

History

of the

U. S. Food and Drug Administration

Interviewee: Burton I. Love

Interviewer: Ronald T. Ottes
and
Robert A. Tucker

Date: September 11, 1996

Place: Washington, D.C.

INTRODUCTION

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

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INTERVIEW INDEX

General Topic of Interview: History of the Food & Drug Administration

Date: September 11, 1996 Place: Washington, D.C.

Interviewee(s): Burton I. Love

Address: [REDACTED]

Last FDA Position: Regional Food & Drug Director, Midwest Region

FDA Service Dates: From 1/16/66 to 7/3/96

Interviewer(s): Ronald T. Ottens & Robert A. Tucker

Address: U.S. Food & Drug Administration, Rockville, MD 20857

Number of tapes: 3

Length: 115 minutes

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RT: This is another in the series of the FDA oral interviews with former FDA personnel. Today, September 11, 1996, we're interviewing Mr. Burton I. Love, former Regional Food and Drug director, Midwest Region at Chicago. The interview is being conducted at the Washington Sheraton Hotel, and the persons present in addition to Mr. Love are Mr. Ronald Ottes and Robert Tucker.

As we begin, Burton, we like to start with a brief autobiography, picking it up where you were born, educated, perhaps any significant work experience prior to your joining the Food and Drug Administration. So would you lead us into it in that way.

BL: Sure. I'd be glad to.

I was born in Fort Worth, Texas, in 1941, June 4, 1941. My parents moved from Fort Worth to Dallas in 1950, I believe, and I went to school all of my early education in the Oakcliff area of Dallas. Went to an elementary school interestingly called Lida Hooe after an educator in Dallas, and Greiner Junior High School, and Sunset High School, unfortunately of recent drive-by shooting fame in the Dallas area.

In my senior year of high school . . . Let me back . . . Let me back up a little bit. In 1958, my mother passed away in September of that year. My wife and I got married in that same month, a number of weeks later with the intention of taking care of my father. My father passed away the following year. I graduated from Sunset High School in 1959, and my wife and I continued to live in the area while she finished high school, and I went on to my first year of college at what was then Arlington State College.

Very candidly, I didn't focus very well in the first year of college, as a lot of students didn't, and I entered the navy on active duty in 1960. My wife and I moved to the New York City area, and I served for two years, nine months, and twenty-eight days at what was then Floyd Bennett Field, the naval air station in New York. We lived in the Brooklyn area, and then we lived in Long Island.

While I was there, I was a hospital corpsman and worked part-time as a medical technician at Idlewild Airport. So I'd work during the days as a hospital corpsman for the navy, and then midnight to seven in the morning, I'd work at the airport on alternate days, and then go to college at Long Island University on alternate days. Sometimes I would wake up on the Belt Parkway in New York and have no clue where I was. I guess the car knew where I was. No, but I didn't have anybody ever hit me, so I got very fortunate.

But, anyway, when I concluded my active duty, I got out of the navy, honorable . . . Well, honorable discharge later because I was in the reserve and had a reserve commitment to meet, but out of the navy to return to school, and I returned to what by then was the University of Texas at Arlington, same school, different name. My initial intent was to finish pre-med work, but while I was going to school I decided that really wasn't what I wanted to do. I concentrated on biology. And while I was going to school, I worked two places, one at a dairy as a lab technician running butter fat samples and things like that, and going to school at the same time. Then I got a job with the U.S. Post Office, and I worked at the post office from four in the evening till midnight, and then went to school during the day.

I graduated in the fall of 1965, you know, during a half semester, so I got my degree, actually it was about a week after I started with Food and Drug Administration in 1966. I had already completed all the requirements, but in order to walk across the stage, that ceremony didn't happen until '66. But I started with FDA--actually transferred from the post office, because I was working full-time for the post office as I went to school--transferred to FDA.

RT: Do you remember what date that was at in 1966?

BL: It was January 16, 1966, when I started with the agency. And I started in Dallas, and some people would ask, "Well, why did you start with Food and Drug Administration?" Well, I took the examination for federal service, and the Food and

Drug Administration and the Social Security Administration were the two folks that called on me. I looked at what they were both doing, and concluded that the Food and Drug Administration had a whole lot more to do with what I had been studying and working on, and it sounded like a challenging job. So just a little background there.

But I started in Dallas. I was in Dallas as an investigator from 1966, traveling out of Dallas, until the latter part of 1967, and I transferred to Oklahoma City as the second resident investigator there.

RO: A couple of questions, Burton. When you joined Dallas, who was the district director and who was your chief inspector?

BL: Sam Fine was the district director, the commander himself, and Jim Anderson was the director of investigations. Boland Sheppard was my supervisor and was the person who visited and recruited me. So I've always had a special fondness for Boland. Tucker Lightfoot was one of the supervisors.

RO: What kind of training did they give you when you first entered?

BL: Well, they gave me a whole lot of manuals. It was principally on-the-job training. I remember one of my first opportunities to go out in the field. The investigator that I went with--we went to Fort Worth to do some kind of a, I believe, it was recall check--but the investigator, who was a senior investigator, had left his credentials. He had no credentials. So we used my credentials to complete the task. But it was principally on-the-job training.

I was fortunate during that first year to get to go to one of the first salmonella training courses in Minneapolis. Ken Lennington was principal mover on that and was actually at the course and helped with some of the presentations.

RO: What were the principal investigations that you were involved in? You were only in Dallas for how long?

BL: I was only in Dallas about one and a half years. I had a fair mix, but in Dallas at that time, principal obligation was food, and that was what I did a large number of things. I had a real neat opportunity . . . Well, I wasn't there but that short period of time. I was very fortunate, because I got a lot of experience during that short period of time in Dallas.

I made a follow-up inspection of a firm. I believe it was in Dennison, because it was very close to the border, a 7-Up plant. This 7-Up plant had had sanitation problems, and they had already been prosecuted once, so they were waiting to have real problems. And sure enough, they did. They had not done sufficient repair and hadn't given sufficient attention to cleaning their bottles, and, you know, at that time that was a big problem, and they were bottling crap. In terms of establishing interstate commerce, I mean, all you had to do was drive twenty miles up the road, you were over the border, and you collected samples. And I had the opportunity to testify before a grand jury, since it was a second prosecution (a felony), and we had clear evidence. And for a young investigator to have an opportunity to testify before a grand jury, that was pretty impressive to me.

John Rynd was the compliance officer on that case. And, of course, they were a little nervous about a young investigator who had only been in about a year or so testifying in this grand jury presentation, but it worked out fine. They were successfully prosecuted.

Then as I said, I had the opportunity . . . Well, in answer to your question, it was primarily foods. I'm remembering some of these neat experiences in the Texas and Oklahoma area.

RO: Pretty much sanitation.

BL: Oh, yes, absolutely. One of the inspections, I'll never, ever forget this. I was taking a trainee . . . I mean, I was the only new hire at the time. There were some people that came in six to eight months after I did. Well, I trained some of those folks. If you want to call it training. I mean, I guess it's the blind leading the blind.

But I took a young fellow, and I don't remember his name now, but we were out in west Texas at a cottonseed oil mill, and we had done the inspection of the auger pit, and we had found sheep droppings, because they'd allowed the sheep to wander through the auger pit. Well, we thought that was suspicious. We'd seen a few rat droppings, but just a few, and for whatever reason, we didn't have our camera. So I was going to go back to the car for a camera which was all the way at the other end of the seed house. But what I was going to do was come in the door of the other end of the seed house and meet them in the pit. Well, I knew that we had something when I opened the door and a rat, which at the time I thought was bigger than I, jumped right in front of me. I mean, there was no more than six inches from my face, jumped off the belt into a crack in the side of the building. I thought, "Uh-oh."

Well, we proceeded with checking the pit, and then we began to work our way to the head house. And when . . . And my skin still crawls when I remember this, because when we got to the head house . . . We'd found a couple of dead rats on our way up the landing, but when we got to the top, I just stood there frozen, because it was the middle of the day, and the rats were literally playing and jumping and running along the cables and diving into the seed, and these were not tiny field mice. These were the big rats. That resulted in a seizure of their cottonseed oil, because they had no earthly way of separating any of the material that went into the presses and what have you. But I still don't want to go into seedhouses, because, you know, rats aren't my favorite thing or anybody else's favorite thing either.

RT: Was there any testing of the product, or was it primarily inspectional evidence per se in this case that was used in trying to determine if the filth was eliminated by the manufacturing process?

BL: There are some indicators, and I believe that they did do some testing. But, yes, primarily, you didn't really have to. And, frankly, this was one of those interesting things where you knew you had a problem, you collected the samples, you put all your stuff together, and you send it in, and then you went on to something else.

As a matter of fact, Owen Lamb called me up on a road trip and said, "Oh, you know that seed mill you all did? We seized their oil in a tanker truck that you documented, you know, several thousand miles down the road." And that was all I knew that happened to it. So very candidly I really can't tell you whether they tested it or not. I don't see any reason that they would have to, because we documented the fact that there was no way to remove anything. So whatever could get through the press was there.

That was just, you know, one of many experiences. I had an experience, I took a trainee out in east Texas. You hate these kinds of experiences, but I took a trainee out to do a warehouse in east Texas--actually I think it was Tyler--and there was some minor rodent filth in this place, and we were taking pictures, and we were taking pictures all over the place. Well, you know the answer to this story. You get back, "Gee, this camera's not supposed to take that many pictures." No film in the camera.

