

History
of the
U.S. Food and Drug Administration

Interviewee: Mervin Shumate

Interviewer: Ronald T. Ottes

Date: March 11, 1987

Place: Rockville, MD



Deed of Gift

Agreement Pertaining to the Oral History Interview of

MERVIN H. SHUMATE

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Last position held: Director of Enforcement, ORE

Date: _____

Interviewer: Ronald T. Oates

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CASSETTE NUMBERS

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

DATE: March 11, 1987	PLACE: Rockville, MD	LENGTH: Information not provided
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FDA SERVICE DATES:	FROM: 1955	TO: 1986
TITLE: Director, Office of Enforcement, Office of Regulatory Affairs		

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Interview with Mervin Shumate

March 11, 1987

RO: This is another in the series of FDA oral history recordings. Today we are interviewing Mervin H. Shumate, retired director of the Office of Enforcement in the Office of Regulatory Affairs. The recording is being made in the Parklawn Building, Rockville, Maryland, and the date is March 11, 1987. I'm Ronald T. Ottes.

Merv, we'd like to start by asking you to give us a brief resume of your career, starting back as far as you want to go, and bringing us up into the FDA; and, along the way, bringing up some of the interesting and important incidents that happened in your career.

MS: Thank you, Ron. I was born on a dairy farm in Richland County, Wisconsin, on November 10, 1930. I was one of a pair of twins that were born, and it was quite a shock to my parents because, of course, it was at the time of the Depression, and my parents had not expected to have any children, let alone twins, at that particular time. However, my dad was extremely proud of having twins, and certainly let everybody know far and wide that he had a pair of twins (laughter). We were raised there in Richland County, Wisconsin, and then continued through grade schools

and on into Blue River High School, which is at Blue River, Wisconsin, and graduated from there in 1948. I then went on to the University of Wisconsin at Platteville, Wisconsin, and studied agriculture, thinking that I would be an agriculture instructor in a high school.

In the height of the Korean War, the draft was very much of concern, and we received our notices in our junior year and promptly went off and enlisted in the air force to avoid the infantry, and served four years in the air force, getting out in October of 1954, and then finishing college and graduating in 1955.

I then entered the Food and Drug Administration at s in September of 1955 as an inspector. On the day that I was hired, another inspector was hired as well, and he was hired exclusively for the purpose of being a Salk vaccine inspector. I was hired as a general inspector. However, I spent almost the first year exclusively investigating Salk polio vaccine to make certain that it was not diverted into the black market. The Congress had specifically directed the Food and Drug Administration to see that its distribution was controlled.

This was an extremely difficult experience for me, coming off of the farm, coming right out of college, not having any experience in the business world. It was one

very difficult job, in that I would have to visit from ten to twenty different pharmacies, doctors' offices, wholesale and retail drug companies to check the inventory right on down. We would have copies of invoices from the major manufacturers and we would have to verify it right on down to the physician. Physicians, particularly, were extremely abusive to young investigators because they seemed to just have a very intense dislike for government agents generally. And specifically they could see no reason whatsoever for the federal government to be sending somebody out to their busy practice to be checking something like this. They just didn't see any sense in that at all.

Well, usually when they would get abusive or obnoxious, it would be in the presence of an office full of patients, and this was just excruciatingly difficult for me. However, I learned pretty soon how to cope with that, and the way I did is that I would try my very best to be as polite and as professional as I could be in responding to them, no matter how difficult they were. I would always say the Congress had passed this law and that we were simply carrying the congressional wishes; and if they had any complaints, they should write to their congressman, that I didn't particularly like the job any better than

they did, but that we were doing this, really, for their best interest. We were trying to make sure that the products they had were quality. I would usually say this in the most official manner that I could in front of all these patients, and then I would promptly depart. But at the end of a day, I would just feel like, "What in the world have I got into that I have to be putting up with this kind of stuff?"

I remember one other incident that might be of some significance. It was a pharmacy in a very small town in eastern Iowa. It was a rainy, cold day, and the drugstore was full of farmers that were there for coffee, I guess. And I walked in to check the Salk polio vaccine, and as soon as I introduced myself and showed my credentials, the pharmacist just went berserk. He had on kind of a baseball hat, and he took it off and threw that thing across the place and let out a few expletives as to why was the federal government out here wasting their time on this kind of thing. I just, as I had in physicians' offices, simply responded as professionally as I could, but I remember when I left that drugstore . . . I was only thirty or forty miles away from my home town just across in Wisconsin, and I was extremely tempted to just check right on off over there and say, "You can take this job and shove it"

(laughter). Of course, I didn't know that song in those days, but it was perfectly appropriate.

RO: Merv, when you came in, what kind of training did you get? Were you put right on the street checking this?

MS: Yes, we were put right out there. The only training we had was very little on-the-job training. you could say, but really hardly any training in this. And that's what made it so difficult. It was extremely intimidating, because you really weren't trained in how to cope with this kind of adversity. I had many experiences where it was really quite intimidating to a young person, particularly from the kind of background I was from. You would come up to an extremely large facility, and you're supposed to go in there and investigate this place from top to bottom; it's quite an intimidating experience. I remember driving around some of those places a few times and wondering whether I ought to go in there (laughter).

I remember another incident out in Fort Dodge, Iowa. I was out there, and there was a fellow by the name of John Thomas, who had graduated from the same college that I had, that was newer than I was. We had talked before we'd gone on this road trip that on Wednesday evening we would meet at this particular hotel. So on Wednesday evening I checked into the hotel, and there he was, already in the

room. He said he wanted to talk to me in the worst way, because he said he had an assignment to inspect this place there, and he'd gone four blocks one way and two blocks the other way, and there was no way in the world he was going in this place. Well, I got out in the inspectors' manual and I sat down and I gave him a kind of course on just how he should proceed, and that he ought to go in there in the morning, that it may look awfully difficult. Of course, I had a year or so, so I was a very experienced inspector, see. And so he did the next day. He went in there; I didn't go with him. But that's indicative of the kind of experience you had.

Also, very soon after coming into FDA, I was trained in filth work, because that was a very big part of the program in Minneapolis District. I noticed there was extremely fierce competition amongst the investigators to see who could get the most legal actions. Jim Swanson and I, for example, were two that had come in almost the same time, and we were competing with each other, not openly or with any kind of a checklist, but there was intense competition there as to who was doing the best. Of course, we were trained by some of the absolute best in the nation, and I thought at the time, and thought more so as I got

more experience, that some of the practices that they were engaging in were simply not right.

I recall specifically, for example, Everett Atkinson. He was an entomologist. He'd transferred in from San Francisco. He was an absolute expert on bugs. He did not compete with other inspectors; he competed with other districts. He himself. And he would often have more legal actions, usually seizures, than most districts in the whole United States. That was his intense interest, and that's what he did. Of course, he was not well liked by the other investigators, because he would not take any assignment that wasn't likely to generate a legal action. And so he would take his assignments on the road just like the rest of us, but he never touched his; he just went after seizures. Then, of course, you had to go do these other things, and therefore he wasn't well liked. In addition, of course, he was getting tremendous recognition because he was generating all kinds of legal actions.

I accompanied him on a few training inspections, and they were unbelievable in that he would power it over a new person, usually in front of industry, business representatives, which was extremely embarrassing. For example, he would always introduce you as the junior inspector that's just been hired and isn't even dry behind

the ears yet. I remember one particular incident in a grain elevator, where we had to go up top, of course, to inspect. He would take the manlift and he'd instruct you to get up the ladder up the side. Of course, nobody ever took a ladder up the elevator, so there'd be two or three inches of dust on top of every rung. One time I was going up the ladder just like I was told. Of course, he's already up the top, and he's up there kicking more dust down on top of me and telling me, "Get on up here," giving me the business, you know. It would almost push you at time to where you would want to smack him one.

And, in fact, I did one time. We were in Keokuk, Iowa, doing inspections, and he had a habit of always jabbing you, giving you little pokes as he was giving you the business. I had been a boxer in high school and in the air force, so I was very well trained on how to reflex action if somebody poked you. He did this one time too many, and I just gave him about a six-inch punch right straight in the solar plexus and just knocked the wind out of him. I said, "Now, don't do that again. Do you understand?" He never poked me again after that. But that didn't mean he didn't hold it over you whenever you were out making inspections.

RO: District management must have condoned the fact that he was not carrying out routine assignments.

MS: Oh, yes. Bud Kerr was the district director, and he was very sensitive about legal actions. He kept a legal pad on his desk, and he always wrote on a ruler, if you remember. And he kept a list of all these legal actions. So there was tremendous incentive to get these actions, and they would overlook whatever conduct he was engaged in because he was generating so many of these. But, let me tell you, having gone with him a few times, how he did this. He had a three-by-five card file that he kept notes on every establishment that he ever went to, and he would instruct you . . . He was an entomologist, so he would go in, he'd find one lot that would be heavily infested, or two or three; he'd sample only those. But he would keep good notes on other adjacent lots that weren't really infested that much but were going to be within a certain time, and he'd have notes: "Return in two weeks or thirty days," and he'd go back and he'd have some more seizures. He could just keep seizures going forever this way. He never wanted them to totally clean up, because that would dry up his legal actions.

Well, I thought that was pretty ridiculous, because in some of these incidents, I remember the businessman would

be more than happy to destroy whatever the adulterated article was. But Everett had some very clever techniques to keep them from destroying anything. And I learned the techniques and did the same thing myself. I've got an incident to tell you that almost caused me to quite another time. Whenever they'd say, "I'd be more than happy to destroy these one or two bags of beans here," he, in the most official manner, would straighten up: "No, I'm telling you, just hold those goods until I've got those in the laboratory, and when the laboratory reports back to you, then we'll let you know." Of course, the next thing that they would see would be the United States marshal out to seize the one or two bags of beans. I accompanied Everett on a couple of reconditionings after seizure, and I can assure you it was a very difficult experience to go out to recondition after he had treated some businessman like that.

I remember in Cedar Rapids, Iowa, at a warehouse where we were out there to recondition some flour that had been seized, this man in this warehouse was a very formal, elderly man that had a stand-up desk, and he was obviously in total charge and had always been. Everett went in and announced that we were there to recondition, and the man had the crew standing by, ready for us to supervise the

reconditioning. But Everett said, "We're going to conduct an inspection here first to make sure you're clean." So he and I went out. We were absolute experts on filth, taking our flashlights, and we went over that whole warehouse. Everett found two or three dry old rodent pellets way in the back corner of that warehouse. He said, "Come here." Up front we go, up to the man's office, and there's this formal old man standing there. He walks up to him and he says, "Mister, you've still got rodent filth in that warehouse. When you get it cleaned up, let us know and we'll come back and supervise this." Out the door we go (laughter). This guy was just sputtering madder than heck, because he had this whole crew there. And it didn't look to me like anything active at all; it was just something they hadn't got absolutely every pellet. But that's very indicative of the way this man operated.

Another incident was in Dubuque, Iowa. It was just a small wholesale warehouse, and we went in, went back. He had a nose for filth, and I developed one very quickly myself. Sure enough, we found rodents in some flour back there. Everett says to me, "Come on with me," and up we go. And he was just a little guy. He's even smaller than I was, and I'm only 5'8". So we were very small. We walked in the office, and the owners of this place were two

brothers, each 6'6" or more, and 230, 240. They came to the outer office with all their employees there, and Everett walks right straight up to the biggest one of the two, and he looks up at him, and he says, "Mister, do you know you're feeding the public rodent-pissed-on flour?" This man looked like he'd been hit in the face, and I thought instantly, "We're both dead. I mean, there's no way we're going to get out of here alive." But he was able to intimidate people, and he just seemed to get tremendous joy out of doing that. Those are a couple of incidents that really illustrate just what kind of a character he was.

But everybody, to some degree, was similar, in that he was held up as such a great and successful inspector, everybody else was trained to emulate this guy, particularly new people. And that's exactly what I did. I know that then I was going on my own to make some of these inspections, and I went out to one place. I was on a trip in northern Wisconsin through Superior, Ashland, Rhineland, or Wausau, making inspections, and it was one of the first trips that I was out alone. I went to Ashland, and it was in the afternoon. I went in this warehouse, and it was an immaculately clean warehouse. I was absolutely amazed how clean it was as compared to what others I had seen. But,

having been a very well-trained investigator, I proceeded to sieve and sift every single macaroni product, nut, everything you could find. Well, I did find one box, about a fifty-pound box of cashews with a couple of castskins and one or two larvae. That's great success to me; I got what I was there for.

So I went up, and it was getting late in the afternoon, and I had to get on to Rhinelander that night; so I went up to the front office and told them I needed the records, and they were closing up. I asked the owner if he would keep open long enough for me to get the records, and he said he would, at which time I proceeded to bring in my samples. Once he saw those insects, he went totally berserk. He just lambasted me for keeping the place open and disrupting his business and ordered me out. Well, I said, "I'll leave. I don't have any intention of holding you overtime or anything like that. I'll leave and I'll come back in the morning." That's the only thing I could do, the man was so mad. And as I left the place to go back to my car down the street, he got in his great, big white Cadillac and he drove right down the street beside me, just giving me the business all the way. By the time I got to that car, I drove downtown to Ashland, and I'm thinking to myself, "You know, I'm not going to take this kind of

abuse. I mean, there's just no way that any person has to do that."

I got on the phone. I went to a pay phone. I didn't even check into the motel, I was so darned mad. I was scared, too. I tried to call Johnny Guill, because I was going to tell him, "You just get somebody up here to get this car, because I'm going home" (laughter). "I've had all I need of this." It was too late and I couldn't get anybody, and so I then checked into the hotel. I can tell you, I didn't sleep one minute that night. I was thinking about having to go back to that place in the morning, and if the guy was anything like he was the night before, I wasn't too sure what might happen to me. Because that man was extremely proud of his facility, and the fact that I'd found an insect in there just had sent him over the edge.

Next morning I got up and I went back over there to that place. I walked in there just as official as I could, with the best suit I had with me. I went in, and he had obviously calmed down; so I got the records and I left. No problem that morning. But I gave him the same routine, which was, "I'm telling you, now, you just hold these cashews here until I get a laboratory examination on this, and then we'll let you know." Of course, he got them seized. Thank God I didn't have to go back there to

recondition. Here it was just one fifty-pound box, but, you see, we had people going out getting samples and sending marshals out for just maybe a part bag or one bag of beans or something.

RO: At some point in time there, I thought they'd put a \$100 limit on seizures.

MS: They did. They did later, but in those days you could just generate any number that you could, and that's exactly what you did. I remember one inspector by the name of Gene Shevling, who's still, I think, in Kansas City as a supervisor. He's a very intelligent young man, and he'd encountered some insect-contaminated flour out in the Dakotas somewhere, and the man had offered to destroy them. He certainly agreed with him, and he witnessed it. Then, when he got back to the district office, I mean to tell you, he got chewed out royally for letting that man destroy that flour.

That had an extremely lasting effect upon me for the rest of my career, because it didn't seem to me to be the most efficient way to handle an adulterated product for several reasons. One, if they held those goods, it was purely voluntary on their part, so by the time that legal paper got around and the marshal got out there, the chances were either most or all of the product was gone. So there

was no way you were protecting the public in this kind of thing. You were just getting numbers. Actually, as I got more experienced, I would actually solicit; I would pressure the man: "What are you going to do about this?" If he didn't have enough sense to tell me he'd destroy it, I'd try to get him to understand that that was an option he ought to consider, because I wanted to see those things destroyed. There's value there, and particularly if you had 100 or 200 or 300 bags of something, there's a lot of money there. Those people are not going to just throw away that kind of food; they're going to sell it if they can. So there was some good common sense there. But that was the policy that there was; it was very strong.

On the other hand, there was something there in Minneapolis District that I never saw in any other district, and that was a tremendous camaraderie, a tremendous esprit de corps. When you came off the road as a new investigator, always on Monday morning you'd go down to the canteen for coffee, and you would trade war stories. And that's how you would learn how to cope. If you'd encountered some very difficult situation, you could ask a senior inspector, and they would tell you how they would handle the situation. They didn't do this in an overlord

manner or anything; it was a genuine concern for each other.

I remember one time Joe Durham, who was the chief inspector, and I going out on a day or two trip, just searching for a fishing camp for the whole district to go on a three-day weekend for fishing. And that's what we did. We went up and contracted for the whole camp, and the whole district went up there and just had a great time fishing together. Now that fostered a feeling of concern for each other that you just didn't see anywhere else that I was. And that not only was inspectors, that was the analysts, the support people -- everybody was included. It was just a good feeling. There was a little "we-they" kind of competition, but nothing destructive; it was a positive kind of thing.

Norm Foster, I remember, was the chief chemist. I got married a year after coming into Food and Drug, and they were just extremely nice to my wife and me, because they lived out in Wayzata and so did we. His wife, Millie, would just take my wife sort of as a daughter to help her to get through the kinds of things you needed to do, which was very helpful. I remember Sam Perlmutter, who I think is living here in Montgomery County, but I've never been able to get a hold of him. He was going to Israel and

offered us his home for the sixty days they were in Israel; but he did caution us we couldn't use any of their dishes or anything because it was kosher. After thinking about it, I thought we'd better just get ourselves our own place and not get too much involved in that. But it was a very nice thing that somebody would offer that kind of thing for you.

I also spent a great deal of time in grain elevators and cheese factories, of which there were thousands, and had one experience in South Dakota that I think might indicate quite a few things that I hadn't experienced before. But it certainly gave me some experience that I used later on in my career that I'll talk about. Johnny Guill was the chief inspector early on, and he was from the South. He didn't have any idea of cold, but he would often schedule us out into those grain elevators in January and February, in the very deep of winter. I remember going out there and trying to take photographs or rats and things under those elevators, and the film would shatter just like glass, it was so cold. Twenty, thirty, forty below, and if you're in a grain elevator out there, it's magnified because of the drafts that are in there. We had beat-up old cars that didn't have any heaters in them, and if you had the defroster on so that you could get a little six-

inch-square area to see through, you had no heat at all in the car. So we'd wear parkas. I remember pounding my legs and arms to keep from freezing to death as we'd drive out across the Dakotas. It was just awful.

But I went out to do an inspection in Claremont and Huffman, South Dakota, and was going there for a specific purpose. We had been putting quite a lot of pressure on the grain industry; and South Dakota, of course, being a grain state, was quite concerned about the kind of pressure that was being put on. They sent out their top guy from Pierre, South Dakota, and their local inspector. I can't remember either one of their names. But I was to take them with me to show them how we conducted a grain elevator inspection. I remember it being quite significant, because as we were walking up the way to the elevator, I overheard the guy from Pierre say to the local guy, "How did these guys vote here? Do you know are they Republican or Democrat?" (laughter) That didn't seem to ever enter my mind. That wasn't something that I ever gave any thought to and could care less about, but it was obviously important to them.

So I got in there, and by this time I was very experienced and I could just smell rodents if they were around. The place was just totally overrun with rodents;

the walls of this elevator were just tunneled unbelievably. This was on about a Thursday or so. As soon as I found out there was a big, serious problem here, these two gentlemen decided they had some other work to do (laughter). So I take it from that they were exactly the same party. I don't know what it was. But anyway, I called Joe Durham at Minneapolis and said, "I've encountered a very serious problem here, and it's obvious I'm going to have to stay here another week." So he said, "Well, go ahead. If you think that it's a serious problem, why, you go ahead and do what you have to do."

So that's what I did. I spent that whole weekend and the next week inspecting. I think there might have been a couple of elevators at two different towns some distance from each other. So, I mean, it was a heck of a job to gather evidence from all of those different places, which I did. The manager of the elevator was just a super guy, and he was very concerned about what was going to happen to him. Of course, I wasn't saying anything because I really didn't know, but I knew it was very serious. And since it was the Cargill Company, and they are a very large company, they promptly came in, I remember, to see Bud Kerr, and they challenged the findings that I had.

Well, I had been well trained, so I must have had fifty or sixty photographs in addition to the samples that I had. And the photographs were just fantastic, showing all this tunneling and filth. It didn't take them but a short time and they were willing to sign a consent decree. Then we had to go out and supervise this reconditioning. That took quite some time, because we were talking about hundreds of thousands of bushels of grain, and we really didn't have a heck of a lot of experience in reconditioning such an operation. But we went out several different times, and I remember one time Ron Ottens and . . . what was Potas's first name? I don't remember. Was it Howard?

RO: Howard Potas, yes.

MS: . . . and I were there, and we were working like twelve, fourteen hours a day, because they wanted to get this grain out of there. So, I mean, we were supervising all of their reconditioning and then taking samples.

(Interruption in tape)

MS: All right. We were reconditioning this grain and working twelve, fourteen hours a day, because Cargill had all their people there from Minneapolis and they were putting a lot of pressure on us that they wanted to get this done, and done promptly. So one evening, after we'd worked all these hours, just filthy and tired and cold, we

all went back to the motel and got ourselves a shower, and we went down to this little restaurant. I don't know whether it was Claremont or Huffton, but I suppose one or the other. I'm not even sure there was a motel in these towns. We might have had to go to another town. But anyway, we each had a little Pony beer, like six ounces or so, and just after having one of those, we were just silly as if we were little kids, I think only because we were just plain tired, exhausted from the long hours that we'd been putting in there. And, of course, under quite some pressure, too, from Cargill. I had some things to do with Cargill later that I'll talk about later.

One other incident that I had at Minneapolis District that I think is . . .

RO: Merv, before you go on, and before we leave this elevator program, do you think that was an effective program? How did we happen to get into doing the elevators?

MS: Well, the reason we did is that they had a two-pellet per pint of grain tolerance. Now, if you stop and think about that, two pellets per pint in a carload is a tremendous amount of filth. There is a certain amount of filth in grain just because of the environment from which it comes, so, I mean, you could run a perfectly good

operation and have a certain amount of filth. There's field mice and things like that. But at any rate, they had that program, and just at this particular time they had dropped that to one pellet per pint. They were going to make it a little tighter, and then had written this grain elevator inspection program. I think it was a concerted effort. As we did in those days, they would pick an industry that they felt was a serious problem, and then start an inspection program to go out and put some pressure on that particular industry. And that's what this was. I didn't realize it so much at the time, but I remember, when I encountered this filth, I had my inspection program with me and I read that thing, and I said, "Man, this is it. This is perfect." And so that's how I happened to go ahead and develop that one.

But the reason the state people were out there was that they were extremely concerned about what this might mean to their economy, because if we really enforced that to the absolute letter, I'm sure it could have been very adverse to their interests. And what they were there for was to see what they could do, I think, from an educational-industry-cooperation kind of program to try to upgrade for they could head off some of these kinds of

problems. Interestingly enough, we ran right smack into a big problem.

But I think it was effective. I think it really did get their attention. It sure did get Cargill's attention, I'll tell you. I remember in doing that reconditioning, they actually had their engineering department come up with devices just for the purpose of reconditioning grain, because I know you remember, rodent filth and wheat, particularly mice -- there's not enough difference in the density. It's darned difficult to separate the filth from the grain. So they came up with some pretty sophisticated equipment just to do that, I remember.

RO: What was our approach to reconditioning?

MS: We had a pretty strict approach. I'm not sure but what we might have accepted something less than what we normally would, and that was, you had to remove all the rodent filth. In other words, whatever samples we took didn't dare show any rodent filth, even including fluorescence of urine on the grain. And usually that required scouring. They had to scour that wheat. But I'm not sure that that happened on all of that grain that was in those elevators. I don't know how it could have. They just couldn't have done it. There was too much grain. And there was corn and, I think, barley, and oats. So you

couldn't do that with some of those other grains. You couldn't do that with oats, of course.

