History

of the

U. S. Food and Drug Administration

Interviewee:	Lee Gejsmar
Interviewer:	Robert A. Tucker
	Ronald T. Ottes
Date:	April 30, 1997
Place:	Gaithersburg, MD

DEED OF GIFT

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Lee Geismar

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INTRODUCTION

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

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

INTERVIEW INDEX

General Topic of Interview: History of the Food & Drug Adm.

Date: April 30, 1997 Place: Gaithersburg, MD

Interviewee(s): Ms. Lee Geismar

Address: [redacted]

Last FDA Position: Reviewing Chemist- Team Leader

FDA Service Dates: 1947 to 1997

Interviewer(s): Robert A. Tucker
Ronald T. Ottes

Address: Food and Drug Adm.

Number of Tapes: 1 Length: 60 minutes

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RT: This will be another in the series of taped interviews in the FDA Oral History Program. Today we are interviewing Lee Geismar, who recently retired after a long career as a chemist in the Food and Drug Administration. The date is April 30, 1997. The interview is taking place in Miss Geismar's home. Present in addition to her are Ronald Ottes and Robert Tucker.

Miss Geismar, we like to begin the interviews with the person giving us a brief resume of their background, where they were born, educated, perhaps any pertinent or significant employment history prior to joining the Food and Drug Administration.

LG: Well, I guess I was born in Stuttgart, Germany, and came to this country in 1940, New York City, went to Straubenmuller Textile High School, and went to Hunter College. I majored in chemistry and physics and graduated in '47. I worked in a hospital lab in New York for a while, but I came here in 1947 and worked for the antibiotic certification laboratory, which was located in the South Agriculture Building. Dr. Welch was in charge of the whole program.

In 1959 I went over to New Drugs to work for Earl Meyers. We were located in 501 First Street. We were there for a while. We were moved several times and finally wound up in Crystal City before we finally came out to Parklawn.

RO: When you went to Drugs with Dr. Meyers, your job was as a reviewing chemist?

LG: Yes.

RO: And that was pretty much for prescription drugs at that time. Is that right?

LG: Yes, right. No, it was mostly for prescription drugs. Well, it's too long ago. I don't remember . . . I don't particularly . . . At that time . . . I know later on we had OTC (over-the-counter) drugs (Inaudible) where we were reviewing soaps and things like

that. You know, antimicrobial soaps which were OTC. Early on I really don't remember whether it was-Rx or OTCs. It's too long ago! It's fifty years! What do you want? (Laughter)

RO: Well, the only reason I was saying that is because according to your retirement announcement, the last twenty-five years you were in OTC drugs.

LG: Well, that's a different issue.

RO: Yes, well, we'll do that later.

LG: I can explain that. In 1962 they passed the Kefauver-Harris Amendment, prior to that new drugs were reviewed only for safety, not for efficacy. And the Kefauver-Harris Amendment said you also had to evaluate efficacy. You have to show that it works. OK. So that's when all the companies that had previously had NDAs (New Drug Applications) approved now had to send in efficacy data. And, of course, there was more data than the agency could handle; that's why they had these outside people review the efficacy data. We got their review and then either approved or not approved the NDA with the efficacy part in it. Some made it; some didn't.

RO: The article on your retirement mentioned you were involved in the thalidomide review.

LG: That's a different thing. That's a straight NDA thing.

RO: I thought that helped prompt Kefauver-Harris?

LG: It might have, because that was a safety issue. I remember . . . Yes, Dr. Kelsey was the physician on that. There were two NDAs. I guess the companies were related. But I was reviewing the chemistry, and Frances was reviewing the safety and efficacy--I mean the medical part. And she didn't like certain things, like the peripheral neuritis and things like that that people had who were using the drugs. Don't forget, at that time we had sixty-day turnaround. So we had to write an incomplete letter every 59th day until all of a sudden this thing in Europe turned up.

RT: How long a period of time had that application . . .

LG: I don't remember. That I don't remember, I'm afraid. I don't remember that. All I know is it was sixty-days periods, you know.

RT: The reason I thought of that, as I recall, Dr. Kelsey's recognition by the president spoke about her persistence or her, you know . . .