Oh, I guess everybody has some of those. Luckily the public health was not at risk, and we were able to get the place to clean it up and collect some good samples, and those kinds of things. But my, how embarrassing.

RO: This was all still while you were in Dallas before you went to Oklahoma City?

BL: Yes, it sure was. It sure was.

RT: What were some of the main activities or things of noncompliance that you experienced in the resident post? In the resident post, you were able to do quite a bit more on your own plan, weren't you?

BL: Yes, yes. It was still sanitation. As I've told several people, I was in Oklahoma nine months for what seemed like ten years. There's not a lot of complex work in Oklahoma. At least at the time. I don't want to put Oklahoma down too badly, but there just were not a whole lot of things to do. It's a broad spectrum of what I would call minor responsibilities. I don't recall that I had a prosecution. There were some minor seizures and things like that.

I had a neat opportunity when I went to Oklahoma City because Bill Lang, the senior resident, was gone a majority of the time that I was there. So I . . . Bill was a trip, an absolute trip. I mean, there are stories to tell about Bill. But that meant that I got to deal with Jim Anderson directly as the DIB, because Jim supervised the resident post directly. I guess you call it supervision. I mean, you really were not expected to call very often, and it better be important if you called. But I did have the opportunity to chat with him, and I had contact, and again, here by serendipity, I had an opportunity to have some experiences that other people didn't have. The second person at a resident post is not supposed to get the experience of being the first person in the resident post.

RT: Now, as a resident, did you have then some liaison with state officials in Oklahoma?

BL: Oh, absolutely. Absolutely. I did some work with the state. Well, I did plenty of medicated feed firms in the beautiful state of Oklahoma. I suspect I may have inspected one of the first medicated feed operations that was attempting to

computerize. Now keep in mind, we're talking 1968, 1969. I mean, I couldn't spell computer, but they were automating, and looking back you would have to call it a type of computerization. I worked directly with both the folks in the Health Department and in the Department of Agriculture in Oklahoma. I was just trying to think . . .

RT: Well, let's see. Was it Lloyd Parham. Was he there at that time?

BL: I'm not sure.

RT: Burley Walker, I think, was an earlier official, but he would have been gone by that time, I think.

BL: Who?

RT: Burley Walker. But I think he was gone.

BL: No, he wasn't . . . No. It may have been Parham. I don't . . . I can't say that to a certainty. But keep in mind, I mean, nine months is not a long time to stay anywhere. And then a year and a half, about a year and a half in Dallas, which wasn't a long time to stay there.

But these serendipitous kinds of things led Jim Anderson to believe that I might be the right person for a resident post that they were going to open up in Fairmont, West Virginia. And it was a one-man post. Turns out it had one principal industry, a drug firm. Now bear in mind, I had very little experience as a drug investigator, and that turned out to be no problem. It also turned out this firm now has a really interesting history. It was Milan Pharmaceuticals. So I had the opportunity in 1969 to open and provide the work for a one-man resident post in beautiful Fairmont, West Virginia. It would not have been in Fairmont, except they

couldn't get office space in Morgantown, because Morgantown was the location of Milan Pharmaceuticals.

Milan was really a unique firm. It was a wonderful experience for me. They're one of the few companies in the world that made their own soft gelatin capsules, pretty exotic equipment, and to further complicate their life, they made a fair range of antibiotics. They had penicillin products, and their problem was they made a very large range of other drug products, and it's very hard to control when you make a lot of different products.

RO: They were primarily a generic manufacturer.

BL: Absolutely, absolutely. One of the interesting things that we were aware of and involved with, they decided that they could beat Eli Lilly on their patents for Darvon. So they began to make what amounted to Darvon, including the pink and gray capsules. Now, as you might imagine, Eli Lilly took significant exception to that, and the U.S. attorney in . . . Actually I'm trying to think, was it . . . ? That had to be northern West Virginia. (The U.S. attorney) thought that that was not a good thing to do either, so we enjoined them. Now, the interesting part of this is I've noted within the last couple of years, guess who makes Eli Lilly's Darvon? Milan Pharmaceutical makes it for them, which I think is just fascinating.

But, anyway, that was the primary industry that I worked on. Now, I covered the northern half of West Virginia and several counties in Maryland. Obviously, there were a few food firms, warehouses, distribution firms, small manufacturers, things like that. I had an opportunity to work with the state, provide some training courses for them. I was just trying to think. I worked . . . At that time, Glenn Dennis was my supervisor, and I was trying to remember . . . This is terrible. I don't remember the name of the resident. Joe Pendergast. I just thought of it. Joe Pendergast was the resident in Charleston. So he and I were partners in crime in terms of working with the state and providing training for them.

RO: At one point in time, there was a suspicion that Milan was connected with the underworld. Were you there at that time?

BL: Yes. I was there when there was that suspicion. The suspicion was that the connection was money, that the . . . I mean, because they had no problem with resources. They needed money, (snaps fingers) they had money. If they needed equipment, they had equipment. So there was some speculation that perhaps that was mafia money, and there were some folks that were associated with them that might in fact have seemed to have some of those kinds of connections. But we were never asked, and certainly I was never asked to pursue that. Those were simply allegations or rumors or those kinds of things.

RT: Was Merv Shumate . . . ? At one time he was over at Charleston. Did he precede Pendergast there? I thought maybe he was the first resident in West Virginia.

BL: I believe that he did. I believe that he did. Now, Joe was there with Willie Bryant when I first got there.

RT: Because I know Merv one time mentioned that he got into some sort of drug surveillance activities there that were kind of new to him at the time, too.

BL: Right.

RO: Most of it was OTC (over-the-counter), I guess.

RT: Yes, it was.

BL: Yes, yes, yes. I did very little of the undercover drug work or that sort of thing. When I came into the agency, BDAC (Bureau of Drug Abuse Control) was beginning to split off. As a matter of fact, some of the people that came in about six months after I did actually went with BDAC, and we all had a decision, did we want to do that sort of thing, and I thought, no, it didn't make sense to me. I thought, you know, there were the stories. These folks carried no firearms and no protection and were in situations where everybody else was carrying weapons and what have you. It didn't seem to me like the odds were real good there, so . . . Anyway, I never looked back. I never had any reservations about that whatsoever.

RT: You were really supervised out of Baltimore then, were you?

BL: Yes, yes. Bob Rice was my first supervisor, Glenn Dennis was my second supervisor, and they were in Baltimore. I was in Fairmont two years, and then transferred on to beautiful Falls Church, Virginia, for what amounts to the Washington resident post. I was the senior resident there from '70 to '72, and then I was selected as supervisor in 1972, and I supervised people in the Washington resident post and all the other resident posts in Virginia.

RT: When you came, you were a single assignee as resident inspector?

BL: No, no, not in the Washington resident post. The Washington resident post, wherever its location, had been around for quite some time, and there were I want to say three or four other people there. But, you know, it was my responsibility to work with the D.C. government and the local Virginia people, those kinds of things.

RT: Were there any particular experiences in working in Falls Church that are noteworthy in your recollection?

BL: The principal work it turned out--and I was aware of this, but it was more significant than I thought--it was consumer complaints. The people in the Washington area are obviously sensitive to what's going as consumers, and if anybody's going to complain, they do. I and John Dietrick, who was one of the investigators there, were written up in I don't know, I think it was *The National Enquirer* or one of those kinds of papers. John, who's quite slim, was described kind of negatively in the article because he was slim and the author of the article said something like, "Well, this person doesn't appear to be eating at all, so what does that say about the food supply?" It was an insect in green beans kind of complaint follow up. But we did just an incredible amount of complaint follow up. It was an effort to do some inspections. I did some.

RO: There was always a problem with the Washington resident post, being an extension of the agency. Instead of getting assignments directly out of Baltimore, it was usually out of the bureaus, or the Office of the Commissioner or whatever. Did you have problems with that?

BL: I wouldn't characterize it as problems. We had some assignments, but we had been sensitized to that before I got there to make sure and maintain that balance. Now, at . . . You just reminded me, I did an investigation and coordinated directly with headquarters on a product called Isoniazid. I was trying to remember what in the world were the circumstances. There were problems with the product, and I believe that there were some injuries, and we did some investigation with that. But I worked directly with Curtis Noah at the time to pull that information together so that they could make some decisions directly in headquarters about what to do about the problem.

I don't recall that being a major problem. By that time I think people were a bit more sensitized. Of course, I always knew that if somebody from headquarters

called and wanted me to do something, I was going to chat with the folks that I worked with first, because they were the ones that were responsible for scheduling my time and the time of the other folks at the resident post. So I think we had that pretty well ironed out. I think that probably was more of a problem when the office was right in downtown D.C. and so were parts of FDA. That's, you know, when Taylor Quinn was the resident in D.C. I think that may have been more of a problem then, because we, being out in the suburbs, may have helped it a little bit.

Probably . . . I was there from 1970 to 1974. Probably one of the nicest things that happened to me is I had the opportunity as a supervisor to serve 30-day intergovernmental detail with the State of Virginia, and I want to say . . . Well, I can tell you whenever Spiro Agnew was ridden out of office, that's when I was on that detail. I think that that was '74. During that period of time, just to make sure that I wasn't playing in the street or getting into any real trouble, I was going to GWU (George Washington University) . . .

(Interruption)

BL: . . . where I was working on my master's degree at GW University. The reason I remember that is because I got that in 1974. A whole bunch of things happened in 1974. But the other point was the detail to the State of Virginia. As the supervisor I had the opportunity to meet and work with a significant number of state folks.

