Dr. [Donald] Kennedy made some promises publicly of something that the agency would do which was unethical to do, in my opinion. We had a big debate on the committee. It had to be approved by the committee.

RO: What was that?

LA: I don't remember the specifics, but we had public members and we had nonscience members. I was a nonscience member, the lawyers were, and so was the public member. All of us voted against that particular study, but it was approved anyway. That was the only time in my experience that we had a split vote on anything.

We did have one time when the medical devices people proposed studying condoms in a way that I thought was really disgusting. They wanted to do the study using women. It was in the early stages of AIDS, and they particularly were trying to avoid any interaction with the gay community, I think, but they wanted to know the durability and so forth of condoms. They wanted to use some devices to test these things, and the devices would have been passed around from woman to woman. They didn't make any provisions for proper cleansing or care or anything. That one was defeated with a great deal of animosity from the committee, which at that time was primarily comprised of women. I mean, it was funny and it was serious at the same time. The funny part was Dr. Kelsey's contributions. I mean, she was really incensed by it.

RO: I say this affectionately, she's rather a character.

LA: And one that I admire a great deal, but she is a character.

RT: Of course, you've primarily worked in the Office of the Commissioner organization, haven't you?

LA: Yes, exclusively.

RT: Dr. [David A.] Kessler, of course, made a number of organizational changes in the structure of the immediate office--

LA: Could I get back to the former question that I didn't really answer? And then I'll get to your question.

RT: Sure.

LA: I think Dr. Young and his deputy, [John] Norris, had a positive influence on the Research on Human Subjects Committee and also the women's health issues. They tried. I don't know that it turned out as successfully as it could have so far as the women's health issues were concerned, but they made an effort to bring those issues into the forefront of thinking. So I would say those were the ones who had primarily the best impact.

RT: That's of interest. I was going to ask you, the administrative configuration in the commissioner's office under Dr. Kessler was modified. I don't know that impacted on legislation or legislative affairs, functions. If it did, we might be interested in hearing how those changes might have altered the way the agency interacted within itself or with outside entities.

LA: Well, I think the reorganization, the way Dr. Kessler did it, made no sense whatsoever. He added a layer of management. I think he discovered when he got here he couldn't just fire people, even though they might be associate commissioners, who he really didn't want to have working directly for him. So instead of replacing the structure that was there, he just imposed another layer on top of it, which drew people from the centers and from those associate commissionerships up to a higher level where he was more comfortable dealing with a select few people. He wasn't comfortable dealing with everybody in the agency. Neither was Dr. Young. Charlie Edwards didn't seem to mind having a cast of thousands around.

[Begin Tape 2, Side 1]

LA: Dr. Kessler imposed a layer that drew these people up from other functions. So in that respect, it drained from places that really needed more resources. That had an impact, I think, on the entire agency as far as the legislation was concerned.

Dr. Kessler also, I think, was uncomfortable with the management of the legislation function when he came here, so he changed things significantly. Whether that was for the good or the bad, it's hard to tell at this point. It certainly was different. But I still believe having a layer of deputies and a layer of associates beneath them was a mistake.

RT: It's parallel, I suppose, to earlier times when CPEHS [Consumer Protection and Environmental Health Service] was a layer between the Food and Drug Administration and the

Office of the Secretary, which complicated decision-making somewhat in terms of adding more reviewers and time to matters that sometimes were urgent.

LA: I agree with that. Since I never worked for Bob Wetherell, I cannot contrast that experience with later experiences. Hugh Cannon was the Associate Commissioner for Legislation when I came to that function. Of course, he was a Republican, and when [William Jefferson] Clinton was elected president, even though Kessler was a Republican, he carried over, but Cannon was not Kessler's choice, so Canon left shortly after Kessler became the commissioner.

The Office of Legislation always functioned less like an associate commissioner and more like a deputy commissioner. The commissioner or associate commissioner for that function was always involved at the highest level because of the nature of the job, I think, and it probably never should have been subordinate to another layer, which at that time was the Office of External Affairs, I believe. These are just my impressions, you know. It seems to me that is not an efficient way to operate, that is, to have too many layers between the top and the working grunt, however, I think that is what happened.

RT: With the legislative matters and related issues, those often have congressionally imposed time frames. Therefore any extra level of review and clearance certainly can be problematic in meeting those congressional response times, I would think. I used to work in the legislative office and recall the quick turnaround that was required.

LA: Yes. It wasn't just the quick turnaround. That's, I think, an important aspect of it, but the issues brought up through the Office of Legislation are political in nature. They are always going to have an impact on the agency because some congressman or senator or committee has determined there's a problem or an issue they want to address. That is always going to have to go to the commissioner, sometimes to the secretary.

It's a different function from most of the rest of the things which may only surface to that level occasionally or may never surface at all to that level. You can be assured if a congressman is asking a question and threatening a hearing or holding a hearing, that's going to get publicity, and it's going to have some effect on the agency, usually negative, sometimes not, but usually negative. Wouldn't you say?

RT: Sure. That's right.

RO: I always thought that office probably should be almost like a staff to the commissioner, because you need access to that level and you need it now, particularly because of the publicity involved in it and, of course, the relationship with the department. We've had some of the people in that office who have gotten in trouble with the department.

LA: Yes.

RT: We've had some folks who have felt very strongly about an issue and have gone over to the

Hill to testify without going through the usual channels, and that's been a problem for them and for the agency.

