History

of the

U.S. Food and Drug Administration

Interviewee: Raymond M. Mlecko

Interviewer: Robert A. Tucker

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Place: Oakbrook, IL

RT: This is another in the series of taped interviews in the FDA Oral History Program. Today, June 15, 2003, Raymond [M.] Mlecko, former director Chicago District, is being interviewed at the Oakbrook Hills Resort in Oakbrook, Illinois. The interview is being conducted by Robert Tucker of FDA's history office.

Ray, we like to begin these interviews with a brief review of your personal history, your education, where you were born, and any other pertinent information, such as where you may have worked prior to your joining the Food and Drug Administration. So if you go from there, we can get under way.

RM**:** Sure. I was born in Chicago, Illinois. I was raised in the Chicago area, and I went to Northwestern University in Evanston, Illinois, under a Western Gulf scholarship.

After I graduated from Northwestern, I went to the University of Illinois Dental School. About during my first year, I realized that dentistry was not for me. One of the reasons why I didn't particularly like dentistry is because as a freshman, we had patients, and these patients usually were "skid row people," and I was making a denture for a skid row person and I realized that I didn't want to do this for the rest of my life.

So I left dental school, much to the chagrin of my father, and then I didn't know what to do. So I joined the army, and when you join the army, they give you a battery of tests, and I scored very well.

RT: What year was it?

RM: That was 1956.

RT: You were in dental school prior to that time.

RM: Yes.

RT: So when did you first enter university-level work?

RM: At Northwestern, I started Northwestern in September of 1951 and graduated in May or June of 1955.

Then in September of ’55, I started dental school. Again, I decided it wasn’t for me. It was kind of interesting, when I left, I had an interview with the dean, and the dean indicated that when he was checking my records, that I didn’t score that high relative to neuromuscular control, which you really need to be a good dentist, but I did much better in other than the neuromuscular control areas.

I didn’t know what to do, so I joined the army about September of 1956. As I indicated previously, I took a battery of tests, as all incoming people do. I must have done extremely well, because I was asked to apply for the Counterintelligence Corps. When you apply for counterintelligence, you take more tests, but you had to write an essay. The essay was compare

and contrast capitalism, socialism, and communism. It just so happened that when I was in undergraduate school, my area of interest was communism, and I had done a lot of study and research in communism, so when I had to write this essay, I just creamed it.

I was selected for the army counterintelligence. I went to Fort Holabird in Maryland for training, and it was a six-month course. When it was time to graduate, they asked us, "Where would you like to go? Where would be your assignment?"

I thought I was a wise guy, so I said, "I want to go to Hawaii." All my classmates laughed, "Hawaii, ha, ha, ha. You'll never get to Hawaii. Only the veterans go to Hawaii." But sure enough, I got to Hawaii, and I was just so excited about going to Hawaii. So I spent my army career, I actually lived on Waikiki beach in civilian housing. I worked at the Schofield Barracks, which was a drive from Honolulu.

But I often say that my army experience was the best years of my life. For example, we had individual physical training. One day a week when I was training on my own, I went to the beach and laid on the beach, read on the beach. One afternoon, we played volleyball to keep in shape, and then the other afternoon, we went to the pistol range and practiced. So those years were very good.

Our assignments were to provide the security for the 25th Infantry Division. We did security surveys, and every so often we'd get word that one of the visiting officers from another country like Thailand were known communist agents, and our job was to keep track of these folks during the evening hours. During the day, they would be in uniform, they would have their nametag, and the regular army people then would keep tabs on them, but in the evenings, it was our job to keep tabs on them.

This is a terrible thing to say, but it was true; to us at that time it seemed like all these officers were about the same height and they looked alike to us. In civilian clothes, we couldn't tell them apart. So what we would do is determine what color aloha shirt they had on before they went out for the evening, and then we would follow the aloha shirts around. Hopefully, we picked—nobody switched aloha shirts on us. But those were fun years. They were very good years.

Then when it came time to leave the army, I applied for a job with the government in Hawaii. I took the FSEE [Federal Service Entrance Exam], and I was told there weren't any vacancies for my particular grade level in Hawaii. So I came back to Chicago. This was in the fall of 1959.

I accepted a job then with the—I believe it was the Continental Insurance Company. The job was that I was going to be the assistant manager or the deputy manager in the mail department, and I'd be the second in command of about twenty-nine female clerks who processed the mail. I was all set to take that job when I got a call from the FDA asking me if I was interested in working for the FDA.

Now, my first contact with the FDA was a gentleman by the name of Doug Hansen. Doug, I thought at the time, was a very impressive man. He had been, I believe, a P.T. Boat captain during the war, or something to that effect. He was a very gregarious and a very likable individual, very impressive, and he convinced me I should come to work for the FDA.

RT: At that time, was Douglas a supervisor?

RM: He was a chief inspector in Chicago.

What was interesting, I remember walking into the office my first day, and all the investigators—there were maybe twenty to thirty—they all had white shirts and ties on. I remember that I was very impressed, the way those gentlemen looked. You don't see that today, but in those days, they looked just—

RT: Almost like FBI agents, I guess.

RM: They looked very, very good. I was impressed by the caliber of people they had at that time.

So I figured, well, Doug had told me that the kind of workup you do would be a lot like what I did in the army, but it wasn't the case. My first three months were spent in cold-storage warehouses checking cranberries for aminotriazole, and I was about ready to quit. Those cold-storage warehouses were pretty cold.

Now, I've got to tell you a little something that happened at that time. One day when we were in a cold-storage warehouse, we got the word that reporters from the *Daily News* were going to come to visit us. What we would do is to identify the sacks of cranberries that we wanted pulled out of the cold storage, put into hallways so we could then sample them in the hallway. Now, the hallway was cold, but the cold-storage rooms were probably fifteen degrees below zero or thereabouts. So when we found out that the reporters were coming, we set up our sample room right in the cold-storage area, not in the hallways, and when they came in there, they just couldn't believe that we were working in this cold, cold weather.

Then they took pictures. The pictures were on the front page of the *Daily News*. There were about four of us, Jerome Bressler and Dick Tank and me and some others, but they left my name out in the caption. My picture was there, but they had omitted my name. But that was my introduction to dealing with the media.

RT: Before you came to FDA and you were completing your service in the military, what was your military rank?

RM: I was a sergeant, but in those days we didn't wear insignias, so people didn't know the rank, because we were dealing with all kinds of people. When we were on the base, when we're on the base, we wore a uniform without insignia, but when we're off the base, we wore civilian clothes.

RT: I see. I just wondered, because you mentioned the possible difference in grade from army to your civilian work.

RM: No, what I meant was they didn't have anything like a GS-5 or 7.

RT: I see.

RM: That military thing reminds me of another factor. Sometimes what we had to do is to live in the bachelor quarters for the officers. I remember one day some woman saw me. She was a

nurse or something. At twenty-two or twenty-three, I looked like I was eighteen at the time. I remember her telling me, "You're the youngest-looking major I've ever seen." [Laughter]

And it goes on. My son's a commercial pilot, and when he first started flying commercially, he was about twenty-five years old. Some of the flight attendants would tell him, "You're the youngest-looking pilot I've ever seen." So it's hereditary. We all look young in my family.