RT: Who was in charge of the Virginia program at that time? Do you recall?

BL: Yes, I do. He passed away and he worked for Gerbers.

RT: Yes. That was . . . That was Farmer was it?

BL: No, no. No. It'll probably . . .

RT: Ray Van Huss.

BL: Yes, Ray Van Huss. Ray was in charge of food inspections at the time. I think that his right-hand person was Don Foley. I might have that name wrong. Don't bank on that. Art Dell 'Aria was a supervisor at the time. Of course, Art recently headed up the program and has since retired. But for sure, Ray Van Huss. Tom Price was the one that engineered this assignment and was encouraging that kind of intergovernmental exchange because he was in charge of the federal/state program for the region.

RT: Do you think that may have helped you later? Because your career certainly showed an interest and a participation in intergovernmental affairs later on.

BL: Absolutely, absolutely. I would have to credit Tom Price with getting me interested in and aware of the activities of state folks and teaching me to value what they did. Because as you all know, there has been, and frankly there still is a bit of elitism within the Food and Drug Administration about what we do and the suggestion that states can't do or are unable to do the same things, which is not true, and I never bought into that. But there's no question that that period of time and that experience helped me better appreciate the values and the qualities of the state folks. And, of course, Tom encouraged me to begin to participate in the Central States Association of Food and Drug Officials, CASA, and I had many wonderful experiences there.

RT: That's just . . . Correction, Central Atlantic States Association, as you'll later . . .

BL: Yes, I'm sorry. What did I say? Central States?

RT: Central States and you did work in the Midwest later on.

BL: That's right. That's right. And then we changed the name out there. You're absolutely right. Central Atlantic States Association.

Now chronologically we're in 1974. In addition to some of these other things that were happening in '74, I was selected for the first class of the mid-level (training) program. This was. . . . They had had the intern program for some time--the management intern program--but this was a program designed for elevens, twelves, and thirteens to provide management on science experience There were actually two tracks: there was a scientific track and a management track, and as a supervisor, I chose the management track. It was an absolutely wonderful experience. They have continued the program. They have now changed the name and made some modifications, but it has continued over the years, and I think the success rate of the people coming out of that program is pretty high.

But that I was in that program from 1974 to 1975, and Mr. Ottes here was kind enough to find me a job in the Field Compliance Branch.

RT: Was Mr. Ottes the mentor or manager or student trainee liaison person when you were in the program?

BL: You know, I know that he was very active. I don't remember the

RO: You're right. In fact, the first two mid-level programs.

BL: Right. Well, I thought I knew that you were actively involved. The precise role, if that were a test, I would fail that, because I just knew that you were a supporter and actively involved. This is kind of an interesting interview, because

you were my mentor for a significant period of time, absolutely, and were very helpful to me.

But, anyway, I was in the Field Compliance Branch as a, I guess the title was associate director or whatever, which everybody had to have some kind of title, but I handled drugs and veterinary medicine and the other duties were distributed to other folks. Unfortunately, I got to handle FOI (Freedom of Information). What a shock that was. Because as you can imagine, purging FOI documents, and I got to do some of that, actually because in a controversial legal case where you're worrying about discovery verses FOI and things, nobody else would do it. So I ended up . . . And I don't remember what the case was. I just remember it was a king-sized pain in the whatever, and it took a significant amount of time.

That same time, I guess my principal responsibility was coordinating the development and clearance and content and what have you of compliance programs, and that was certainly fun and a challenge. Pat Ryan was the director of that group. Remle Grove was in there working on recalls and those kinds of things. Chuck Everline was a part of that group. I'm trying to figure the other folks' names. I'll probably come up with a name at a time when it doesn't matter to anybody. But, you know, I'm sure that first name . . . I can see this fellow, because he was working with devices. His first name was Charlie, a rather large fellow, real good natured, but he made a career of commenting on programs about devices.

RO: It wasn't Karademos, was it?

BL: No, no. But, anyway, I'm sure you'll get other information from other people on things like that. But candidly, what I was doing when I was kind of in a holding pattern, because I really wanted to return to the field. The target that I had set for myself was director of investigations. That was what I wanted to do and that was what I wanted to be. I first competed for a position in Kansas City, and luckily they didn't select me because I was too much of a smart aleck. I guess the fortunate thing

was they actually . . . They didn't use that term, but they told me, they gave me feedback, and that's probably one of the best things anybody could do. They told me exactly what they did and why.

RO: Who was the interviewer?

BL: Lloyd Claiborne and Jim Adamson. Clearly they didn't like my attitude or my approach or whatever; I don't know what it was. But it was excellent feedback. They told me that and that was super. Then I had the opportunity to compete for the position in Buffalo, New York, and I was interviewed by Pitt.

RT: Pitt Smith, yes.

BL: I'm trying to remember who was before Caesar Roy with the regional director.

RT: Clifford Shane.

BL: Cliff. Clifford and Pitt interviewed me, and certainly for my betterment, I was selected and spent nine years in beautiful Buffalo. Nice place. I have very fond memories. As a matter of fact, the first place I met the founder of this organization--they're having their meeting here in the hotel where we're having this interview--was in Buffalo, New York. He still lives . . . It's Richard Greco. He still lives in the Buffalo area, works as a consultant. At the time I was there, he worked for a firm called Mogul. Just like you think about somebody representing themselves as a mogul, that was the name of the firm. They were into biologics and some of the more exotic drug manufacturing products.

RT: Now the firm or the organization that you referred to as meeting here . . .

BL: Regulatory Affairs Professional Society.

RT: Regulatory Affairs . . . And the acronym is RAPS?

BL: RAPS, R-A-P-S. Correct. They were founded in 1976, and they had their first annual meeting in 1977.

(Interruption)

RT: So when you were up at Buffalo, you were in charge of the investigational group there then. Is that correct?

BL: Correct. Right.

RT: Were there specific incidents there of career notice that you'd like to mention?

BL: I was thinking about that question obviously before we sat down. There are a number of cases that were of significance and were of significance for the agency. One . . . Unfortunately I don't want to miss . . . I think it was General Foods, but it was geotrichum mold in green beans. It was a situation where our investigator went in, and clearly the place was moldy. The mold was getting into the green beans. We moved to seize the product. Of course, the firm contested that. As I recall, the judge released a greater portion of the lot that we seized, and we retained enough to fight over, and we lost our you-know-what.

And we lost because George Burditt, one of the best legal minds in the food and drug law community, put on the stand a grandmother who was a supervisor in the plant. And, of course, she testified as to how this plant was just fine and clean,

and she'd eat the stuff right off the floor. Since it was a jury trial, they said, "Well, it's good enough for us." It was a significant loss. We were all crushed.

RO: They claimed really that it was machinery mold that we were finding?

BL: Yes, it was. Geotrichum is, in fact, machinery mold. Of course, they maintained it was no hazard to health, and we hadn't contended that it was a hazard to health. We just contended that it was filthy, and it was inappropriate, and it shouldn't be there. But, as I said, we lost that.

The other really big case--and here again, I apologize, because I don't remember the name of the firm. Pitt will remember it absolutely immediately, but it's the apple juice case. They were simply faking apple juice, and we won a very significant fine . . .

RT: Was that apple juice for . . .? It wasn't Beech Nut, was it?

BL: Yes, it was. That's exactly what it was. It was Beech Nut. Thank you. And, of course, that apple juice found its way to children and infants and young folks and adults. But it was . . . They were faking it. We made that case, and we successfully collected the fine. I think at some point some of the principals who were actually responsible managed to get themselves off. But the firm was found guilty and was fined a couple of million dollars, as I recall. It was incredibly significant. Pitt copied the check and has it dutifully enshrined.

RO: We're not through with Buffalo yet, but Pitt has a reputation, and I'm sure that it was interesting working with him and for him, a couple of Texans, because Pitt's from Texas, and maybe that's the reason you got along well. Or didn't you?

BL: Yes, we did. We did get along well. I mean, you know, in nine years you have your ups and downs. But Pitt's like ever so many people. You need to learn what it is they need, and if you can supply what they need, and then get the things that you want to get done done, then you've got a pretty good deal. And that was kind of the deal I had. I knew that Pitt had a need for information about what was going on. He didn't necessarily want to tell you exactly how to do it all the time. He did have his opinion. But most importantly he wanted to know what was going on, and as long as you dropped by and let him know what was going on, he gave me a great deal of latitude. I really didn't have much difficulty with Pitt.

He had some attributes that frankly I wanted to kill him about, but I told him that. I mean, he . . . The thing that I remember . . . And, you know, you learn good things, you learn bad things. Well, unfortunately one of the things that I learned is never, ever get two or three people working on the same project and don't tell him about it. Pitt would do that. Well, in the district, we learned pretty quick that Pitt would do that, so you did some checking with your peers and with the other folks in the district about who was doing what to whom, and so you wouldn't cross over each other. You make accommodations. In fact, one of the things that I did learn from Pitt was don't get a whole bunch of people started on the same job and forget that they're all working on the same thing.

RO: Who was the head of compliance when you first went there?

BL: Ray Sweeney. Ray Sweeney. Felix Sabatino was the director of laboratory.

RT: While you were in Buffalo, as I recall, you became active again in the I guess it was the Buffalo conference . . .

BL: It's called the Niagara Conference.

RT: Niagara Conference, which is a subset somewhat of the CASA organization.

BL: Correct.