I think we probably had to figure out a way to . . . We made them skim those bins, and we made them run them through cleaners, and then we took samples. And if we found any filth at all, it just went straight into animal feed, as I remember. A whole lot of that went into animal feed. They, I'm sure, thought for a while there they were just going to divert the whole thing; it wasn't really worth their time to try to recondition it for human use. But I think whenever there was any question, it just went to animal feed. That's the way we took the line. I don't think later on, after we got into Salmonella and things, we would even have accepted that, because it would have had to be cooked or something.

In those days, shoot, if you were in farm elevators or on farms, to talk about rodent filth being something that would cause any problem with grain for animal use, you'd get run clear out of the country. I mean, nobody thought there was anything at all wrong with that. That's as part of people as . . . You did encounter that on occasion with federal judges, too, who had been raised on farms. They simply could not see the seriousness of what we were talking about, coming in there taking a whole grain

elevator. And it would affect how they would let you work out an agreement.

RO: Do you suppose that some of that contamination happened out on the farm?

MS: Yes, some of it did. But we were trained, and I know I specifically developed some pretty good techniques to prove it occurred there. We were always prepared, by taking surface samples and things, to prove that the contamination in fact occurred right here.

RO: Do you think any of the elevators had a program to screen out that contamination that could have occurred on the farm?

MS: Yes, they did. They all did. And I think that's where we had an effect, since there were notices in every grain elevator, that were not distributed by Food and Drug but by different cooperatives, that warned them about rodent filth and other filth in treated grain. I think that program that we had really got their attention and got a lot of people working.

I remember I noticed right away in making all those inspections that there were some grain elevator chains, some of these co-op chains -- and I can't think now for sure which one it was; it might have been Occidental or some of them -- where they had an excellent program, and

you could tell as soon as you went in that elevator that place was clean. They had a program that required that manager to keep that place clean. You could see it right away. And then others you'd go in and, as I say, if you went up to the top, you knew no one had ever been up there for years. It would be four or five, six inches of dust and dirt all over the place. Nobody ever went up there. They thought you were crazy for going up there. So I think it did have a pretty good effect.

Now that I think about it, I had to negotiate one other injunction up in North Dakota, and I took along with me a young inspector by the name of Fred Hibison. I don't know if you remember him.

RO: I remember Fred.

MS: He had a problem of falling asleep when he was driving the car, so I never let him drive the car. But he had farmed with his dad in South Dakota, I believe, and had very strong ties to the Dakotas. I remember, he was just a new inspector, and we got in there, and boy, you can imagine this board of directors were not friendly at all, because we were going to negotiate how we were going to recondition this place here. Fred kept interrupting me, as I was very formal at trying to get this settled. One time I remember he said, which was the straw that broke the

camel's back, "Well, we really don't care anything at all about insects or insect filth. We're just concerned about rodent filth." I said "Excuse me, gentlemen, I'll have to step out here. I want to talk to Fred a minute." I went outside the door. And Fred was a pretty hefty, rawboned farm boy. I said, "Fred, you either keep your mouth shut or I'm putting you on the next train back to Minneapolis. I'm not going to have you disrupting this negotiation anymore."

So I went back in then and got the whole thing settled, and we went on. But I was within an inch of putting him on the train. That guy just didn't have any sense at all when it came to negotiating with somebody. But I was pretty young, but on the other hand I was very experienced at that time, and certainly knew filth and knew how to handle reconditioning and things. But, still, it was quite a challenge to be sitting up there trying to take on some elderly men in their business and work out an agreement to get that thing accomplished. These people were not easy. They had their lawyers there, of course, that made sure you explained every darned provision of the law that there was as to what your authority was.

But anyway, I was going to talk about one other incident, and that was my first experience in doing

undercover work. I was sent out alone. I had gone with senior investigators before. I remember Armond Welch specifically, because he was a pharmacist, and he had made a lot of closeouts of drugstores. A closeout simply means you made illegal buys and then you announced who you were and you did an inventory of all of their drug purchases as against their prescriptions to determine whether or not they could account for legal sales or whether they were illegal. I swear that you couldn't have found a legal drugstore in the whole area if you really wanted to do a thorough job.

But, at any rate, I had been assigned this particular drugstore in Sac City, Iowa, which is the popcorn center of the world. I had a marked government car, and as you can imagine, I was very nervous being all alone. I pulled into this little town, and you just stand out like a sore thumb with that government car. So I drove around and thought, "Well, I'll park in the post office, because at least government cars are there," so that's what I did. Then I walked down a couple of blocks and into the drugstore, scared to death, and sure enough, made my buy, no problem at all; went back out, got in the government car -- pretty darned nervous, of course -- and I backed out. I couldn't go the opposite direction from the drugstore because of

traffic or something, so I turned and went right up by the drugstore and I looked around and, my gosh, the pharmacist was looking right at me. And I swear that he saw me.

I took right on out of town, and I thought I was being followed. It certainly seemed to me this car was just tailing me. Of course, you imagine all kinds of things under the circumstances, and I floored that old Chevy government car just as hard as I could, and I bet I drove forty miles before I stopped (laughter). I'm sure there wasn't anybody in the world following me, but I thought there was.

Then I went back again with Welch, I believe. I'm not positive, but I think so, and made a purchase. Then I introduced myself as an investigator, and I'm telling you, that pharmacist, it was his turn to be in total shock. It was just like you'd undressed him right there. We did our inventory, and I don't have any idea what came of it. I don't imagine he got anything more than a fine.

But those were the kinds of cases we were making in those days, and I really think that there could have been a much better way of handling that problem than going in and doing these undercover purchases, because you were posing . . . And we were pretty good. I remember Tom Kingsley, he was an absolute expert at this. By the way, he's right

here in this suite here. He'd just been out of World War II, and he was in this predecessor of the CIA (Central Intelligence Agency). He would put on some old lumberjack coats and he'd go in with a terrible limp like he had a terrible war wound. And he could get a buy just about anywhere (laughter). They'd give it to him as a matter of sympathy.

But I really think there could have been a far better way to approach that problem than by us going . . . It's extremely time intensive to do that, too. We would have to make several visits just to become familiar to these people, because they're pretty cagey; they wouldn't sell to just some stranger walking in. They'd sell to any of their local friends or family, but they wouldn't sell to a stranger. So you'd have to go in there, and if you were way out in a remote part of the district, that could really burn up a tremendous amount of time making one of these cases. And really, all you were buying was a couple of dozen pills or something; it wasn't any great, huge quantity of drugs. I know it generated an awful lot of intense dislike on the part of the pharmacists, because those pharmacists didn't perceive themselves as being criminals under any circumstances. They were usually pretty upstanding people within their community.

RO: When you would ask for these buys and things, were you trying to get some addictive drug?

MS: Oh, yes. We always did. We always targeted very carefully on those drugs of abuse that could pose some hazard. And also, we didn't just go in on a "fishing" expedition. We always went in only where we had some kind of a complaint. You just didn't go fishing in every pharmacy in the district. You had some kind of a complaint, and then from there you would go to a friendly physician, get yourself a prescription, and then file your prescription. Then you'd go ahead and get refills without authorization and expand it to the other drugs. You always had that core of barbiturates. Sometimes you would go for antibiotics, posing as having gonorrhoea or something, and buy an antibiotic over the counter.

That just brings to mind something that I did have an experience there that was really a shocking experience for me. And that is, we had a program to go out and follow up on all injuries and deaths caused by penicillin. Penicillin was very much in concern at that time because of the anaphylactic shock that it caused. I must have investigated a great many of these incidents, and I remember going into one small town in Minnesota with Armond Welch. It was a farm wife in her early forties, forty,

forty-two, perfect health. Had a cold, and she came in to this physician and he gave her right in the office like 1 million units of penicillin. And she went into shock and died right in front of him. He couldn't even -- heroic measures, he couldn't save her.

So we go charging in there, announced -- and he'd never seen a Food and Drug inspector in his life -- but we announced who we were and what we were there for, and we wanted the medical records. He went through a replay of his shock of this death. He just had a terrible time talking to us about it, but it surely had a terrible effect on me to think that somebody perfectly healthy could just die instantly like that. And it certainly had an effect on what I thought about taking drugs, and particularly penicillin, for the rest of my life. Whenever I go to a doctor even to this day, I'm very careful about what they give me in the area of antibiotics because of that experience. Anyway, that pretty much represents my experience at Minneapolis District.

RO: Before we leave Minneapolis, though, you've mentioned that some of your early work there was on Salk vaccine. How long did that program last?

MS: I can't recall for sure, but I don't think it lasted hardly a year after I came in, because I think this

other person was hired only for a year, strictly for Salk vaccine. Then others of us had to do it, and of course the senior investigators just wanted no part of this at all. We never, ever, to my knowledge, ever found a single vial ever diverted; it was just not a problem. But we had to do it because we had a program that required us to do it.

I remember something of a little interest in this area. Down in Iowa, you had tremendous professional competition between the M.D.'s and the D.O.'s (doctors of osteopathy). As you know, there's a D.O. school there at, I think Drake (University), and so there's a tremendous number of doctors of osteopathy in Iowa. They felt that there was an unreasonable amount going to one segment as compared to the other, and that's the kind of stuff that you would get. They would complain bitterly that we were restricting who got what. It was rationed, so they could never get enough to cover all of their patients, and there was tremendous demand for it. So they had a problem in how they portioned out this drug. But we never found, ever, a single incident of any diversion. It was not a nice program.

But one other program that we had there that was intensely disliked by investigators, it was the P.E.P. Program.

RO: What does P.E.P. stand for?

MS: Well, it's the oleomargarine act. I don't have any idea.

RO: Public eating places, wasn't it?

MS: Public eating places. I guess that's what it was. I just never thought of that. But that was a line item in the budget, as I recall, that the dairy lobby -- which, of course, for the Midwest, was where it was -- required the agency to put in so many hours per year on these public eating places. What you were required to do is, when you were on the road, you just took the Yellow Pages and you picked however you wanted to, at random, several eating places, and then you went out and inspected them. You'd usually go in to eat, and that's when you'd check it out.

Now, I'm telling you, the abuse you would get there would come close to what we got with Salk vaccine. And that was that you would, of course, eat, and you'd see what the menu . . . If they served butter, fine; but if they served oleo, it had to be in a triangular patty; there had to be an announcement either on the menu or on the wall. So you could tell just by eating, generally, whether you had a violation or not. And as soon as you had pretty good focus of what you had, you'd go up and announce, "Inspector

Shumate, I'm here to check out your oleomargarine," and the guy would look at you in total disbelief. Of course, the place would be just full of customers, and they'd have no understanding whatsoever as to what in the world you were there for. But I had learned from my Salk experience by then to say, "Sir, I know you may not like this. I can assure you I don't like it a whole lot better than you do. But the Congress requires us to do this, so if you have any real serious problem with it, I suggest you write to your congressman." That's the only defense you had. I don't think we ever had any prosecutions or anything. There probably were letters sent to these people.

But I do remember Cincinnati District and Sam Alfend. They had prosecutions after prosecutions of these P.E.P. places.

RO: Well, did you actually sample and do a test of the margarine?

MS: Yes. We would actually carry a kit with us and carry that kit right in there and examine it and show them. Of course, there was usually no difficulty in proving what it was; you'd just go right to the refrigerator and there's the oleo. So it was easy; it was an easy one to prove. But if there was some question about it, if they denied it or something, well, you had your test kit and you brought

it right in. It was quite an impressive kit, too, that you used.

Of course, another thing I did there in Minneapolis . . . There's just a tremendous number of cheese factories, and we would carry a kit there to do phosphatase to see if they were pasteurizing properly. I inspected a lot of these in Wisconsin. My dad was a cheesemaker and I'd been raised on a dairy farm, so, I mean, I was perfectly comfortable going into these places.

Maybe I ought to say a little something about Frank Fiskett here. I haven't mentioned his name. He was a character beyond any imagination, and one of my first trips was over to Wausau with him. He wanted to play cribbage in the evening, and we played cribbage. I'd been warned, "You don't win. You don't beat this guy, because if you do, he doesn't like it." Well, I beat him, and as we went to the room to go to bed . . . There was a big, bright light right smack over the middle of the bed. We were both in the same bed, which is a thing I'd never do later. But in those days you did (laughter). Because it's cheap. We had a list of the places that you could stay the cheapest, and that's where you stayed, because we only got, like nine dollars a day for motel and meals and everything.

But anyway, he said, "Now, I'm telling you, when that alarm goes off in the morning, I want you to hit the deck and I want you out of here in a hurry, because we got to be out there by five o'clock." And it was cold; oh, it was cold. So the next morning the alarm went off and I hit the light just instantly. And he went into an outrage. "You idiot! What are you turning that light on for?" He just gave me absolute hell for turning that light on. I said, "Well, you told me to get up as soon as that alarm went off, and that's just what I'm doing." But we would go out there, and if you can imagine, in Wisconsin, with those milk cans coming in right off that truck. It was absolutely frigid in those factories where they were coming in. But, of course, we were sampling every one of those for sediment.

RO: Every can?

MS: Every can. Or every other can, I think, is what we did. It was a tremendous job, and you had to give it all the muscle you had to do it. And, of course, you being the junior, you're the one pulling the sediments; he was mounting them (laughter).

I remember going on a road trip myself in cheese factories, and one cheese factory I went to down at La Farge, Wisconsin. I was in there pulling sediments, and I

got one can that was the filthiest can; I mean, it was just black. The cheese factory manager came up to me and he says, "Mr. Shumate, do you know whose milk that is?" And I said, "No, sir, I do not." He said, "Well, that's Bernard Shumate's. And I think he's some of your relation, isn't he?" I said, "Well, if he is, he's got the filthiest milk, and anybody that has milk like that ought to throw it in the damn gutter." He was my uncle, and he must have had . . . I think the cow must have stood in the doggone milk pail or something; it was just filthy. But anyway, in order for me to have any kind of credibility, I had to disown any kind of protection of my own uncle (laughter). It's quite an experience.

Minneapolis District was famous for being a very fertile recruiting ground for investigators -- probably analysts, too -- for other districts. It was obvious that that's what was happening. And, of course, we were in constant fear of being transferred to New York or some other place we had no interest in going. But inevitably, as was happening to a lot after a reasonable time, I was transferred to Detroit, Michigan, as a resident out of Chicago District, because they had plans in the next year to open up a new district office there.

RO: Before we get involved in some of the things that happened in Detroit, one other thing that I'd like to have you talk about if you'd care to, Merv, and that's the Poultry Inspection Act, because I think there was some of that back in the late fifties.

MS: Oh, yes. We did do poultry inspections there in Minneapolis. I'm a vegetarian, and that was not something I enjoyed a lot, I'll tell you. But we would go in these places, and the feathers and the stench and everything was just enough to really get you. But we inspected all of those poultry plants all over North, South Dakota, Wisconsin, and Minnesota, because you had a tremendous turkey industry up there. That was the one program that I was extremely happy to have the USDA (United States Department of Agriculture) take over, because it was not something we were that well trained at. You're looking at birds, but how do you know whether they're diseased or not? Unless it's so obvious, you wouldn't know. You could check sanitation, and that's mainly what we did.

RO: I remember going into a cold storage plant with you and inspecting, I think it was chickens.

MS: Pullets. Yes, I remember that. Yes, we did. We had a request to sample some pullets that had been processed in an insanitary facility, and what we were doing

is checking to see if we could find fecal matter. And I think we did.

That brings up another thing. This could go on forever, but another experience that I had up there . . . We were experts at filth, and I had found . . . Well, just to say on the side, I did on my own develop a prosecution against Ralston-Purina for their Rye Krisp plant for insect filth. That was not an easy thing to do, because this company didn't appreciate having that kind of adverse publicity about their facility; but they did plead to the charges and paid the fine.

But one other incident. I went out to inspect a Chinese warehouse and noodle manufacturer. I got in this place and it was just overrun with rodents, just filthy. And they couldn't speak English, or they said they couldn't speak English. So I developed the case, and, actually, in that instance, went down to Madison myself and collected some samples I had reported, and actually found whole rodent pellets right in the noodles down in some fancy restaurants down in Madison.

The case was written up for prosecution. And it turned out, in doing investigation on the owner of this place, that he was actually a Chinese scholar and a person that the post office and others went to whenever they had a

question about some Chinese correspondence. So he could speak English just as well as I could. But when it came up time for trial, I went over to court ready to testify, and in he comes with . . . He was on crutches, his head was all bandaged; he was just on the edge of death. He couldn't speak any English. He got off just very well. But it was purely an act, we were sure of it.

But going into that doggone place and finding those people not speaking English or anything and just a filthy operation, it was easy for me to develop a case on them, because they were, in fact, feeding the people filth. These were going to institutions, too, so if you got yourself an order of noodles or something, you got it cooked right there. There was no way that you could see it or anything. So that was pretty significant.

I did have a tremendous amount of encouragement there, too, by district management. I remember Johnny Guill and Joe Durham and Bud Kerr, they would give you tremendous praise for doing a good job, and that kind of made you feel good, too.

Now I'll talk a little bit about Chicago District, which is about as opposite an experience as you can imagine. The first day at the resident post, when I went in . . . This resident post was in the Federal Building

where the FBI (Federal Bureau of Investigation) and the court, and U.S. attorney and all these people were. It was on East Lafayette in Detroit, right downtown, absolutely no place to bring samples or . . . We parked our cars some distance away in a parking garage. It was just very bad to try to have to handle samples or anything in that building.

But my very first day on the job, I noticed that the office was extremely small. There were four other residents there already, and it was Irv Pollack and Ted Herman and Ken Cofert and Mel Kaump. And these were all Chicago inspectors; I was the first one from outside. I got the desk right at the very door. Right at my right elbow was a wash basin with a mirror, and extremely close quarters. At about three o'clock in the afternoon, Irv Pollack, who was the senior inspector resident, he gets up and he walks back and he urinates right in that wash basin, right beside my elbow. I said, "For God's sake, what in the world is going on here?" He just calmly took a drinking glass, ran water in it, and rinsed out . . .

(Interruption in tape)

MS: He went ahead and rinsed out the wash basin, and then said in a completely nonchalant manner, "Well, that's okay. It rinses out. And it's a long way to the restroom. It's clear on the other side of the building." That was a

clear indication of the character of some of those people in that room. It was just awful to be in such cramped quarters, but it was a lot worse to be with people that didn't seem to have even the most basic respect for others. It was indicative of some other things that went on.

Then we moved several other times while there, because they were trying to find a site for the new district office and get the contracts let and the equipment coming in and the whole business. And then we moved from this building, the Veterans Administration Building on East Jefferson as another temporary office. It wasn't much larger, but just a little bit, and of course by that time we were getting other people coming in.

We had Howard Bollinger come in from Los Angeles, who was going to be the chief chemist. I remember he wanted to go out on inspections because he didn't really have much to do except try to order equipment and oversee it coming in. And he didn't have any common sense at all. He went with me to a tomato cannery. It was a pretty hot afternoon, and we'd been there all morning and all afternoon. On the way back, I felt like I wanted to have a Coke, something cold to drink. I hadn't had anything hardly all day. So I pulled into a little station, little ***** or something similar to that, and said, "How would you like to have a

Coke?" "No, thank you." He just sat right in the car. He didn't get out or anything, which kind of quashed my idea of going in; I didn't want to go in alone. But that was indicative of him. He, I'm sure, was a very good scientist, but when it came to common sense, he seemed to not have any (laughter).

In the spring of 1959, we opened up the new district and we had quite a lot of people coming in from all over the country; however, predominantly from Chicago, Cincinnati, and Minneapolis, I believe. George Daughters came from Chicago as the new district director. Ted Maraviglia was the chief inspector, and Howard Bollinger was the chief chemist.

Most of the investigators that came in there new were from Chicago District, and the Chicago District's investigators were . . . I'm not sure, but it seems to me that many people that came in there were people that other districts wanted to get rid of. Because George Daughters had a very serious drinking problem, and most of the investigators that came with him were also drunks. I think specifically of Pat Ryan, of Howard Pilson, and of Dick Anderson, all of whom are dead. They'd be sixty years old if they were alive today. But each of those, whenever they

went to a party or on the road, they just seemed to make it their business to get plastered.

Of course, George did, too. Every time we had a Food and Drug party or picnic, George and his wife both would be totally drunk and out flat on the floor. I mean, I remember one time it was Ted Byers' going-away party. He was going into Washington. Maybe he was even leaving government; he might have left government. He went down to Ross Labs in Columbus, I believe. But anyway, it was actually kind of dangerous, because Pat Ryan, I remember, and some others, once they got really drinking, they'd get belligerent. And you just didn't know whether you were going to be challenged or something. It was always a little tension there.

I remember George. He gave the most blistering speech as to Ted, which was part of his kind of humor. But there was a serious note there, too. He was slamming chemists generally. But he was drunk; he was drunk. He could speak pretty well even if he was drunk. But when they got ready to go home, I remember he and his wife -- and she was trying to put on her galoshes and she just went flat on the floor and the chairs flew. I had a terrible time from then on getting my wife to go to any party, because she has no respect whatsoever for any of these people.

I had great respect for George Daughters, because when he came to work in the morning . . . Like, the next morning after this particular party, you wouldn't think he'd even be able to get to work. Well, very early the next morning he is in that office and he is as sharp as a tack. And he walked up to me and he said, "Merv, what did you think of those remarks I made last night?" I said, "Jesus, George, I thought they were doggone sharp." He reaches quietly in his side pocket and he pulls out a three-by-five card and he says, "You thought they were ad-lib, didn't you?" (Imitates his laugh) He had that all planned.

Before I get too far into the new district, I do want to recall one experience I had at the resident post not too long after I had been there. I had used my skills in filth work to really get into the grain trade there in Michigan, which hadn't had hardly any attention from FDA. I had been told by some of the senior inspectors in Chicago District - - I'm thinking of Vince Balaty and some of those people who considered themselves experts -- their view was there just wasn't any problem in the grain industry.

Well, I had become an expert on the grain industry, and I just made a few visits to some of the state sampling and grading people and immediately developed a rapport

whereby they would let me know whenever they saw anything that was suspect. So I could focus right in on the problem shipments right away. All the grain out of Michigan went down to Toledo for shipment on the Great Lakes or by train, and so it was an easy place to get samples with any grain in Michigan. I promptly got an awful lot of seizures down there and put a lot of pressure on the state, same as we'd done out in the Dakotas. I remember Senator (Arthur) Vandenberg from Michigan, he was really upset about what was happening and generated a meeting at Michigan State University at which I was invited to talk to them, because, again, they were trying to figure out what they were going to do to get rid of this problem, if they could.

But, I mean, I really kept the pressure on and got a few injunctions. And I did do an inspection at Carrollton, Michigan, of wheat germ. I forget the name. It's a famous brand, though. You know, this wheat germ. And it's at Carrollton, Michigan. I forget the brand name. But anyway, I went up there, and I found them to have rodents in the place, and I developed the evidence the same as I had in Minneapolis and submitted the case. Nothing ever happened, absolutely nothing. And I was quite frustrated because it was pretty serious. It wasn't just a marginal kind of filth; it was pretty filthy.

So we had a district conference not very long after I had gotten there, and we took the overnight train from Detroit to Chicago, got there just in the morning in time to go right to the conference. As soon as the opportunity arose, I proceeded to relate some of my experiences, because I really was eager to get some cases going and I wanted to describe what I had done. I wanted to get some explanation as to why there wasn't anything happening with these cases. As I just got myself really pumped up and going pretty good, there was a chorus in the back of the room with George Daughters sitting in front of the room, that said, "Aw, who cares?" Who gives a shit anyhow?" I just couldn't believe, because having come from Minneapolis, where you were looked on as a really up-and-coming investigator if you told of some successful experience, here in Chicago by contrast the very fact that you're even talking about it, you're booed in chorus. So that just stifled any discussion, not only by me but by any other investigators; you didn't want to subject yourself to that kind of wrath.