RT: Well, that's good. Now, when you entered the Food and Drug, did you come in as a GS-5?

RM: GS-5, and as a matter of fact, I remember I made forty-forty a year. I took home sixty dollars a paycheck, and my transportation on the Illinois Central was probably about twenty dollars, so I really didn't have that kind of money.

RT: I'm sure.

RM: I was ready to quit after three months.

RT: What changed your decision to stay?

RM: Probably apathy. [Laughs]

RT: After you had that cold-storage introduction to the agency, what did you get into next?

RM: I don't remember specifically, but I kind of specialized in special assignments and drug work. One of my big assignments was that I was, I'll use the term "the lead investigator" in the X-33 investigation. X-33 was a water repellant—and we did this under the Federal Hazardous Substances Act. It was a water repellant that had a very, very low flashpoint. As a matter of fact, the laboratory in Chicago had a couple of fires testing the product. I remember stories where some consumer would use it in his basement to waterproof his basement or whatever, the sump pump would go on, and there would be an explosion. I know of another case where a man was using this to waterproof the exterior of his home, and some spark lit the stuff, and part of his house singed. X-33 was very, very flammable, and probably was as combustible as gasoline.

RT: As I recall, that was under the Federal Hazardous Substances Act, which, as I recall, was enacted in 1960. Is that about the timing?

RM: I would say I did this in about 1962.

RT: I know that was one of the big problems after that legislation was passed to us.

RM: Yes. Then I remember inspecting drug companies before there were GMPs [Good Manufacturing Practices]. One of my colleagues in my present job asked me just last week, "How did you inspect if there weren't any GMPs?"

I thought and thought and said, "Well, that's a pretty good question. I really don't

remember." But all I remember is my bible in those days was *Remington's Practice of Pharmacy*. We didn't have the wonderful training courses that the FDA has today.

RT: In those early days, what was the focal point of most of those inspections or investigations?

RM: I don't remember, because I can't picture making inspections without GMPs, but I remember one, a firm by the name of Maizel Laboratories. I remember inspecting them before there was GMPs. I really don't know. I can't remember what we were even looking for in those days.

RT: You were working in the manufacturing or production area. You weren't so much involved in the illegal distribution?

RM: I did a little of that with regard to illegal sale of amphetamines and barbiturates. I remember going to the area around Loyola University and going to drugstores and trying to make buys, and I would pose as a college kid. Again, I was just telling one of my colleagues last week about that. We would call the pharmacist "Doc." "Hey, Doc, I've got this," or, "I've got that." In those days, as I recall, we always called the pharmacists "Doc," for whatever reason.

RT: That was a practice even in the rural communities for many years. A lot of people would go to the rather well-informed pharmacist because it was cheaper than going to the physician, and they got a lot of counseling that way.

Did you get into the truck stop surveillance work?

RM: I didn't do any truck-stop work. About the only thing I did was drugstores.

RT: That was in Chicago district?

RM: Chicago, yes.

RT: You remained there in Chicago for how long? Were you there a number of years?

RM: I was in Chicago until 1967.

RT: In that period of time, had you risen in grade?

RM: When I left, I was a GS-11. When I left, I went to Dallas for a 12.

One other story I think you should know about is, it was about 1965 or so, was when Jerry Bressler and I were inspecting Abbott Laboratories, the large-volume parenterals area. We got a call from our chief inspector, Cliff Shane, to get out of there, terminate the inspection. Of course, we weren't done.

So we were going to go out. We were going to leave. But Jerry was the lead investigator, and he happened to like the cafeteria at Abbott. So we didn't leave immediately, but we had lunch at Abbott and then we left. I guess, if my memory doesn't serve me right, they

wanted us out of there right then and there, and we didn't leave as quickly as they wanted to.

RT: Why was that?

RM: Why they wanted us out of there?

RT: Yes.

RM: I'll tell you what happened. Later, now, Jerry and I—Jerry was the lead investigator, and I was the junior investigator. My job primarily was to take the notes, so I had copious notes as to what happened.

A number of months later, when I was working on the Krebiozen trial, and I was at the U.S. attorney's office, I got a call from the office indicating, "Come back to the district office. There's some congressional investigators that want to talk to you, and they want to see your diaries."

I knew where the diaries were, because I had just looked at them. I came back to the office, and my diaries weren't in my desk. I was petrified. I went home to make sure they weren't at home, and I was—you don't know how scared I was, because here they're congressional investigators, they want to see my diaries, what I have about the termination of the Abbott, and I couldn't find my diaries. As I recall, there were two of them.

They interviewed me, and I didn't have the diaries. A few days later, John Guill, the district director, came up to me and said, "Ray, don't worry about your diaries." That's all he

said. "Don't worry about your diaries." What I thought had happened is that somebody, he or somebody else, had taken my diaries. That's all I know.

Now, Jerry later testified before a congressional committee as to what happened, and as I recall, John Harvey, who had been the deputy commissioner, his brother was a vice president of Abbott. I don't know the details there, but that whole thing resulted in a number of people at headquarters being interviewed, and they denied or they said that they don't know anything about the fact that we were told to terminate the inspection. I don't know the details. All I know, we were told, and from what I gathered, it was from headquarters to the district, district to Bressler and Mlecko, to terminate the inspection.

RT: It sounds like, I'm not sure, but to make a presumption, it sounds like this was a request of the deputy commissioner's brother to terminate the inspection.

RM: Well, I don't know the details. Somehow or other, [Alan] Rayfield was involved. I hear stories that [Jim] Nakada was involved in it somehow or other, and I think that Nakada called Rayfield a liar or somebody a liar. I don't know all the details. All I know is, I was there and we didn't leave quick enough. We got chewed out for not leaving quicker. My diaries were missing, and I was scared, because I was a young person. I didn't know the power of anything about headquarters, but I assumed that people in Washington had supreme power over me. And this is the way we were trained in those days, to respect authority.

RT: Yes, there was much more of that, I believe, in that period of our agency's history, and

certain individuals certainly gave the impression of ultimate power, and you've named one of them, Mr. Rayfield.

RM: I can't impress upon you how scared I was.

RT: I'm sure. That was certainly a most unusual procedure for the agency to do that, to suddenly withdraw without personnel knowing why.

RM: With us?

RT: Yes.

RM: I'm sure it came out, but I never—

RT: I know that was an interesting historical event, and when I interviewed Jerry Bressler, he also touched on that, but left a little bit of mystery, as you have, as to what the real scene was behind the curtain.

RM: Yes, we don't know. Cliff Shane was the one who was our chief inspector at the time. He was the one who called Jerry to terminate the inspection. Maybe he knows. I don't know.

RT: Were there problems with large-volume parenterals in the industry or was it maybe more

centered in this firm?

RM: I suspect at that time that there were a number of recalls of large-volume parenterals by Abbott, and I think that was beginning. They had subsequent problems, but I think that was their first problems with large-volume parenterals. I remember there was a recall involved, but Abbott had subsequent problems after that.