RT: And you were very active in that organization. I think you were secretary/treasurer.

BL: I was an officer. I was president of CASA, and I did participate actively in the local chapter, as we've said, which was the Niagara Frontier Chapter. Of course, that was an extension of my experience in Falls Church and in Virginia and my contact with Tom Price and those kinds of things. I became a board member of the CASA board while I was in Buffalo, and then that . . . Well, of course, once you become a board member, that develops an extensive commitment to continue. I enjoyed and got to be quite active in that organization, both locally and regionally.

RT: So does that pretty much cover the time you were in Buffalo? From Buffalo, where did you go?

RO: Before we leave Buffalo though . . .

BL: Yes, I was quite some time there.

RO: I think that before you left, Burton, there was a big cattle investigation that happened there.

BL: Yes, yes, yes. We . . . That . . . Thank you for reminding me of that. There was a very significant case, because . . . The outcome of the case was the court ruled there that veal on the hoof, cattle on the hoof is food. Before that time, there was no court case that actually differentiated and the contention was that in this case

where the veal was contaminated with drugs, well, the contention was it's not food; it's a live animal. We argued and we were successful in arguing that it is food.

But we had an extensive program to determine that medication in animals, and there . . . And this is not unusual for several areas, but two primary problems are veal cattle and culled, dairy cattle. Both of those present problems, because the dairy cattle, they'll medicate them and not solve the problem, and then try to sell them and recoup their money before they go down completely and try to get them slaughtered. Well, they're all medicated up, and they certainly don't go through any waiting period.

RO: Well, weren't they trying to market a veal calf that really wasn't veal as we normally know it, through the use of drugs?

BL: I don't recall that being the situation. No, they were just simply misusing--at least in my experience, what I remember--and that may have been the case someplace, and I don't recall it, Ron.

RT: Now, were you then taking an action against, what, a firm, a slaughtering firm or . . . ? Who is the . . . ?

BL: No, we were trying to take action against the grower, the person responsible for medicating the animal and not withholding the animal for the period required. In other words, the person responsible for the residue in the animal.

Now, of course, we tried to catch the people all along the chain, but we were going after the grower, because that's where the problem was. I mean, you could try to get the trucker and you could try to get the slaughter house, but it was the grower who was not withholding the animal. And, of course, some of the challenges were the identifications of the animals and trying to do the trace back, and nobody knows where the animal came from, and the ear tags are lost, and . . .

Now, in the case of the . . . I'm trying to think . . . I believe it was a veal calf. They actually bought an animal. FDA bought an animal, and sold the animal undercover and traced it, which was awfully unique. I don't think anybody had ever done that before. But we did a few different things like that.

RO: Do you recall the drugs involved, Burton?

BL: No, I don't. No, I don't. And I know that . . .

RO: Was it DES?

BL: No, no. I don't think so. I apologize for not remembering that. Pitt is the one with the mind for all of these details and history. You might want to talk to Pitt before he retires, because I think he probably is going to expire in office, so you might want to anticipate this. (Laughter) I don't mean to tease about it, but I think that Pitt is going to continue as long as he's physically able, so you might want to chat with him beforehand. But he'll be able to fill in a large number of these things. He just has a wonderful mind for that sort of stuff. Unfortunately, once I'm done with it, I tend to move on and look down the road and not look back too much.

RO: Delete it from the memory bank.

BL: A little bit, yes. A little bit. That's not real good for history, but it works for me.

RO: Oh, we all do that.

RT: Were you in Buffalo when a rather unusual circumstance occurred where one of the investigators I guess had left the agency and came back and wanted to see management, and somehow management wasn't available and . . . ?

BL: Yes. You mean the great flying buffalo incident?

RT: Yes.

BL: Oh, certainly. This fellow is the union rep., but he was actually outside the agency, and we had a small buffalo statue in the lobby, and he came in and wanted to see Pitt. I don't remember whether Pitt wasn't there or Pitt just couldn't see him, but he had to wait a while. He didn't like the idea of waiting a while, and so he picked up this small memento and put it through our display case. I'm sorry! He put it through the front window! The front window! I'm sorry. I was thinking . . . No, he put it through the front window. Of course, we had the Federal Protective Service and we had all those kinds of things.

RT: I was with the Division of Federal/State Relations in the mid sixties involved in the food inspection techniques courses for state folks, and we went to Buffalo. That particular individual was, at that time, maybe one of the better persons in the eyes of management, because he was an instructor in that course for us.

BL: Interesting. He was simply cantankerous. I didn't have a chance to work with him or have contact with him, but he was a union representative.

I will share with you, you get to work with characters throughout your career, and, of course, Buffalo had a few. But one . . . I want this to go down in history, because this guy was a real piece of work. His name was Leon Stawacz, and Leon was there at least as long as I was there until he retired . . . And by the way, when he retired we had a party, but we didn't invite him.

RO: How did you spell that name?

BL: S-T-A-W-A-C-Z, I believe. Leon Stawacz.

But one of the stories that really characterized Leon for me, Leon was on a road trip to Albany. Now, Albany was--and still is--a pretty good-sized resident post. At the time, we had two supervisors there; we had a number of people actually in the office in that supervised resident post. Well, he was assigned to do some travel out of the area, and there was flooding in some of the Albany area and west of Albany, between Buffalo and Albany. Now, Leon is going into this office in Albany everyday.

So Leon writes me a note about the need to cover issues with respect to this flood, and he sends it to me by U.S. mail. He's going into this office every single day. He's seeing the supervisor. And I look at this note, and I, "Well, surely he must have said something to the supervisor." So I called him up and I said, "I've got this note." And I knew they were already covering these flood issues anyway. I said, "Did Leon say anything to you about this?" "No." "Has he been in the office?" "Yes." And that kind of characterized Leon Stawacz. I mean, I'm not quite sure why he did that, but it didn't make any sense at all, and often that was kind of the way he was. He couldn't always tie it together and make some sense out of it.

RO: And . . .

BL: Well, I was just trying to recall. You know, there were a lot of nice people there. Dave Keissling and Russ Miller were supervisors for me. Bob Hart and George Tilroe were in Albany. I had a female supervisor; her name was Cindy Engle. She wasn't there about a year and a half, two years, something like that. A very, very competent lady, but unfortunately--not unfortunately for her, I guess--she got married, moved to North Carolina with her husband. As far as I can tell, they're quite successful working in the research triangle today as we speak. A lot of really good folks.

My secretary was probably a saint. She went on to become an investigator and now the recall coordinator for beautiful Buffalo--Joan Trankel.

RO: Who became chief or the head of the laboratory when Felix retired?

BL: Gerry Roach. And I'm here to tell you the difference between Gerry Roach and Felix Sabatino was the difference in night and day. Felix knew only one response, and it was always, "No." And Gerry pretty routinely would say, "Well, let's give it a shot. Let's see if we can find a way." That was such contrast. It turned out, Felix and Pitt did not get along; and over the years, Gerry and Pitt had an absolutely monstrous falling out. I've been told--I have not talked to Gerry myself--but I've been told that he is quite bitter over his experience. Too bad. That's really too bad. I would take it back to what I said earlier: if you learned what Pitt needed, you got along just fine. The folks in the laboratory routinely balked at telling Pitt what's going on. Get with the program. Figure it out. You need to tell him what's going on. Tell him what's going on, and go on about your business.

Anyway, there are probably lots of other things from beautiful Buffalo, but that's all that comes to mind. And probably those aren't terribly significant; they're just interesting, at least to me.

RO: Well, I think those are surely three kind of precedent cases that you mentioned here, as far as FDA was concerned.

BL: You know, I hate to digress . . . There was another case that I had the opportunity to work with a fellow while I was in Falls Church. This was a warehouse case, and it was one of those . . . You know, you go into the warehouse, you find a few things, you . . . I think we may even have seized a little something. It wasn't of much significance. In fact, I was scared to death it might turn into something, because this investigator was not very good. Anyway . . .

But it did actually turn into something, and it proved a very small point, and that was once the firm has accepted the notice of inspection, they have given you permission to inspect. I mean, and you can't take that back. Once you got . . . I mean, you've done your duty. They contended that even though we issued them the notice that we still didn't have the right to inspect, and the Supreme Court said, "No, no." You've got . . ." That's of small significance. At least it's one of the few things that I'm aware of. And we never anticipated that this would go anywhere near the Supreme Court. It was not something that looked like that, but it did. Anyway.

RO: I think it was interesting when you mentioned that Pitt had some problems with his own staff when they told him, "No," because they weren't the only ones . . .

(Interruption)

BL: OK. I think we've pretty well worn out any significance in Buffalo. Nine years in Buffalo is wonderful for living, but professionally it's time to move on.

I had committed to my children that they would be able to graduate from high school in Buffalo, and I was able to meet that commitment by about seventy-two hours. My daughter walked across the stage, got her high school diploma, and the moving truck moved up the next day because I had been selected as director of DFI (Division of Field Investigations). Of course, I was in DFI from 1985 to 1988.

RT: So at that point you really had achieved your earlier career goal, correct?

BL: You know, that's interesting. If you had said, "What's your career goal?" and you had asked me that as an investigator, I would have said, "To be a GS-12 investigator would be just absolutely wonderful." But the DIB (Director of Investigations Branch) position was really my target, and then when I reached that relatively early, I had actually targeted DFI (Director of Field Investigations). DFI

was the only position that I aspired to in headquarters. There was no other as far as I was concerned. I felt very fortunate that you all brought me in. Mr. Ottes had some say about that, too.