But anyway, Frank Hereford was the compliance officer, and he pretty much told me right there in front of everybody that this was nothing of any consequence. I think he was simply just too darned lazy to write it up.

He had been a resident in Detroit, and he said something to the effect that the people running this wheat germ place were nephews or cousins of the district judge that was sitting up there in Saginaw, and there wasn't any way anything was going to happen anyhow. And I said, "Well, you'll never know if you don't try" (laughter). But anyway, the message was loud and clear that this kind of case, we're not really interested in.

But I did have a great deal of success in the grain industry there that I think had a major impact upon them. I remember going down to Toledo after the district opened and starting inspections down there, and one of the terminal elevators there was a Cargill elevator. Now they have a manual, an SOP manual that they have to do certain things if an FDA investigator shows up. As soon as he wired in that this was Shumate in that terminal elevator, he was visibly nervous (laughter). Because apparently they had said right away, "You better watch this guy. He's damned dangerous. He's caused us a lot of trouble out here." They were pretty clean and I didn't have any problems, so nothing happened of it. But anyway, that pretty much took care of being a resident.

But then the district opened, and we had quite a hodgepodge of people there, as I've indicated. But I

remember we had an open house, and it was a very big affair. I got to work that morning and George Daughters met me at the door, and he said, "Merv, you get out in the car and get out to Willow Run and pick up the secretary." I said, "Yes, sir," which was my custom in those days, and I went out and back. We didn't have any cars yet; just had the cars that the resident post had, and the only car that was available was a '56 Chevy that was just filthy. So I threw everything out of that thing. There was no back seat. I threw everything out of it and took it out and ran it through a car wash, and then took off for Willow Run.

When I got to Willow Run, of course I didn't know who the secretary was. I'd never seen him before. There were a lot of people there, and I was really quite concerned that I wouldn't pick him up. I didn't have enough sense to page him, I guess. But anyway, I watched pretty carefully, and I saw a man very well dressed and pretty distinguished looking, and he looked like he was looking for somebody. So I walked up to him and asked him. I'm not sure if it was Secretary (Arthur S.) Fleming or not. I think it was, and it was. And so then I took him on into the district office.

I'll never forget it, because as I got him at the district office and delivered him to George, one of the

investigators said to me, "Merv, you know George has already been over at the crisis. He's already had two double boiler makers." The opening ceremony was a ten o'clock in the morning, and he's already had two double boiler makers. So they had the opening. And it was not just the secretary. The governor, and the mayor of Detroit -- there were tremendous dignitaries there. Then I know (Allen) Rayfield was there. I'm not sure that (George) Larrick was there, though. I don't think so.

But at any rate, we had the open house. And then that evening there was a banquet at the Sheraton Cadillac, downtown Detroit, a very big, fancy affair that had been put on by industry that George had drummed up. And they put on a fantastic banquet in a ballroom, with a head table with all these dignitaries sitting up there. Immediately the Chicago boys start -- and I was sitting at the same table with a couple of them -- putting the pressure on industry to go out and get booze. I mean, "Bring in the booze." And they're getting really stinko. I looked up, and George Daughters was out cold at the head table. I thought to myself, "This is the end of George. There isn't any way in the world that he's going to survive this."

Well, he did. There was never anything said about it. But, of course, somebody mentioned to me just last night

that George's first wife was the daughter of George Larrick, and I didn't know that. But that might have had some effect on his longevity, because certainly from where I had come, say, Minneapolis, there's no way in the world they would tolerate such conduct. It just shocked me. It was embarrassing, quite frankly, to see not only George, but to see the other people working the trade like these people were to just blatantly get them to go out and get booze and bring it back for them. I was supposed to be in law school, but I had skipped law school that night just because of this affair. I remember going home, and I thought, "Boy, that's a despicable sight if I ever saw one, the way people conducted themselves."

But the next day, as usual, George was back in the office, just as sharp as a tack. I remember he kept a fifth in his bottom right-hand desk drawer, and for only those that were very well know would he invite them in, say, about four in the afternoon for a drink before they went home. Because George would start then, and I'm told that he and his wife would each consume a fifth of whiskey every night -- that's just routine -- until they were totally out of it. But at any rate, he never invited me in there, because I was not one of his close friends when it came to boozing. But enough other investigators,

particularly from Chicago, were invited in that I knew it was going on all right. And at four-thirty sharp he left that building. There was no way he stayed around.

Except on one occasion. We had the deputy commissioner, Jack Harvey, out, and it was going on and on and on, and he was telling stories. And you can imagine with these Chicago types and others, they didn't give a damn if it was the president of the United States. They didn't care if they showed respect for him or not. But at four-thirty they're all getting anxious, because George is the first one out the door and they're all out there with him. Well, you know, in Minneapolis we never thought about going out the door. You worked until you got the job done. Just a totally different view of things.

But anyway, right at four-thirty, George, totally uncharacteristic to him -- he always scratched his mustache -- said, "(Imitates laugh) Tell another one, Jack." So Jack goes on and tells another one. It goes on to five and after five, and people are getting really disgusted about holding them over. But anyway, it finally broke up. Next day we had a picnic at Metropolitan Beach, and, as usual, the Chicago guys are really drinking it up. And there was George Daughters, and Dick Anderson, and others, Joe Hannegan, I remember, playing poker right out in the sun

and drinking like crazy. Every few minutes Dick Anderson, as only Dick Anderson could do, he'd pretend he was scratching his mustache and he said, "(Imitates laugh) Tell another one, Jack." And George would almost, you could just see he'd like to kill him every time he said that. But that went on all afternoon. But that just further proved to my wife that these were things to avoid (laughter), because these people would just get flat-out obnoxious. They'd be on the ground, drunk.

I was going to the Detroit College of Law while at Detroit, but I could not let that be known. I had to take my road trips just like everybody else, because in those days you were looked on as being somewhat disloyal if you went to law school or something; that meant you weren't going to make a career of FDA. So I just did this on the side, and I can assure you it was really difficult, because I remember a few times being out in the fish markets collecting fish, and I'd only have time to grab a candy bar and run right over to law school. I remember a time or two running into class, and the other people would ask me, "Where did you say you worked?" (laughter)

But I'd have to go on the road, and they would give you just unbelievable assignments, cases to read and to brief, and it was extremely difficult to do when you had to

go on the road and whatever. Most of the law students there were from the auto industry, where they were given formal encouragement to go to class. And they were given time off, and they could study. Particularly when exam times came, they could take off whatever days they needed to study. Man, I was trying to make sure I was going to be at home when the exam times came around.

And then, after a while, we got transferred to Charleston, West Virginia. I was a resident.

RO: Did you get to finish your law?

MS: No, I did not. I had a year and a half, three semesters, carrying ten hours a semester. But as I was going to say, I got transferred. I was taking finals, and my wife was in graduate school at Wayne State University. We had a new home, and they gave us two weeks to get moved. So right while I was trying to get finals, I was trying to sell a house and move.

In those days, you couldn't raise a question. If you were told to go somewhere and that was your career, you had to go. You couldn't question it. But I mean, I was extremely bitter, because we had taken all of our money to buy this house, and it just happened to be a recession at the time, and we couldn't give that house away. We could not sell the house. I remember George Fowler was coming

in, and I called him and offered him to take the house if he'd just take the payments, and he wouldn't do it. And it was a brand new, dandy brick house in Saint Clair Shores. But we had to go. I remember remarking to George Daughters that it was a very good thing that both my wife and I were working, or there was no way in the world we could make this transfer.

So we left there; we left there with nothing. We didn't get anything out of the house. And, of course, it costs you to sell houses, and in those days you got no assistance on any of those kinds of expenses. So we just went to Charleston and checked into kind of a townhouse and made our monthly payments; that's all we could do.

RO: What grade were you then?

MS: I was going to a GS-11. I was a GS-9 going to a GS-11, and, of course, that was a very important move. As I say, you just didn't question it. If you were going to make a career, you had to do it. But I've often thought, "What would have happened had I just said 'no' and stayed there and finished law school, and Ellen would have gotten her master's degree?" We would have probably been far better off had we stayed. But you didn't have an awful lot of resources, and there just didn't seem to be any

question. You just had to move; that's all there was to it.

RO: Well, there were some that rode it out, if you remember.

MS: Yes, some did. But, of course, almost to the person, they never, ever did get anywhere. Of course, they're probably better off in that home we were in, why I mean, it was only \$100 to \$115 a month. It would have been long paid off by now. So who's to say? Had I gone through law school, went into the practice of law, Ellen continued to teach, you can't be sure what you might have done. But I know I had an extremely difficult time in law school there because of this conflict of not being able to tell anybody. I remember taking some trips down to Toledo, for example. I would take my own personal car on the trip because I'd run back to Detroit to go to law school that night. God, I mean, it was rough. I didn't want to miss class. But I didn't have any choice.

RO: When you were taking law, Merv, had you intended to make FDA your career?

MS: Oh, no. What I intended to do was get my law degree. See, I was very much interested in being a lawyer for the Food and Drug Administration, because I was called an eager beaver and I truly was an eager beaver. I really

wanted to do everything I could for Food and Drug, but that experience in Chicago District was quite a shock, believe me.

Anyway, I transferred down to Charleston, West Virginia.

RO: That was part of what district then?

MS: That was Baltimore District. It's about 350 miles from Baltimore, and it was just like you were in total isolation, because I found right away senior inspectors did not come out there; they didn't want to make that long trip. And the assignments weren't that great because you didn't have that much industry. What you had was a tremendous amount of undercover work. I remember George Sooy calling me -- he was the chief inspector -- and asking me if I had done any undercover work. I said I had done a very little bit in drugstores in Minneapolis, but I hadn't done very much. He said, "Well, you're going to now." And I found out that that was absolutely true. I just practically lived in undercover work. I had never done much of this. In fact, I didn't like this kind of work. As I told you, I was scared to death on that little job back there in Iowa. But, as a matter of survival, I had to learn how to do the best job I could.

But I wanted to say, the first day that I went up to this office, I had to go through the U.S. attorney's office. It was in the Federal Court Building on Quarrier Street, and I noticed that the desk was just jammed full of religious literature and brochures. It took me a day just to clean all that out of there. The resident inspector before me had been a religious nut. I had to go through the U.S. attorney's office that I had to go by in and out of the office. After only a few days, she said to me as I came in one morning, "You know, Mr. Shumate, I've seen you more in these few days that you've been here than I saw the resident in the whole last year." So that meant to me he never went to the office; he worked strictly out of his home. I don't know how he ever did that, but that's what he did.

I didn't know quite how to work with the undercover work because I just hadn't had that much experience. And obviously, this was mostly truck stops and things of that sort. One thing Robinson had told me, who was the resident -- he wasn't there when I got there; he'd been gone. But he'd called me and he said, "The one thing you have to do a lot of down here, Merv, is you have to do a lot of undercover work. And you want to be awfully careful, because these people will kill you for nothing. I mean,

they don't value anything here. So you just have to be very careful." He indicated to me he was extremely scared, nervous to do any undercover work, and he did very little of it.

RO: This was different, then. You were getting away from, really, getting prescriptions and things.

MS: Oh, yes. This was, now, strictly buying drugs, illegal drugs. So what I did is, I went down to the Federal Highway Administration and got some contacts there with their equivalent resident to find out what kind of cooperation I could get from truck companies, because there wasn't any way I was going to get in these truck stops out in these -- these truck stops were right out in nowhere -- without a truck. It's the only way I could get in there. There's no way I could be driving a government car. I did have an unmarked government car, and I had all kinds of license plates of different states, and driver's licenses. I had all kinds of cover. But you couldn't drive in with a government car; it just wouldn't work. I tried it a time or two, and they wouldn't even talk to you when you got out of a car and walked in there. They knew something.

Those people were cagey, and they were cagey, I found, because they had a moonshine mentality. It's a game with them to compete with the federal regulators, and so they

have just a sixth sense. I had many of them tell me in the middle of the night in a truck stop that they just had a feel that there was some federal agents around here. I had a cover statement every time: "Aw, that's impossible. There couldn't be anybody around here. Out here? You're kidding me." Of course, I was the federal agent, sitting there trying to get them to sell, see.

But anyway, he put me on a trucking company in Huntington, West Virginia, and their business was hauling cars out of Detroit and Toledo. They hauled a lot of Jeeps, as I recall. They put me on with their young guy that was a dispatcher or something; he was pretty high up. But he was immediately interested, and so I met with him. He said, "Sure, I'll provide you trucks. No cost to the government whatsoever." I think I did pay some fuel a time or two, but there was no charge. "And I'll drive the truck for you," because there wasn't any way that I could be driving a semi through those mountains. I'd never driven a semi. But he volunteered to do that.

Well, we covered that whole doggone state. He would even go get cattle trucks. They didn't have any cattle trucks, but he was in the trucking business and he knew people that were owner-operators. I remember we got one in the middle of the night over in Gallipolis, Ohio. It was a

cattle truck. I checked out that glove compartment just as soon as we got in that truck. We never saw the owner. He worked it out, so we just picked it up. And that damned glove compartment had bennies (amphetamines) in it. Well, I cleaned that out of there. There's no way we were going to be driving a truck with any drugs in there unless I bought them. So we took off, and we covered that whole state from east to west. I mean, all the way from Wheeling to Princeton and from Parkersburg to Alderson, West Virginia. We just covered that state. You could buy bennies in any one of these places. You might have to develop a little bit of rapport, but I got so I was pretty good at that. And scared to death half the time.

I had a mini phone recorder on my back that I could record what was going on, and I remember I made quite a few buys across from Gallipolis, at Point Pleasant, West Virginia. A truck stop up there. There was a guy by the name of Red who was selling, and I made several purchases from him in the middle of the night, always in the middle of the night, out of a truck. I wanted to get the owner of that station, so I kept upping the amount of drugs I bought until I knew he didn't have enough stashed out in the area where he sold fuel. And sure enough, he had to go in to the owner. And I watched him. He went right out and

rapped on the window, and the guy went back in the back of the restaurant. He brought his pills up front and handed them out the window to him, and then he came in and gave it to me.

Well, before we went to trial, in those days, of course, you didn't know their names; so you had to give them a notice of hearing under 305. So what I'd have to do is, I'd have to make out a notice of hearing, except the name, go identify the person, and then hand them the 305. So this guy -- I only knew him as Red; I didn't know him. I went up there, and he wasn't there. He was gone. I kept tracing and tracking him, and I got over to Chillicothe, Ohio, and finally I found him in Columbus, Ohio, in a jail. I went to the sheriff and I asked him if I could have this prisoner down to the interrogation room so that I could talk to him. He said yes, and he brought him up. Well, I took a look at him, and he didn't look at all like the man I had made a buy from, and I was just in shock that I had the wrong person. So I said, "Red?"

(Interruption in tape)

MS: In order to identify this man, I said, "Red?" He said, "Yes." Well, I knew I had the right man, and I started asking him then if he'd worked at this particular truck stop, and when he'd worked there. And he admitted

that he'd worked there. I said, "Well, my gosh, you certainly look a lot different than the last time I saw you." He'd been on a binge; that's why he was in jail. And he was totally emaciated. I mean, he just looked terrible. He admitted everything, confirmed it. I wrote up an affidavit; he signed it. Just had everything wrapped up perfect. Gave him the notice. I had in that affidavit, I had the owner of that place just tight.

Well, after I transferred out of there to Buffalo, I had to come back for trial in this case, and I testified. He denied anything in that affidavit. He just simply said that I had so scared him that he just wrote down anything, and there wasn't anything true in it at all. Well, this totally destroyed me, of course. But I testified exactly as I told you about them handing the drugs out the window. And then the defense attorney gets up and he says -- and this has been a year or two after I'd been there -- "Mr. Shumate, isn't it true that that isn't even a turn-out window at all; it's strictly a casement window that doesn't turn out at all?" I said, "No, sir. I have my notes here, and I recall that very vividly, that it did turn out. And he handed those drugs out through that window."

Well, about that time we had a recess, called the state police up at Point Pleasant, asked them to get a

professional photographer, go out there and take photographs of that truck stop, and get down there to federal court. I'll never forget it. I was on the stand when that state policeman and this photographer came into the courtroom. Well, you can imagine the suspense I had: "I hope to God I'm right, because it's been so long I couldn't swear to it." He walked in there and he put those photographs into evidence, and they were precisely as I'd testified. I mean to tell you, I was ten feet tall.

But I thought that there wasn't even the slightest question that these people were going to be found guilty. They acquitted them. The wife was in the courtroom, and she was screaming and crying and carrying on. I remember one time we had a recess, and I went out back. I smoked in those days. I went out back of the courtroom, and she and her daughter -- they were great, huge people -- they came out there and they were swearing at me and just giving me the business. I turned to her and I said, "Ma'am, you can say anything you want to, but just don't do anything else. You understand?" (laughter)

They acquitted them, because down there they didn't consider this that serious an offense, and they just simply didn't like the Feds, and you never knew what a jury was going to do. I was totally crestfallen, because I'd spent

many, many nights and hours developing that case, and had the case go on just as perfect as you could ask. And then they acquit them. I think they did convict the guy that had written the affidavit. He might have even finally pled guilty, but they never convicted the owner, which is the one I wanted. He was the guy, and I had the total story of how many thousands he had purchased and where he'd kept them. I had all of that right into evidence and the whole business. They just let him off. No problem.

That's quite a shock when you've gone through . . . You put your neck on the line, too, when you go out to do these kinds of things. And you know what they expected you to do in those days. You didn't go out just to do truck stop investigations. You conducted your regular inspections during the day, and in the night, only, did you get on your gear and go do truck stop inspection. That was extra overtime. You didn't do that during the day. Of course, you never got any overtime, ever.

RO: In district offices, though, there were a group that always kind of felt that they were the people that did the undercover work, and . . .

MS: Well, there was an expert in Baltimore who worked with me. And I tell you, his credibility was very questionable to me, because even though I was doing this .

. . . I noticed narcotic agents and some state agents, they got to be almost as bad as the crooks. If you were successful, you had to mimic them as best you could. But there was a line. I just wouldn't do that.

But Ed Wilkens, he actually would, I think, go beyond the line in the way he would get people to make sales to him. I remember, I just had a kind of a concern about the way he would do this. But he was extremely effective; he was good. He'd been with the circus, and he was absolutely ring-wise with this kind of thing, and he knew exactly how to work these people. And he did; he really did. I mean, I wanted to keep it as absolutely straight as I could. I'd put it right straight to them, and it was strictly their opportunity to do it or not do it. I wasn't playing any games about anything with them. And I got quite a few people.

I know up in Wheeling . . . Now, this will give you a clue as to the kind of corruption you had in that state, which is a very serious concern of mine, and that led back to what Robinson had told me. But I trusted absolutely no law enforcement official other than the FBI, because you could find very quickly upon going into a community the sheriff usually had the largest house in the community. It was well recognized that he was taking payoffs from

everybody. There was no liquor by the drink anywhere, but you could find a club within a matter of minutes of going into any town where it was wide open, selling liquor with no question, prostitution, gambling -- everything was wide open. Well, if it was wide open to a stranger coming into the town within a few minutes, it's obviously very well known to the police. But yet they were operating openly and with no questions asked. Even in Charleston this happened.

And so I was up in Wheeling, and Wheeling was well known. They had the underworld element up there that were in competition with each other, and they would bomb each other's places of business on occasion. One of them was this guy by the name of Muldoon, as I remember. He was a hood up there, and he had a huge Pure Oil truck stop out to the east of Wheeling that was well known for selling bennies, selling drugs. Well, I went out there, and I had to get a truck. This was too far from Huntington, so I couldn't get my usual guy to give me a truck. So I inquired of my friend in the Federal Highway Administration as to who I might contact, and he gave me the name of a trucking company.

I went out there and I asked them if they could give me a truck that I could take through these truck stops, and

I'd find out from them who I should talk to or the most credible people to talk to. The man said yes, he could provide me a truck, but it would have to be a truck with a load; they wouldn't be just running a truck out there just for the government, that if I wanted to ride with a truck, I could ride through and they would stop. But once they got out to the east or wherever we were going, that truck was going on, and you were going to have to get back the best way you can (laughter). It's unbelievable what I did.

I went out there. I made buys, no problem. And then they went about twenty miles on, and you're pretty doggone keyed up if you've been through this kind of an experience. And this guy just lets me off at a crossroad out there, not even in a town or a restaurant. I bailed out and I got to the first phone, and I called an insurance guy that I had met in Wheeling that day on some food inspection or something. He was a very nice guy, very friendly. I called him up and asked him if he'd come and get me (laughter). He said he'd be glad to, so he came out and got me and took me back into town. It's hard to believe that you can actually work like that.

But anyway, again I had to identify these people to give them notices, a 305 notice. So I did, I had my notices. It took me a while, because these people don't

last very long; they're just there and they're gone. I found this young man that had sold me the drugs, and there was a young woman, too. I had to question them somewhere, and there wasn't any real good place to question them. This guy did work at the truck stop yet, and I didn't want to be anywhere near that truck stop, because I already had information that Muldoon would put some plastic on your car if he didn't like what you were doing.

So I got him to come down to the state police barracks in Wheeling, and he came down there. I got him in an interrogation room, and I'm verifying who he is. I gave him the notice. And a state policeman came in and asked me to look out the window. It was right outside the window that I was interrogating this guy. There's a great, huge white Cadillac, with Mr. Muldoon in it, sitting out there. He knew I had this guy in there, and he's just going to show me that "Up here, I've got something to say about the law." I got very friendly with some of the state police, and they told me they never even bothered to raid a place with slot machines or prostitutes. It just wasn't worth it, because the district attorney was also the attorney for Mr. Muldoon, and if they seized slot machines or anything, they'd have them back before they could even get back to the barracks. They'd get a court order and get them

released, and they said they just gave up on trying to do anything about it. So they just left it go.

RO: Merv, what was the reason that these truck stops were selling -- what did you say, bennies? Amphetamines?

MS: Mostly amphetamines. Well, the main reason was, that was a big heyday at that time. These truckers were driving unbelievable hours, and in order to do that, they took bennies. I mean, I can tell you stories. These people would come in and play the slot machines, and they were gambling devices is what they were. I was told by some of these truck stop people when I'd get friendly with them that they would make as much as \$1,000 a month on each pinball machine just from these truck drivers. Well, they'd come in there and they'd play those things for hours. Well, yet they've got to be driving, see. And I've seen people come in that would be in an absolute daze. Here's a semi out there with 40-, 50-, 60,000 pounds of steel on, and this guy is walking in, totally in a daze. You'd strike up a conversation with him, and he'd say, "Benny's driving tonight." In other words, he doesn't know where he is. And you think about that guy getting in that truck. Well, I can assure you it gave me great incentive to do something about it, because there were people's lives in jeopardy.

Another thing that got to me in West Virginia is whenever I got a complaint, I would go out and interview the family to try to get as much detail as I could to conduct the investigation. I visited a tremendous number of families that were very fine people totally destroyed because of drugs. Either the husband was a businessman who was on bennies . . . I remember down in Princeton I had a complaint about this one particular young girl, and I got out there and started to investigate. I found out this sixteen-year-old girl was on bennies. She was a prostitute. Just a high school kid. I went out to see her folks, and I went to the high school. And her folks, they were very dirt-country-poor people, not too unlike what I had come from. But good, honest people. There were totally distraught. There wasn't a thing they could do. She could go down here to the truck stop and make more money than they'd ever seen. As far as they were concerned, she was doomed to hell for sure. I mean, that can really get you dedicated to go out and try to do something about it, because you knew this girl . . . By the time they were in their twenties, they were old women. And so, I mean, that's what gave me tremendous dedication to go out and try to catch these peddlers.