RT: Were there any deaths?

RM: I'm not aware of any fatalities, no, of any injuries or deaths.

RT: Perhaps some adverse reactions to it.

RM: If you have a large-volume parenteral that's not sterile, it can cause infections and all kinds of problems.

RT: Thank you for telling what you can recall about that incident, because that's something historians would probably be looking for.

RM: I should also tell you about my work with Krebiozen. I was assigned to the U.S. attorney's office.

RT: As I recall, was that the product that Dr. Ivy was involved with? Wasn't it the preparation derived from horse urine that was distilled for which therapeutic claims were made? What were those claims? Did they relate to cancer?

RM: Yes. What happened was, Dr. Ivy was the leading proponent. Dr. Ivy was a leader in the area of biologics of things. As a matter of fact, he wrote a textbook that was widely used. He was at the University of Illinois, a highly regarded individual. There were two brothers, the Durovic brothers, Marco and Stephen, that I think were the alleged founders or inventors of Krebiozen. They got Dr. Ivy involved, and then there was during the trial a fourth defendant, a doctor, Dr. Phillips, who was a practitioner in Chicago who made a lot of injections of Krebiozon.

There was a trial. I believe the trial lasted nine months, and I believe at that time it was the longest trial involved with the FDA. The government eventually lost the case. It was jury trial. There was a fellow by the name of Gilbert Goldhammer, and he was assisted by Robert Brandenberg. Then the lead investigator in that case was a guy by the name of Bob [Robert] Palmer, and he was from headquarters. Bob Palmer did the bulk of the work, of the investigational work, and then he was assisted by an individual by the name of Roland Sherman from Chicago.

RT: Right. I remember and I knew him.

[Begin Tape 1, Side B]

RT: Ray, we were talking about the trial on that Krebiozen, so we might continue there.

RM: As I indicated before, I was assigned to the U.S. attorney's office, and my job was to be responsible for all of the thousands and thousands of court exhibits. The trial lasted about nine months, and I was always the first one in the courtroom with a large cart with all of the exhibits for the day. So I sat through the entire nine months' trial.

As I previously indicated, the lead government FDA investigator and witness was Bob Palmer. Bob was on the witness stand for six weeks, and when he would walk down the hall there, some of the Krebiozen supporters would spit on him. I've seen that. They would make derogatory remarks towards him. What I saw was that kind of treatment affected Bob after a while, and Bob would kind of lament the fact that he wishes he were in a government agency that gave out money rather than what we're doing because of the tormenting that he—he went through hell.

I believe there were four defense attorneys, and quite often Bob would say something, and then four attorneys would all jump up and object, and then each one of them had to give the reasons for the objection. That was the reason why the trial took so long.

One of the next witnesses was a government witness, Roland Sherman, R. D. Sherman, who was a Chicago investigator. I still remember the fact that the defense attorneys made a big point that in one of Mr. Sherman's diaries he had a statement in there that Durovic is hard to understand, and I don't remember which Durovic it was. But every time he got up and said, "Well, Dr. (or Mr.) Durovic said this, this, this," four attorneys would jump up and say, "I

object. How does he know what Durovic said when he's indicated in this diary that they're hard to understand?" And that impressed upon me the very fact that one has to be very careful what one puts in their diaries.

RT: Those diaries were available for the defense attorneys to review?

RM: Yes, what happens was, each witness, before he testified, had to turn over through the U.S. attorney's office all of his notes, all of his diaries, everything that he had on the case, for review by the defense.

RT: Does that qualify under the term *discovery*?

RM: No, no. That was considered what we call Rule 3500, and you did it just prior to your particular testimony.

RT: Who was on the prosecuting team? Did Billy Goodrich—

RM: No. The lead attorney was a criminal attorney from the U.S. attorney's office in Chicago, a fellow by the name of Art Connelly. Then he was assisted by the head of the civil section, a fellow by the name of Tom James. There was another attorney—it escapes me. He was another junior attorney. There were three government attorneys. There weren't any attorneys from Washington working on this case.

RT: My question was prompted by wondering whether some of the top legal people from Washington were involved.

RM: I remember Goodrich reviewing some of our work and having a fit on some of the things that we saw, because he indicated that "Some of the things you folks were doing were illegal."

For example, I could tell you—I guess the statute of limitations has long gone. But we actually built this case in part from empting garbage cans. In other words, at midnight, Carl Sharpe and Jerry Bressler and I would go to Dr. Phillips' place and raid his garbage can, and get names of out-of-state patients to develop interstate commerce. And when Billy Goodrich saw this, he had a fit, because he said it was trespassing, it was illegal, and things like that. And we actually did it at midnight, believe it or not.

RT: Hasn't there been some indication that J. Edgar Hoover had some of his folks doing things like that?

RM: I would imagine he did.

RT: Then I seem to recall, too, that there was a report that at one point in time others were looking at J. Edgar's garbage as well, so it came around.

RM: But we actually did this at midnight.

RT: That was unusual, wasn't it?

RM: Yes.

RT: After that case was closed, did you get into some other things in Chicago that you wish to cover?

RM: No. I kind of think the highlight of my Chicago work was X-33 and the Krebiozen. Basically, when I left Chicago, I was a GS-11 inspector.

RT: I think you went to Dallas next, is that correct?

RM: What happened, another funny story. I applied to go as a compliance officer. The reason I did that was because I thought that the promotion opportunities were better as a compliance officer than as a supervisor. So I applied for Dallas.

RT: Was that early in the Dallas district operations?

RM: That was 1967.

RT: Dallas opened when?

RM: I think it opened about 1960, if I'm not mistaken.

RT: So they were still a young district.

RM: Yes, but now there's a funny story there. Again, all I had known up to that point was Chicago District. Chicago District was not, in my opinion, and retrospectively, was not an enforcement district. I would always joke that the compliance officer in Dallas, when he reviewed a case, he'd review it in terms of how could he kill this rather than how he could build this, and Chicago did not have that many legal actions in those days.

Well, I applied for Dallas, and when I got off the airplane in Dallas, the heat was tremendous. I thought, "Well, this must be hot because of the engines from the airplane." Then I went to a restaurant near the office, and the margarine was melting. It was so hot that the air-conditioner couldn't keep up with the high temperatures.

I had my interview on whatever day it was, and I didn't want to get there at eight o'clock, because I figured, just like in Chicago, the district director has things to do, so I'll get there about nine o'clock. Well, that's what I planned to do, but before I got there, Sam Fine, who was the district director, called the office in Chicago and wanted to know where the heck was Ray Mlecko.

RT: Sam was a very punctual and orderly man.

RM: He was something else.

So, I came back, and my wife asked me, "How did the interview go?"

I says, "Not too good. I got chewed out for being late, when I really wasn't late."

She said, "Well, you don't want to work for that man anyway."

And I said, "Yeah, I don't want to work for them."

Then I remember getting back to the district office the next day in Chicago, and everybody had heard about what happened, and everybody was laughing and making jokes about me being late for the interview and things like that.