RO: Then I retired.

BL: Yes, I gave you a hard time about that, too. Several folks either retired or left. You retired, and Tony Celeste left, and Paul retired, and I was beginning to ask myself, "Is it something I said or, I mean, is there something in the water here or whatever?"

RO: I thought we had you in headquarters; they didn't need us anymore.

BL: I don't think that was it, Ron. I don't think that was it at all.

It was a very, very wonderful experience in DFI. We got to do a lot of different and neat things. DFI . . . I don't mean to get into self-aggrandizement, but DFI had kind of--I think, in a sense--had fallen on, if not bad times, the reputation had slipped a little bit. And so you're always in better shape if the unit or group is on the lower end of that scale, because anything you do will move it up, and I had the opportunity to work with some folks to move it up now. Some folks were already in place: Dick Dees was already in investigations branch; Dick Klug was running import operations; and Jim Lyda was running the technical support branch. And those are good solid folks, so there was a team there that was ready to roll.

So we did a fair number of things. One of the things I insisted upon was some kind of telephone coverage until the West Coast went home. I'm here to tell you that was not popular with the staff. I think they stopped that the day I walked out the door. Although, I think they may have reinstituted that now that Gary Pierce is in that position, but be that as it may.

Of course, Imports was expanding exponentially. Foreign Inspections were expanding. At that time, Don Martin and Don Darrow were running Foreign Inspections. When Don left, we merged the Foreign Inspections with the Technical Support and made that all one package, because, in effect, the national experts, who were part of the Technical Support Group, were doing the foreign inspections and leading that effort. So it made some sense to put that effort together. So that was put together.

What else did we do that was significant? We did reorganize again during that period, and Jim Lyda took over Imports and Dick Klug took over the Technical Support and Foreign Inspection efforts, and those efforts continued to grow.

During the period of time I was there, I identified . . . And a number of other folks. I mean, I didn't just come about this miraculously by myself one day. But we figured out that the time lag for data on imports was terrible--import detentions. I mean, you would know that . . . You would know about import detention data maybe three or four months after the things had been detained. So you couldn't really tell trends, you . . . I mean, it was too late by the time you did tell the trends, and the data wasn't very useful. So it became obvious that there was a need for a new data system. So we put together a working group to begin to design a computer system. The first part of that computer system was just recently initiated. It was about 1987 when we're doing this, getting this started. They just put the first module in place within the last year and a half.

Now, Ron knows me well enough to know that I tend to think, well, you know, you do these things, and line these things up, make these plans, and we get it done in a fairly short period of time. Not with that one. Not with computers. That system was reinvented so many times I can't even count the number of times. It was investigated by GAO (General Accounting Office); it was investigated by the department; it was reinvestigated by anybody and everybody that thought they knew anything about computers.

And part of the problem was internal, as I look back on it, because people kept adding things and adding needs to the system instead of saying, you know, "Stop. This is it. Let's go from here." They kept redesigning it and adding and adding material. But it was an important need that was identified while I was there. It just took nearly forever to begin to put something in place. And just now, they have got something going and most of the modules are coming on line.

RO: This is intended to give the agency information on what is being imported, what the problems are, and so that when these things are entered, you can make a decision on whether or not it should be sampled or stamped off.

BL: Exactly. A rather simple-minded thing that we realized that we couldn't control, port shopping, which is a matter of an importer determining the best location to bring an import product in where its least likely to be looked at or where the importer perceives that the standards are less strictly applied or whatever was pretty common, and we realized we had no way to control that. We had no . . . There was no way for an inspector or an investigator say in Los Angeles, Terminal Island, who was getting a shipment to have any clue that that same shipment had been rejected in New York, and that was not uncommon. You put that thing on a ship, send it through the canal, out on the other side. It's been rejected in New York, nobody has a clue that that is a problem in Terminal Island and any other kinds of arrangements of towns or what have you.

It was clear that we had to have some kind of system where you could share information quickly and tell who was having what problems and where, and that was part of the reason for this. Plus, we need to be able to tell some trends nationally, what kind of problems are you having, and where do you need to apply your resources. Hopefully, they're going to get there, but, wow, it's been a long time.

RO: You probably both remember a fellow by the name of Dr. Robert Angelotti when he was in Foods.

BL: Yes, indeed, at Center for Foods.

RO: That was back in the seventies. I can remember one time he said, "What we really need on imports is to have the inspector out on the dock have a terminal. He just plugs this in, enters the product, and he could make that decision right on the dock." Well, we all laughed at him. We thought that would be great, but . . .

BL: That's exactly where we are now.

When you mentioned Bob Angelotti, you . . . I hate to jump around, and I apologize for that. But there was a . . . I had the opportunity to participate in a significant activity when I was back in headquarters in Field Compliance Branch. I had the opportunity to participate on a team that developed the good laboratory practices program, and that was a whole lot of fun, because they locked us in the basement of FOB 8. That's where we ate. And said, "Don't come out till you have a meaningful plan."

I remember Tom Schwarz was a part of the team . . . Gosh, I'm trying to . . . There's a fellow . . . Ed Steele was another member of the group, and there were several other groups that were developing similar kinds of biomedical research follow-up programs. But that was exciting, because that program was in place for quite some time. That was really the beginning. I'm sorry to digress, but it was fun.

RO: While you were in DFI, were you able to get advanced grades for investigators without being so-called national experts?

BL: No, no. It was one of those things that was in front of us, but the environment at the time was simply not appropriate for that. As you know, recently they've

been able to get the journeyman grade moved up to the twelve level. We were struggling with getting thirteens for national experts when that was appropriate. And while I was there, we were successful in getting a couple of fourteens, and that was pretty precedent setting.

At that point in time, the personnel offices in the field took the position that if you had a thirteen expert in one region that was enough. That person was the expert, had all of the information. Everybody should come to that expert, but, heaven forbid, you didn't need two. And the work didn't have anything to do with it. They've gotten completely away from that. Of course, now we have our own personnel activity, so that's no longer an issue at all. But we were struggling with that at the time. No, we weren't successful in pursuing that.

I know that a number of things are going to occur to me about that period of time, but . . .

RT: I seem to recall that one of your methods of operating was to have a staff discussion perhaps each day and usually before the beginning of the official work time. Is that correct?

BL: That's correct. When I left DFI, the staff had made t-shirts that said, "I survived Love's standup." Now the unfortunate part of this is that at that part of my life, if you encountered me before 8:00--maybe 9:00--you were in some trouble, regardless of what was going on, because my attitude was not very good at that point, which didn't help the staff. Because we had this standup meeting before my attitude got any better, and those meetings were infamous.

I don't think I abused anybody too badly, but I got the list of everything that we were supposed to be doing and when we were supposed to be doing it, and expected everybody to know whether it was done or not and what the status was, and we would share that with each other. Some of the folks did get sensitive when they hadn't done what they were supposed to do, and I was asking about them. I mean,

I didn't yell at them or anything, but they just weren't pleased with being held accountable at that time in the morning.

RT: Not to single out people, but there was an individual in your group that you had some trouble with.

BL: Mr. Bob Dobratz?

RT: Yes. And it's perhaps noteworthy in that I think it went further than most kinds of personnel problems do.

BL: Yes. We tried to fire Mr. Dobratz, you know. At least my opinion is that Mr. Dobratz had been allowed literally not to work for a long period of time, and so Dick Dees and I thought he ought to be held accountable for getting work done. So Richard began to document what he was doing and what he wasn't doing. To make a long story short, we did fire him.

He got one of the prominent civil service attorneys, and they took us to the Merit Systems Protection Board, and we lost, not because he was doing wonderful work, or not because we hadn't documented what he wasn't doing or the quality of his work. We lost because we had terminology in his performance standard that said, "A good faith effort." It was vague, and I assume that the theory is if you got up in the morning and your intention was to go to work, that you've made a good faith effort. We lost on that basis.

He in fact was reinstated with back pay and came back to work for FDA. I thought it was particularly appropriate that he went to work for a fellow that used to work for me. His name is Dave Haggard, and Dave is one of the toughest task masters I have ever worked with. Fair, but I'm here to tell you, tough. And I thought, "Hmm, interesting." Mr. Dobratz has since retired again.

RT: The only reason I brought that up, the matter of performance plans or quality assurance has come into play in the agency, and I assume that the performance plan element played a role in this particular personnel matter.

BL: It killed us. We had not done a good job . . . These had been in place for some time, and we had not done a good job of providing adequate language to describe the performance that we wanted. It was that simple, and they killed us.

My . . . I would do it all over again. I would do it again. The man was out of the agency for two years, I think we made twice his salary because of the time he didn't waste of other people. But unfortunately he came back to work. It's one of the challenges of government managers, as you all know. Just because somebody doesn't work, it's kind of irrelevant.

RO: I think he came back only long enough, didn't he, to be able to retire?

BL: Yes. Well, the interesting thing is he could have retired at the time we fired him. You know, there are some ways that you can do that if you resign right before . . . I mean, he had a number of rights and things that he could do that he didn't exercise, and he did . . .

RT: But I suppose as far as performance plans or quality assurance is concerned, Mr. Ottes was an early leader in that I recall. It was difficult and probably remains to this time a difficult task of really defining, in ways that are authentic measures from the management viewpoint, the performance of individuals.

RO: What did you think of the performance plans?