But it absolutely amazed me at the time. I would find drug sales going on in the smallest coal towns. See, it was a depressed area, and people sometimes would get hooked through their physicians. Because they were depressed people, and they had pains, many of them, arthritis and other things. They might even start through their physicians, and then maybe the physician would be the one peddling. Or they would go into the truck stop and get them. But it seemed to me to be a very, very serious problem. This gets to one point I wanted to make.

I want to cover one other thing, though, first, and it kind of fits back to South Dakota and state politics. There was tremendous state politics here, just rank politics. I developed a rapport with the counterpart state people, and they were good people. Harold Amick, and I can't remember the guy that was the head of the Feed Grain Fertilizer, but . . . Snyder, I think, Marvin Snyder. Very nice guy. But they had no control whatsoever over who they hired, because the secretary of agriculture ran for election, and that meant you had to contribute part of your salary. And you had to campaign for the secretary of agriculture. That meant that whoever did the best job of campaigning got the job; it didn't have anything to do with their training or background.

I remember one particular person was an undertaker, and he was sent out with me to do an inspection of a cream station. This cream station was the most filthy place you've ever seen. That cream had been sitting alongside the road; there was two or three inches of mold on the top of the can. And I was tasting every one of these cans. I would just gag whenever I would take a taste of that; it was just that bad. This guy is nitpicking me throughout this entire inspection as being overly aggressive and "There isn't anything wrong with that cream. It would make perfectly good sour-cream butter, and I don't know what your problem is." Just causing me unbelievable trouble. He was running his undertaker shop at the same time he was an inspector. But that was the kind of people you had to put up with. They just didn't have any training at all.

But they did invite me to their annual conference every year, and they would always introduce me as "their Food and Drug inspector." I was treated with a tremendous amount of respect. And it was a good experience, because I would try my very best to instill in them the professionalism and the need to do the best job you could and all this kind of stuff, see. And, as a matter of fact, I went back twenty-five years later just before I retired and spoke to their conference again, and it was a good

experience. I found some of the very same people still there, and politics is just as bad, if not worse, today. I couldn't believe it that it still is, but it is. You can imagine how difficult it must be to put in a career in a place like that. But at any rate, I remember the secretary of Harold Amick's . . .

RO: Do you remember his name?

MS: Her name. This was his secretary. I don't remember the secretary of agriculture.

RO: Gus Douglas?

MS: No, Douglas was after this. I think his name was Johnson, but I'm not sure. Douglas is still the secretary. Douglas was a young man that was there at the time, but he wasn't the secretary. But anyway, Harold Amick's secretary called me up and she wanted me to make a case against Harold Amick, because he wasn't doing his job. I found out that she had much more power than he did, because she had really worked hard for this secretary of agriculture's campaign. Put me in a terrible conflict situation, and I simply told her I would take whatever information she had and I would certainly follow up on it to the best of my ability. But there really wasn't anything to it. It was just that she was trying to get him out of there. But it was just amazing to me that that kind of thing could

happen. I mean, I'd never, ever experienced anything like that.

It was what I would classify as the classical example of the spoils system, that people got their jobs solely because they campaigned. One young girl I noticed in this office that had worked very hard, and she was from Lincoln County, which is one of the worst moonshine counties you've ever seen. I went down in there to do some investigation on a benny peddler, and boy, I was warned not to go up in the different sections, because they're armed up there, and that's moonshine country. Well, that didn't stop me, because I had by that time felt that I could go anywhere, and I did.

She came to me one time to the office and described to me the politics and how she was expected to accompany certain officials on weekend trips to motels and stuff like this. And she told me this story, and I said to her, "You know what you ought to do? You ought to go to college and get yourself trained so that you're not going to have to do this, because, you know, this is going to just be a terrible thing for you as you get older." She wrote to me after I got to Buffalo, and she had a master's degree from that school there in Charleston. I really felt good about that, because I think because of my encouraging her, she

was able to get herself out of a situation that could have been just terrible in the future. But it had quite an effect upon me.

And I noticed, too, on the state board of pharmacy, there's a very fine gentleman that ran that board of pharmacy. I just can't remember his name, but he had one of the biggest pharmacies right downtown in . . . It was a classic pharmacy, too. It wasn't a drugstore; it was a pharmacy. And he was a high professional. But politics were so bad he couldn't do a thing.

One thing that happened is that Senator John Kennedy became president because he beat Hubert Humphrey in that primary campaign in West Virginia, and as a result of that you had federal money running into that state like nobody ever, ever could imagine. There was a medical school put up at Morgantown, just a beautiful facility. There were post offices going up in every town that you could go to. I mean, it was just unbelievable the federal money that was going in there. I recall that as soon as they opened up that medical school -- and they hired top-notch, first-class heads of departments to really run a fine medical school -- they promptly corrupted it by outrageous contracts and things.

I remember the chief pharmacist up there contacting me -- Morgantown's a heck of a long day's drive up there and back, believe me -- that he was getting some very inferior drugs in response to contracts he was letting, and he just didn't know what to do about it. I said, "I'll come up," and I went up there. And, boy, physicians' samples, outdated antibiotics -- that's what he was getting when he would put in an order through the state purchasing for drugs. I said, "I'll tell you what you do. You just destroy any of these, and you sign a statement, and I'll be the one responsible. If anybody raises any question, I'm the one responsible for having these goods destroyed." That's the way we did it.

Well, I followed up from there, and I followed up through my friend at the state board of pharmacy. He was a good man himself. I traced these contracts back to a guy by the name of Haddad. They were Lebanese, and they had a drug company. I think it was called Haddad Drug Company; I'm not sure. Right there, either in Kanawha City or in Charleston, and he had a direct link to the governor's office, had absolute contracts on any drugs of any kind. I went out there, and I found physicians' samples all over the place. I started sampling those. Then I got the state guy out there with me, and he warned me that there isn't a

thing in the world he could do, but together maybe we could do something. The guy offered to take those things to the dump. Of course, I was very anxious to witness that.

But when I was really getting the evidence on them, I'll never forget it that the guy, Haddad, came up to me and he said, "Mr. Shumate, you see that young girl over there?" Beautiful blonde girl, just a beautiful thing. He said, "She's going to be the queen of the Forest Festival at Elkins, West Virginia, in another month or so. That's (Governor) Wally Barron's home town, you know. And she's going to be the queen of that festival, and if you'd like we can arrange for you to have a date with her."

"Absolutely not. There isn't any way in the world I'm interested in any such thing as that. I'm interested in taking care of these drugs here." And I witnessed all those destroyed.

Well, it continues on. There was a billiard hall and a kind of tobacco joint right below my office adjacent to the Federal Building, which I had learned was a place for bookies and others. It was Haddad's that had that, too. Well, when Governor Barron was inaugurated as governor, it was done right on the federal steps, right below my office, and I witnessed this. I was watching it. It was a bird's-eye view. As I witness this, who should come out of the

Haddad Smoke Shop but Mr. Haddad, walked right up on the federal steps, and Wally and he throwing their arms around each other as great cronies. Well, that just further confirmed to me that this guy had a direct connection, see. Just totally affected everything I could think of, because it was so corrupt it was just hard to believe. I had an informant that had information right directly into the governor's office about every kind of a thing that you could think of. I wrote up an awful lot of this.

Shortly after I'd gotten heavy into this drug business, there was a Congressman Harley Orrin Stagger of West Virginia, who was holding hearings on the drug abuse amendments. There was an invitation for me or anyone to write up anything you could about the problem. Well, as you can imagine, I was excited about writing up everything I could, because they really needed something done out there. It was just out of control, and there wasn't any effective way to do anything about it. It was just coming in by the droves. Certainly there wasn't going to be anything done by any state and local official.

So I wrote this thing all up, sent it in to Baltimore. Not too long after that, by gosh, they arranged a conference at Charlottesville, which was Region III at the time. And they had an assistant attorney general --

Lustigan, I think, was the guy's name -- from the Justice Department, and the Region III HEW (Health, Education and Welfare) director, the governor, the colonel in charge of the state police, and Dick Williams (District Director), and I don't know who else from headquarters. They were there for the purpose of discussing this drug problem in West Virginia. The feedback I got was that as soon as they raised the issue, the governor simply announced that there simply was no drug problem in West Virginia; this man out there, there must be something wrong with him. And so because there was such a tremendous link between the Kennedy administration and this governor, there simply was no problem, politically.

It wasn't very long after that Dick Williams called me and said that I'd been transferred to Buffalo, in that they were concerned about my health. Well, I mean, I was concerned about my safety, too. But I took it hook, line, and sinker. It was true. I'd been testifying in court by this time and had revealed quite a few of my aliases, and I was concerned. Also, my informant was telling me that there were people watching me. When I left the office, when I went on the road, they were watching; I was under surveillance. It can get you somewhat concerned if you're all alone in a resident post and you don't have anybody

else around. So I developed a way to handle that. I would bring in somebody from Baltimore, and they wouldn't even bring them into the district. I'd meet them somewhere and give them the assignments to go on, and then I would take off somewhere else just to mislead these people where they might think I was going, because my effectiveness was getting compromised just because they knew what I was doing.

But at any rate, it wasn't very long and I was given the word that I was transferred to Buffalo. Of course, everybody in the Food and Drug Administration knew very well that if you were transferred to Buffalo . . . Buffalo was recognized as the Siberia of the Food and Drug Administration; that's where people went that were troublemakers. I was outraged, because here I had developed all these cases. I thought I was one of the most successful . . . Because I was probably getting about as many prosecutions per year as some districts. Like Everett Atkinson back years before, I was really successful.

So I asked to go in to see Dick Williams. I was outraged. I wanted to know what in the world was going on here. I thought I was doing a good job, and that I ought to be promoted. I knew they had a compliance officer's job open there, and I wanted that job. So I went in, and I can

assure you, by the time I got there I was really hot. I was ready to really lay it out there, and I did. But Dick was a very savvy, experienced person, and he handled me just like a piece of cake. He explained to me that he would like to have had me as a compliance officer, and that was his recommendation and it still was, that he really was very appreciative of what I had done, but that he couldn't do anything about it and I was just going to have to transfer.

Well, I left there and went back home, and I was just totally distraught about having to make a lateral transfer at that particular time. As I said before, there wasn't anything you could do about it in those days. You were told to go, you had to go, or you quit. And, of course, I couldn't quit. I didn't have enough money to go anywhere else. It was right at the time of the birth of our first child, and they wanted us to go right now. I said, "There's no way we can go now. My wife's just about to have this child. She's got this physician; she's comfortable with the physician. There's no way we can move." Well, they gave us six weeks. So six weeks after this child was born, we transferred.

RO: What year was that, Merv?

MS: That was in 1962, July. We didn't have any money again. We got up there, we were living in a motel, eating in a motel, with this little baby screaming its head off, and no darn money. And just totally distraught about life in general, because here you're working your buns off day and night, weekends, and now it looks like you're really on a bad track here. But I didn't have any choice. I went up there.

I have to relate one other thing that I did for Dick Williams that I think was a fantastic experience. It showed how ingenuity can do things for you. Right after I got there, a very short time, Dick called me up and said, "Merv, there's a cattle auction barn down in Virginia that's just been peddling drugs like crazy, and we've tried several times to make a case down there and have never been able to do anything. And I wonder if you'd try it." I said, "I'll try anything once." And so I let my beard grow, and got on the oldest clothes I could get, and took my miniphone, and I went down to this auction barn. As I drove into the place, I was dictating on the miniphone where I was, just like you did.

I went into that auction barn, and there was a guy by the name of, I think it was Dr. Dalton, who was supposed to be the guy peddling. Well, when I got in there, I saw

these people, all mountain people, with their trunks and their pickup trucks just loaded with chickens and pigs, and all of them had muskets and pistols in their belts. They were trading guns and all kinds of stuff, just loaded. I mean, it was just a mountain scene, is what it was.

I pulled in there and I walked right on in there where I'd been told this guy was. It wasn't Dr. Dalton; it was somebody else. It was a guy by the name of Fry. And he was peddling like crazy. And I went in and had my story. It wasn't me that I was asking for drugs for, it was my parents that had various ailments. And he'd keep poking me and feeling of me as though I were the one, and I kept telling him, "No, it's not me. Don't. I don't want you touching me." Because I had that darn miniphone on, and I was afraid he was going to get his hands on it, see. But anyway, he sold me all these different drugs. No questions at all. He was telling people to get off of insulin. You just name it. It was something I was really pumped up for, because, I mean, it was like . . .

(Interruption in tape)

MS: So when I got ready to pay him, he pulled out his billfold, and he had a wad of bills in there that were just about two or three inches thick. Of course, I was trying to be as friendly as I could so he wouldn't raise any

suspicion. I said, "Mister, aren't you concerned with that much money here?" "No," he said. "I'm not worried one bit. All I have to do is let out a little shout or raise my hand and that person won't take a step. These are my friends here." I thought, "I'd believe that, all right." There were enough guns around there to take out the whole county.

So I left and I went right out of there. I went right down to the next town, got myself a shave and a haircut. No, no. I proceeded from there right up to this doctor's home, because he was the one that I was supposed to record. And he was recognized as kind of a nut, in that he'd been into Washington and allegedly armed, and he was going to take out Food and Drug for previous investigations. So I was aware that he was dangerous. But I went into his home and into his place, and I recorded him. And he sold me drugs, too. Then I went down and got my hair cut, and shaved.

The next day, I put on my best suit. This guy was from Bristol, Tennessee, this Fry. So I went down to his home in Bristol, and I went up to the door, and I said, "I'm Inspector Shumate. I'd like to make an inspection of your place here." He said, "Haven't I seen you before?" I said, "Well, I don't know. I don't know a thing about

that." I said, "Do you make any claims for these drugs?" He said, "No. No, sir." I said, "Are you sure you don't make any claims?" "No, sir." I sampled everything he had.

Then we took him to court. And I remember very vividly just this week, because this is the anniversary of (John) Glenn going around the world. Dick Williams came out there, and he rode the train because he was afraid to fly. He was with me in federal court. That morning when we got up, Glenn had gone around the Earth. It was quite a day. We went into federal court in Roanoke, and I testified against this man. He pled guilty. As we were leaving the courthouse, he came up to me and he said, "Mr. Shumate, I just want you to know that I'll never, ever sell any drugs again." I looked back at him as formal as I could, and I said, "Well, sir, I suggest you don't, because you never know when there's going to be another Food and Drug inspector around" (laughter). And left.

That I had done for Dick, which I know he appreciated, because it was a tough job to get somebody. I had never seen such country folk as this ever before. It was like a totally different world. But to go in there amongst those people and to be successful was quite a thing. But I had done enough truck stop work, and I had been scared enough, that I had taken on the mannerisms of mountain people. I

could talk just like them. Just because of fear. You just have to be that way or you won't be successful. But doing all of this was really quite a challenge, and being successful at it. But that was all I was thinking of when I went in there to visit with Dick, because I felt I had really been let down by the Food and Drug Administration for all that work I had done out there. And I wanted an explanation as to why, but I didn't get anyway.

Anyway, I then transferred to Buffalo. I've got to find my notes here. A day at work in Buffalo was quite an experience, because it was not too unlike what I'd experienced in Chicago District. The employees were jammed together extremely tight. We were in an old post office building, and there was just desk right up tight to other desk. I noticed the person on my left was Willard Orr. I just saw him just now downstairs. And on my right was Dick Nacewicz. Each of them had been given a letter by the chief inspector charging them with all kinds of discrepancies in their inspection reports, in their T&P cards, in their travel vouchers, in their work accomplishment reports, and demanding that they respond to explain every one of these discrepancies. I know Willard showed me his. And these people were totally disgruntled. They had no esprit de corps; they hated the world. I saw

this and I said, "Boy, I tell you, this is going to be a fine place to work. I can see that right now." Of course, I'd had quite a lot of experience.

RO: Who was the chief inspector?

MS: Chief inspector was Bill Prilmayer, and the district director was (Allan) Retzlaff. Prilmayer had a terrible insecurity complex, but if he were threatened, he would totally go out of character, and he could be extremely vicious. I mean, he could just fire somebody instantly if he felt he were threatened. And he did, with almost impunity. One thing that was clear to me right away was that Retzlaff was a very close crony of Allan Rayfield, and I had been around long enough by then to know that Rayfield was all-powerful, and if he said anything, that's it. There wasn't any appeal, no nothing. So he could act with almost total impunity up there without any question. Though I didn't recognize it at the time, I obviously was sent there for safekeeping under Retzlaff.

But I was somewhat fortunate in that I had a lot of experience and a lot of court experience; so right shortly after I was there, they asked me to work with Ray Sweeney as a compliance officer. Now this was as an inspector. I worked for a year and a half as a full-time Food and Drug officer, just acting status. And every other week, I'd

have to go on the road just like everybody else. I was getting doggone unhappy about that, too, because I felt if I was going to work that much as a compliance officer, I ought to be a compliance officer. So I asked one time to speak to Rayfield when he was out there on one of his visits. Now, you can imagine that took a lot of courage, because this man just had terrible fear, and I remember I went to Chief Inspector Prilmayer, and I told him I wanted to speak to Rayfield. Well, that would make them a little bit nervous, because they weren't too sure what I was going to say. But he said, "Okay, go ahead. If you want to speak to him, you go ahead."

So he came out, and he was touring the district. It was getting along in the afternoon, and one thing you didn't do when Rayfield came is, you didn't sit at your desk. You got out of there if you were an inspector. Well, I was getting very antsy in the afternoon. I wasn't getting any meeting, and I wasn't about to ask him for a meeting. It seemed to me that was what the chief inspector should do. So I, about two o'clock in the afternoon, went in to see Prilmayer, and I said, "I'd like to know when I'm going to" -- I'm getting anxious as heck, too -- "get to meet with Mr. Rayfield." "If you want to meet with Mr. Rayfield, you make your own arrangements, do you

understand?" I said, "Yes, sir. That isn't what I understood. But that's what I'll do, if that's what I have to do."

So upstairs I went, and I found Rayfield in the lab. I said, "Mr. Rayfield, I'd like to speak to you." Somebody must have talked to him, because he wasn't totally surprised. And he said, "Yes, you come right in here." So we went into just a little cubicle there, and I looked him right straight down the nose. Because I was ready to quit Food and Drug. I felt that I'd had all I could take, and I'm either going to get some resolution to this or I'm going to leave. I didn't know where I was going to go, because I didn't have any job. And I didn't have enough money to transfer back home, then. I couldn't do it. I'd lost all my money on the home in Detroit.

But anyway, I told him right straight down the nose that I want to know just where I stood, that I felt I had done an outstanding job as an investigator, but I didn't seem to be getting anywhere. I just had to know whether there was any future for me or not, because if there wasn't, I was going to have to go somewhere else. Well, he wouldn't give me any satisfaction, yes, no, or otherwise. But he couldn't look you in the eye. He had an eye problem. He couldn't look you in the eye. He had to look

everywhere else. But I kept looking him right straight in the eye (laughter). And he left.

Then we had an open house, the new office, and George Larrick came out. I went up to see George Larrick, and I told him again that I felt that I really ought to be given some opportunity. For whatever reason, I don't know what, but I really feel that I'd been performing as a compliance officer and I ought to have an opportunity. It wasn't but about a month later that I got promoted to a compliance officer. So obviously that little exchange I had with Larrick is what did it, whatever he must have said. He must have said, "Look, this guy, whatever he's done, he's done enough, and you give him a break." And I got it, just like that. But if it would have been left to the district, I would still be a GS-11 in Buffalo, no question about it.

But Retzlaff was very close to industry, and he would make that crystal clear to you. For example, there was a very filthy winery at Lewiston, New York. They brought in wine from California, and then they blended it with New York wine to make for wine. They'd found heavy drosophila infestation in that California wine, and they had the whole darn winery tied up. I had written up the seizure recommendation, because, boy, I mean, we're going to control this one really close.

As always, whenever you wrote up a legal action, it had to go in for his initial. It went in there, and he called me and he said, "You know, the federal judge is not going to like the federal government bringing an action against this man. You know, he's a paraplegic; he lost his arms and legs in World War II." I said, "Mr. Retzlaff, I wasn't aware that a man's physical condition had anything to do with the enforcement of the Food and Drug Act. I don't understand this." "Well, I'm telling you, they're not going to like it. And I'm going to take care of it." So he referred it over to his buddies in the state to take care of it. See, he was too cagey not to just walk away from it, because I was making book on him. There was no question that I would have been prepared to try to take him on if I could. But I knew, having observed as much as I had, that there wasn't any way in the world I could do anything with Rayfield there. But at any rate, that was one incident.

Another incident, we had found a big Salmonella thing at that time, and we had found Salmonella in H. P. Hood's nonfat dry milk. So I had written that up for seizure, and Retzlaff called me in and he said, "My friend isn't going to like this." H. P. Hood wasn't even in Buffalo district; they were in Massachusetts or someplace. "Are you sure of

these results here? You can't be sure of that." I said, "Yes, sir. It's consistent with everything we've ever done before." I remember I tried to make the point by saying, "I can hear the plane circling now, with Lennington in it. I mean, this is impact action here. We should be taking action." He said, "Well, I don't think these results are worth a damn." He called down a microbiologist, and he questioned him. And he got that young microbiologist who he had hired because he was the son of a crony in New York state. And he got him to write right on the lab sheet, "I cannot swear to a certainty that I did not contaminate this sample in the laboratory. NAI (no action indicated)." He asked me to sign it. I said, "No, sir." I would not sign that. He said, "What's the matter? You chicken?" He wrote, "NAI, Allan T. Retzlaff." And I said to myself, "Boy, this guy here is just awful."

But when I was inspector up there, I noticed that when I would go into some of these sauerkraut canneries that they would immediately make it clear that they were very good friends of Retzlaff. Of course, that simply made me more dedicated to do the best job I could, because I wasn't about to be intimidated by this.

RO: NAI. That was . . .

MS: "No action indicated." He just marked it; didn't have any problem at all.

Another time I experienced that is that I was on a road trip and I was in Albany, New York, on a Thursday afternoon. I ran out of assignments. I asked the resident if he had any assignments today -- Larry Turness was the guy's name -- and he said, yes, he had this terminal elevator out here. He'd never been in an elevator and he didn't know when he was ever going to do it. I said, "Well, I'm an expert at grain elevators, so I'll go out there." It was a Cargill terminal elevator. I went out there and I introduced myself, and they were immediately concerned about me being there. I just knew instantly they were just overrun.

The largest elevator you've ever seen. I mean, in each bin they had 8,000 bushels per bin, and they had, like, 8, 10, or 12 of those bins, plus they had 100 or so other bins. I went up there, and I had the resident with me. He stayed with me about two hours and he left, because you're walking up to your knees in wheat. I can tell you, that's mighty hard work. If you're not in very good shape, you can't do it. He left; he wasn't going to have any part of that filthy place. I called in to the district just like I had back in South Dakota, and I told them, "I've got

into a mess here and I'm just going to have to stay here the weekend and work on this elevator." I stayed there for at least two weeks, developing the evidence. And they were overrun. They'd had labor union problems. I mean, you can't believe how bad that place was. There were dead pigeons on the surface of that grain, with rodent nests in those dead pigeons. And the top of those bins were just tunneled with rodents. Just unbelievable filth. Those mice must have been up there for generations.