But I got the job, and I remember talking to Joe North, who was a deputy, later about it, and I said, "Joe, I just can't believe that after what Fine said to me, that I got the job."

He laughs and said, "Yeah, you should have met the other guy." In other words, I understand he was interviewing me and another person. Joe laughed, "You should have met the other guy."

But I worked in Dallas for five years. I worked for Sam Fine for two years. When I worked for Fine, I learned how to be an FDA'er. Up to that time, I didn't have the foggiest idea of what an FDA'er was. As a matter of fact, Sam Fine is the only man in FDA that I've—when he was still alive, I used to refer to him as Mr. Fine, because his presence—and he was a regulatory man, and he was so disciplined and everything, that I felt I had to respect the man. There was something about the guy that was really something. I learned more from Sam Fine than anybody else, and whenever I had a regulatory problem later in my years in my career, I'd ask, "What would Sam Fine do?" In those days, he was my role model.

My first year there, the district had twenty-one prosecution cases. They were a

combination of the amphetamine, barbiturate cases, dirty warehouses, because Arkansas was loaded with dirty warehouses, and I could remember some days holding two citation hearings, one in the morning, one in the afternoon.

I really learned FDA and what FDA is all about from Sam Fine. Now, I only worked for Fine for two years there, because then he went on to Washington and he became the first field coordinator of things. As I indicated previously, Fine was my role model.

RT: In Washington, I used to have, when I was in the legislative office, occasion to go in to see Sam. He was, as you said, very matter of fact. He always had a clean desk. He never had a lot of stuff piled around. And as soon as the business was over, Sam would just look down, and you knew it was time to leave.

RM: Time to leave.

RT: Yes. He wasn't one that wasted frivolous time.

RM: I remember going on trips, too, with Fine, maybe a four-hour trip driving someplace. And it was my modus operandi that I wouldn't talk to him until he talked to me.

RT: That was probably prudent.

RM: But he was some district director.

RT: Yes, he was a unique individual.

Now, let's see. You were in compliance work. Were you in charge of a compliance group there?

RM: In those days, they didn't have a compliance branch. When I got there, there was an individual by the name of John Rynd, who was the senior compliance officer, but he was never there. He was on detail, and then finally he was transferred to Boston as some kind of a deputy director in Boston. Then his place was taken by Bob Hatfield. Bob was the senior compliance officer. I was the junior compliance officer. We worked together for a little over two years. Bob had previously been at headquarters, and I believe he was in drugs and then he came to Dallas.

RT: Was it a two-year stint in Dallas for you?

RM: I was in Dallas for five years, but two years directly for Fine.

RT: Then was there anything else in Dallas that you'd like to mention?

RM: I worked for Joe Durham, who was a district director, who came in from Minneapolis District. He transferred. Then Louie Weiss became the—they formed regional directors. Louie Weiss was the regional director there.

RT: Did you and Mr. Weiss later work together in Seattle?

RM: No. He came from Seattle to Dallas, and as I recall, we were quite close socially with the Weisses and with the Hansons. Louie retired, I believe, at fifty-five. He retired early. I remember us helping him pack when he moved from Dallas back to Seattle. He retired very early.

RT: That was kind of unusual in earlier times, too, wasn't it, early retirement? A lot of those folks had been in the agency for many years and didn't necessarily leave as soon as they could.

RM: When Louie left, he was not a happy camper, and I could never quite understand why, because he achieved the rank of a regional director, but he wasn't happy. I don't know whether you interviewed Louie, but the story he told me was previous to that time none of the district directors were chemists, and I believe he wrote a letter to whoever, complaining about the fact that chemists weren't getting ahead in the agency. In those days, everybody who got ahead had an investigator background. Maybe Louie was the one who started the ball rolling to get more chemists involved in those top positions.

RT: There's another individual who then moved across and into leadership at higher levels, this was Sam Alfend, who was a chemist.

RM: I never knew him. I heard stories about him.

RT: He was also a rather unique individual.

RM: I heard he was very demanding, and but, you see, the way I look upon it, we needed those kind of people to instill excellence. If you didn't have a Sam Fine or Sam Alfend, you lose that passion for excellence.

RT: That impressed me as a state person.

Let's see. What was his name now? I've got a mental block. But anyway, the guy that was head of Chicago for a while.

RM: John Wilkes?

RT: No.

RM: Bob Stevens?

RT: No. It doesn't really matter.

RM: Sam Hart?

RT: No.

RM: When was he head of Chicago?

RT: He had a mustache, and he went into head of headquarters planning years ago. Shelby Gray is who I'm trying to name.

He was the kind of guy that really, to state people, really impressed you. He'd go to a meeting, and there'd be an issue, and before he'd reach his full stature standing up, he'd recited two or three sections of the Food and Drug Act. I always thought, "Boy, that guy's really something." Those kind of people were an inspiration not only within the FDA ranks, but also to their associates at other levels of government. And there were quite a number of those kinds of people.

RM: I never knew this individual.

RT: He was a very impressive individual. That's getting off the track, I guess.

Let's see. Then after—

RM: During that period of time, here's another little story about while I was there. Mr. Fine asked me to apply for the—I don't remember exactly what they called it, but it was the Executive Leadership Program. I said I wouldn't want to go to Washington. One thing I remember, though, is I was up for a 13, and he walked my promotion through headquarters.

Some of the people there later told me that was the fastest they've ever seen a promotion being walked through. So, Mr. Fine was disciplined. He was all business. He could be very short, but yet he did a big favor for me by walking my promotion through headquarters.

RT: He obviously held you in high esteem, or he wouldn't have done that. It's good to have a few folks of that stature on your side.

RM: You need those.

RT: —to move ahead, whereas you might otherwise not do so, so quickly.

RM: Yes. So anyway, I was in Dallas for five years, and I did the routine casework, a lot of seizures on pecans because of E. coli. It was basically a food district while I was there. We did a lot of food work.

RT: I suppose that imports from Mexico were—

RM: That brings up a good point. I was in charge of imports there, and I had an import inspector in Houston, Dave Roberts, and then I hired an import inspector for Laredo, who was Jim Rahto, who later became the district director in Minneapolis. I remember hiring Jim Rahto, and I never thought he would leave Laredo, but much to my surprise, he left. He transferred. He did what he had to do as far as transfers are concerned.

I remember a number of occasions visiting all the ports along the border, checking with the port directors for the liaisons.

RT: Didn't you have a person there for a number of years that was sort of the Mexican liaison? I've forgotten his name.

RM: Yes. In fact, Ramon Longeria took my place. When I left Dallas, Ramon took my place. Yes, he became the Mexico liaison, and later he left the agency. I understand he opened up some kind of a consulting firm or something down there.

RT: Yes, and probably did very well.

Let's see, Ray. Did you next move to Seattle?