BL: I always thought they were a usable tool. It really boils down to holding people accountable for what they have agreed to do, and the performance plans

provide you a way to write that down and to reach some agreement about it. I always thought that they were valuable. People complain about them all the time, and, of course, they're difficult to characterize, difficult to get the information correct, and the supervisors hate to do them, and all those kinds of things, but they force a lot of issues. They force the supervisor or manager to sit down with the person that they're working with and hopefully reach some agreement about what they're supposed to do, and then you give them a benchmark to look at at the end. You say, "Well, you said you were going to do this. How'd you do?"

So I think they're a valuable thing to have. I think we need them in some form. I don't think you can toss them out. I never had a problem with them, except sometimes I had a problem with the format or sometimes I had a problem with some of the process, but the concept always seemed to be like it should be to me.

RO: I think the process--especially in the agency--that we probably overburdened ourself with the entire process.

BL: Yes, we did. Absolutely.

RO: And it got so that when you gave a person a rating, and, you know, I've forgotten all of the terminology, but "meets," for example, if an employee got a "meets" . . .

BL: Well, they thought they failed.

RO: Absolutely right, while really they were doing good work.

BL: Hopefully they're going to move back more toward . . . As a matter of fact, when I left, they were in the process of making major changes to the way the performance system operates, and it was supposed to be a pass/fail with no money.

RT: Yes, one of the problems I think in personnel management was some segments of the agency would tend to evaluate high, and field organization I think was always more conservative. Thus, persons in the field organization as contrasted with a center might be disadvantaged in applying for a job because they didn't have as high a rating, but they might really be a better performer.

BL: Absolutely. That was a good . . .

RT: That's a problem.

BL: The equity problem was a continual one.

One of the things I should mention that was a part of my experience in DFI was the opportunity to work on the action plans for Dr. Young. We've . . . For better or for worse, we were able to work with some groups and complete a number of action items, and I have stored away at home at least one of the awards that the group got for pulling the rabbits out of a hat or whatever it was. I never can remember the deputy commissioner he had, because he was such a buffoon.

RO: John Norris?

BL: Yes, John Norris. He chaired one of the meetings where we were reporting on our accomplishments, and I forget what it was that we did that he thought was good. Anyway, I ended up with a bottle of I think it was Jack Daniel. I'm not much of a drinker, but he said, "Well, what are you drinking?" I said . . . So whatever it was I said, I got a bottle of it.

RO: Could you briefly describe what that action plan was supposed to do for the agency?

BL: Sure . . . Actually, as much as I did not think that John Norris was effective, he is credited with doing that. What it's supposed to do for anybody, as well as the agency, is focus people on the things that the people really believe are important and try to get some of those things done. I mean, you've got your usual work plans, and you've got your day-to-day work, and you've got all those kinds of things, but everybody has a list of stuff that says, "If we could just get this done, it would make so much difference in everybody's lives." And it gave the people in the agency an opportunity to say, "I've got an idea. Here's what we ought to do," and to actually get some of those done, and involve everybody. It was effective from that standpoint. A few things got done; people felt like they'd been asked what was important; and they got to participate. So it was really a good approach for a commissioner coming in.

But it got kind of silly when they started doing the, you know, pulling the rabbits out of the hat and that sort of stuff. That made it kind of trite. But as a tool, it was a good management tool--fumbled in several cases--but in my opinion, that's what it's for.

RO: OK. So then you left DFI.

BL: Then I had the opportunity to be selected for the regional director position in beautiful Chicago, the Midwest Region.

RT: What year was that, Burt?

BL: Well, that's the end of . . . The executive selection and transfer process is kind of like watching sausage being made. But I actually sat down with the commissioner, Dr. Young, in April of 1988. My transfer to Chicago was effective October 16, 1988. It took all that time to go through the process, and get the papers blessed, and passed up and down the line, and go to the department, and go to OPM.

And I am grateful to say that in the reinvention effort all of that got tossed out the window like it should. Although there is a ceiling for SES appointments, the clearance process is within the agency. It still has to go to that OPM, I believe, but it doesn't have to languish for literally months at the secretary's level, which it did at the time that I came in.

But, anyway, I actually reported to Chicago pretty close to right after that due date, because I knew that I was going to be going. I felt that the . . . Interestingly enough, even though you find out that OPM has approved it and that's the last approval, well, you can't go anywhere because the papers have to come all the way back down that chain of command. So right after the middle of October 1988, my wife and I moved to Chicago.

RO: If my recollection is right, you were the first regional Food and Drug director that had not gone through being a district director.

BL: Yes, I guess that's true. I was thinking of Maurice Kinslow, but Maurice was a district director, I guess, in Baltimore, wasn't he? Right. That could be so. I never stopped to analyze that or pay close attention to that. It's not the case now, because there have . . . Susan Setterberg was not a district director. But, yes, I guess I was.

RO: You set the stage.

BL: (Laughter) I suppose. I guess you can put it that way. I was tickled to death to have that opportunity, and I was really pleased to go to Chicago, and I haven't changed that a bit. My only surprise is that more people are not interested and willing to go to Chicago. It's just such a wonderful area to live in and work in, and there are wonderful people there.

While in Chicago . . . You're probably going to say, "Well, what was the most significant thing there?" First thing I did when I went to Chicago, as I said, the regional office is not in the business of reviewing in minute detail regulatory actions. They never should have done that. That's not our business. These people get paid a fair amount of money out here to know what the heck they're doing. If they screw it up, then we'll hold them accountable for it. But in the meantime, we're not going to do what they're already doing. That doesn't make any sense to me.

RO: Do you recall how that happened that the regional Food and Drug director was supposed to review that?

BL: Well, the quality issue, and there were a number of screw-ups. And so Paul Hile looked it over, and he said, "By golly, you are responsible, and you better make sure that they're all perfect." So everybody saluted, and they had somebody, a director of compliance at the regional level or whatever, who went over these things in minute detail. I said, "Well, going over them in minute detail is okay, but how about the people that are paid to do that originally? Let's hold them accountable." So that was a little bit of difference.

One of the programs I considered a significant program that we brought to the Midwest is a program called Investment in Excellence which a number of people continue to use. It's a program for individuals which allows them to understand a little bit better about why they do the things that they do, and most importantly, if they choose to, allows them to have a mechanism to change habits. Changing habits is one of the toughest things that anybody ever does. I mean, I don't know if either one of you all smoke, or everybody knows people that smoke, and that's an incredible habit, or as we know now, an addiction. But this is really a positive program that allowed people to understand that if they chose to, they could take complete charge of their life.

(Interruption)

RO: How was this brought about?

BL: Well, actually I think that John Turner was the first to encounter this material. The Education and Training Branch had actually had some contact with the people that provided this information. It turned out that Percy Thomas had actually bought the program--I learned this years later. He bought the program. He used some of the concepts himself, which are quite valid concepts, to teach some courses, but he'd never shared the material with anybody. I mean, after we had talked with the vendor, and we'd arranged for some training, and worked with Education and Training Branch, they said, "Oh, we've got all the videotapes right here." I said, "Excuse me?"

But this particular program is one where you train facilitators who present videotapes and then allow some discussion of the videotape, and you use that kind of adult learning mode to get the information across. And as I said, some of the people in the Midwest are still using that material and that approach.

RO: This is nothing like hard copy, that the employees write down certain things, and then you're held accountable for those things. This is all . . .

BL: No. This is all personal accountability. If you choose to stay on it . . .

(Interruption)

BL: . . . to have you guys talk to somebody that really knew something. It must take days.

Anyway, that was one of the things that we did. I would say that probably the reorganization in Detroit is the thing that I would look at as the most significant or

most precedent setting, because we began to try to break down the traditional lines between compliance, investigations, and laboratory, and we began to move more toward teams.

When the Compliance Branch director left Detroit, I simply told Detroit, "(A), you're not going to get another one, and (B), you're going to have to find a way to begin to put your processes together." Now my theory was what was happening is we had a mentality that we called the "throwing it over the wall mentality," where Investigations Branch would do whatever they did, and they would throw their work over the wall, never to bother with or pay attention to again. Of course, investigations would sit and say, "Well, those folks in compliance, they'll won't ever do anything about it." And the folks in compliance would say, "Well, the stupid people in investigations branch don't know what they're doing because they . . ."

Well, it seemed to me that one of the answers to that was to bring those two together, not just occasionally, but on a continuous and constant basis, make them part of the same team, and see if you couldn't impart more of the compliance information to the investigators so they got it right the very first time, so they didn't have to do it over again, and so that you could acquire some efficiencies in report writing. So the compliance officer and the investigator could work as a team and put a package together the first time. No walls, get it done as a team.

There are risks there. Some people said, "Well, you're pulling out the checks and balances of the Compliance Branch Office." Well, OK. You may run that risk there, but it's a risk worth running if you're running out of resources and you're running out of people and you can't afford to be doing it over and over again.

That seems to be still progressing. Each of the other districts in the Midwest--Chicago and Minneapolis--approached it in a slightly different way. They did not do away with the Compliance Branch, but they began to develop teams where the compliance officers worked directly with--not just on a case-by-case basis--but worked directly with a team, say a biologics team or a food team or a drug team. And I personally think that that will serve them well.

During the period of time I was there, we regionalized the computer setup. That was something that was done nationwide. Established . . . Each of the districts in essence lost their mainframe computer, and all the computing was put in six locations throughout the field.

RO: Let's go back to this. So you don't have a director of compliance?

BL: Correct. And in that case they have a director of the Field Operations Branch.