LG: Right, yes. Well . . . Yes, well, I mean, if it hadn't been for her I'm willing to bet they would have approved that thing. Yes. Because in Europe it was approved, and they were using it.

RO: Yes.

LG: And some people brought it to this country.

RT: Well, that's the argument that is sometimes used even with today's drugs: things are available over there, and why do we have to . . .

LG: The main thing about thalidomide is that people who are pregnant shouldn't be taking it, because right now they're testing it for people, you know, older people for other indications. But they definitely say, "Don't take it if you're pregnant." But I think that's the first time that a drug had shown up to actually affect the fetus. I don't remember anything before that that they had tested it for pregnancy conditions. Yes. So anyway, that was a big deal for a while. Anyway, and then Kefauver-Harris Amendment . . . I don't know. That was a safety issue. I don't know whether that triggered it or that plus something else.

At any rate . . . We found . . . We reviewed all these things that came in for the NDAs that had been approved prior, and after a while they realized, around '70, that most of these drugs are prescription drugs and most of the OTC drugs are old drugs, and they're not sending in any data on that. We need to do some way of covering the OTC drugs that are not covered by a new drug application. And that's when the OTC review started, in '71 and '72. We published in the *Federal Register* and asked for all the companies to send in data.

RO: What was the NAS/NRC review (National Academy of Science/National Research Council)?

LG: They reviewed the submissions that came in on efficacy of the drugs covered by an NDA, because there was so much material, there weren't enough people at the FDA to handle it all. So these people had experts in that area, so . . .

RO: Was there anybody in FDA that reviewed their review, I mean, as far as . . .

LG: Oh, probably. That I don't remember, since I was a chemist. I'm sure it went through . . . You know, they came in and the medical people looked at it, but I don't remember who was in charge at that time.

RO: As a chemist, what was your responsibility as far as the review of the NDAs?

LG: No, the chemistry was all . . . Most of it was done. We had to, at that time, the chemists wrote all the letters. You know, you'd get a few words from a doctor, and you'd write a long letter.

RO: You weren't involved then in the analytical procedures they submitted, or was there somebody else . . .

LG: Oh, yes. We looked at it. Sure. We always looked at the chemistry, but don't forget these NDAs had been approved prior to that for manufacturing and safety.

RO: Yes.

LG: So that wasn't the big deal. It was just the efficacy and the labeling. And we wrote all the letters. Yes. Don't forget, that's before the time of the computers.

RO: Yes.

RT: What general volume of these kind of drugs did you have to deal with? They were many in number, I assume.

LG: That's too long ago. I really don't recall. Don't forget, Earl Meyers was the chief chemist, and he would assign them to people and make sure that was evenly distributed. But I can't give you a number anymore. You . . .

RT: Oh, yes. That's a while ago. You were not the only chemist working on the staff, were you, in this area?

LG: Oh, no, no, no, no. There were lots of people. I'm trying to think if I can remember some of their names. Earl was in charge, and--let me see--for a brief, well, Jean Mansur and Mary McEnerny were chemists.

RO: That was before Mary started in writing regulations.

LG: Yes, right.

RT: Sure. Well, there was a staff of people.

LG: Yes, oh yes. There were quite a few, sure. Certainly.

RO: You mentioned the OTC review you were involved with. That involved panels? Is that correct?

LG: Yes. Yes, we published the notice in the *Federal Register* asking for data by groups, by different categories, like internal analgesics, let's say. We published in the *Federal Register* to say, "This is the kind of data we want," and we asked them to send in eight copies of everything. We got inundated with data. Then we asked different experts to be on different panels, and I remember we had to make all the phone calls to the people that were nominated, sort of, or suggested. We called to see if they were willing to serve and explained to them what was involved, what they had to do. They had to come to Washington and spend a couple of days here for meetings once a month or something like that. And some people accepted and some didn't.

RO: Were these panel members, once they were selected, were they provided the information that the companies had sent you that they could review?