RM: I applied. Okay, this is interesting, because about 1970 there was a movement to do away with compliance officers. Cliff Shane had done a study someplace, either in Kansas City or Chicago, I don't know where, whereby the supervisor did the work of a compliance officer, and there was a lot of talk to do away with compliance officers. But what did they do? They didn't do that, but they established compliance branches. Heretofore, there were no compliance branches. So the first compliance branches and staffing was done about 1972. There was a vacancy announcement for the directorships of all these different places, and we applied. Then there was some kind of a system whereby the districts were prioritized in the order of their selection of whoever they wanted.

I had applied—gee, I've forgot where I even applied for, but I was to go to Cincinnati. Jim Swanson, whatever he did, got me in Seattle, but I was supposed to go to Cincinnati. Up to this time, there were no compliance branch directors. The position became a 14. So I moved to Seattle as a GS-14 compliance officer, and I spent fifteen years in Seattle as a director of compliance.

RT: You having gone there in 1972.

RM: '72.

RT: During that time, there were a number of rather significant problems. There were some problems in the Alaskan salmon.

RM: Yes. One of the big problems was the canned salmon control plan, and this was a plan whereby a cannery would join, and they all joined, and samples of their production would be sent to Seattle to the National Canners Association for organoleptic examination. Then if it passed, the product could be distributed. If it didn't pass, it had to be reconditioned again. There was a plan and we monitored it. There were a lot of problems with it.

I remember talking to a guy by the name of Denton Sherry, who was the head. Gee, I forgot the name of his company. It may have been Key & Eye Packers, but I'm not quite certain. Denton and I got to be business friends, and he admitted to me that he would buy marginal salmon and can it. I asked him, "Yes, but isn't it costly when you get caught with that bad

salmon?"

He says, "Yes, but if you get away with one," and then he put his hands together over his head and waved his hands in a victory, indicating to me that if you get away with one, you make a lot a lot of money. But we had seized a lot of his production.

RT: You mentioned that the basis of that plan apparently was based on organoleptic exams.

RM: Organoleptic.

RT: Which is, what, smell, taste, appearance, and so on. Were there no laboratory or scientific examination procedures at that point? And if there weren't, were some developed later?

RM: All I remember was that it was all subjective. They had different classes, number three, two, one, of things. The leader in the FDA, the principal organoleptic expert, was a guy by the name of Dick Throm. Dick was very good. I've often kidded, it looked like Dick always had a cold, because he was always sniffing. But Dick was extremely good. As a matter of fact, when there would be a calibration of various people, industry people and association people, nobody would be willing to say anything until after Dick Throm smelled a fish, and then they would make their comments.

RT: Was the National Marine Fisheries Service involved?

RM: At that time, they weren't involved. In those early days, they weren't involved.

RT: I think later, then, there was some differences between FDA and the National Marine Fisheries Service.

RM: They got involved much later, but I'm talking about the early years. It was basically the National Canners Association.

RT: I think Taylor Quinn from the Bureau of Foods was assigned out there to do some investigational work. Was that in the early stages?

RM: That was before I got there. I understood before I got there something happened, but I don't even remember what it was. They did replace the district director, and Taylor Quinn came in as the acting district director. They got rid of everybody in the top level there.

RT: Was that Ken Monfore?

RM: Yes. They got rid of everybody except Bill Kupp. He was the chief inspector, and he survived, but everybody else was replaced. I've forgotten what was the reason for it. It could have been with the canned salmon. I remember Bill used to kid that when all this occurred, he was out of town, and so he escaped it all. Yes, they got rid of everybody except Bill Kupp.

There was a compliance officer who they shipped to New York. I forgot his name. They

thought he was going to quit, but he didn't. He went to New York. He was an older fellow. From what I understood, he had money. He and his wife went to New York, and they lived a good life in New York going to these shows and places and things. But, yes, they got rid of everybody there.

RT: Well, sometimes it didn't work to transfer people. Oftentimes when people were to be transferred to New York, they would leave the agency rather than go there.

[Begin Tape 2, Side A]

RT: Ray, we'll continue. We were talking about your experiences in Seattle District. Do you want to continue with that?

RM: Yes. I recall that when I first arrived in Seattle, I asked several of the investigators if they had many dirty warehouse cases, and they indicated they had not. They indicated that the rodents weren't a problem in Seattle, and the reason why I asked this is because I learned while I was in Dallas how to develop dirty warehouse cases, rodent and insect infestation cases.

Well, as it turned out, later the investigators developed a rodent problem in a warehouse that was about seven acres in size. It was a huge warehouse. We submitted our recommendation, and it was approved. The legal documents were filed with the U.S. attorney, and the marshal's office went to make a seizure, and there was a question as to whether we should seize the stuff in the freezer, and some other questions.

So I remember calling Al Gottlieb, and I described to Al what we found, and I asked him whether we should seize this or seize that. His response to me was, "How much have you seized?"

I said, "Over a million dollars' worth of food."

He said, "Isn't that enough?" Basically, what he said was, "You don't need to seize anything more." So I said yes.

Later, we seized another equally big warehouse, another about a seven-acre warehouse in Seattle. As I recall, the compliance unit in Seattle was quite active. What our modus operandi used to be in those days was to write up the recommendation and do whatever we had to do, and then one of the compliance officers, usually Al Ducenak, would take the red-eye special to headquarters and be at the Center for Foods or the Bureau of Foods, whatever it was called in those days, when they opened in the morning, and we would walk our cases through headquarters. The coordination was so good that at times we could get the whole case approved and walk through headquarters and the legal documents at the U.S. attorney office in Seattle within two days, which in those days was very good. Seattle became very proficient at doing things like that.

While I was there, my regional director was Jim Swanson. What I learned from Jim was that he was remarkable for being able to establish good relationships with headquarters. I learned that you can get a lot of stuff, equipment and resources and things, by making sure you had a good relationship with the people at headquarters.

My first chief inspector I worked with there was Leroy Gomez, and then later he became the district director there. What I remember about Leroy is that he could make a decision very,

very quickly. Right or wrong, he was able to make a decision, and most of his decisions were good decisions. I worked in my career for a number of managers that would procrastinate a long period of time, but Leroy was very, very quick in making decisions. Then Leroy Gomez transferred to Denver district to take Pitt Smith's place. Then Ken Hansen, who had been the laboratory director in Dallas, came to Seattle to be the district director.

My experiences in Seattle were very positive. I learned how to build cases and do things like that. We had a lot of injunctions against bean warehouses, and we became very proficient at developing and recommending injunctions, particularly in bean warehouses.

Then something happened I didn't anticipate. I never thought I would go back to Chicago, although I had started in Chicago. I didn't particularly want to go back to Chicago, but my wife was an only child, and her parents were there and up in their years. So when a vacancy occurred for district director in Chicago, I applied for and got it. I arrived in Chicago July the fifth, 1987. It's easy to remember, because it was the day after July the Fourth.

At the time, they were located in the Post Office Building. The laboratory was situated near Cominsky Park on the South Side, and the office was scheduled to go there also. No sooner had it been announced that I was going to be the new district director in Chicago when I started getting phone calls from people begging me that they didn't want the office to move to where the laboratory was. As a matter of fact, I understand that a few people had quit in anticipation of the move to where the laboratory was on the campus of the Illinois Institute of Technology.