RO: And they're responsible then for the investigations and any compliance efforts.

BL: Yes, or any work with the firm or the whole package. And, of course, the laboratory is made a constant part of that team, too. They have a slightly different charge or expectation, but they have to be a part of those teams, and they have assigned people that are.

RO: So what an old . . . I shouldn't say old, but what a former compliance officer did is done now by supervisors in the Investigations Branch now?

BL: No, no. And that was never my . . . The compliance officers thought I was trying to do away with their job. My position then and my position now is you need somebody with compliance expertise to do the training of the investigators so they can do more of it, but somebody that has the full picture with respect to all the nuances of compliance, and that's really not something the supervisor ought to do. The supervisor ought to be doing the coaching, ought to be arranging the training, ought to be helping the team figure out what the priorities are and how to get the work done. I saw the supervisor more as a facilitator and the compliance officer more as a compliance expert, because the compliance officers routinely complain,

"Gee, we don't know enough about what's going on in the industry." Well, fine, go out with them. See it for yourself.

RO: So the compliance officers really then reported to the director of this operation?

BL: Yes. Right. With a fair amount of problems.

RO: I would suspect.

BL: . . . and discomfort and . . . But they've done a real nice job of working on that.

RT: Now since this was an initiative of your region, you were involved in some RFDD level planning and committee work. Do you want to go into that a little bit as to how perhaps this idea or others might have been shared on a national basis that originated in the Midwest?

BL: Well, let me see. You mentioned committees, and there were all kinds of things I had an opportunity to do there. But let me start with the most recent thing, which I consider one of the most positive, and that is the regional directors have organized themselves into a team. I won't say a committee; they were always a committee. But a team, and they actually share information and activities at a level that they never did before. I don't know whether it's the, you know, the sign of the times, or it's the personalities or whatever, but when I first became an RFDD, you could call and talk to a couple of people, but after that, you didn't do that. And you didn't really share that much, even with our meetings. I mean, you didn't share as much as they're sharing now. But there really is more of a team than there has been in the past, and perhaps it's just they're time has come.

But through that mechanism, the approach to teams, the approach to reorganization, the Pacific Region actually supposedly did away with all their branch directors, and we knew that immediately. But the group of RFDDs has begun to make sure that they coordinate what they're doing and do it at the same time. For instance, when the journeyman level moved to twelve. Implementation does become a little bit of a problem there. So we coordinated when we did it and how we did it. So it was semi-equitable throughout the country.

RT: Is there any individual or small group of individuals that is in leadership on these things or is this more of a communal cooperative?

BL: Well, really there are only six involved.

RT: There are not very many. But I just wondered if like . . . Maybe you don't need a leader then in that small of a group.

BL: Well, I will tell you that the two principal movers and shakers are Ron Johnson and Susan Setterberg, both creative folks that have good ideas, both interested in making sure that people are wired up and together, and making sure that people are doing the things that Ron Chesemore and Gary Dykstra, the leaders of field operation right now, need to have done.

Another more recent iteration--that's within the last two years--I had the wonderful opportunity to serve on several committees. My first, I chaired the CAO, *Consumer Affairs Officer Committee*, in the field. They are now called *Public Affairs Specialists (PAS)*. During the time I worked with them, I had the wonderful opportunity to try to move their focus from individual meetings to the mass media, because there were still a number of--and frankly there may be today--people that concentrate on going out and meeting with ten people and fifteen people and thirty people. And I said, "You know, you've got this thing called television, you've got

radio, and they give you the most bang for the buck, and they educate the most people, and they get the most information out there, that's what you need to concentrate on." And they did begin to move that way. I had the opportunity to work with Claudette Guilford, a wonderful person to work with, who headed up the CAO and PAS operations.

After a couple of years at that, they moved me to chair of the Field Food Committee, and I had the opportunity to chair that group until we changed how the committees were chaired. Just for the purpose of this recording, these committees are advisory committees to the associate commissioner for regulatory affairs, appointed at his pleasure and in essence reporting to him. The Foods Committee, of course, as the other subject matter committees, provided liaison between the centers and the field, and I had the opportunity to work on a regular basis with Dr. Fred Shank.

Dr. Shank made and continues to make just a wonderful effort to interface with the field and makes sure he knows what's happening out there and working directly with that committee. He's one of the few that I know that shows up at every single one of those committee meetings, and it doesn't matter where it is. If it's in San Diego, he'll make the effort to get there. I just really, really enjoyed that experience.

You know, we worked through several issues, the planning of research in the field, the issue of whether the field even "needs to do research." You've gone through some of those battles certainly. The problems of loss of expertise within the center. As a matter of fact, the nutritional laboratory responsibilities are now all in the field. They have no nutritional folks in headquarters. They do that in the Atlanta nutritional laboratory. Of course, all the kinds of things that have been food issues: HAACP (Hazard Analysis Critical Control Point), the establishment of the Office of Seafood . . . That was, of course, exciting. I had the opportunity to participate in that. The selection of Tom Billy as the first director of the Office of Seafood. Unfortunately, we couldn't keep him; he went to USDA.

I'm trying to remember how long . . . I believe it's been about three years ago. I lobbied for and some other folks lobbied for moving the chairmanship of these subject matter committees to the district directors to get the district directors more involved. The RFDDs would continue to chair some internal committees and would serve as senior advisors on these subject matter committees. I chaired the Human Resources Committee and the Facilities Committee. And, of course, the Human Resources Committee, we worked on the movement of the journeyman level, performance plans, long list of things right there. Of course, the facilities, we got the opportunity to deal with the ORA laboratory reorganization and a large number of the headaches to go with that and lab closure and consolidation and . . .

Probably one of the biggest things that that group did was it facilitated the development of the laboratory I'll call it detoxification or lab closure. You know, when you close a lab, a significant process that you have to go through to shut it down is to assure that you have not done significant environmental insults and to bring the building back to the clean level that it was at the point that it was leased to you or whatever. There was no template to do that, and not only ORA, but there are some other headquarters laboratories that are shutting down. Anyway, the facilities committee worked with the people that know that sort of thing and work on those issues and came up with a template: here's what you have to do; here are the time lines; here are some people that you have to contact; here's how much it will cost you on the average when you set about this. So that was a very positive thing and absolutely necessary for these laboratories.

RO: Where does the agency stand on the laboratory closures?

BL: It's moving right along. Chicago, New Orleans, Buffalo, and I believe Cincinnati. Don't hold me to that one. The first three for sure are scheduled to shut down in '97.

RO: Gee, I thought Minneapolis was going to be one of the first to close.

BL: No. Minneapolis . . . As a matter of fact, Minneapolis and Detroit are in the group that is targeted around the year 2000. Minneapolis is actually a fall back position. Depending on what happens with the Arkansas effort, the development of that laboratory, and that actually looks like that's going to go somehow. They're going to get that done. If they get that done, then Minneapolis will in fact close down. This is still planned for the year 2000.

RT: The Arkansas effort is, for the interest of anyone that's reviewing this transcription, you're referring to . . .

BL: The National Center for Toxicological Research (NCTR) site in Arkansas just south of Little Rock, near Pine Bluff. They have some unused facilities and significant unused land, which FDA owns, which is one of the advantages of putting a facility there. It's much more economical to have land you already own to deal with.

RO: Whenever you talk about that, I can't help but think back when the agency first acquired NCTR back in '70, '71, somewhere along in there, and we were considering putting not a laboratory there, but a resident post in NCTR. And we were going along with our plans when all of a sudden--Dr. Charles Edwards was commissioner at that time--someone decided that this was going to be a research facility, and there was no way that they wanted to have that even remotely connected with enforcement. So that was the end of even having a resident post located physically at NCTR.

BL: Well, as you know, over the last two or three years, people have begun to ask of NCTR and that activity, "What good are you doing us? How are you helping with

the public health? How do you fit into the scheme of regulating those things that we regulate?" Frankly, they've had to scurry a little bit to redefine their role. But part of their role is going to be to house a major laboratory compound for the field organization.

But all that effort seems to be on track. I actually ran into Lou Carson on the subway while I was in town, and he confirmed that it's on track, and plans continue ahead for consolidations and construction. So . . .

RO: With all the fun you were having in Chicago, whatever prompted you to think about retiring--other than wanting to get back to your native Texas?

BL: Interesting question, particularly since I was having fun, and I did enjoy my job. But, of all people, you know that after a while I get bored, and it seemed to me that . . . I told a couple of staffers, "I have personally made a number of significant philosophical changes about how the world ought to look." I'm to the point that I believe in that line, as far as Food and Drug is concerned, I had gone as far as I was comfortable going, and the agency does need to go farther and make more changes and do different things. Somebody else needs to shepherd that. I've been there too long. I mean, you get to the point where a lot of the processes you can literally do half asleep.

There are still a lot of things to do that are fun, but I thought, "I'm relatively young; my wife is relatively young; we're in good health; there are a lot of fun things out there in the world that we can do; and they're going to pay us not to work here anymore." And I thought, "I think I'll go out and see what some of the rest of the world is about." And I don't have any intention of working eight hours a day for anybody else. I did that for the Food and Drug Administration. That was my career. I'm not going to do that. I'm going to stay active with food and drug issues and things like RAPS and AFDO and that sort of thing, but I don't have to work, and I

don't intend to do very much of what I used to call work. Long-winded answer, but it just seemed like it was the right thing.