LG: Right. Like we had seven members on each panel--deliberately had an odd number so there would be no ties--and we sent out . . . That's why we asked the companies to send in eight copies of everything. All panel members got their own whole set of everything the company sent in. So if twenty companies sent in something, each person would get twenty of whatever they sent it. Some of them got a lot of data. I mean, we physically . . . We did it ourselves. We put them in boxes and mailed them, and all that. Everybody had to pitch in, even the director.

RO: Who was in charge at that time of the OTC review?

LG: I'm trying to think who was. Gary Yingling, a lawyer, was in charge for a while, then Bob Pinco, and then after that, Bill Gilbertson.

RO: What commissioner was that under? Was that under Dr. Kennedy?

LG: Might have been.

RO: This started in 1972, you said?

LG: Yes, '71, '72, thereabouts, yes. And yes . . . The first panel that met was the antacid panel, if you remember that. Armond Welch was the panel administrator for that one.

RO: Your responsibility was to be sure you got all the information out to the panel members.

LG: To the panel members. Make reservations in the hotels, and provide rooms for them to meet, and all that kind of stuff. Yes.

RO: And then when they came in, you had to make sure that everybody had reviewed the data?

LG: Well, I mean, they had a panel chairman, you know. And then they . . . Well, they didn't all review everything. At the first meeting they said, "You cover this, and you cover this, and you cover that." You know, they made assignments. Because there was an awful lot of data. I mean they had hundreds of volumes. You couldn't review it all at once anyway. But they met mostly once a month, and there was an assignment for each meeting.

RT: Was a record made of those meetings?

LG: Yes, they had to have transcripts of all of them. Yes.

RO: I see. Usually was there a decision or a recommendation made then to the agency.

LG: It depended. Sometimes yes. Sometimes they said, "Well, we need to look at some more." Sometimes they asked for more information. Don't forget, they had open meetings where people could make presentations. Companies could come in and make presentations to the panel, and you know, they'd never say right then, yes, no, or whatever. And then they had a closed session and discussed things. And sometimes they made a final decision and sometimes they didn't. Some would say, "We need more data," or "We need to look at this again." You know. Don't forget, they weren't looking at just one NDA. They were looking at a whole marketplace. Aspirin, for instance, is made by a gazillion people, so it doesn't affect just one company; it affects the whole marketplace. So they wanted to be careful that what they did was adequate for everybody. And there were others.

Actually, I found it very interesting. It was very educational. Of course, a lot of people made very interesting presentations, and the panel members were all very nice and knew their subjects very well. So it was interesting and educational for me. I would take care of making sure they had a room to meet in and making sure I sent out the notices and the minutes.

RO: Roughly, how many panels were there altogether?

LG: About seventeen or eighteen, I think. At the very end, there were two miscellaneous panels, one internal and one external, in order to cover those items that weren't covered in the other panels.

RO: Was it during this review that they did away with some of those combinations. Like I was thinking of APCs, for example.

LG: Yes, because . . . Yes, that's the analgesic panel. They didn't like phenacetin. That's right. Because phenacetin had problems, particularly in Europe. For some reason, in Switzerland, people took APCs to work better. It was used as a stimulant.

RO: When I was in the navy, that's the first thing they gave you--APCs.

LG: That's really a drug abuse, you know. But anyway, as I say, it was very interesting and educational to me to learn all these things.

RT: During the enactment of the Kefauver-Harris Amendments, were you involved in developing information for testimony by the agency?

LG: I wasn't the supervisor at that time, so I don't know whether they took any of my things or not. I don't know.

RO: Just to back up a little bit, I was wondering why you moved from antibiotics over to drugs.

LG: From a lab into an office.

RO: Yes. You didn't . . .

LG: Oh, they were raiding the labs for people to do the reviews. I hadn't applied. They came around and interviewed people and said, "Do you want to talk?" I said, "Sure, why not." In fact, one of the supervisors in the lab told me, "Well, if you stay here we'll give you a promotion, but that's the last promotion you'll ever get." I mean, that's no way to make people stay here, you know, so I went over to the New Drugs. I think Dr. Ralph Smith was in charge at that time. He was a nice person.

RT: Yes, he was.

LG: Yes. No, wait a minute. I take it back. The guy before him. Dr. Smith came afterwards. The first one was . . . Oh, God, what's his name? I'm getting terrible with names. There was somebody else in charge when I came over, the one who preceded Dr. Smith. I can't think of the name right now. But anyway, Dr. Smith was in charge for quite a while.