I got to Chicago, and the place was a rat hole. The facilities were in terrible condition. It was located in the Post Office. The Post Office didn't give it any kind of maintenance. Actually some of the ceiling in some of the offices had fallen down. The place had not been painted in

about fifteen years. Half the lights were off because during the [James "Jimmy"] Carter administration there was a movement to conserve electricity. The place was just a complete disaster, and the Post Office didn't want to give us services.

I remember my first talk to the whole group, and I told the people there that they should have gotten Christmas presents from the people in Seattle, because Seattle was getting the money that should have gone to Chicago District for supplies and for other things, and that we were really being cheated, because this was not the way a district should be. I remember I called it a rat hole, and I think I antagonized some people, because I talked very derogatorily about the condition of the office.

As a matter of fact, my son came to visit us, and my son is a fairly decent photographer, so he came to the office and took pictures of the ceiling and the walls and all that. I still have those pictures today.

The first thing we did is, we talked to the Post Office. They cleaned up—as a matter of fact, the floors, the juncture between the walls and the floor looked like a street gutter, there was so much debris and garbage there and things like that.

Well, we talked to the Post Office. They cleaned and they painted the walls, and we had some of the furniture spray-painted, the electro process. Some of the furniture was so bad that the gray paint had been rubbed off and you could see the silver metal below it. So we got that office pretty well cleaned up. It started to look more like an MDA office.

At the time, the regional director was Bill Clark. Shortly thereafter, Bill retired, and Burton Love came in. One of the things that I have to admire Burton for, there was a seminar course called "Investment in Excellence," that was the property of a firm in Seattle. Burton put

all of our 300-plus employees in the Midwest region through the seminar course. We learned how to motivate. We learned how to goal-set. We learned how to listen to our employees. Basically what I learned for the first time in my life was the value of goal setting.

I remember I was in charge of the project, and it cost us about $83,000 in per diem rates and other things to get everybody trained in this thing. Also, in retrospect, it was kind of a bonding thing because terminology in the districts when people talked, they would include some of the terminology we learned from this course. So in many respects, it bonded the employees together.

What I emphasized when I was a district director was regulatory work, because that's what I knew. As a matter of fact, I'm very proud of the fact that recently in the past year, the Gold Sheet had a listing of all of the pharmaceutical injunctions of the FDA during the past year, and about 25 percent of these originated in Chicago District.

Probably the most significant case that I was involved with in Chicago was the injunction case that we took against the firm by the name of Centhion. Centhion was a firm that made various blood products, and previously they were inspected by the Center or the Bureau for Biologics. At that time, Biologics was really not enforcing GMPs of the Food and Drug Act. Chicago District got our foot in the door, and we made an inspection, and we were ready to make an injunction recommendation.

We asked for an ad hoc meeting at headquarters. Now, the people at headquarters did not want an injunction, because basically the firm had been inspected by Biologics for all these years, and as a matter of fact, after the ad hoc meeting was scheduled, I received a call from somebody high up in the organization asking me not to come up with a recommendation at the

ad hoc meeting. I said, "That's not the way I do business. I'm going to have a recommendation. It won't be written, but I'm going to give an oral recommendation."

What we did is one of the compliance officers, George Bailey, and I went to Washington, and we had our four investigators on the case on pigtail back in the district. We had the ad hoc meeting in Washington. There must have been thirty people there. George and I opened the meeting up, indicating what the situation was, and then the investigators individually gave their findings.

I remember one of the people from the Biologics center standing up and saying, "I've heard enough. These folks ought to be enjoined."

Well, they eventually were enjoined, but that resulted in the field taking over the inspections from the Center of Biologics, and it also resulted in team biologics. The way I look upon it is when we first started out, Chicago District was the only unit that wanted an injunction. Everybody was against it, and we prevailed. It's had a tremendous impact on the agency.

The other case that I thought was very significant was the Abbott injunction case. About 1995, we found a problem in the Abbott diagnostic unit. In those days, headquarters wanted us not to go directly with injunctions, but they wanted us to use some non-regulatory means to achieve compliance. So I wrote some kind of a voluntary agreement with Abbott.

In those days, there was a lot of talk about partnering and partnerships. I originally called it a partnership. I got a call from Gary Dykstra telling me not to call it a partnership; we weren't at that stage of the development. So I just termed the thing *agreement*, and this was 1995. But as it turned out, Abbott didn't do the right things, and Chicago District made a recommendation for an injunction. What it turned out then, Abbott was assessed a hundred-

million-dollar disgorgement fee, and as far as I know, at that time that was the first and largest such fee lodged against the pharmaceutical industry. So that was a first.

Since that time, Shearing-Plough has been assessed a 500-million-dollar disgorgement. The *fee* may not be the proper word for what I'm saying, but they had to pay. Shearing-Plough had to pay 500 million dollars because that's the amount of money that they profited by selling a product that was not in compliance with good manufacturing practices. So I kind of think retrospectively—*retro*spectively, not *recto*spectively, the real significant cases I've worked on were quite significant.

Also, I'd like to point out that in 1997 I was asked by the regional director, Susan Setterberg, if I could also serve as acting director of Detroit District. I asked her for how long; she said about three months. As it turned out, it was four years. So for four years, I was the director of Chicago and the acting director for Detroit.

Detroit was kind of in a mess, because of what they had done. They had tried an experiment where they terminated the positions of supervisors and compliance officers, and teams were running the district. Their productivity was extremely low. They had no legal actions.

As a matter of fact, I remember receiving a call in August of 1997 from Jerry Vince, who was the head of ORO, I believe, at the time. Jerry says, "Ray, we've had a meeting with general counsel and others, and it was said that Detroit District hasn't had a seizure for eighteen months. What's going on?" But if you know Jerry, his language is a little more colorful than just saying, "What's going on?"

I said, "Well, Jerry, why don't you ask Brenda Holman," who had been the previous

district director. "She's at the meeting with you."

So my goal in Detroit was to establish the branches again, which I did. We established a compliance branch. We made compliance officers. We made supervisors. We established the traditional organizational structure. We did all of that.

One of the things that I think I'm responsible for is that Detroit District today has one of the nicest offices in the whole country. I remember again, parroting what I said in Chicago when I first got there. I told the people in Detroit, because their office was horrible, that "This place is a pigsty, and my vision is that we have one of the best offices in the whole country. I want everybody to think about what they want," and things like that.

Also, when we were talking to the people from headquarters, we told them that we wanted our office to be better than the one at Orlando, because we heard that Orlando had a freestanding office that was very, very nice. So we said we wanted something better than Orlando. As it turned out, Detroit has a very, very nice office. It's an art deco building, and it's owned by the Stroh's Foundation, the former brewery people, and they have a marvelous office.

RT: Detroit, in the earlier history, wasn't that one of the upgraded districts at one time? I suppose that had already deteriorated since.

RM: Yes. Detroit was formed about 1958.

RT: Wasn't that one of the so-called Rayfield buildings?