RO: You worked for a number of different administrations, let's say, as far as commissioners, as far as the EDRO organization is concerned, the ACRA organization. What differences did you see as far as the changes in each one of the commissioners, the agenda they had, etc.?

BL: I'm just thinking back. Of course, the last ten years has been Dr. Young and Dr. Kessler. And starting in reverse order, Dr. Kessler is probably the most politically astute. Whether you like what he does or not is irrelevant. The most politically astute commissioner that FDA ever had. Best at getting through the political land fields.

Dr. Young was by far, as far as I'm concerned, the most enthusiastic. Not always the best directed, but certainly the most enthusiastic. A very, very nice man. I enjoyed his approach. As we talked about, he did kind of know the unique effort to set about getting some things done through action plans which involved all of the people, and I thought that was unique. It hadn't been done before, and it was a very positive sort of thing.

Candidly, prior to Dr. Young, I didn't have much contact in the field with what the commissioners were doing. It may seem like this shouldn't be so, but you guys back here at headquarters had to deal with those folks. I had to get inspections done, collect samples, take regulatory actions, and in all the places that I worked, we continued to do those things. Even though the regulatory pendulum swung back and forth, we just kept trying to do the right thing. And not disobeying, but trying to continue to find the things that were incorrect and help to fix them.

Now there were some of our, as you know, some of our folks in the field who had perhaps what one would call bad experiences with the regulatory approaches, and they literally withdrew. They said, "Well, if I can't get this regulatory approach

done, I'm just not going to do anything. I'm not going to submit any actions." There are at least two districts I know that took that approach. I was fortunate to never be in a position where that was the case. So I can't give you a really good sense of how that affected me. Young and Kessler affected me the most, because Young, of course, selected Ron Chesemore for the associate commissioner's position. Since I worked for Ron directly, when he was head of the Office of Regional Operations, and then as the ACRA, you know, that was meaningful to me because I had worked with him and had the opportunity to work with him.

Kessler had the biggest impact on enforcement from my point of view as anybody. And, you know, it's funny to me because he gets a whole lot of credit for taking action on orange juice and the fresh label, and the funny thing about that is if the firm had reacted slightly differently, it would have never happened, never happened. They were in negotiations with the firm about the label, and the firm walked away from the table and said, you know, "We're not going to do anymore." All the seizures and all that stuff were already done, so all they had to do was just literally turn the button. So it was strictly serendipitous that that was the target. That happened to be what was on the table at the moment. I guess some people think that we did this grand scheme to pick out that one thing. Well, yes, it was sitting on the table at the time and seemed like the right thing to do.

But that did cause a fair amount of enthusiasm in the field in terms of someone who cared about those kinds of things, cared about regulatory actions. The problem is Kessler let all that fall. I don't believe the field has that sense of Kessler at all. He doesn't show up in the districts anymore. He did it for show initially. But he really gives the sense now that he just doesn't much care about the field. When the folks have meetings, he doesn't show up--you know, when the RFDDs or the DDs coming in. It doesn't take very much to show up for that sort of thing, but he hasn't shown up for quite some time.

RO: Of course, he's removed himself from that with his deputies.

BL: Yes, he has, he has. But there's a certain amount of leadership which wouldn't take more than about ten minutes, fifteen minutes that you can provide that in my view he's not providing right now.

RT: Well, in contrast between the two commissioners you've cited, Dr. Young had more rapport with the field and with people generally. And commissioners in the past have been somewhat . . . Like Goddard was a guy that used to walk the halls and drop in, and you never knew when he might pop in just to say, "What are you doing?" So it's a different style.

BL: They call that . . . What is that? MBWA, management by walking around? (Laughter) So . . . Yes. But . . . Yes, Dr. Kessler has done good things for the agency. I wouldn't take that away from him at all. He's certainly shown leadership and flown in the face of the storm. Probably one of the most devastating things to happen happened, of course, on Young's watch with the generic scandal. I mean, we took such a bath over the poor behavior of such a few that that was really hard to stomach. Very, very difficult. And, of course, it was not Dr. Young's fault. He didn't have a clue. He was simply the scapegoat, or the sacrificial lamb, or whatever you want to call it.

RO: It's always kind of interesting to me just how much the agency knew about this generic scandal before it really broke, and . . .

BL: I didn't have a clue. Didn't have a clue.

RO: I'm sure that some in the agency must have had some knowledge of it.

BL: Oh, yes, you bet.

RO: And you kind of wonder whether if there were those signals out there and people ignored them. If they hadn't been ignored, if maybe that problem could have been kind of corrected without all the fanfare.

BL: Well . . . Now this is just supposition on my part, but I suspect, yes, some people knew that drug reps were wandering the hall and were perhaps too close, and I've got to believe they didn't do anything about it. But, be that as it may . . .

RT: Well, as you look back in at the agency and see the current initiative on tobacco, does that instill any particular reaction in your thinking as to the agency's role in this area?

BL: Well, I told the RAPS group yesterday evening that the timing of my retirement had been further scored by the fact that the agency was going to pursue tobacco. It's what I call an approach/avoidance situation. The approach . . . The positive side is somebody needs to deal with tobacco. It is a health issue. It does cost the American public a great amount of money. However, the avoidance part is it pains me that it's the Food and Drug Administration, because they do not have the resources, the expertise, they don't have any resources. They don't have enough to deal with what they're already assigned to deal with. I know the theory is, well this won't cost much money. Well, that's what they say about all of the things that have been added over the years that were not funded. So it's, I think, an appropriate public health thing to pursue. I hate to see the agency be the one to pursue it without any kind of resource to deal with it.

RT: Well, that certainly is an accurate assessment of many of the actions of the Congress over a number of years of not funding or saying, "Absorb it," and that is a real problem.

BL: We counted at one time, I know that there were at least fourteen different acts of Congress that put new responsibility on the agency, but they added no money. I'm sure that number is different now, but . . .

One of the things . . . I had the opportunity as an RFDD to participate in one of the first efforts to personally visit Congress persons from regions and districts in our region, and one of the few messages I gave them, obviously you're not lobbying them. You're trying to give them just information about what FDA is and what happens in their area. One of the things I told them is, "Please, don't pass stuff without paying for it. If you can't pay for it, don't do it. We can't afford to do it anymore." That was a wonderful effort though, and they have not done that since.

It's wonderful to visit the congressional offices here. We were doing it . . . That's another thing that we did start. It was Chicago District's idea. We started the effort to visit congressional offices in the congressional districts out in the local areas and make sure that they knew that we existed and what kind of information was available. Because they often get consumer complaints. They don't have a clue then who to call. So we've been very successful at that, and that has become a national program. All of the PASs or CAOs, consumer affairs people, do that now. But that originated in Chicago. And from that idea came the idea of . . . It was Hugh Cannon who followed this up in actually visiting the Capitol Hill offices. He was associate commissioner for legislative affairs at the time, actually making visits to the Congress people on the Hill.

RT: Now, Burton, I'm aware that as you retired and since you retired, you've expressed an interest in developing some kind of a retiree roster of former FDA employees. Do you have any thoughts as to what purpose or what objective might be pursued in that way?

BL: There are a large number of possibilities. Obviously the first one is just to allow people to remain connected to the people that they worked with . . .

(Interruption)

RT: I hadn't pushed the recorder in. So if you want to continue.

BL: We can step back. In addition to someone maintaining contact with the people they used to work with, keeping them aware at some basic level of what agency issues are, what's going on in the agency. A number of folks have mentioned the possibility that this group of people might also provide expertise from time to time on agency issues. Some of the consultants in the industry have said, "Well, that's a wonderful source for potential third party inspection efforts." I really wasn't thinking about that at all. But I think if you brainstorm some of those kinds of things, there are a number of very positive things that can come out of being able to connect ourselves together.

There has been a fair amount of interest on the part of people who are FDA alumni that are not retirees. Folks like Tony Celeste who had a significant positive career with the agency, who left the agency but did not retire. Dave Chesney, he was in the same kind of category, and, you know, there's a significant number of others. So there's a lot of positive thought. I get a lot of correspondence, a lot of people saying, "Yes, good idea." It looks . . . I haven't counted. I've got about sixty-something actually punched into the database now. I think I have in possession over 150 names, addresses and telephone numbers. My intent is to get all of that stuff in the database, send a letter to the folks who have actually told me, "Yes, I'm interested in doing something," and then send another letter to the folks who I just simply have their name and address to say, you know, "OK. What do you think? What have you got in mind?"

That would be the first effort. You know, we're going to need to have some level of organization. Somebody asked me, "Will there be dues?" Frankly, at some point there's no way to avoid that because I'm not going to spend \$8 million for the postage for the rest of my life. I don't mind priming the pump, but after a while

we'll have to do something to be self sufficient. Hopefully there might even be maybe a meeting here and in the D.C. area. So there are a bunch of possibilities.

RO: All right. Probably a good note to close this interview then, unless you've got something else you want to add, Burton.

BL: No, no. I do want to say how much I appreciate you guys doing this and doing this with others, and hopefully others that have a whole lot better detailed memory than I about the kinds of things that go on. I really believe that this is important to capture this information.

RO: Well, this interview will be placed in the FDA's history program in the National Library of Medicine. And I'm sure there are a lot of researchers that go back and look at these interviews and gain an insight into FDA's personalities.

RT: Well, it gives a little more of the human touch. I've learned just from hearing other tapes, information, background, things that one doesn't know about on the surface.

But we really appreciate your letting us interview you here, Burton, and we'll make it a part of the record.

BL: It's been fun.