RT: I think he was in charge when you folks were in Tempo D, if you remember that one, because our office was in the same building there.

LG: Could be.

RT: Which would have been under the George Larrick administration.

LG: Yes, could be. I'm not very good at dates and what happened when and where. I sort of can think of the sequence, but not what year it happened, other than like the 1962 amendments and the 1971-72 start of the OTC review.

RO: How long did that last?

LG: What?

RO: The OTC review.

LG: It's still going on.

RO: Still going on!

LG: Well, no. I mean, they finished the part with most of the panels. We still have two advisory panels left. A standard panel for problems that you can't resolve. You know, at the time we started we said, "Oh, we'll be finished in a couple of years." We didn't realize how much information was going to be forthcoming and how many issues there would be to be resolved. It was a lot more complicated than anybody expected. In fact, it's still going on.

We still haven't published all the final monographs, because by the time you publish one monograph there's more information coming in on that, so you have to publish amendments. And you publish three times, because since the panels were outside the agency, we considered the first publication a proposal--not a proposed regulation, but an

advanced notice of a proposed rulemaking. We published everything that the panel said, even if we didn't agree with it. And then we got some more comments, and then we published a tentative final, and that was the proposed rule for the agency. And then more comments, and then published a final, and then you go in the Code of Federal Regulations. Or if it's negative . . .

RT: How large, in terms of numbers of consultants, were most of the panels? You had several people, I suppose, from more than one discipline in most of those.

LG: Well, as I say, we had seven panel members, and depending on what the substance of the panel's review was . . . Like, for instance, the topical analgesic panel also covered otics for instance, so we had a specialist in that area. We tried to have a specialist in whatever areas we were going to cover. In fact, the topical analgesic panel, you can thank that for the SPF (sun protective factor) on sunscreen. It was originated in Europe, but at that time it wasn't done in this country yet. They were the ones who developed that and put it in their first report.

RO: How long were you actively involved in these panels?

LG: Well, the panels ended in the middle of '85.

RO: Middle of '85.

LG: But then we still had all the . . . Since all the monographs aren't final yet, we still have ongoing back-and-forth data coming in on the evaluations and asked the advisory panel if we had a problem. I mean, new drug people do that, too; they check with advisory panels. But there's just one panel, one for internal and one for external drugs. They don't have one for each topic anymore like we had. As I say, the monographs aren't

all final yet. And even after they're all final there will be amendments, because modern technology changes things. And there are things you can do now that you couldn't do then. You know, like testing that's different and some drugs show up with an adverse reaction that never happened before, because now you have a different mixture of OTC drugs on the market.

RO: And a bigger population that are taking them, too.

LG: Although, let's face it, some drugs are really everyday things, like a toothpaste is a drug if you make a claim that it prevents tooth decay; it makes it a drug. An antiperspirant is a drug if you say it's an antiperspirant rather than a deodorant. Deodorant is a cosmetic; antiperspirant is a drug. So mouthwash, you know, if you make an antimicrobial claim, it's a drug, and it's covered by one of the monographs. So some things that are drugs really aren't considered drugs by a lot of people. Yes. But to make a claim, you have to show efficacy.

RT: So a manufacturer that wishes to go into the market as an antiperspirant . . .

LG: You have to follow the monograph.

RT: Yes, he follows it.

LG: Except that wasn't final by the time I left.

RT: So he's letting himself in for a lot more government involvement than . . .

LG: No, you can just follow the monograph and just have your product meet the monograph requirements. There's an efficacy test in there, and no problem. You don't

have to file any data. People who market drugs do register. The OTC review is not involved in that, but anybody can market a drug that's covered by a monograph.

RO: Monograph, yes.

LG: Yes, all you have to do is follow what's in the monograph and good manufacturing practices.

RO: When you're talking about monographs, is that like the U.S.P. (United States Pharmacopeia).

LG: The OTC monographs. Right. U.S.P. is part of it. In fact, if a drug is in the U.S.P., we can use the U.S.P. reference. If it's not in the U.S.P., they have to put that kind of testing in the monograph.