RM: Yes, it was. As a matter of fact, the fellow that owned the building was Irv Pollock, and he's—not Irv, but Pollock, Mr. Pollock. I had an opportunity to chitchat with him. He was an old gentleman. He told me that when they were negotiating with the building, he was led to believe that the government was interested in building that building. So he was very generous in his negotiations with FDA. He later found that that wasn't the case, although he laughed about it now. But he leased that building to us for over forty years, and he made his money many, many, many times over.

What happened was, that property where the building was was had been intended to be a casino area. I believe the city had bought all that property for casinos, which is one of the reasons why we had to move out of that area.

I should also say that in the mid-nineties or so, there was a plan to reduce the number of field laboratories. Detroit laboratory was scheduled to close about 2000, and the morale of the laboratory staff was very low because everybody thought the lab would close. I can recall coming back, I believe it was in '98 or so, from a morning of looking at potential sites for the office, not for the laboratory, because the laboratory was scheduled to close. I walked into the FDA office in Detroit, and I was told that Senator Abrams [phonetic] was going to have a press conference in front of the building to complain about the closure of the laboratory, and he wanted to talk to me. Mentally, I said, "Oh—*blank*—this is all I need today."

As it turned out, he had a press conference in front of the building, and said that he was going to take steps to effect our appropriation so FDA would not use any of the money to close the laboratory. Later he came to my office, and he was a very nice man. He said, "Well, how does it look?"

I said, “Senator, I understand, but your facts are wrong.”

He gave facts about closing the building and what this office does. He said to me, “That doesn’t matter. I’m representing constituents.” Pointblank he said, “It doesn’t matter what the facts are. I’m protecting my constituents.” As it turned out, what he did was to put a rider on an appropriations bill that none of the money could be used to close the laboratory, and he actually saved the laboratory. But it was scheduled to be closed. Chicago closed in ’97.

RT: Is the lab still in operation?

RM: Still there, a beautiful laboratory. What happened was, as I recall, while I was at one of the universities in Detroit talking to the chemistry department, we learned of this laboratory and space in the Stroh’s brewery building. We went there, and found they have a very, very nice laboratory which was built about 1985, state of the art.

Susan Setterberg, the regional director, later saw it, and she said to me, “There are features in that laboratory that we’re just putting in our FDA laboratories today.”

I said, “Yes, because that was a state-of-the-art laboratory. They spared no money.” Detroit District’s got a wonderful laboratory. It’s on the sixth floor, and the office is on the fifth floor.

RT: The agency has gotten into laboratory specialization. Is Detroit a specialized lab?

RM: When I left, it was not a specialized laboratory. It was basically doing import work, and it

was doing some samples for Philadelphia District, I believe it had to do with ANDAs [Abbreviated New Drug Applications] and NDAs [New Drug Applications] or something. But it wasn't one of the nationally recognized laboratories.

RT: Does most of the import work relate to Canadian imports?

RM: Yes, but, you see, a lot of the Canadian imports could be from India and other places. What they could do is come in through one of the seaports in Canada and then shift across Canada, and then be entered through Detroit. Detroit's a major port of entry.

RT: Would there be some favorable outcome of doing that rather than, for example, importing in Seattle or somewhere out on the coast, either coast? Is there an advantage to importers to come to Detroit?

RM: I don't know, but I do remember seeing things from India coming through the port there. The port is extremely busy.

RT: During this dual management responsibility in both Chicago and Detroit, did you physically have to spend a lot of time at Detroit?

RM: What I did was to try to go to Detroit every other week. There was about a 6:15 a.m. Southwest [Airlines] plane from Midway Airport, and I would be on that plane. I'd try to do it

about every other Monday. Then I would try to be in Detroit for several days, but sometimes I wasn't able to do it. In retrospect, what made Detroit difficult was that I was trying to change the culture there from the team culture. I was trying to establish a different organizational structure. The employee's union was very active in Detroit. The laboratory was going to be closed, so we had a morale problem. We had to find a new office and then, subsequently, a new laboratory. When I look back, I think to myself, "How in the hell did I ever do that?"

RT: Was the union opposed to the changes from the team approach? Were they involved?

RM: The union wasn't so much involved with that, but the union was more involved with hours. The union became very, very active in Detroit. In Chicago, there was a union, too, but the union was more passive there. In Detroit, it was almost on a confrontational basis in Detroit, and it [tape malfunction] stays.

RT: That union, was that a union of federal employees?

RM: The union was in those days the National Treasury Employee Union [NTEU], which had an agreement with the American Federation of Government Employees [AFGE] to take over, so both Chicago and Detroit then were NTEU, and NTEU was a more militant union then AFGE.

It's just amazing, I think, that we were able to do the things in Detroit. In a way, it's a reflection—there were some good people. One of the things I must admire about Detroit, I was a stranger when I came in, is that I made all kinds of changes, and people cooperated pretty much

with me. Jack Dempster, who was the chief inspector there, wanted to be the district director, and I don't blame him. But yet he never really sandbagged me.

[Begin Tape 2, Side B]

RM: I think, as I said before, the people in Detroit were a good group. They really went through hell because basically they were going to close.

Oh, by the way, I didn't tell you this. In about '97, they were thinking of closing the district and merging the districts, that is, merging Chicago and Michigan and Indiana and Cincinnati. So those people in Detroit went through an emotional roller coaster about closing the district and merging it with other districts, plus closing the laboratory. It was very traumatic, but as far as I know, they're all doing very well today.

RT: Did that anxiety result in requests for transfers to other locations?

RM: Not that much. I think a lot of the people had been there quite a while. They liked living in Detroit, and it wasn't that kind of a situation.

RT: As I recall, the Detroit location at one time was in kind of a rough environment, and a few of the people were mugged going from work and so on. Gene Spivak, I think, was one of those.

RM: As a matter of fact, yes. When they had the riots in Detroit, I remember there were

National Guardsmen on duty.

This brings up a point about the Chicago laboratory that I forgot. I think this is important. As I previously indicated, when I got the job in Chicago as district director, I got a number of phone calls from people begging me not to move the laboratory. They didn't want to move the office to where the laboratory was. I later found out that thirteen people in that laboratory were mugged, and apparently, headquarters didn't know about it.

Catherine Chung, who was one of the supervisors, was mugged twice. Another guy, when he was mugged, the muggers lifted him by his ankles and was shaking him to get coins. He left real quick, and he went to L.A. Paul Smith, who was a chemist, went to the local McDonald's, and he was handing a bill to the cashier for his hamburger or whatever. Somebody ran by him and grabbed the money out of his hand and went out the door. Paul chased the guy, and the guy stopped, turned around, and says, "Come on." He was waiting for Paul, and so Paul forgot about his money. But that laboratory was really bad.

There was a guy by the name of Voyce Whitley. Now, Voyce was in charge of real estate somehow or other. And when he found out that I did not want to move the office to where the laboratory was, he called me, and was yelling at me that I ruined the relationship with GSA because "I don't want to move, and I've got to move, and it's written in granite," and all these other things. I've never met the guy. I've heard of him. And he was yelling over the telephone at me.