So I developed the evidence and I submitted it. I inspected that place five times. Every time I'd inspect it, I'd have to reinspect it until I'm beginning to wonder what in the world is going on. And Cargill was just working their buns off to try to get the place clean. But, of course, they couldn't; it was just too much. Finally got to court, and the day that I was to go to Albany to go to court, Retzlaff called me in his office and he said, "You know, my friend over here," the superintendent of Cargill, "isn't going to like it, the Food and Drug Administration testifying against them. And I'm cautioning you, you'd better be careful what you say." Oh, that teed me off good. I looked him right back in the eye and I said, "Mr. Retzlaff, I've been in court before. I'm going

to testify to the facts and just the facts. That's all I'm going to do." I walked out.

I went over there and I went up before this judge. We had the USDA testifying against us, because all of that grain met all of their grade standards, because it was blended when it went out the lake into the ships. The port was frozen; the Hudson River was frozen. But I saw on this superintendent's desk where they had cablegrams around the world for ships to come in there and unload that elevator. They were going to try to unload it and get it out of there before we could get an injunction. I was trying to get the State Department involved, because it was all going over to Egypt and other countries. I thought it was atrocious that this filthy grain was going outside this country. See, I wanted something done about it. Couldn't do a thing. And they were moving grain like crazy and trying to clean up the place, too.

But anyway, I got up there and testified. I had to testify just exactly to the facts. They were doing a tremendous amount of work, and we didn't get the injunction because it was just too darn slow. I was making these reinspections and calling Billy Goodrich to update the . . . I suspect there was some heavy pressure being put against Food and Drug to not bring this action. That's

probably what it was. Of course, I wasn't privy to that. But at any rate, I got the place clean, and that's what I was happy to see happen anyhow; so I didn't feel bad about it.

As I went to leave that court that day, they had to bring back a vice president -- his name was Sanders, I think -- of Cargill from Europe. He was over in Europe on a trip. Had to bring him back to testify. As I walked out of that federal building, he came up to me. He had a vicuna coat on; I mean, he was obviously an extremely successful person, with his whole entourage of Cargill people. And he said, "Mr. Shumate, I'd like to have you know we're shipped something over two and a half billion bushels of grain since the last time we had a problem with you in South Dakota, and we have never had a problem since." I turned to him in the most formal manner I could and I said, "Well, sir I just do the best job I know how." And walked away.

But I felt good, in that we really had that place whip-snip clean by then. Every time I went back in there, I was so well trained I could find filth. I remember the last time I went in, they had all those big bins empty, 800,000 bushels. They'd transferred a whole lot of it over to these hundreds of other smaller bins. But I remember

one of those bins. I was examining every single one of them very carefully, and I saw a rodent and a rodent nest in one of these. I got a boatsman's carriage, and they dropped me down in it at least sixty feet, and I got that damn mouse and I brought him out as an exhibit, see. Oh, they hated to see me. They'd have liked to dump a load of grain on top of me, I'm sure. But I was so dedicated to prove what the facts were. That place was so filthy that I just felt that they had to get cleaned up. And, boy, I mean, they did get cleaned up. No question about it. But the point I wanted to make is that there again Retzlaff was giving me words, "You be careful, now. These are my friends." All that did was make me all the more certain to do what I did.

But one last thing, and then I suppose we ought to break here, is that I don't think I could have survived Buffalo -- I know I could not have survived Buffalo -- had I not had experience in other districts. There was a guy there by the name of Loveridge, a supervisor, who was as close to corrupt as anybody I've ever seen.

RO: That was Ted, wasn't it?

MS: Ted Loveridge. He was a terrible character. He took pride in always meeting precisely the program numbers that came out of Washington. The way he did that is, he

would instruct you to log time, say, while you're in travel. If you're traveling on the New York throughway, if you see a load of hay, you load up on pesticide time or food additive time, you're always going to hit the number. Well, to me, this is outrageous. And he's training new investigators in these tricks, and I'm an experienced investigator. Absolutely refused to ever do such a thing like that. I would not do it. I didn't care what they did. There wasn't any way that I would ever do it. But that was the kind of experience that I was having.

I asked after I'd been there a while . . . Most of the investigators there were Buffalonians, and they were World War II people that were coming into a career after they'd been somewhere else. After I saw what was going on there, I said, "Why don't you people speak up on some of these things that are going on here?" "Well, we're not going to say anything. It doesn't bother us." I remember I made my point with them by saying, "You know this morning when I came from the bus stop, I noticed a blind stand over there. Now, somebody could rob that man and he'd never even know it. None of my business. Why should I do anything about it? I don't understand that. If something's wrong, it's wrong, and you ought to do something about it." They'd never do a thing because they

didn't want to leave Buffalo. And that management there was cautious enough to know that that's the way they fostered it, too. Total fear, and you don't make waves.

I kept applying for jobs and I never got selected and I was just totally distraught, but I was going a damn good job as a compliance officer. I was holding, I would say, up to 200 hearings a year. Because in those days you didn't issue regulatory letters or anything; you cited for warning. That was policy. And we were citing people. I had attorneys coming into hearings; they knew it was a joke when they came in there. They were just picking up a fee. It was extremely difficult, but I developed some pretty good skills in putting the pressure on those people to get compliance; and I got a lot of compliance.

But, oh, I had some hearing experiences too that you can't believe. I had one hearing with Sterling Drug, and they brought in five people: the medical director, their in-house lawyer. Their out-house lawyer was a guy by the name of Hogue, I believe. It's very significant, because this guy was a very formal, elderly gentleman, who had a stiff-neck collar and an old-time tie, with a cane over his arm. He claimed to be the author of the '38 act. The guy's name was Hogue, from New York. But very formal. He made me go through -- and there must have been fifteen or

twenty different products and every imaginable charge you've ever seen -- and explain every single one of those. I wasn't even in agreement with every charge that had been given me from headquarters, but I had to do it.

When he sat down at that table, he took every competitor's product that was identical to the ones that were the subject of the hearing, and he put those from one end of my desk to the other. And I remember, when he did that, I was scared, of course. But I just straightened up and, in the most formal way I could, I said, "Mr. Hogue, I acknowledge what you've put on this desk here. I shall make a record of it, and we shall follow up accordingly. But it will have absolutely nothing to do with the proceedings that we're here for today." Hogue says, "I know that." Just like, "Sonny, what kind of an idiot are you?"

So then we proceeded. It went on for like six hours. I had sitting in, just as an observer, Norm Greenspan, who was a supervisory chemist. He did not say a word. Of course, I'd instructed him I didn't want him to say anything. At six hours later, we broke up, and I was absolutely, totally exhausted, as you can imagine. The guy from Sterling said, "Mr. Shumate," as they stood up. "What we'd like to have you know is that we're going to fly from

here directly," I think to Fort Myer, Pennsylvania, "to a celebration with the governor of New Jersey for the one billionth Bayer aspirin tablet. We're going to celebrate this tomorrow." And Norm, who has not said a word -- he had his lab coat on -- he says, "Gee, I hope they counted right" (laughter). I almost fainted. I was so exhausted anyhow. These guys were in total disarray. I couldn't believe what he'd said. But anyway, they left and they went on to their celebration. But I have to make a point there, and that was that even though I made the statement that I made when they put all those products out on the desk, it did have a major effect on me to be holding hearings for some products, knowing that the marketplace is full of the same product. I never felt right.

I don't know how much longer you want to go, but let me just wind up here on this part of it. Well, I probably ought to wind up the Buffalo part of it. But about that time is when Dr. Goddard became commissioner. Now, most Food and Druggers, particularly field Food and Druggers, were very unhappy with a political appointee becoming commissioner. They absolutely were opposed to it. I looked at it as a great opportunity, because with Rayfield and all of the others that were involved, there was not

going to be any change on anything. It was going to be business as usual, and total control over anything.

When Goddard came in, he immediately started putting out feelers to come in with suggestions for change, and that was a great thing for me. I started writing memos, because I felt that we ought to try to proceed by class as to these problems and not product by product, because if you go product by product you're playing right into the hands of the Food and Drug Bar. They can drag you out from here to the end of time, and you'll never get compliance. And in the process, some people will be taken out of business. Other people will walk right in and take the business, and they know we're not going to come after them, because we don't have the resources. Just seemed to me to be totally unfair; so I started writing all kinds of memos. I actually felt good that I could do it and they were being accepted and looked at by somebody. I think, as a result of that, there were some changes that started to occur. We started the regulatory letter policy; we started recalls; we started a lot of things that never, ever could you even think of before. I mean, they just weren't done.

RO: It was about that time, Merv, I think, that we stopped citing for warning.

MS: Stopped citing for warning, which was a great thing, because that was a joke. And we started issuing "reg" letters. We started doing other things, too, because we were issuing "reg" letters. I had developed a lot of skills in holding all these hearings on how to conduct a hearing to get people to do what needed to be done. So I used those skills when we started issuing "reg" letters. I would actually call people into meetings, and I would get tremendous compliance just by the way you handled yourself. And you had to be careful that you didn't abuse power; but on the other hand, if you handled it properly and you showed them what you had, most businessmen would immediately respond. They could see what was going on and they wanted to avoid any kind of a court action if they could. Well, you could use that to your advantage.

It was difficult to do under Retzlaff, in that he was of the old tradition and he didn't care too much for that - - unless it was one of his cronies, of course. But I did use it an awful lot when I got over into Detroit District, because Town Brown was a totally different person. He left you entirely to yourself to do what you felt needed to be done, and I guess I just had a field day exploiting the experience that I had had.

That Buffalo experience was totally negative. I tried to get out of there from the day I got there. I couldn't seem to get out of there. I was ready, absolutely ready to just leave and go to a state government or do anything. But I had two small children, and I couldn't. I didn't have enough money to do anything. Of course, Ellen couldn't work then. She had two children. If she were working, I might have been able to do something. But finally, I got selected by Brown with a promotion, GS-13, to go to Detroit, and it was just like a brand-new life for me. It was just like an experience that was terrible and totally negative. But, on the other hand, I really recognize now how much I learned from that experience in Buffalo. I learned exactly all of the negative things not to do as a manager.

RO: You went to Detroit, then, as a Food and Drug officer?

MS: I went there as a GS-13 Food and Drug officer, so that meant I felt I had gotten myself finally out of whatever cloud I was under. And I think about this time, too, I had gotten some feedback from (Jim) Beebe, because he was in Washington at the time that I think I got that transfer. I never talked to Him about this myself, but I've heard it from someone else that I was in fact

transferred as a disciplinary action, see. I never knew that; I never had known that. But I did get that confirmed some time later indirectly. I never talked to Jim about it myself. I should sometime, because he was in here and I think he knew what was going on with Retzlaff and all that stuff. Let's stop it a second here.

RO: Well, we're right at the end of this tape.

(Interruption in tape)

RO: This is a continuation of the interview with Mervin H. Shumate. The date is March 18, 1987.

Merv, I believe when we concluded the interview last week, you had just been transferred to Detroit from Buffalo; so you may want to pick up on that.

MS: All right. The most significant thing that I noticed at the time of the transfer was the major difference in district management as between Buffalo and Detroit. Buffalo represented the Old Guard by Retzlaff. He'd been there for over thirty years; he was thoroughly satisfied with the way the agency had operated throughout all that time. And, of course, you know that's right at a time when Goddard became commissioner, and he was shaking up people like crazy to change that, to delegate more authority to the districts.

This shook up Retzlaff. I remember him calling Ray Sweeney and I in one day. It had appeared in the pink sheet that district directors were being summarily moved to state governments and to other positions to remove them from management, and Retzlaff's name had been indicated that he was going into Washington for one of those interviews. He called us in, and you could see he was genuinely shaken. He really didn't know what to do because, as I've described before, up till now he was in total competence. He could take personnel action or anything with absolute impunity, because his good friend Rayfield supported him on anything he did. Now, all of a sudden, he has no connection, and, in fact, he has a Young Turk down there that he doesn't know what he was going to do. He was really uptight. I was actually overjoyed myself, because it made him to recognize that there was something beyond Retzlaff in the world (laughter).

Okay. So then I went to Detroit, and Tom Brown was one of those younger district directors. I recall one other, from New York. I can't think of his name.

RO: Weems Clevenger.

MS: Weems Clevenger. The two of them were kind of Young Turks that were raising all kinds of questions, and kind of rousing things up. Well, as it turned out, that

was a great benefit to me, because I had enough experience now that I knew how to handle enforcement actions of all kinds. But I had to act in the traditional manner. You either recommended seizure injunction or prosecution or you cited them, or you didn't do anything.

Well, I had held hundreds and hundreds of hearings. I recall a few years there after the Hazardous Substances Act was enacted, I would hold as many as ten to fifteen hearings a week. These would be gas station owners coming in, and it would be the most unbelievable experience you can imagine. Those people never heard of the Food and Drug Administration, never had anything to do with the government. Here they come in their grimy, greasy coveralls and they wanted to know what the hell the government's doing to them. And you're trying to be as formal and official as you can, and as serious. But you know in your heart that you're just warning them; you're not really intending anything.

RO: What were the violations?

MS: The violations were hazardous substances violations. We would send investigators in with cans other than red cans and without appropriate warning statements on it, and then we'd have our buys and we'd haul them in and give them the business, see (laughter). Oh, God, it was

awful. But I had the same experience with a lot of industry. I mean, there was a whole segment of lawyers who served the food and drug industries that knew very well there was no case whatsoever. They were simply coming in to state their case, and that's all there was to it. There wasn't going to be anything more from that. And they would just come in and pick up their fee. I've even had company officers call me after a hearing date and ask me what the outcome was. The attorneys had never even discussed the whole darn affair with them. It was unbelievable, what we were doing.

So with that as kind of a background, it was very refreshing for me to go to Detroit, first of all, to find people who seemed to be much more in tune with the new way of trying to deal with problems -- seeking ways to give notice different than citations and to do things. Well, I jumped right onto that; I liked that. And Tom delegated; he was a great delegator. Some people say he's lazy. I think he is lazy. But that did result in him delegating anything and everything to you, sometimes far beyond what he should. In other words, if you had a major enforcement problem with a real head-to-head showdown, the district director really ought to be sitting there just to give the moral support that you need to do what you need to do. He

didn't do that. I mean, you took care of it. I liked it, because I had enough experience that I could do it. I started immediately to put in the new principles, and that was, if I had a . . .

I recall, for example, Hy Grade Food Products. That's a very large company. They had a Salmonella problem in their animal byproducts plant in one of their packing plants in South Bend, Indiana, or near there. Mishawaka, I think. We had Salmonella in that nonfat dry milk, and in those days, if you found Salmonella, that was what we called "impact action." You don't fool around; you get some action going. I just picked up the phone and I called the president of Hy Grade in Detroit. I told him what I had, and that I was going to have to make the decision and very promptly, and I'd like to have him in to a meeting before I did that. So promptly they came in, with a whole entourage. We sat right there and, man, we hammered out right now what's going to happen: recall the whole thing, shut down the plant, completely clean the place up. Well, an experience or two like that really gave me a charge, you know. This is a heck of a way to achieve compliance. I started to do that as a kind of a routine, and Tom, he supported it all the way. I would report it at weekly staff meetings and things like that, and no problem at all.

I think he was happy, too, to have that kind of thing happening.

But now, I remember a few incidents where I had to learn what to do with Tom, and that was an incident involving a Hazardous Substances Act problem where a small fireworks dealer in Saginaw or Bay City, Michigan, had sold fireworks, M-80s. They're supposed to be for agricultural use, and there were some child injuries. He had been arrested and was in jail. It was Tom Brown, and Jim Beebe was deputy director; Cliff Shane was chief inspector; and Tony Celeste was the lab director. He sent in Bill Carlton, who's crazy. This is an investigator that was a very close friend of Brown's, and Weems Clevenger, too. He had a hunting lodge up in the Upper Peninsula, and they'd go up there hunting all the time. But he sent him in there, and he did an unbelievable job. He had photographs of these injuries, and he had done all kinds of things. I didn't know a single thing about it; I'd not heard a thing about it. I understood it had been presented to the investigators in a meeting, but compliance branch didn't know a thing about it.

So one day I get a call from Tom to come into his office. I walk in there, and there is Tom, Cliff, and Jim, and Tony. Tom says to me as I walk in -- and he has a

stack of files in the middle of his desk -- he hands me several photographs of these horrendous injuries, and he says, "I want you to write up this case for criminal prosecution." Well, I'm a pretty experienced compliance officer, and I turned to him and I said, "Well, I would be happy to if the facts supported it." "I didn't ask you if the facts supported it. I'm directing you to write it up." I said, "Well, then, I guess there's nothing more to discuss." I picked up the file and I left.

But I worked over the entire weekend, carefully reviewing that file. And as I kind of suspected, when you had a Bill Carlton involved, you had to be very careful because this guy paid no attention to other man or law. He paid nothing. He writes profusely, so he'd written everything in great detail as to what he had done. On Monday morning, I had prepared a memorandum to Tom Brown turning down the prosecution for having violated at last four provisions of the United States Constitution, and a memo to Cliff Shane, strongly recommending that he initiate personnel action against Bill Carlton and that I would be happy to testify or participate in any personnel action that might follow. I named it chapter and verse what this guy had done.

As I told you, the sheriff had put the guy in jail. So Bill goes up there and he wants to get in the man's place of business; and he can't get in there, he can't get the key. So what he did is, he found out the name of a sixteen-year-old kid that had worked for him part-time. He goes and gets that kid, who had a key, goes over, and gets in the place and thoroughly searches it. He goes over the whole place with a fine-toothed comb. He's got enough information then that he goes back to the sheriff and he asks the sheriff if he can take this guy in his custody from jail.

He takes him from his custody back over to the place of business, and he works him over a little. And, as I recall, he found out from somebody that the guy was allegedly queer or something, and he was making all kinds of statements about his particular personal habits, and in the process found that the guy had stashed some of these M-80s on a farm somewhere else. So he takes the guy and puts him back in jail, and then he goes and gets the sheriff, and he and the sheriff go completely out of the jurisdiction over to this farm in another county, load up all those fireworks, and bring them back and put them under seizure at the sheriff's office. Well, that's only a few of the things, but it gives you a good flavor of how this

guy was just running wild. He wasn't using any common sense or due process. And, as I recall, there was very, very weak evidence as to any FDA action that could be taken. I mean, we just didn't have any. But yet we had all of this God-awful pictures and story of how they'd done all of these kinds of things.

I just turned it in. I never heard a word for several months. And then all of a sudden, when it was coming around to the annual appraisal, I get called into Brown's office as everybody else did that reported to him. He and Beebe were there. And he and Beebe both go through quite a dissertation of how well satisfied they were with my work and how great a job I was doing and everything was fine. But out of the corner of my eye I could see that file sitting in the middle of his desk, and I thought, "Well, this is going to be something when he gets around to that." But at the very end of the interview, nothing but good things were said. Tom picked up a buck slip and he scribbled on it, "I agree, T. W. B.," put it on the file, and handed it to me. Well, you know, that meant to me that professionally I had done what I felt was right, and I had withstood some very extreme pressure to do something that I professionally didn't feel I could do, and I was able to prevail.

But I can tell you, back in those days you took your life in your hands when you did things like that. There were many district directors -- because I kept good contact with a lot of compliance officers around the country -- that they would get an order to write up something and they would do it. It had nothing to do with professional review; you just do it. Retzlaff had done that a time or two to me when I was a brand-new acting compliance officer. He just didn't like this guy. It had nothing to do with the facts; he didn't know the facts. He'd just tell you to do it. Well, I didn't like that, and it was fortunate I had enough experience that I didn't have to do it. Of course, all of these experiences did serve me well later when I came into headquarters, because there you get further and further away. You didn't have the benefit of knowing the Bill Carlton, the guy who's questionable. You didn't know what kind of a district director. You're having to live with what's on the record, what's written. So you had to be very much more careful about what you were taking. But all of those experiences taught me how to find indicators that would indicate there's something screwy with this case. I used it whenever I felt I had to do what was right.

But anyway, that taught me an awful lot about a lot of people. And by the way, I never heard a single word from Cliff Shane. He never did a single thing that I'm aware of; never even discussed it with the man, nothing. I remember that there's a kind of a crazy Dutchman who Roy Sandberg would know very well, Clarence Bozarth. He was a resident in Grand Rapids, and he had heard this presentation that Carlton had made with respect to these fireworks; and he was just infuriated about what he had heard. He was kind of a different person, but he was one that would do exactly what was right. He wouldn't be playing around at all. And he was going on . . .

This was sometime later; this wasn't at the time of thing. But sometime later, he was really giving it to me. They had then, right after I had sent that memo, promoted Bill Carlton. And this Clarence was really unhappy about it, him being promoted and he wasn't. He had more time and all of this. He was going on and on to me, and finally I looked up and I said, "Clarence, you really ought to consider getting yourself a hunting lodge up in the Upper Peninsula. It'd probably help you an awful lot" (laughter). Because he knew all about those details a lot better than I did. I didn't know much about that. But

anyway, that was a great experience there in Detroit, because the attitudes of people were good.

I particularly liked Jim Beebe. Jim would kind of stay aloof, but he would give me more supervision by far than Tom, and he would assist in, say, strategy discussions or in maybe polishing up a memo. I remember one time that Tom Brown, through Weems Clevenger . . . Weems wanted to promote one of his GS-12 investigators to compliance officer, and the New York people would have nothing to do with him. They didn't care for him; he wasn't, in their opinion, competent. So he works it out with Tom to send him over on a sixty-day detail to work with me, and I would give him all the honors that he needed, and he'd get promoted. Well, after sixty days, I wrote up a blistering memorandum of just how incompetent this individual was. And to show you just how incompetent he was -- this is a GS-12 investigator -- I would give him the simplest correspondence to respond to, and he didn't even know such things as a CFR; he didn't know the Code of Federal Regulations. And I am saying to myself, "This guy as a compliance officer? There isn't any way he can be a compliance officer."

So I wrote that up, and I wrote it up pretty sharp, because I felt very strong about it. Jim comes in as only

Jim could do, and he says, "I think that's a little strong, don't you?" I said, "Well, it is, but that's the way I feel about it." "Well," he said, "I worked with it a little bit here. I think maybe if you think about it a little bit, it maybe shouldn't be quite that strong." I read it over and thought about it, and I said, "You're right. I guess that's right." It carried the same message, but it didn't have near the sharpness in it. And he helped a lot in those kinds of things, so I had a lot of respect for Jim. Jim also was action oriented, but he was one that you could talk to as a professional as to what should be done, and that was nice.

I remember one other thing where Tom Brown really got himself into hot water with Sam Fine, particularly, and it had to do with the Coho salmon. There was no way in the world we had any kind of a charge we could make as to those salmon, because they were from Michigan waters, and there wasn't any way that you could think of . . . Well, Tom was determined that he was going to take action on those Coho. He didn't get me to write it up; he wouldn't ask me to write it up. He had Hannigan write it up. Joe Hannigan was a nice fellow, but he was a terribly poor compliance officer. His compliance clerk, legal clerk, knew far more about compliance work than he ever knew. She did most of

it, by the way, and some of it was rather shocking. But he performed a good service, because if Tom needed something done and he didn't need any professional review, why, then, Joe did it (laughter).