RO: OK.

LG: That's why we encourage a lot of people to send their data to U.S.P., and U.S.P. has been working with us very nicely. Yes.

RO: Did you get involved in, your branch, in these prescription drugs going OTC?

LG: In the labeling.

RO: Just the labeling.

LG: See, we're considered the "experts" on OTC labeling. Because, you know, OTC language is different from prescription language. It's one thing to talk to a doctor; it's a

different thing if you're talking to a layman with, you know, who may have gone only to two years high school. Everybody is supposed to be able to read an OTC label and understand it.

RO: So then, I'm thinking of like Zantac and Pepcid and all of those that have recently been made available over the counter.

LG: They're new drugs. They're approved as new drugs. Actually, right now OTC is handling new drugs. That's one of the problems. They now handle new drugs and old drugs for OTCs. But anyway, the labeling, even if the NDA was handled by the people in the new drug, the labeling would come over for input from OTCs.

RT: While the patient package insert . . .

LG: Well, that's with a prescription drug.

RT: Yes. But is there not an objective with patient package insert to make it understandable?

LG: Make it understandable? I'm sure there is, but as far as I know . . . I mean, I don't remember seeing any, but that doesn't mean that somebody else in our division might not have seen some. Especially right now, since things have changed so much. OTC doesn't just do monographs anymore. They do OTC NDAs. You know, they now have medical officers on board and everything, so it has changed a great deal from the original OTC review.

RT: Can one conclude from that then that the criteria for classification of a drug as an over-the-counter (OTC) are more stringent than in earlier times?

LG: No. Well, no, because don't forget, to begin with we reviewed drugs that were already OTC, had already been considered OTC by the agency and we were just reviewing efficacy. Now when you're switching an Rx to OTC, it's under review. I mean, it's a new drug application that you're switching. Of course, then you have the reverse thing, like aspirin being used for prescription indications to prevent heart attacks. That's professional labeling, which the physicians reviewed it, but we put it in the monograph. Now, they could have made that an NDA, but they didn't want to bother having aspirin as an NDA.

(Interruption)

RO: I was curious about the different bureau directors or center directors that you worked under. You had a number of them.

LG: Gee, if I could remember all them. (Laughter)

RO: I was wondering if you noticed any difference in their style.

LG: Well, it wasn't so much their style, I don't think. Congress has a great deal to do with how much money the agency has and how they run with what they can afford. Who did I like best? It's hard to tell. I mean, Larrick was nice, because in one sense he would come and talk to you. You know, I mean he was a person you could just talk to, man to man, like this, you know. He was always accessible, which was nice. Of course, at that time the agency was smaller, too. I remember going to a meeting, and the door wasn't open, and he was sitting outside on the front steps, and we'd just all sit down together and gab. You know. He was the last commissioner who wasn't a doctor, I think, too.

RO: Right.

LG: He came from inside the agency.

RO: Sure, yes.

LG: In fact, I think it's . . .

(Interruption)

LG: I'm sure there will be other things, particularly with the modern technology. Now they can make drugs with electrons and stuff like that. Things have become so much more modernized, or whatever you want to call it. I'm sure there will be other reasons why you need different people to review things, different equipment to look at things.

RO: Did you notice any difference after the agency got user fees in the way the reviews were conducted?

LG: The review was done. I guess they hired more people. I don't know. I think user fees came after I had left New Drugs. Didn't user fees come after '71? Didn't it?

RO: I think so. Yes.

LG: Yes. So I never was involved with user fees, fortunately.

RO: I see.

LG: Not only that, but don't forget, then they changed the time from 60 days to 180 days for review, which is a big difference.

RO: Yes. During the late eighties, the agency got involved in a generics scandal. How did that effect . . .

LG: I don't know, because I was in OTC, and we were just doing monographs. We never got involved in actual marketing drugs. All we do . . . Because you write regulations, you do not get involved in enforcing the regulations. You know? That's just like a lawyer isn't going to be a physician, you know. (Laughter) Unless he's both, like our commissioner.

RO: Yes.