LA: That happened a lot in the seventies and eighties. Gerry Meyer's term for those persons, at least in his staff meetings, he called them "allegators" because they were always alleging that something was true.

RO: Yes, and always snapping at your heels.

LA: Yes.

RO: Was there anything else, Lois, in your career in this area? This has been very interesting. Some of the things you've been involved in, I wasn't even aware that the agency had.

LA: Those are primarily the things I did. I know it sounds kind of one-dimensional, but because of the nature of what I did, it literally was multi-dimensional and getting into everything the agency did. But the thing I really liked the most, I think, was the Research on Human Subjects Committee. I found that to be very interesting and challenging.

Dr. Kessler was the one who decided that this committee was being obstructionist in slowing down the agency's research. Therefore, he wanted to be rid of the people who'd been on the committee for a long time, and that is when he got rid of me, Dr. Kelsey and some of the

people from the general counsel's office. A lot of the people who were very familiar with the work.

RT: You mentioned the work you did brought you in contact with all the elements of the agency, and the entire Office of Legislation. That is a fascinating part of that office's function because you deal with everything. There are many people in this agency who are tunnel-channeled or parochial in the work they do during their whole career and they never really know too much about other parts of it.

LA: Well, that may have been true when you were there, Bob. In my experience, the people in OLA or OL, as it's called now, were assigned a particular area to work in, and they didn't work anything else.

RT: I think that's a development since I was there, because that office at one time was an extremely small staff and dealt with everything.

LA: Which makes it more interesting. I was the only one on the staff who worked with everybody and had knowledge about every program. I was the only one.

RO: That should have been a stimulating effect for you.

LA: It was in some respects because I pay attention. I don't take notes, but I listen and remember. I have things I could contribute, but this often was disregarded because somebody else had the primary responsibility, it puts you in kind of an awkward position. But I literally worked on everything from the housekeeping side to the most intricate programs.

RT: Let's see. I think before we really went on the record with the recorder, we established that your career went from 1970--

LA: With FDA.

RT: Yes, with FDA, to the beginning of February of this year, 2001.

LA: That's correct.

RT: You've had an interesting and expansive career.

LA: It's been very interesting, and I'm sure that most of the particulars you can get better from other people, because I could go on and on about what was happening at various times. I worked some on the DESI program, I worked some on a number of different things like that, but more in the sense of doing the planning, the Management by Objectives for those things, and I was there when some of those programs were devised and created.

One of the budget aspects that our office worked on which I did to a certain extent was the program management system, designing that and forcing various things into common terminology and common blocks because you couldn't do it otherwise.

So a lot of the things happening when I came to FDA I think were more interesting and exciting than the things later on, because FDA was changing then and moving into a new area of thought, really. That was when Peter Hutt was here and he was changing from a court-based enforcement to regulation. I think he was right in doing that. I think it's helped the agency overall and helped the country.

RT: It probably did, in the sense that in the earlier history, when we were primarily a through-the-courts-type enforcer, some of those cases would be carried on and on and it was a long time before they were closed out, whereas there's a more short-time response to regulations compliance than the court process of old.

RO: What do you think of the future of FDA? That always has come up, split up FDA and give this and that to other agencies.

LA: Well, that's an interesting question. I think FDA is always going to be the center of controversy because of what the agency does. They regulate so much of the gross national product and are involved in so much of the world economy, really, that it's got to stir up controversy. I think there'll be kind of a cyclic nature to it, that there'll be times when people say

we need more regulation and then there'll be times like now and other times when it'll wane and they'll say, "Let's do away with FDA," or, "Let's put it somewhere else."

I suspect over time, foods will be taken away from FDA and made hopefully not part of USDA, but it could very well go there, but possibly an independent agency, independent in the sense of not being a part of FDA and not being a part of USDA. That's got a lot of momentum behind it over time, and I think it probably is going to happen within the next ten years.

RO: What department would that go under?

LA: I don't know. It shouldn't go to USDA, in my opinion, because that's a conflict of interest. You can't promote something and regulate it effectively, and I think USDA has demonstrated that, and I think they're ineffective in regulating the meat and poultry industry. They may be more effective now than they used to be, but you can't really do an adequate job if you're only looking at the surface, as they have primarily done. That's not where the problem is. You have to look at the microbiology and the parasites and all of those things that aren't visible. The way they're set up, they can't do that. Their primary function is to promote agriculture, so there is a clear conflict of interest there.

I think the best arrangement would be to move USDA functions to FDA because I think there is a positive effect of having the combination that we have now. Until recently, drugs have so outweighed foods over the last thirty years that food regulation has not received the full share of attention that it needs.

RO: HHS?

LA: Possibly. Commerce would be another place they might put it. If they were so lucky, it might become an independent agency like EPA [Environmental Protection Agency], but I think sooner or later they're going to do that.

One of the first things I worked on and other people in our office when I came to FDA was getting a single campus for the agency. Guess what's still being looked on and just recently was knocked down again by the current budget? The money was not in the budget to move any of the agency to White Oak. I said years ago that I would be long gone before that move was ever made, and I'm now sort of predicting I will be dead long before it's done.

RO: Well, we hope that won't be soon.

LA: Well, me, too, but it doesn't matter if it's twenty years, it still will precede a single campus for FDA.

RO: We appreciate the time you've given us, Lois.

LA: You're most welcome.