He wrote up this thing, and Sam came back with a twitch, as I recall, and he really came, because there was a lot of heavy politics involved in this. He came right back at Tom, and Tom fired one right back at him. He had Jim and I in there talking about it. That was the time that a guy by the name of Bologna had come right in out of -- and he'd just left Food and Drug and was running a chicken franchise. I said, "Well, Tom, I hope to hell you either win or you have a chicken franchise available, because I think you're going to need it from what I see in this twitch from Sam." "Oh, well, we'll do it. Don't worry about it." And he did. He had guts. He would push something like that, and people knuckled. We never really contested the thing.

RO: What was the trouble with the Coho salmon?

MS: Oh, it had DDT in it, and PCB. But it was mostly DDT then. But Coho was a great initiative by the state of Michigan and the Department of Interior, fisheries, and they did not want anything that would disrupt this great and wonderful thing they had done. So there was heavy

politics involved, all the way up to the governor, and pitted Interior against us, FDA; and there were all kinds of things going on. It really required somebody just sitting down and working this thing out, because there were a lot of good things about it. But, of course, as you can imagine, when the salmon runs came in, there were just hundreds and hundreds of thousands of pounds of salmon that people were just chomping at the bit to sell. They were either selling it for human food or animal feed or whatever. It was going out of the state, and it was a heck of a mess there for a while.

RO: What was that, 1966, '67?

MS: Yes, '66, '67. That's when it would have been.

But anyway, I remember after I'd been there at Detroit for a while, I began to feel a lot more positive about things. I went to lunch one day with Beebe and Don Sherry. There'd just been a notice come out for people to apply for the Executive Development Program. I said to Jim, "You know, I'm going to apply for that." He said, "I don't see any reason. What in the world do you want to apply for that for?" I don't know what anybody would want to get into that mess for." I said, "Well, I've been a compliance officer five, six, seven years, and I know about all I could know about that. I want to do something else. I

want to get on." He said, "Well, if you want to go ahead and apply, I won't do anything to deny that. Just go ahead and do what you think you have to do."

Sherry, he didn't think much of it, either. But as it turned out later, he and I both applied, and we both were interviewed down here in Washington by Sam Fine and Danny Banes. And, as I recall, those are the only two that interviewed us. It was a rather rigorous screening process that we went through, written and oral. And then I went back to Detroit, and after some time I get a call that I'd been selected, and Sherry wasn't. As it turned out, Sherry was better off than I was, because he got a 14 much sooner than I did. But over the long run, I was better off.

But at any rate, I remember when I went home that night. This is after having all of these negative experiences for these many years, and having applied for job after job and having never been selected. You get a feeling that you don't have any chance. When I got selected to this, I went home that night, and when I went through the door, why, I just of let it all loose and just cried like a baby and said, "You know, I don't know anybody. I have nothing going for me. But I got selected. Isn't that great? By gosh, I got a chance." We just bought a new home, so we had to sell another home. The

family was very small and just starting to school. We moved down to Washington. That was in July of 1969.

I had been told of the kind of assignments that I could expect, and the first one I thought I was going into was a pretty good compliance type assignment, working in compliance, looking, really, over the new program. We just had given over to us a milk ordinance and other interstate travel; and there were some conflicts in those as to such things as food additives and other things that somebody needed to carefully look at and be sure they were consistent. I thought I was going to be in on something like that. Of course, it would have been kind of interesting, because it would have been entirely different than what I'd been doing.

Well, I get into Washington, and the very first day I'm informed that, no, I'm not going to that assignment at all; I'm going over to work in Mickey Moure's organization. His first name was Larry, and he was not well thought of by anybody, period. But I didn't really know much of him before that, and I'll have to find out his name, because I don't remember it. It was Larry something. He left the agency sometime later and went to NASA (National Aeronautics and Space Administration). But anyway, this guy had been through the executive development . . .

RO: Larry Stern?

MS: Larry Stern, that's it. He was in a hurry. And he, I think, thought if he could get someone like me assigned to him, that somehow it would do great and wonderful things for his career. I don't know; the guy was a strange bird. But at any rate, I go into this office, and I'm in there with another person who I had a lot of respect for, a guy by the name of George Northway. He left government later. And we had absolutely nothing to do. Here's a couple of guys that are very experienced, competent people, and they have nothing to do. After a couple, three days, I said to Larry, "Hey, I . . ." And every time I'd go home at night I'd say, "You know, I can't do this. I just came from a real good job where I was working hard, and I can't stand this. I can't take a check sitting there doing this." The most we did was to cut and paste statements for the budget hearings or something. It was nothing of any substance, and I got really uptight.

So I went to Larry and I told him I was unhappy, that I had to have something to do. Well, he didn't have anything for me to do. I could sense in this organization they were motivated exclusively by fear. Now, Mickey Moure ran that shop with absolute fear. I was told by others that if you just keep quiet and you don't make any waves,

you can't do anything but succeed. But you must not make any waves, because if you do this guy will make sure you never get anywhere.

Here again, I'm faced with a professional decision. Am I going to sit here and do nothing, or am I going to do something about it? (laughter) I had all I could handle. So about after two or three weeks, I called up Mickey Moure's secretary and I asked for an appointment, and I got it. I went up there. He had a rather impressive office, very nice furniture. I sat down there and I said, "Mickey . . ." I had thought pretty carefully how I was going to say this, but I said, "I have an assignment here, but it's just not something that's any good for me in my training. It's just nothing of any benefit to me, and I'd like to be considered for some other kind of an assignment." Well, what I didn't realize, and I did later, is there was a little power play going on between Barnard and Moure, and I happened to be the pawn. So he said to me in a rather short kind of a way, "Well, if you don't like the assignment you've got, I suggest you go find yourself another one." I said, "Yes, sir." So I got up and left, and I went out.

I went right out and started looking for an assignment. It just happened that John Jennings, the

director of the Bureau of Medicine, needed a special assistant. He grabbed me up, and I grabbed him up. I went back to the office and I moved right over there, never even told Larry Stern. After a couple of days, he's coming trying to find me. It really totally destroyed the man that I would leave without telling him, one. And, two, it embarrassed the hell out of him, because the word was getting around that this guy has nothing to do (laughter). But I really didn't care. I absolutely wasn't going to tolerate that. After you've worked a lot of years with more than you can ever do -- the stuff just keeps coming at you -- you simply cannot tolerate having nothing to do. So I had to do something about it. And took a lot of risk, but did it.

A little while after that, I don't know exactly when, but Barnard still wanted me back in that assignment. Somehow, I got caught between Moure and Barnard, and I was so concerned that I made an appointment to talk to Rankin. Now, if you talk to Rankin, boy, there was the man with the absolute power. But I was right up against the wall, and all I was going to do was go in there and lay it right out to him.

RO: He was deputy commissioner?

MS: Deputy commissioner, and he was a tough guy. I'd never had anything to do with him before, either, but he'd come to the district a time or two and he had the appearance of being a very cold, hard-nosed man, and he had your fate totally in his hands. But anyway, I got the appointment. Before I could get to -- because it took some days to get the appointment with him . . . The problem was solved before the time came. Well, I certainly couldn't cancel, so I went in at the appointed time. I'll never forget it, because he didn't sit at his desk; he went over to his table, and he had a footstool that he had his feet on. He sits there in the most formal, rough way. "What have you got? What's your problem?" Well, I hadn't any bitches now to make. I'm just here to talk about my career and my experiences, and I had a heck of a good discussion with him. He never knew that I had a problem; just thanked him and left (laughter). Got out of there. I thought for a while I was doomed, because when you went in there to see him, you really had to be careful.

Oh, I remember how I got assigned to Larry Stern. The first day here, I got on the elevator, and I expected to go into a compliance operation and really get into something really heavy. Elevator full of people, and he -- Larry Stern -- and Phil White were on there. Both had been

through the Executive Development Program. Phil White had known me from a course or two somewhere. He puts his arm around me and he tells me that he worked for Rankin, and if there's anything he could do for me anytime, he'd be glad to take care of me. That, to me, really causes me to say, "Well, friend, I don't need any of you." And Larry says, "And you're coming to work for me." I was shocked, because I had in writing that I wasn't going there; and I thought, "What in the world have I got into? This is going to be awful."

But anyway, it was a really great experience, because I got to go to congressional hearings; I got to go to every commissioner's staff meeting. I really got my eyes opened on very important issues. And as you remember, I'm sure, that was the time when (Ralph) Nader's Raiders were coming into the agency. The consumer movement was in full bloom. Freedom of Information was coming up. And people were coming from the outside looking into the agency files that had never been available before. The agency was, I would say, almost terrorized as to what this was going to do to us. It was a very tense, exciting time. And, of course, that just gave the congressional people an opportunity to really work over the agency. Of course, participating in those hearings, I got to see some of this.

I recall, for example, and as you know, cyclamates cost Commissioner Ley his job. I witnessed that. I'll talk about that in a second or two. It was quite an experience. But we went down to this hearing, and Commissioner Ley gave -- and this was the Senate Finance Committee, chaired by Senator (Warren) Magnuson, Senator (Norris) Cotton, Senator (Hiram) Fong, Senator . . .

(Interruption in tape)

MS: I've always been very interested in keeping up with civics and civic affairs, and I read a lot and I watch a lot of documentaries and public debates and things. These names were extremely significant names to me, and very powerful, important people in government. As I say, Commissioner Ley gave a very careful, very thoughtful, detailed presentation of his budget proposal. And he was questioned, not about most of anything that he had to present, but immediately got to cyclamates and saccharine.

Senator Magnuson, knowing that Senator Fong would be certainly of great concern about sugar and cyclamates . . . And Fong wasn't saying anything; so he turned to him, and he was half asleep is what he was. These men all impressed me as extremely old men who were having difficulty even staying awake. They certainly couldn't focus on what the discussion was. They were wandering around, and it wasn't

impressive at all. But at any rate, he turns to Fong and he says, "Senator Fong, coming from the great state of Hawaii, wouldn't you have any comment to make with respect to this?" And Senator Fong turned to the commissioner and he says, "Commissioner, could you tell me what is the status of the tsetse fly and the papaya?" (laughter) Well, the commissioner was totally stunned. He said, "I'm not sure we have anything to do with that, Senator, but I'd be glad to look into it." I guess the tsetse fly had more to do with USDA than FDA, but at any rate, that's all he had to say. He went back to sleep and that was it.

But then Senator (Clifford) Case -- it might have been Cotton. Senator Cotton was a particularly elderly man, and he said, "Commissioner, I have a dietary problem, and I can't take sugar. Now, you've been talking here about some kind of testing of saccharine. You just keep your damn rats away from the saccharine, do you hear me?" (laughter) It was this kind of a discussion of personal concerns on issues of major importance to the public, the nation, and I left there just sort of depressed because I certainly had expected to witness a whole lot more serious and substantive kind of discussion of these issues. But it was a charade is all it was. And, I mean, that hearing room

was jammed to the rafters with every consumerist and everybody you could think of sitting around there.

Well, as you know, not too much later Commissioner Ley got fired by Secretary (Robert) Finch on cyclamates. He'd taken that issue into his own control and he was extremely critical of the agency and specifically fired Ley. I remember, because we were at the FDLI in December of, probably, 1969, and the commissioner was to give a keynote address as always commissioners did. They kind of laid out the past achievements and the next year's agenda at the FDLI; it was a very important time. Well, being in this training program, naturally I was very eager to hear everything that was going on; and I was over there, and the commissioner didn't show up. Sam Fine walked in as a stand-in. Before him, though, was a guy by the name of Malek that spoke; he was an assistant secretary, I believe, or chief of staff under Finch. He laid out the complete 1970 reorganization of FDA and made clear there were going to be management changes and all kinds of things. Then Ley didn't show up, and poor Sam had to stand up there and give the commissioner's speech.

Right after that speech, why, all of us got the word we were to get back over to the Crystal Plaza because there was a commissioner's staff meeting. So over we go.

Everybody knew by then something significant was going on or they wouldn't be having this kind of thing. We got back over there, just got seated. In walks Commissioner Edwards with Maurice Kinslow at his side, and he announced right there at the opening that "I have just been appointed commissioner. I'm not the commissioner yet. I have to go through confirmation hearings, but I've been appointed, and I am as of now the acting commissioner of the Food and Drug Administration. And Commissioner Ley is hereby fired. The deputy commissioner, Rankin, has been reassigned elsewhere in the department. And Associate Commissioner of Compliance . . ." Just can't think of his name, and I've got a distraction going on. Let me think. "Ken Kirk has agreed to retire." Well, I mean, that was one hell of a shocking experience to witness, because here's a very good-looking, obviously wealthy, very much in control man that no one had ever seen before in their lives (inaudible). He had Maurice Kinslow with him, who he said he had brought in because Kinslow had worked on the Kinslow Report, making recommendations for certain changes. So that's why he was picked up.

I know when I left the building that night, I went down to my car, which was in the basement to the carpool, and across I saw Mickey Moure going across with Rankin.

Rankin was crying just like a baby, and I thought to myself, "Where is Mickey going to wind up in this deal here? He's pretty close here, too." Well, we were pretty astute. Because we were in this program, we had a lot of exposure all over the place. Within days after Edwards came into the Crystal Plaza Building, new carpeting goes down, new furniture comes in. You couldn't believe the furniture that was rolling into that suite. Moure is establishing himself very well with the new commissioner as a person who responds to whatever his needs are. And it was at a time when it was difficult to get those kinds of things. There was no question, seemed to be no limited to what he could get. And he got it.

RO: When did FDA move out of Crystal Plaza out to Parklawn?

MS: Well, you see, as a result of the 1970 reorganization, we moved out of there, probably, in '70. See, that would have happened in December of '69, and I would say we moved out of there probably by the next April or so of '70. But I can't be sure of the date.

But I remember Sam Fine, then, became the associate commissioner for compliance. Paul Hile became Sam's position, ACFC, assistant commissioner for field work. And I was over in the Bureau of Medicine, but I did, then, take

an assignment with Paul. But at any rate, it was a very, very tense time. This is the first time that we had somebody right smack walk in and take over the agency, and not just one person leave, but the three top people leave. I had gone to the hearings where they had debated the 1970 reorganization, and Rankin really carried the ball there as far as . . . If you remember, we were in CPEHS (Consumer Protection and Environmental Health Service), and that was an organization that wasn't well liked by FDA at all. Rankin had a very tight rope to walk to testify about that because, of course, being in that organization and reporting to Administrator Johnson, he wasn't free to just say anything he wanted; but he came pretty close. He had to be very careful. Anyway, there was the reorganization that came off, and that's when we left Crystal and moved out to the Parklawn Building.

RO: Merv, do you want to back up a little bit and describe a little bit more of this Executive Development Program?

MS: Yes. This was a mid-level program. There were eight of us in that program, and that would have been Lloyd Claiborne, Bob Bartz, Dick Dawson, Mary K. Ellis, Voyce Whitley, Bill Cooper, Merv Shumate. How many is that?

RO: Six.

MS: Did you get Claiborne?

RO: Claiborne, Bartz . . .

MS: Claiborne, Bartz, Ellis, Whitley, Cooper, Dawson, and Shumate.

RO: Seven.

MS: Well, I'll have to figure out the other one.

These were people that were selected from various places, headquarters and the field, and it was a place to bring someone and to give them exposure to the organization and the issues, with the feeling that once you went through this program you would then be in a much better position to assume greater responsibility. Having gone through that program, I really do feel it was a great program. It certainly did great things for me. It broadened my horizons. I had a total experience of the field.

In the field, you're quite sheltered from politics and the big issues. Life is a lot simpler. Issues aren't nearly as difficult. You have a law and you have an industry, and you gather evidence and you recommend it. And it's not very often marginal; it's usually fairly clear whether there's a violation or not. A lot of our work was filth, of course. We were getting very heavy into drugs, too, the IDIP (Intensified Drug Inspection Program) and those kinds of things. That was what was called an

intensified drug inspection program, which I happened to believe in.

We in Detroit used that in any program area that we had a serious problem. We didn't bother with just drugs. If we had a firm that was seriously out of compliance, we simply would put somebody in residence until we got the firm either in compliance or out of business or whatever had to be done. And I wrote a tremendous number of memos of assignments to do this kind of thing. That's why I was saying, with Tom Brown and Jim Beebe, they were very receptive to that kind of thing, and it really worked great. I mean, we achieved a lot of compliance that didn't come out as a notch in your gun as an enforcement action, but we were getting a tremendous amount of enforcement.

RO: That as one of the initiatives under Goddard, wasn't it?

MS: It was. That was one of those things that he was trying to get a better communication with top management to get them to do as much as they would on their own responsibility. And, of course, I just jumped at that. I explained to you how in Buffalo I would have a hearing and a company would come in and line the desk from one corner to the other with a marketplace just full of exactly the same products, and here I'm giving them a hearing for

possible criminal prosecution, and them looking me in the eye and saying, "Is this fair? Why are we being singled out for prosecution?" It raised a lot of questions in your mind as to the fairness of that. It had a great impact on me later, too, when I got into high-level position.

But anyway, that Executive Development Program was great, because not only did you get this exposure, you got intense training. You could pretty much select what you wanted, but I went heavy into management. I hadn't had a lot of management before that. I remember that I really got heavily into and got excited about what was going on in industry at the time, which had to do with project management and program management. You had an organizational structure, but in addition, you had project managers that could go anywhere across the organization to solve problems and to make things happen.

I used that when I got assigned to the Bureau of Drugs, because it makes sense. If you're in a complex organization, line organizations just won't work very well. You've got to go across. The government wasn't organized well, and I think -- I can tell you -- that the 1970 reorganization really was an effort along those lines, and I was excited about it. Up till then, we had a Bureau of Science, and a Bureau of Medicine, and a Bureau of

Compliance. And now, all of a sudden, we're reorganized along the program lines: Bureau of Drugs, Bureau of Vet Medicine, Bureau of Foods. And they split up everything.

But I really feel, after all these years after that 1970 reorganization, that it really complicated the agency's activities. Many of the problems of FDA today, in my mind, are directly because of that 1970 reorganization. What we really wound up with was, basically, as many as six or seven FDAs and now down to four or five. Each one becomes their own independent institution, and it takes an extremely well-organized commissioner's office to try to do what I was saying, to make things that ran across the organization.

I remember Paul Hile -- I was special assistant to him -- and the field wasn't reorganized. They were left as a special entity without regard to program, but all the bureaus are now programs. One of the very first things he had to do with Danny Banes, he made a move to take over all laboratories, going into drugs. Paul responded with the most massive effort that he could to make a pitch to keep them as they were. It was a very difficult thing for him to do, but he did prevail. But there still are labs that are headquarters and labs that are field, and there's no real good coordination between them. It just complicated

the heck out of things, particularly to have the field that goes across all.

And then I went in there out of the Executive Development Program into drugs, and I got a very good dose, all of a sudden of what happens to them and their programs when they don't have a resource they don't have any control over. They have to work through another headquarters office to get anything done they want done. So just as an example, if they wanted to do -- and we were getting big into that at the time -- a survey of a particular drug, digitalis, they'd get their statisticians to lay out precisely how many firms and samples, and everything was to be done in precision order to come out with a very good report. They could do all of that, but they couldn't implement it unless it fit with other programs that were going on. They'd get extremely frustrated and they wanted to know, "Why in the world can't we have control of that?" So that was a benefit of me, though, having seen and getting to witness all of these from different viewpoints.

RO: Of course, the field was always considered a generalist field force, and it would be kind of impractical for a commissioner to have to start in to make those kinds of cuts as far as drugs and food and things.

MS: It would be very hard, but if you really wanted to get down to it, I think that you could perform. You see, I noticed right away when I went into drugs that if there was a hearing, it was this bureau director that immediately got hauled to the hearing. Maybe the commissioner, but usually the bureau director. There was no one from the field there, but often the problems or issues were field related, investigations and things. Well, they had no authority or control over that part of the organization. They'd get very frustrated about that and they'd let you know that: "Well, damn it, why can't I decide what we're going to do and get out there and do it?" And they couldn't do it. So you see, I really think you ought to have one way or the other. You shouldn't split the organization in the middle. I'm not saying that's simple. That would be very difficult to do, because of the number of facilities and everything.

RO: I'm not sure, Merv. With the situation the way it is now along product lines, we've still got the bureaus that have been given from the commissioner complete authority, at least, over their product lines.

MS: That's right. And they hire these people with those instructions.

RO: That's right. You feel that maybe we'd be better off if the field was organized along those same lines?

MS: See, what I'm saying is, it ought to be either/or. Either you ought to go back to where we were prior to 1970 so that there is a Bureau of Compliance and there is a Bureau of Science . . . And then, of course, these so-called regulators are considered the primary movers of the agency. The scientists don't run it; they support it. Whereas, when they reorganized and went program line and the commissioner goes out and hires a bureau director who is not a career employee -- he's a political appointee -- and he says, "I'm hiring you with the understanding you're responsible for that program," and then that guy comes in and he says, "I'm in charge? It doesn't seem like I am." It's frustrating, so it ought to be one way or the other, not partway. That's what I'm saying. And I'm not saying that would be simple; it would be difficult. You'd probably have to just have a Drug Administration and a Food Administration, and that sort of thing. But you could probably do it. You could have, say, a drug and device administration that are related in many ways, and a food and cosmetics and those kinds of things that are different.

The act itself is part of the problem, of course, because it sets out different standards for different classes of products. But my point is, I got a very good dose of the frustrations of trying to reorganize along those lines, but I like the concept of programs product oriented. But, you see, when they did that and they brought those scientists in, all of a sudden those scientists now are in charge of programs, and science becomes the controlling motivation of the agency, no longer enforcement, regulatory. A shift. I remember Charlie Edwards giving speeches and writing things: "We're a scientific regulatory agency." He kept saying that. And we are. But it's a question of a balance, and who supports who. It would be very difficult to change, but what I'm saying is, it's practically impossible to manage this agency when you have it structured the way it is today. It's very difficult. I had a very good dose of both sides, so I have a good feeling for both.

I must say that when I went in as a special assistant to John Jennings, I was absolutely in shock at what I saw in that bureau. I had come from the field, where most people came out of college into FDA and really were trained from the ground up into regulatory work. All of a sudden I'm in a bureau where all of the people of senior

management are seniors, and none of them came into Food and Drug in their formative years. They have extensive experience in medical practice or with industry or someplace. They have no particular loyalty to the Food and Drug Administration, and they wouldn't hesitate to say so.

And I noticed another thing, that the medical people, they'd been called rejects and all of this stuff. I can confirm that for the most part; they were. They were all the way to alcoholics, senility. There was the damndest mess of people I'd ever seen. I can recall one particular staff meeting right after I had been there that I think will sum it up very well. Absolutely shocked me. It gave me the greatest management experience you could ever have, in that John Jennings called the staff meeting, as he did. It was all the office directors and the assistant bureau directors there. I can remember specifically Marv Seife, Bill Gyarfas, John Palmer, Mary McEniry, John Jennings, and there may have been others; but they were the principals. We got in there, and it was one of my first times in. And I'm just sitting there kind of low profile, because I don't know anything about these. I was sort of in awe at that time of M.D.'s, Ph.D.'s. I had a different view after I had some experience there, but up till then those were people on a pedestal for me.

Jennings had a congressional inquiry or something that was really concerning him, and he was discussing it at some length. He was giving Dr. Seife some instructions as to what he wanted him to do. Seife wasn't even listening to him. He was just shooting the breeze with that Bill Gyarfas and paying no attention. Finally, John -- and John had a hair-trigger temper -- all of a sudden he turned beet red, and he turned at Marv and he says, "Marv, goddammit, pay attention. I want you to listen to me. I've got something for you to do." And Marv Seife is a very big man. He stood up, straight up. He turned beet red. He took his fist from well down below his knees somewhere and he came right over the top of his head, and he hit the center of that table so hard I thought he was going to break it. And then he takes his finger with the sign, and he says, "Screw you!" And out the door he goes. And I'm sitting there. I'm loaded with all kinds of training, and I'm saying to myself, "Jesus Criminy, did I actually see that?" I couldn't possibly tolerate that if somebody did that to me. He never did a thing. I mean, that was it. "Well, that's just Marv." And I'm saying to myself, "Well, this is a different organization."