LG: No, we didn't get involved. There's Office of Compliance. Once we published the monographs, Compliance takes over in making sure that people meet the monograph and everything and check up. Have to follow GMP and things like that, but we didn't get involved in GMP at all.

RO: For the record, are the monographs published in any place, like the U.S.P.?

LG: *Federal Register.*

RO: In addition to *Federal Register.*

LG: Oh, no. There's . . . I'll show you one if you turn it off for a second.

(Interruption)

LG: This is what they look like. It has the ingredients and the labeling, and some of them are bigger than others, because some of them include the testing, like the

antimicrobials include the testing. If they include the testing, then it's a longer monograph.

RO: The Bureau of Drugs was merged at one time with the Bureau of Biologics. Did that have any effect at all on your operation.

LG: Not that I know of. No. But we were an office at one time; now we're just a division, which is too bad, because we're not quite as well-teamed any more, you know as well . . . We don't have as many people doing the work anymore, and it's not so much aimed at the monographs, because there's more push for NDAs, because they get PDUFAs (Prescription Drug User Fee Act).

RT: Now at the time when Peter Hutt was general counsel . . .

LG: Yes. He was great. That's when we started it. When the panel first met, he would come and explain it all to them. He was terrific. Yes.

RT: So as far as this preamble and all that business, that never really affected the monograph publication, did it? In the enforcement of the regulatory process, Peter initiated a more formalized system of publishing preamble and history and kind of establishing the face of it.

LG: Well, there is an introduction in here which tells you how the OTC things are done. Let's see if I can find it without . . . It tells you, you know, how . . . Here. It starts here. General procedures and everything.

RT: OK. That's right, but this wasn't particularly something that during the tenure of Mr. Hutt . . .

LG: Well, don't forget, when we published for people to submit the data, we published a fairly long thing asking for what we wanted and what they knew. We say, we put in, "We know this is on the market for that use. Do you have anything, risk data or anything like that? Send in whatever you have." There was a publication to begin with just explaining the OTC review.

RT: So it was kind of an administrative practices procedure that was used.

LG: Oh, yes. But, you know, some small companies didn't pay any attention. They said, "Oh, it will go away. It will go away." Well, they didn't realize once a drug is covered by the monograph, they have to meet the monograph. Or if your drug wasn't reviewed because you didn't submit it, well, it's off the market eventually. Sooner or later you have to either be covered by a monograph or by an NDA.

Now there are some grandfathered items--very few.

RO: We were never very involved in the monographs, other than hearing about what they were.

LG: Well, it was sort of a novel approach, because . . . Now, I know they have monographs for antibiotics, but that's usually just for the testing.

RO: Yes.

LG: They're still covered by NDAs or what they used to call antibiotic NDA or whatever.

RO: So this amounts really, the monographs, almost like the old food standards.

LG: Yes, I guess so. But, you know, it's both the scientific and the legal aspects are mentioned in it. But it was, as I say, it was a real education for me. Good thing I went to law school! (Laughter)

RO: How many are still working in the OTC Division now?

LG: I don't know how many they have right now, because things have changed quite a bit in the last year or so. I really don't know what the numbers. I don't know. There are quite a few, because they're handling NDAs, too. Like when I left the (Inaudible) to go where my old office is, they hired a doctor. You know. And don't forget, we used to have three branches, and then they changed the branches to sections, and then they changed the sections to teams, and you know, you can be on more than one team and all that kind of stuff. But team leaders are not supervisors. We only have one supervisor.

And so while they had the physicians as sort of a separate team, I think now the physicians are part of each team, depending on what kind of drugs they handle. But the physicians aren't particularly the team leaders. Yes, I mean, most of the thing the team leader has to do is coordinate. You know, keeping track of things, and making sure people do what they are supposed to and everything, coordinate and all that--a supervisory job.

RO: Sure.

RT: Let me ask you in that connection, in most of the organization--I guess in all of the organization--a few years ago we went to performance plans. Was that a difficult requirement in terms of defining goals and objectives and performance.

LG: No, because on the performance plan you gave, you say, "We were told you need to publish the final regulation on this, on the internal analgesics, publish a tentative filing

on the antiperspirants, publish something on the antimicrobial within the year." And that kind of thing was . . . And then supervision. At that time we had supervision, you know, to make sure . . . It was just like anybody else's. I mean, you can treat a monograph like an NDA, if you will, sort of.