Then later, I got a call from the ACRA [Associate Commissioner for Regulatory Affairs], and I don't remember who it was any longer. It may have been John Taylor. I was told, "Don't worry. Keep a low profile on the move, and do what you want to do." Again, I've forgot who

that was. I know it wasn't Chesmore.

RT: Might have been John.

RM: It could have been John. So that gave me a signal that what I was doing was the right thing.

RT: Sometimes from the abstract in Washington, it's not the same as having to deal with your own staff at your location.

RM: For whatever reason, the district did not tell headquarters about the thirteen muggings, because Voyce didn't know about the thirteen muggings. Then later he came to Chicago, and I asked why he was there. I was told, "If you have a need to know, they'll tell you."

RT: Voyce, I think, was involved in EEO work for a time, so when he found out those were the circumstances, he might have had a different perspective, too.

RM: Yes.

RT: I think you mentioned in some notes that I had, that you were polygraphed by the FBI during the generic drug problems.

RM: Oh, yes. That was an interesting. Again, looking back, I say to myself, "How do I live through all that?"

What happened was, there was a firm by the name of Alar Laboratories. Before I got to Chicago, the district [tape malfunction] injunction recommendation, and it was disapproved. Then later, when I was a district director there, we made another injunction recommendation, and I remember it was disapproved. I think it was disapproved because the Center for Drugs held it so long that it got old and it was disapproved. I remember telling, I believe it was Nick Buhay. Maybe you know Nick Buhay?

RT: No.

RM: And I believe it was Ed Fry who said, "They're going to have to answer to somebody for disapproving this injunction." It was a real, real sloppy operation.

Well, then during the generic drug scandal, the subject of Alar Laboratories came up, and a guy by the name of David Nelson, who was a chief investigator for Congressman [John D.] Dingell of Michigan, came to Chicago, and he's asking questions about Alar Laboratories. The documents associated with that first injunction could not be found, so one morning Burton Love, the regional director, came to the district office and impounded all of the Alar records, and he locked them in a vault that we had, all the Alar records.

Nelson thought that I was protecting somebody at Washington, D.C., and [tape malfunction] polygraphed by the FBI, and they wanted to know what happened to those early documents disapproving the injunction case. Well, I was polygraphed, and after the first session,

we took a break, and the polygrapher said, “Well, you’re not doing too well.”

When we started the second session, he said, “Do you think you’re going to flunk this test?”

I said, “You’re damned right I am.” I really had visions of my career going down the tube.

But what he told me was sometimes highly ethical people have problem passing this because you’re asked questions like, “Have you ever stolen from the government?” Of course you’ve taken paper and pens and things. I think of that as it’s not my property; it’s stealing. But apparently I got by, but I was scared.

Then years later, I think it was pretty close to my retirement, one of the compliance officers told me that later, they found these documents had fallen down behind a file someplace. They had found them, but everybody was too afraid to tell me that they’d found them.

Now, a number of attorneys since then, including George Burditt and a lot of other people, have told me that I was foolish to allow myself to be polygraphed, because test results sometimes depend upon the experience and qualifications of the polygrapher. My response to that was, “Well, I had nothing to hide,” which I didn’t. But maybe, in retrospect, it may not have been too smart for me to agree to be polygraphed.

But then, again, I said this before to you, sometimes I look back and I think, “How and the heck did I ever live through that?” Because it was a lot of pressure.

RT: Yes, it certainly was in some of those situations.

RM: The very fact that Burton Love embargoed everything, quarantined everything was—and Burton, you've got to know Burton. Burton came in there with a very serious, very stern look on his face, and he embargoes everything, locks everything up.

Later I testified on the congressional subcommittee, and I remember Congressman Dingell introducing us, and he said, "And these gentlemen wear the white hats. They're the best in the business." I looked at the congressional record afterwards to find out, and that was deleted out. It wasn't in there. [Laughter]

RT: Over this long and interesting career, Ray, you've worked under many managers, many commissioners. Do you have any impressions regarding any of the upper-management people in terms of how they may have contributed or maybe even complicated the regulatory work?

RM: The one I liked the best was Frank [E.] Young. As a matter of fact, Frank Young gave me a picture of himself that he engraved, and I had it in my wall. One of the cleaning guys came in one day in Chicago and said, "Oh, you've got a picture of you." He thought that Frank Young's picture was me.

Then I remember walking into an auditorium once, and I think it was Jim Benson, and I believe he was talking about the commissioner. I walked through the door, and he said, "And here he is now." [Laughs]

RT: There may be a little resemblance.

RM: But from a distance, probably.

RT: Yes.

RM: What I liked about Dr. Young was that he had a good appreciation of the field, and I remember he would come to a district like Chicago, and would have his little case full of the little plaques that he gave out, the little medallions that he gave out for the people. As far as I was concerned, of the commissioners that I've known, he was probably the most pro-field commissioner.

I really didn't deal with or know some of the commissioners that well. Some of them I wondered where do they come from? I mean, we had commissioners who would accept free rides on corporate airplanes and things. You wonder, where are these guys—what are they thinking about? Then there are commissioners who it appears like they used their position to get ahead to get better jobs.

RT: Since the days of the career commissioner, there's certainly been very frequent turnover in leadership. There may be some advantages of that, but on the other side, if a commissioner gets something going, he is likely not around long enough to either get full credit or full discredit because he's gone somewhere else.

RM: Yes. I liked Dr. [Jane E.] Henney a lot, too. She was a very nice person.

RT: We've covered lots of ground. Is there anything you would care to summarize?

RM: Yes, what I'd like to say is I talked about some of the district directors. I mentioned Sam Fine and Jim Swanson. I used to call Burton Love the Lee Iacocca of FDA. I thought Burton was a very shrewd regional director, and he is my idea of what a good corporate manager would be like. He was all business, and he knew all the state people. He made it a point to know all the state people within his region, which is quite an accomplishment. But of everybody I worked for, the regional directors, I would think that Sam Fine and Jim Swanson and Burton Love were probably the most memorable. They all had their different areas of specialties, so to speak. Fine was regulatory. Swanson was relationships with headquarters. Burton was the overall firm manager.

RT: Was there any particular basis for your decision to leave the agency when you did, or had you just had enough?

RM: Well, I had forty-five years in the government, and it was probably time. Financially, it was the right thing to do.

RT: Since you're doing work for the private sector, does the agency look different to you today?

RM: Yes. I'm on the other side now. I once told one of my colleagues that I'd like to go back to FDA and be a regional or a district director with what I know now. I look upon things from

the other side a little better, and I have difficulty understanding sometimes what the agency's doing.

Right now I'm having difficulty understanding why there aren't more injunctions, but it may be a political decision not to take injunctions. I know some of the industry secrets now that I didn't know before, so I do things in terms of what the agency was in January of 2002 and what I've learned in eighteen months from the industry, and there's things I just don't understand.

RT: Ray, I want to express appreciation for your participating in the oral history program. Your experiences, I think, will be of interest to researchers and historians looking at the oral history record in addition to what's been written about the agency, so thank you very much.

RM: You're welcome. It was a pleasure.

[End of interview]