But you can understand it after you've been there a while, in that these M.D.'s come into the agency -- they

already have their wealth; they have all the security they need. They don't have to operate on any semblance of fear to the organization or anything, and that becomes readily apparent. Well, you can imagine what a shock that is to a brand-new guy coming out of the field, where if somebody told you something, you did it. You might not like it, but you did it. You certainly never told your boss to screw himself in front of all his peers. You don't do that. So, I mean, that's an example of what I saw much of that just absolutely boggled my mind.

But I then took an assignment in that bureau, and I had to learn how to deal with some of these kinds of personalities. I mean to tell you, it's not easy; but it can be done (laughter). But I got to work on things, for example, that were very exciting. We had hearings by Fountain that were really tearing us up on clinical investigators and fraud. We were not doing a great deal in that area, so I got to look into the area and to try to write programs. I remember I took the first shot of the draft to monitor the sponsors, and I got to review a lot of other governments' laws with respect to drugs. I learned a lot about the British and the Swedes and others. I got to meet a lot of foreign officials. It was a fantastic experience for me, because I had never . . .

Also, I noticed right away, as I said before, the issues that you were confronted with were far more complex than anything I'd ever seen before. Safety and efficacy were terms that I had some real meaning to when I talked of them before I went into that center. But as soon as I got in there, I found out benefit-risk judgments went on all the time; they had practically no meaning to people, relative safety and efficacy. I saw yesterday they had this big meeting here -- or the day before -- on minoxidil, this hair grower. That, as far as I can determine from the public press, has practically no efficacy. But the Food and Drug Administration has recommended to them by an advisory committee that it should be approved. I'll be you Food and Drug will approve it and people will be paying \$600 a year for something that's probably marginally effective. That's safety and efficacy? (laughter)

Well, I got to thinking a whole lot more about efficacy, and I went and did some studying, too. I really studied adequate and well-controlled studies and those kinds of things to try to understand. I actually rewrote some memos on benefit-risk judgments, because that was all purely judgment. There was never any organized, formal way of addressing these kinds of problems. They were just handled in the most informal way, and that didn't make any

sense to me. But you see, that executive development training is what gave me exposure to these management concepts and things to deal with that.

I remember when I was first hit with that safety and efficacy thing, and cost-benefit or benefit-risk, I went over to the library, which you had time to do, too, and I did some research on earthquakes in California. Those people in that state have had benefit-risk decision-making with respect to buildings -- structures -- for years. I mean, it's an art; it's not something brand new. So, you know, if somebody really wanted to go do that, they could develop something that would not be perfect, but it would be far better than what was going.

I wrote a memo to Dick Crout on this, and I got an excellent note on it -- still have it to this day -- from Dr. Finkel. People had never focused on it, and he wrote me a note that said, "Great idea. We're not going to do it now." And, you know, I don't think anything's been done to this day (laughter). The interesting thing is, they had biostatisticians and others in that bureau who had the technical skills to do this. I talked to them; they could do it. It would have taken a lot of work. Basically what I was saying is, "What needs to be done is, rather than simply ad hoc any problem that emerges, you should have a

formula where you plug in all the knowns you have -- scientific studies, animal, human, whatever -- and then put your judgment call right in there as part of a basis for your decision, which then goes up to the bureau director and to this commissioner so at least he has displayed in front of him the best information you can put together. That ought to be done every time.

Never was done. They'd just write up an action memo and narrative. You could have entire glitches in there and there wouldn't even be anybody know about it, because there was no process to follow, see. It would have made things a lot better and, more importantly, it would have then served as the foundation to build on on all subsequent problems. That's the other thing. Every time you were confronted with a problem, it was just like you're starting from scratch again. You really didn't have any organized way of approaching it. They did it, but they did it in a very informal way. So, I mean, it did happen.

But I was totally unimpressed with the medical officers, specifically. I noticed an awful lot of Ph.D.'s who I am sure were outstanding in their own right in their younger days at industry, but in coming to government, all of a sudden they're over the hill. They burn out. They've

done all they could do. Yet that's what that center was staffed with. It was amazing they did as well as they did.

(Interruption in tape)

MS: I think that fairly well summarizes my experience in the Executive Development Program. It was an exciting time for me, with a lot of experiences that really did what it set out to do. That is, to broaden your horizons and to give you exposure to a Food and Drug Administration that you probably would never get working in a particular organizational setting. It was excellent in that regard.

In addition to all these training courses, you went out to various training courses, public and private, and got a lot of exposure to people from other agencies or industry that also expanded your thinking. I recall the one thing that I noticed more than anything is, you could go to a meeting on the environment or on public policy or whatever, and many of the problems that Food and Drug was confronted with were exactly the same problems that other agencies had. You don't often think of that when you're doing your job. It's good for you to benefit from each other and to have some cross-fertilization in trying to deal with some of those problems.

RO: How long did that program last?

MS: Well, there were several classes before me. It was a frustrating program for people, because I remember Billy Hill coming in. He was in a class before me, and he simply didn't graduate out of the program and you're left in limbo for months and you get very concerned because, of course, you have a family and you want to know where you're going to go. He kept getting hyper and he finally went up to see Sam Fine, and he got to go laterally out of the program to Kansas City without any indication of any kind of promotion. Well, that's a pretty depressing thing after you've gone through this program. You really feel that you ought to be going ahead. But there were many people who didn't.

Now, that's not to say you shouldn't flunk; some people should. But it wasn't something that you graduated in one year. I remember at the end of the program, somehow it precipitated a meeting with Edwards for graduation. But no one had any clue that they had graduated or any assignment. I remember he ordered that we be promoted before this affair. I got my wife, and the others got their wives, and we came in for this ceremony. It was just kind of a jury-rigged promotion; there wasn't any assignment or anything for you.

But it was still a very good program, in that you got tremendous exposure to things that I think they ought to continue to this day. But I don't know; I don't think there were many classes after that. I can't remember. You probably know; you were on the executive committee.

RO: Yes, there was one other program, if I remember, after the one you were in.

MS: See, it lacked credibility in that the only people who made a commitment to this program was the EDRO (Executive Director of Regional Operations) organization, and they would take people out of the program. Other centers, bureaus, they didn't feel committed and wouldn't necessarily have a job opening; so it wasn't well administered that way.

RO: Some of the problem that we had in a mid-level program, which was a little lower -- grades at least -- was that a lot of the center, or the bureaus at that time, that put people into the program didn't give a darn whether they got a job for them when the program was over or not. So we really had to try to find jobs for them. It sounds to me like here you almost had to find your own job.

MS: Yes, you did. In fact, I'll just describe how I got my job. It was a very amazing thing to me, in that I was in a training course over to Front Royal, Virginia, on

the management grid, as I'm sure you're familiar. It was a week-long course and a very tiring one, because you'd go from eight o'clock in the morning till midnight or later. So you were just exhausted. On Friday, I came home, and I got home quite late. And Bob Bartz, who was in the program . . . But he was in the Bureau of Drugs; he was in that bureau, in the Office of Scientific Evaluation, as an administrative type. He called me up at home and he said, "Merv, did you know that they announced today that you are the chief Food and Drug officer of the Bureau of Drugs?" I said, "Absolutely not. I have never heard of this before. I don't know anything about it." He said, "Well, Dr. Simmons announced that today in staff. So I'm telling you you'd better be ready, because they're certainly going to talk to you Monday."

I thought an awful lot about it that night, and next morning I called Paul Hile, who was ACFC, and I asked him to come into Parklawn so I could talk to him. He did. I came in and I said, "Paul, I got a call last night, and I've been told that I've been selected for a job that I know nothing about. My inclinations are to the field. That's where my career goals are, but I feel, since they've announced this, if I don't have something else, I'm going to have to take it. I don't have much choice." He thought

about it carefully, and we talked a heck of a lot, as you can imagine. He said, "No, I'm sorry, Merv. I just don't have a thing at this time. There's nothing I can promise you." So I went home and I figured, "Well, this is it. I'm going to have to take it."

Sure enough, on Monday morning, Dr. George Leong, who's a Ph.D. pharmacologist, interesting individual in that his appointment was now announced from Finch's San Francisco, California, office -- he's a very well-connected Chinese Republican -- he came to see me, and he said that this announcement had been made, that they had been impressed with what I had done while a special assistant over there, and wanted to know if I'd take the job. I said, "I don't know anything about the job, but I'll give it a go. I'll take it."

So I immediately went into that program. I had no idea what the job was. As it turned out, it was a brand-new job. They had a chief pharmacologist, a chief chemist, and a chief Food and Drug officer. And we were called "discipline officers." It was something Henry Simmons had come up with, partly through . . . It made an impression on me because of what I had said earlier about project management, in that he recognized . . . He was the chief medical officer, and he felt that these particular

disciplines across the bureau -- Compliance, Scientific Evaluation, Regulations, everywhere -- had no commonality as to the discipline, and there ought to be somebody who addressed those kinds of problems. Well, as you can imagine, that turned out to be one of the most difficult jobs that I ever got into, because it was brand-new, the line managers hated us from day one because whatever we did at least had the appearance of interfering with their prerogatives. So you were not well liked.

But the way I tried to carry it out is, I immediately wrote roles for Food and Drug officers, for the center. I rewrote the PD's for the whole bureau. And I met with personnel, because there were tremendous inconsistencies in grades and functions and whatever. I tried to get those consistent one with the other. I mean, those experiences with personnel were totally negative, because every meeting you went to there was not a positive response to try to work with you to solve a problem. It was always, "We just can't do that. We're not going to do anything, period." And I'd get so frustrated because I couldn't get them to do anything.

But anyway, I wrote these role papers; I presented them to the bureau at the top level; I presented them to the Food and Drug officers. Now, I have to tell you, it

was obvious to me right then that I had Food and Drug officers that for the most part were rejects from the field, that had been relegated to a role as servant to the M.D.'s, primarily, and they had neither the inclination, the ability, nor the intelligence to carry out the role I had in mind for them. I mean, I was excited, because what I used as a model was the field Food and Drug officer's model. There's a great need for it then; there is to this day.

What I had in mind was someone well trained in the Food and Drug Administration -- in the enforcement business of the administration -- who is very sensitive to possible violations of law or regulations, who will recognize it, elicit that from the scientists, the reviewers, convert it to assignments to the field, get them out and back, and then convert that to some form of action. That's a professional job that scientists, I found, abhor even the thought of criminally prosecuting some other scientist for indiscretions. They just don't find it comfortable to do. There's exceptions but, for the most part, reviewers didn't want any part of that. What I wanted to do was to develop a cadre of compliance officers that would be thoroughly knowledgeable, that would take that . . .

And there's plenty of indicators. If you're looking at data day after day after day, you can almost immediately spot something that's questionable. It doesn't mean it's fraudulent or that it's phony or that it's whatever. It does mean, though, you have a "for cause" situation to go further into to see if there *is* something wrong with it. That requires somebody other than a scientist to do it. And, furthermore, you don't want to waste the time of a scientist to get into that. Their expertise is in a science and in the cutting edge of new drug approval, and they shouldn't be messing with that.

Well, I remember I had one meeting, and as I went to that meeting -- and that individual is still in that center today -- I noticed him to be pushing a grocery cart with some INDs for an M.D. I walked up to him and I said, "Mister, you're a Food and Drug officer. You're not someone that's to be pushing these carts around, and I want you to understand that. That's not your job." You can imagine. I walked into that meeting, and I gave a very charged pitch as to what professionalism was and what I expected. And it was my view that if I ever got a spark in these people, into the role I had written, they'd never relegate back to that because there'd be a lot of

excitement and satisfaction in doing that. I couldn't do it. I simply didn't have people that could do it.

So I did my best. We went to go-aways; we did all kinds of things. I remember we had a lot of go-aways. That was one way Simmons tried to get people to talk and to work together, and that was done quite a lot. I went to one of them up in Harper's Ferry, and I was fairly new. The morning after the first day there, an article appeared in the (Washington) *Post* on isoniazide and some injuries; and the *Post* was extremely critical of FDA. I saw that, and I happened to comment in one of the first sessions that it seemed terrible to me -- now, this is after I'd had all this training and everything, and I'm really tuned to problem-solving -- that the Food and Drug Administration has to find out about a major problem in the *Washington Post*. It seems to me we ought to have a system whereby we can have those indicators coming to our attention. We can be on top of that if it seems to be an emerging problem, and then when it becomes public, we will have an action plan. We may even be able to act before it becomes public and we can look good, rather than always having to be on the defensive and saying, "Oh, my God, we let some more people die." Dr. Simmons said to me, "Merv, that sounds like a good idea. Why don't you go work on it?" And I

did. I went and I wrote what was called a Project Management Coordination System, and I used Armstrong. What was his first name? You know, in EDRO?

RO: Charlie.

MS: Charlie Armstrong had written, which excited me some time before. I had written this project management concept, and he had written a thing for the Kansas City District which required different laboratory, inspectional, and compliance to coordinate and to communicate and to work together to a common goal. He had this in a system. I liked that, because I had been in districts . . . I didn't happen with me, because I happened to keep a rapport with the chemists and with the inspectors such that I could always communicate. I never had a problem. But I knew other individuals in some districts wouldn't even speak to their counterpart inspectional branch people, and that's totally unacceptable. You can't have a system that permits anything like that to happen. So that impressed me.

So I latched onto that, and then from that, based on some other management I had, I wrote this thing, and I presented it to the bureau director, Simmons, and all of his staff. He liked that; he really liked it. And, basically, the principles were, anybody anywhere in the Food and Drug Administration could recommend to the bureau

director a critical problem that they felt required special management attention. They would have to do that in the form of an action memorandum that would set out the problems and even some proposed solutions and options that the bureau director would look at and would then have to sign off on, because you'd have to commit a lot of resources to single out something like this. It's not something you just do; it takes a lot of money to do a really first-class job on a problem like that. If he signs off on it, then you designate a principal coordinating officer.

And my idea, of course, was a compliance officer; that's their job, and I was trying to upgrade their skills. If they ever did that a few times, they would always be accepted. I had a few that did a good job on it. That system worked very well as long as I administered it, because I was interested in it. It took a lot of work. It worked. As soon as I didn't administer it and you didn't have somebody really making it work, it faded into the darkness. Because people don't want to do these extra kinds of things.

Basically what I wanted -- and it would fit with what I was saying about these crises occurring -- in an agency like FDA, you don't even have a repository of what's going

on when something appears in the *Post*, and that's terrible. I wanted somebody that was coordinating such that everybody knew, whether it was Science, Compliance, field, headquarters, everybody would always make a copy of that to this individual so he would have -- or she -- access to the best information you could get on a particular problem, was reviewing it and was constantly coming forward with assignments and recommendations to solve the problem. Then you would have a chance. And it worked; it really did.

Well, as you might imagine, having done that work, that got me visibility with Dr. Simmons, which I didn't have a lot with, and he immediately set me up as a special assistant to him. I remember when he asked me if I would be his special assistant, I said, "Dr. Simmons, what am I going to do about this chief discipline officer? I'm trying to get that going. It's a big job." "Well, you can do both of them. I have all confidence in you. You can just do both of them." Well, as soon as I became special assistant, I had all I could do to manage his office. And I found out that was a fantastic experience in that you had to be the alter ego of the bureau director. This guy is from outside the government, very bright M.D., coming with Charlie Edwards from Booz, Allen & Hamilton, lots of management ideas, a very fast act -- but also extremely

political. And I thought, "Boy, this is dangerous, because I'm surely going to get into something that I just can't do professionally, and I don't know what I'm going to do."

Well, I found that the guy was the most interesting, exciting person I ever worked for, in that he was very bright; he had an ability to spend one or two minutes on very complex issues, convene a meeting, chair that meeting, and solicit all he needed to know to make decisions. That was amazing to me that he could do that, and I learned some of those skills later myself. Because up till then, of course, I was the type of person that I wanted to know everything in the world before I chair a meeting like that. There wouldn't be any way I would even think of doing that. And I didn't like to do it even later, but I found I had to. But I learned from him how you can do that well. You don't try to know everything yourself. You try to pick the brains of those who are experts in front of you, articulate the issues, and elicit answers and make decisions. And it works; it works beautifully. He did that to an absolute master.

But I remember after I'd been there not very long, there was a big flareup in the regulations area of the bureau. I must drop back and explain something first, though, that I forgot. The very first day on the job, Bob

Bartz, Dick Terselic, and I were in a room in that bureau -
- this is my first day, now -- with a computer printout of
over one thousand names, and we reorganized that bureau
that day. We cut and pasted and put people in all kinds of
different organizational settings that day. I went home
that night and I said, "I don't believe what happened
today. We moved people around as if they were nothing but
a piece of chalk. Careers are at stake. I can't believe
what we did."

RO: How could you do that just based on the names?
Did you have with them a little bit of their background?

MS: I didn't have anything. I knew quite a lot,
though, because I'd been a special assistant there under
Jennings; so I knew a lot about the people. But Bartz knew
more than I did. He was in that area there, too. And then
Terselic, he was an implant from outside, a so-called
management expert who I'll tell you about later as a power-
hungry maniac that just summarily did this. Now, once we
did it, of course, it was put out to office directors and
they could come back and argue why somebody shouldn't go
here or there. And there were changes made, but not a
whole lot. I remember we had a whole lot of people --
M.D.'s and others -- that were alcoholics or senile, and we
just dished those out. You had to take them as part of

your . . . And, boy, then the office directors would come in and squeal like a stuck pig that "you put this person on me." Our answer always was, "Somebody has to take him." It was unbelievable to me that you could be moving people around like that, but that's how we did it. And it'd be interesting to hear what Bob Bartz had to say about that.

But in doing that, one of the purposes was that we were going to do away with this business of pre-market and post-market organizations that have different scientific standards. The idea was to merge those so that you had one set of criteria. That worked to some degree, but as you might imagine, the regulations people were immediately having to deal with DESI (Drug Efficacy Study Implementation), and they were immediately starting to develop into another post-marketed operation. There were compliance officers down there that were unhappy about the roles they were cast in as compliance officers, and they came to me and complained, as the chief discipline officer. So I looked into it and I agreed. They had an issue that wasn't right what was going on there; so I said, "Go ahead. You set up a meeting of . . ." And he told me, office directors and everybody he wanted in his office. I couldn't get the meeting that day on his schedule; he was too tied up. I had to do it the next day.

Overnight, Dick Terselic convened a few people and he prepared a sheet which said, "Shumate says, 'True, False.'" Shumate says, 'True, False,'" through a whole page. The next morning, we called a meeting. I had Dr. Leong and Dr. Seife both with me on the matter, whatever it was, and we convened the meeting. This place was loaded with DESI people and chemists, primarily. It was a conflict between chemists . . .

RO: What's DESI, the acronym?

MS: Drug Efficacy Study Implementation. It was a result of the 1962 amendments, and they were just trying to get that implemented. I mean, that was a big job. It was quite a few years after '62, but they didn't get the darn thing implemented. And let me tell you, when Terselic created that organization, he created it with a GS-17 at the head of it, of which he was going to be the head. His deputy was going to be Larry Stern, a person I mentioned to you before. When I saw that, I went to Dr. Simmons and I said, "You cannot possibly let this happen. That would be the most devastating thing that could ever happen." And it didn't happen. But they still got an organizational structure that was inconsistent with what we were trying to do, and so I jumped right into it. When that meeting convened, the people I had with me never said a word

(laughter). And Simmons didn't make a decision; he just left it as it was, and no changes were made. But you learn a lot from going through that kind of experience and exposure, but I learned a lot about these particular people.

But anyway, what made me think of that was what I was getting into there. I've lost my train of thought.

RO: You were talking about there were some problems in the regulation end of the bureau.

MS: Yes, but I can't think of what got me to go back and catch up on that. I wanted to for sure, because I think it was really unbelievable how we tore up that organization. Maybe we can go back just a little bit and review that.

(Interruption in tape)

MS: It was a fantastic experience there. I recall several incidents that occurred where I got the opportunity to use some of those management skills. For example, in DES (diethylstilbesterol), I remember one Monday morning Dr. Simmons was at a staff meeting with Dr. Edwards, and Danny Banes was chairing the bureau staff meeting. Danny Banes reported that Dr. Adrian Gross had come to him that morning and had told him that he had learned from other statisticians -- Mandel Bryant, I think, had done a

statistical study and had found DES to be a carcinogen. And that there is no threshold level for this, even though it was at low level, and that he had already reported it. I'm positive he said he had already reported that to one of Congressman Fountain's staffers. He was saying he was going to report this to such-and-such and such-and-such, and I interrupted, trying to be the alter ego of Dr. Simmons. I said, "Dr. Banes, I do not believe this should be reported to anybody until the bureau director has been informed," and that we should wait until Dr. Simmons comes back and report that to him, let him know what's going on, and then report it however it needs to go. But not until.

I think that's when it became clear he'd already reported it to somebody outside the agency, and that, to me, just seemed to be unfair to the agency. I actually wrote a memo for Simmons's signature -- that he didn't sign -- that said along these lines, that if anybody encountered information with respect to anything under FDA jurisdiction, they had an obligation to report that through channels before they reported it anywhere outside of the agency; and that if anyone did, it would be considered insubordination. Well, in a scientific organization like that, he knew that it wouldn't work. He'd be charged with all kinds of oppression and whatever, so he didn't do it.

But the fact is, you had M.D.'s and Ph.D.'s and others who spent a good share of their day at the Xerox machine, Xeroxing memos and things to hand out to Fountain staffers and others that were in the agency, so that it was not unusual -- and that's why I said, "Wait till Dr. Simmons gets back here" -- for you to get a congressional inquiry before the bureau director would even be aware there was a problem. To me, that seemed wrong.

SO: What do you think motivated people to do this?

MS: That's what I was getting to earlier, in that the scientists didn't have a loyalty to Food and Drug. They had a loyalty to the science. And I think some of them, I could almost say, were disloyal to Food and Drug. They didn't like whatever Food and Drug was doing, and so this was how they could push the agency to do what they wanted done, is by doing their own thing. I thought that was extremely disruptive and very unfair for someone to have to try to respond rather than to handle something in a very careful manner. Because something such as a carcinogen, if that was let out to the lay press prematurely, or to the Congress, it would be out of your control. You couldn't possibly come up with a rational public policy position; it's gone. Now, you're defending, and you probably have to

wind up banning the thing because you don't have an opportunity to do any staff work to justify it.

But anyway, Dr. Simmons came back, and I was waiting for him. I went right in and I briefed him what had happened. He turned to me and he said, "Merv, I want you to get Dr. Van Howeling and Dr. Banes and Dr. . . ." And he rattled off five or six different people. "And I want you to get Dr. Rahl up here." Dr. Rahl was from the Triangle Center, and he was a world-recognized expert on toxicology, and had done the Rahl Report, if you remember. So I went and I got all those calls made and got those people to come at three o'clock that afternoon.

At three o'clock that afternoon, I'm in the outer office, because these people are starting to form and Dr. Simmons, I know, hadn't had two minutes to even read the memo that Gross had already sent to the world. I wanted him to read that, so Dr. Simmons said to me, "Hold them out for a few minutes. Let me have a couple of minutes to read this." So I'm just holding them out there, and Dr. Van Howeling came up to me. He said, "I need to speak to Dr. Simmons." I said, "Well, he needs a few minutes before I can let you go in there." "I need to speak to him personally" (laughter).