RO: You could or you couldn't?

LG: I mean, in the evaluation, you know. It's a document or an NDA. It's the numbers game.

RO: I see. Sure. It's an output.

LG: It's an output.

RT: Yes, in terms of evaluating individuals' own performance and rating them as excellent, fully met, and so on, defining those levels of accomplishment, did that create any problems?

LG: No, because the way we do a monograph is we look at the data that is submitted, and you separate it into issues. You know, issue one, two, three, and then you group the issues by topic. And then you write out, "Issue number one is this and this, and our response to that is . . ." whatever it is. So people were assigned issues. Now some people ran a whole document, did all the issues; or if it's a huge document, you'd assign the issues to different people. It's just like writing a story, you know, writing this thing here. You wrote them up to say why you agree or not agree with whatever it is.

Some people are better than others at writing. For a while we had professional writers. Each branch had a professional writer. Then they did away with that and then just had everybody do their own writing and had the supervisor edit it, and had Gerry

Rachanow edit it, you know. It went through a lot of editing, because the documents went through New Drugs, too, for their input, once they were final. But the individual issues they circulated within the office until they would say, "OK. Final type." And then you went on to the next issue. I mean, writing, some people are better at it than others, you know, so . . .

RO: And you were having fun when you . . .

LG: I love to write. (Laughter) Yes.

RT: Have you ever thought about doing memoirs of your experience?

LG: No. No, not really.

RO: I guess, once you mentioned kind of in passing that what caused you to retire was a medical problem?

LG: Well, number one, I wasn't feeling too well. Number two, I felt like I wasn't really contributing anymore.

RO: I see. But you were a supervisory chemist.

LG: I was at one time, but when they changed you to a team leader you can't be called a supervisor anymore. See?

RO: All right, yes.

LG: I had all sorts of great titles. I was at one time in Marketed Drugs, I was the assistant associate director for marketed drugs. I was above all the chemists in that office. And then, you know, over there I became a branch chief. But I had all sorts of fancy titles and things, but eventually, you're not a supervisor, you're a team leader, because they're trying to get rid of supervisors. I mean, it's the numbers game.

RO: Sure.

LG: You can thank the vice president for that.

RO: The downsizing.

LG: Yes.

RT: Well, for reinventing government and having fewer middle management . . .

LG: Actually, it's too bad, because they way the office was working when Gilbertson and Rachanow were director and assistant director was doing real well as far as the monographs were concerned. And now, with the NDAs, because of the PDUFAs, they're taking over sort of the monographs, they get kind of neglected. It's too bad.

RO: What did you say? The PDUFA?

LG: The PDUFA? The payment you get for reviewing NDAs. (Laughter) You know, I mean people justify hiring people because they have NDAs to review. And the OTC, there's no money coming in for OTCs, although I think OTC industry and NDMA (Nonprescription Drug Manufacturers Association) would love to have OTC handling

monographs again by itself, but I don't think the agency is going to do it. At least not our current director. At any rate . . .

RO: We've had the expedited review process. That affected, I guess . . .

LG: The NDAs, so they needed more people. Yes.

RO: But if an OTC is an NDA . . .

LG: Right. It's still handled the same way as an Rx NDA. Yes.

RO: So you had to expedite the . . .

LG: Except we'd get the labeling, yes. I think, see, I didn't get involved in the NDAs in the OTC . . . I mean, the physicians were and some of the other people were, but I never got involved with it. And then when I left, I'm sure now they all are involved with it. But it was a sort of gradual thing. You've got a few, and then you get more and more and more. And we'd only look at the labeling; then all of a sudden you look at everything.

RO: I guess after forty-nine years you have no regrets that you joined the FDA.

LG: No, no, no. Actually, I hate looking for jobs, and I was working in the hospital in the Bronx, and all the chemists in my class had taken the civil service exam in their senior year. You know, took the exam and forgot. Never heard it again. You know. And one day I got a telegram: "Would you be interested in working in Washington?" I had an interview downtown in the district, downtown in New York, and the description they gave me was totally different from what I actually came to do. I was lucky. I had

a distant cousin who lived in D.C., and so she got me a room in her rooming house, and so I came to Washington in October, 1947. And I hate looking for work, so I never looked for another job. Everything I went to, sort of, they came and got me or told me to go or whatever. I never looked for another job.

RO: Was Bill Wright in antibiotics when you . . .

LG: Oh, sure. Absolutely. I'm still in touch with him. He was a terrific guy. He still is. But, yes, he was a great guy to work with. In fact, he got his Ph.D. while he was working there. Yes.

RT: Your interview in New York, was that with the district director?

LG: I don't remember. That's too long ago. I didn't even know his name. I really don't recall. But it was in 1947, you know. No I don't recall. I don't recall who interviewed me. But they told me I was going to work with animals, which was the other, the part I didn't . . . Well, I came to the chemistry lab, you know. I mean, there was an animal lab, too, but that's not where I worked.

I was always in South Agriculture. One great thing about South Agriculture is they had the most terrific cafeteria there. I mean, people would eat three meals there, because it was so great--breakfast, lunch, and dinner. Yes.

RO: Yes, I was there from '58 to '60.

LG: In agriculture? South Ag.?

RO: South Ag.

LG: Yes, it was great. Very nice building. And the subway was right there--I mean, streetcar was right there.

RO: Yes, before the subway.

LG: Before the subway, the streetcar, yes. And I lived right at Thomas Circle, so I just took the streetcar on Fourteenth Street. And in nice weather I'd walk. Yes. At that time you could do that. I don't think you can still do it.

RT: Probably not.

LG: That's history. That's so long ago. Gee.

RO: I guess the various reorganizations that the bureau had didn't affect you too much, other than for changing titles and . . .

LG: Well, all the chemists were with Earl Meyers, even the ones who did the veterinary reviews at one time. They didn't have a separate veterinary, but all the vets and the doctors were all in one group in--Bureau of Drugs? Bureau of Drugs.

RO: Bureau of Drugs, yes.

LG: And then when they created Marketed Drugs, I was put in Office of Marketed Drugs at that time. Who was in charge? Dr. Robinson? I forget. I don't know if he was the first one or second one. Jennings, Robinson . . . It's so long ago. At any rate, Marketed Drugs were reviewing all the supplements to NDAs, instead of original NDAs. And we kept up with everything, and when the New Drug people fell behind, they put us

back with the New Drug people to give them more power, more people. And then, of course, then the OTC thing started.

RO: Is there anything thing else, Bob?

RT: I was just trying to think. I guess you've probably covered it. We've already asked you, I think, about directors and commissioners and so on. One of the breakpoints, of course, in the line of top administrators was after Larrick when Goddard came in, and of course, there are more frequent changes now. Are any of those persons ones that in your view were particularly supportive of the drug clearance and approval processes?

LG: I don't know. I don't recall anything special. I'm sorry. I really don't. Don't forget, I wasn't that close to the commissioner's office. I don't particularly remember anything special.

RT: You mentioned Larrick was an accessible person. I think Goddard was one of the ones that was a little that way, too. He used to walk around in the halls and stop in and ask somebody what they were doing and so on.

LG: Well, yes, he might have. I don't remember that.

RT: And some of the others, leadership has been more subdued.

LG: I'm trying to think. Who was commissioner before the present one?

RO: Yes. Frank Young.

RT: Frank Young.

LG: Frank Young. I think he came around, too. Yes.

RT: Yes. Personable fellow.

LG: Yes, because I remember him coming to my office. Yes. I had a big picture of "A Nude with a Snake." You know, that photograph with the snake in it? And I remember he liked that. (Laughter) Oh, well. Yes, he was nice, too.

I published one article in the *Consumer Issue*. Would you be interested in it? It was about NDAs, as a matter of fact.

RO: Yes.

LG: If I can find it.

(Interruption)

LG: Take anything you can get, huh?

(Interruption)

RO: Well, I guess if there's nothing more then, Lee or Bob, we'll close this interview.

LG: OK. Fine.

RT: And we thank you for granting us this interview.

LG: You're welcome.