(Interruption in tape)

MS: Dr. Van Howeling came up to me and he said, "I need to see Dr. Simmons, *personally*." I said, "Well, all right. I'll talk to him." So I knocked and walked in and said, "Dr. Simmons, Dr. Van Howeling wants to see you privately before the other people come in." He said, "Okay, show him in." I went back out, and in a few minutes Dr. Simmons invited us in. So we walked in. Dr. Van Howeling is gone. I walked over to the window -- and this is on the thirteenth floor in the Parklawn Building -- and I looked down at the street and I said, "God, I knew things were bad, but I didn't think they were that bad" (laughter). He'd slipped out the back door in Simmons's office. He wasn't going to be at this meeting. Too hot to handle; he wasn't going to be there.

So they went ahead with the meeting, and it was an excellent meeting of the science that had to do with the fact that there's natural estrogens; and it's a hell of a lot more complicated than just simply finding a few parts in DES. They got into a discussion of the sensitivity of the method and the whole business. Then from that, we're trying to construct some kind of a policy that they could handle this thing. That's the way it was handled. There were some darn good toxicologists in there who could work on this thing from a scientific point of view. And

prepared a position paper. Human drugs were not banned at all. Matter of fact, I don't think the DES in animal drugs there was anything done. But it was an extremely controversial thing as to it being a carcinogen.

I remember another experience with respect to DES, when that was determined to be the very first substance that had been shown to be a potent carcinogen in animals that turned up to be a carcinogen in humans. It was the female offspring of mothers who had taken DES during their pregnancy. I remember when that report came out; I think it was a Hearst Report or something. It was an extremely significant thing, because this is the very first time you had cause and effect that you could tie animal and human experience, and it was a rare vaginal cancer such that they could be reasonable certain there was cause and effect.

I remember at the meeting that this was debated in the bureau right after this had occurred. I was a little emotional about it, because it seemed to me that if there was a substance that would cause cancer in offspring, babies, young girls, that you had no choice but to ban that. I remember my friend Dr. Kelsey again, raising up in righteous indignation and giving me a lecture on physicians and the benefit-risk decisions, and that there is no way that should be banned under any circumstance. That's for

the doctor to decide. And I said, "I think it's also for the patient to have something to know about this thing." It wasn't banned. There was simply a little further warning put in the labeling, but they were not about to ban that from use.

I remember another experience, similar, where it had come to our attention that methotrexate was an extremely potent drug that had caused quite a few deaths in being used for psoriasis, an unapproved use. It was approved for a very, very specific cancer drug. That was one of the benefits of having been in that bureau. I had sitting right next to me Dr. Bill D'Aguanno, who I think is probably one of the most world-famous experts in carcinogenicity. Internationally famous. Very common guy, though. Not a high-and-mighty Ph.D., but a very common guy that could communicate, written and oral, that you could understand. He explained to me about methotrexate that that happened to be a drug -- which opens up your mind if you've never been involved in these kinds of issues -- that is so toxic that the effective dose and the toxic dose are so close there's hardly a distinction. So if it's effective for the purpose intended, it's very likely it could cause death or serious injury. So you have to monitor it very carefully and it probably should have been

administered in hospitals only -- by specialists, not by general practitioners, because it's too toxic.

I think I had a report that Detroit had sent in on this. I think it was manufactured maybe by Upjohn; I'm not sure. I had seen where these deaths were beginning to build on use for psoriasis. Somebody has a skin disease, and they're dying because they used a cancer drug, a doctor. I put that on the agenda for a bureau center directors' meeting and, my God, I got really emotional. I absolutely said that we not only had a legal responsibility, we had a moral responsibility to do something about this because there are people dying out there. And again the physicians just . . . "What the hell's the matter with you? Don't you understand medicine? That's perfectly okay under the supervision of a physician, and you shouldn't be all that concerned about it."

Well, you go through those experiences, you get rather depressed. But, I mean, I was emotional, and you shouldn't be that emotional when you're dealing with something like that. But on the other hand, I didn't think their response was very good. What they're basically saying was that M.D.'s are somehow much more intelligent than others and can decide your fate up or down, and that we shouldn't be concerned about it. Well, I could see that they didn't

know everything, and that that wasn't necessarily the best way to do it.

But anyway, methotrexate became a very controversial substance because of this. And I remember a meeting with Dr. Edwards where it was decided he would call up the company and he would direct them to make certain changes in their labeling because of this toxicity, and he did. Even though they weren't legally liable, because practitioners were using it outside the approved use, he, because of this experience, took it on his own to call them up and press them to do what needed to be done, and he did it. Those are just a couple of instances which expanded my knowledge greatly about the difficulty of scientific issues and that it isn't black or white. There's very difficult decisions that have to be made.

But as special assistant to Simmons, I got tremendous exposure to Edwards and others. I couldn't believe Dr. Simmons. He was a guy that was often a little slow to get to meetings. It didn't matter how important people were. I was responsible for the agenda that we would get from the commissioner's office and would have to see that the center had the right people there and the right staff work and that Simmons was briefed. I would do all of that, and then I'd go up there and he wouldn't be there. I remember a

time or two Edwards would just be outraged; he'd just be outraged. I would start the brief. I would say, "Dr. Edwards, I know he's going to be here soon. I'm familiar with item number three. Maybe I could go ahead and start that until he gets here." I would, and he'd let it happen. But I was just terrorized that this guy wasn't there. Because you can do the briefing, but if you get some substantive questions, you're not the person to respond, and here the guy's not there.

I remember one specific instance of where this happened that I never will forget. It had to do with the overprescribing of antibiotics. Simmons felt very strongly about that and he put it on the agenda, and he made his presentation. And Dr. Edwards, having much broader responsibilities and, particularly, political problems, he didn't want to hear this. "There's no way we're going to restrict those prescriptions (inaudible) antibiotics. It's just something that is accepted by the medical community, and I'm not going to do that." Simmons just kept right on, right on, just like a bulldog. And pretty soon I noticed that Dr. Edwards would not even acknowledge Simmons was alive. He wouldn't talk to him; he totally ignored him. Finally he got really teed off and he really blasted

Simmons. It was so tense I was glad when the meeting broke up.

We left and we were walking down the hall, and I said to Dr. Simmons, "Jiminy gosh, I think you were pushing it pretty far there. I thought he was going to fire you." He turned to me and he says, "Merv, you watch. In six months, he'll think it was his idea" (laughter). That was just the way he did things. But he took tremendous risks. Edwards was a very hard-nosed guy that certainly knew how to manage people. And he could use some pretty salty language, too. But he didn't appreciate that, and no one else could have gotten away with that. Because Simmons was a very close friend of his prior to coming to FDA, and he could get away with it and he knew what he could do.

Okay. So we did that. And sometime later we had a terrible problem with methadone, and the Special Action Office in the White House was just absolutely driving Edwards crazy. That's the White House. And the department, they had designated a person that was just one of the most aggressive people to bird-dog the agency. There were deaths occurring, and politically that was totally unsatisfactory; very controversial, anyhow.

RO: Now, what was methadone?

MS: Methadone was used for heroin users. The idea was that you could give them methadone in a controlled setting that would get them off of heroin. But it was extremely controversial, because if you couldn't control it very well, you could put some people . . . It was addicting as well. You could addict people, or you could just simply transfer them from heroin to methadone, and then they were addicted to methadone. If you didn't have a very well design counseling, job opportunities, everything, you didn't have much of a chance for success. You just maintained them, is what you did, and you did it on the public expense. That was very controversial. Great social questions about that. Very controversial.

So one Friday afternoon, I was at my desk. I was a special assistant to Simmons now. I was at my desk, and his secretary, Mary Jean Lyons -- I think that's her name -- called me and she said, "Merv, Dr. Simmons called me from downtown, and he wants you to accompany the commissioner to a briefing at the White House Monday." I said, "Wait a minute. I don't go anywhere with the commissioner unless I know what I'm going for. I just don't do that. I don't know what you're talking about. Do you know where he is?" She said, "Yes, he's down in the department." "You got his number? Give me that number." I call up Dr. Simmons and

he said, "Yes, Merv, I've been intending to talk to you about it. This methadone thing has gotten so bad and so far out of hand that we've decided that you're going to be the special assistant to the commissioner to just handle this problem. We know you can do it. I want you to accompany the commissioner to the White House, to the Department of Justice, and to the department on Monday." Well, I don't know anything about methadone; very, very little. I said, "Yes, sir. I'll do the best I can."

So that weekend, I grabbed regulations and everything I could, and I read everything I could, because I didn't know anything about it. Monday morning I meet the commissioner first thing in the morning, and we're gone on a whirlwind tour, including meeting the press. Now we're going to do all great and wonderful things about methadone, and here's the man who's going to be in charge of this. He brought me right back from these meetings and he introduced me to all these people in these different locations as the special assistant who's going to take care of all this. I don't know even the first issue about it, and everybody at those meetings are experts.

Anyway, he comes right back with me and he calls a commissioner's staff meeting and he introduces me and said that we have a meeting scheduled for Wednesday afternoon at

the White House, at which we will present an options paper. "And Merv will have that prepared and make the presentation." I'm just about sick, because I don't know what I'm going to do. "He's it and he'll be preparing memorandums that will be circulated to you. So if you've got any problems with methadone, you understand he's the one that's going to manage this." I got that because that project coordination system, they recognized a guy who knows how to manage things; and that's how I got it. So I went back and I worked day and night, and I called meetings of agency people who had been working on it. Immediately you could see there were great turf battles and no direction.

But I have to say something as an aside. That was my first experience with Adam Trujillo. He was in the EDRO organization, and when I laid assignments on that man, that man responded. He delivered. And there were so many of them that would just -- eyes would glaze over, and they wouldn't do a damn thing. They either couldn't or they wouldn't or whatever. You couldn't get anything.

Anyway, I worked like hell. I had a secretary that was just terrible. I didn't have her; it was the discipline officers had her. She wasn't worth a damn. She would gripe if you gave her something to Xerox. Edwards is

out of town, and I absolutely must have him see this darn paper before I present it. I couldn't possibly do that. But he's out of town. He's coming back Tuesday night late, and he wants his driver to deliver this paper to him at Dulles. Well, this doggone secretary barely got the thing typed by then. I remember when she got through that evening -- and I've got the driver waiting for this thing, and I haven't had an opportunity to really fine-tune it -- I almost passed out. I was so tense that I just about folded up.

I got it to him, and the next morning, before we got over to the White House, we met downtown, F.O.B. 8 because he was down there all day. I gave the presentation, and I remember Novitch and . . . I'm not sure if Jennings was still there. I can't remember. No, it would have been Simmons and Novitch and Weatherell and those people were there, and I gave the presentation. Edwards was impressed, because I had used some strategies that would force . . . You see, I learned a hell of a lot in two days. It's a miracle I could do what I did back then, now that I think about it.

But it was obvious no one in the federal government at that time had clear authority to deal with this problem. So Hutt -- and I had tremendous respect for this man

because of these kinds of experiences -- prepared authorities under the Food and Drug Act, under the new drug provisions, to give us authority over methadone that took the most fantastic lawyering job you've ever seen.

RO: What was Hutt?

MS: He was the chief counsel. Brand-new guy from outside, a very intelligent super-action man. A fast act that, if you gave him a problem, he could sit down and almost do that final (snaps fingers) right like that. And that was what he did here. He just designed this thing to give us authority. I couldn't see how you could get authority under the act to do this as a condition of approval, but he did. Edwards had to call him in a couple of times, because he got right out on his own a few times in meetings with other departments. I complained to Edwards one time because it seemed to me he was getting way out of bounds, and if I'm supposed to be trying to manage this darn thing and keep him informed, I can't do that very well with Hutt running around doing what he's doing.

RO: Do you remember what year this was, Merv?

MS: Yes. Well, I've got the papers. I would have been, I suppose, '72. I still have the memo from Peter Bourne. Jaffe headed up the Special Action Office in the White House. Peter Bourne was a deputy to him, M.D. from

Georgia. The reason I bring him up is that he was Jimmy Carter's Washington man when Jimmy Carter ran for president. Which boggled my mind when that occurred, because here he was a deputy in the White House in the Nixon administration, and when Carter runs, he's his principal man in Washington. Politics never ceased to amaze me. I couldn't understand that at all. Still don't. But anyway, he was a very nice guy.

Part of my job was to go to all of these meetings, which I did, and to make sure FDA was represented. And I did. You know, I could do well there, because I had much more government experience than any of the other people, and if I used a low profile and common sense and persuasion, I could direct a lot of what they were doing. And immediately took a tremendous amount of heat off of Edwards. But that option paper I remember I presented down there, God, I'll never forget the office we were in. It was just very plush, and I'm thinking to myself, "Boy, these guys live in much different quarters than we do." Because the day that I was assigned this special assistant's office, unbeknownst to me they summarily gave me an office on the sixteenth or seventeenth floor in the B wing of the Parklawn Building. It was an office that some other agency had left, and it was huge. I mean, huge, just

like a dance floor. But I don't have any furniture. And they just summarily picked a secretary and said, "You work for Shumate." Her name was Effi, and I don't know her last name. The very first day -- and I had a lot of work to do -- that I met her, she didn't want any part of this assignment. I mean, I'm a special assistant. How long am I going to be here? She didn't know, and she's going to quit, or leave. I don't have anybody to help me. No furniture, nothing. And I've got all these White House people coming up here for meetings. It was an unbelievable experience.

But just by sheer grit and determination and a lot of laughing and working, I was able to knit together the agency's position, get it presented. What I did is, I prepared an option paper that forced the White House to consider the funding, because everybody was getting funding in the mental health area and in the enforcement area. Food and Drug is getting nothing; we're taking it out of our hide. Yet we've got a principal responsibility here, and that was wrong. So I had options that went all the way from giving it completely away from Food and Drug to giving to us in a greater responsibility and giving us the funds to do it.

RO: Under what authority were we going to administer it?

MS: Under the Food and Drug Act and under the new drug approval. It's a condition of approval. It was the most creative piece of lawyering that I had ever seen. And regulations were out there and they were in effect. I was accompanying Hutt and Edwards to meetings with the AMA (American Medical Association), and, I mean, it was amazing all the places that I was going and meeting with people I'd never, ever heard of before. Didn't take me very long to become a pretty good expert on this problem. But it was a fantastic experience, and it taught me, again, a lot about the skills you have to have to get people to do things for you when you have no authority over them. I had no line authority over anybody, except I'm speaking in the name of the commissioner. But you have to do that with great care to be sure he backs you if you say something. But I immediately started lines of communication with the department and elsewhere to make sure we weren't getting dumped on simply because we didn't have anybody to be on top of the problem. The fact of my problem coordination system, I'd learned the skills in how to do that. That's what I was doing, exactly. Same thing.

So I did that for a while, quite a while. It calmed down, and I then went back as special assistant to Simmons. About that time, Charlie Edwards got selected as the assistant secretary for health. I remember I was going with him somewhere on a methadone thing when it was announced that he was being selected as the assistant secretary, and just for something to say, I said, "Dr. Edwards, I don't understand how people can walk into those jobs and be able to handle them. They are so immense I just don't know how you do that. I wonder, how do you do this? How do you do these kinds of things?" He said, "Well, Merv, I don't know, either. But what I try to do is to get the best people I can around me, and usually it works." That's pretty good common sense. But anyway, he went down as assistant secretary for health. He immediately took with him Simmons. So now I'm left. And I found out right then, special assistant is a very difficult job, because when your boss, mentor, leaves, you are left high and dry.

Now I'm special assistant to Dr. Crout. Dr. Crout did not get along with Dr. Simmons. He had been put in here, I think, by the scientific community because they were not all that happy with Simmons as to his clinical investigational experience. I don't know that for sure; I

believe that. Because he obviously had more clout than a deputy would normally have. He had his own independent clout from somewhere.

RO: Dr. Crout was in here, then, in the bureau, under Simmons?

MS: Deputy. Came in as a deputy. But I immediately had some feeling that he had clout beyond Simmons. Simmons didn't select him, and I kind of doubt if Edwards did. I think he was put in here somehow by the scientific community, I would imagine, because he had a good reputation as a clinical pharmacologist.

He and Simmons were totally opposite people; they did not get along. Dr. Crout was absolutely in charge, and he knew everything. He didn't solicit an awful lot of advice; he knew what he wanted to do, and he gave orders. So I was very concerned, and after Simmons left there was dead silence for about two weeks. I didn't have no rapport with Crout, and I'm thinking, "Oh, my Lord, what am I going to do now? What am I going to do?"

To give you an example of that, I often got caught between the two. Simmons would give his views. He would ask Dr. Crout's views. They would be almost always opposite, and then I would be somehow got in the middle. Of course, working for Simmons, I went with Simmons; he was

my boss. So he called me up there, finally, and he made it very clear he wasn't all that happy with me. I thought, "This is it." But he gave me a couple, three assignments to do, and I went away and did them. They were not the kind of special assistant jobs. These were pretty much assignments to go investigate problems. One of them was that benefit-risk thing.

Another one had to do with the . . . We had to readdress the question of PDs across the center. The Civil Service Commission was coming in, and they were talking about consumer safety officers instead of Food and Drug officers. We had to do that. Convened meetings and wrote up memos on that. He liked them. He wrote notes on them to me back. He didn't have much on with me one-on-one, but he'd write notes: "This is very good." "This is excellent." So I knew that I was doing what he wanted done. And I finally did get back in his good graces. As soon as he saw "I'm going to work for you. You're my boss, I'll work for you. I don't have strong feelings" . . . I mean, I did, but you can't have them when you're special assistant. You've got to learn how to read somebody and do what they want or you won't be there.

RO: You were still kind of a chief Food and Drug officer as well as a special assistant.

MS: Yes, but that had faded into the darkness. I wasn't unhappy about that, because I didn't have any time to do that, see. But I can just give you an example of how not to do something. Ted Byers, as part of the reorganization, had become the associate bureau director for compliance, and so he had the enforcement side. Simmons had tremendous respect for me, and he would call Ted up there on enforcement issues. Simmons knew nothing about them. Ted would come in there, and Ted did not particularly like the idea of a scientist getting involved in compliance matters, and he made it his point to keep them out of it as much as he could. Well, that always frustrated Simmons, particularly if it became an issue and he didn't know what was going on.

I remember many times Ted would come up there -- and I would always be sitting in -- and Ted would get extremely emotional. He didn't know how to confine his time; he would take way too long. And Simmons was an extremely hyper, busy person that if you talked too long on something that he caught within the first three words, he didn't have much time for you. He wanted to get on to the next, because he had something else he wanted to do right now. Ted was just totally ineffective with him because he didn't know how to handle the guy. And then usually when Ted

would go, Simmons would ask me what I thought, and I'd tell him my views. We had a good rapport. But it was just a matter . . . He had the right decisions quite often, but he would anger him because he didn't know how to relate to the man. Therefore I vowed right then that if I ever got in a responsible position, I would never, ever keep that kind of information away from somebody like that. You're far better off to brief them to gain their confidence, but don't let them have any surprises. Because if they get a few surprises, they lose confidence in you. That's what happens. And he lost confidence.

But at any rate, I then worked there, and it wasn't but a very short time after that that I got . . .

RO: I was going to ask you, after Edwards went up as assistant secretary for health, who came in as the commissioner then?

MS: I think it was Dr. Schmidt.

RO: Was that a period of time when Sherwin Gardner . . .

MS: Sherwin would have been acting for a while, but I think Dr. Schmidt came in as the next commissioner. I'm pretty sure.

But after he'd been down there only a short time, Dr. Simmons called me and he wanted me to come down there as

his executive secretariat, because -- he didn't tell this to me, but I picked it up -- that there was a lot of politics down there amongst the assistant secretaries, and they wanted me in the executive secretariat to the secretary so that they could be informed of what was going on all over. I thought about it and I said, "Oh, no, no, no." I'd been down there enough on the methadone thing to see what kind of piddle-pee politics went on, and I could see I want my career at FDA. I don't want to get involved with these people; they'll cut your throat and you won't even know what happened. Anyway, I denied that.

Then, there was a great big bureau on nursing home (inaudible), and that Simmons invited me down there to a meeting with him. I went down there. I mean, I would be polite enough to meet with him and he could give me whatever he could. I'd think about it, but I had no intention of taking it. You know what he did? He took me into that office with all these staff and he introduced me as the director of this office. And I am absolutely in shock, because I'm not the director of this office; I had not decided. So after we got out of there, I was embarrassed to death, because these people are looking at me. I didn't know anything about nursing. Same thing with the methadone thing, see. But anyway, I got out of there

and I said, "Dr. Simmons, would you give me the functional statements and the funding data and whatever information you have on this office? I'll take it with me and I'll study it, and I'll let you know." I left, and I never, ever said another word to him. But he called me up. I was just going to let it die, see. He wanted to know why I . . .

(Interruption in tape)

MS: Dr. Simmons wanted to know why I wouldn't take the job, and I said, "Well, Dr. Simmons, I've looked over everything you've given me and, frankly, there isn't any way that office can work. You've got a special staff with no real authority or funding or anything. I don't see how anybody could manage that program nationwide out of that office." He said, "We know that, but we know you can do it." I said, "No, sir, I can't do it. I have to stay here at FDA; that's my career. I really would like to work with you, but I can't go down there." What I had in mind was, if I went down there and then within six months these guys left, heck, I'm gone; my career's gone. Well, I had twenty-some years in government service. I wasn't wanting any part of that. Besides, I didn't want to go downtown. No parking. When you went downtown at my level at that time, you were absolutely nothing. I mean, they had

hundreds of people that were above you. You'd be the last guy on the totem pole. I just didn't want any part of it. Besides, that nursing program was extremely political, very dangerous. So that just left.

Not very long after that, Dr. Crout called. He said, "Merv, Dr. Edwards has requested you to serve on a task force in the department on the reorganization of the mental health, drug abuse, and alcohol abuse programs." I said, "Well, Dr. Crout, I'd like to talk to somebody about this first. I don't know anything about this. I don't know that I want to . . ." "No. You go. You go Monday." I said, "Yes, sir."

So I went down there to the department and met with Edwards and Weinberger, who was his secretary of health service, and we got our charge. I mean to tell you, that task force was made up of the most outstanding scientists in the whole damn department. Dr. Bunny, I remember, and others. These were people that were extremely high-level people and very high-level scientists, completely out of my element. But again, Edwards put me in there because he wanted someone there that would be objective and that he could trust to tell him exactly what's going on, because even though these were very high-level people and scientists, every one of them had something at stake.

Whatever organization evolved, they had visions of fantastic organizational responsibility, and so they were going to be influenced by what they did.

Well, of course, I had to gather up everything I could. I didn't know anything about these programs. And studied them. And I actually could contribute. I was involved in rewriting and proposing, and then went with the task force to make the presentation to Weinberger. To show you the politics that goes on in that department, we walked in, and Edwards had very carefully planned this with Weinberger with only him, Simmons, and the task force. He didn't want anybody else to know about this, because he wanted to get Weinberger's approval.

We walked in there and sat down, and I remember Weinberger was right two positions from me, which is quite a thing even then. Now, it would be more. And I looked up, and assistant secretaries and their staffs start filing around behind us, totally uninvited. They'd heard of it, and "there ain't nothing going to happen in here by Edwards without our knowledge," and invited themselves to the meeting. And then started to barb Edwards after the presentation. I remember I got one question that was put to me to respond to, and, I mean, I had a difficult time because it was a pretty high-level kind of meeting. But

got the thing adopted, got (inaudible) organized, which is still an agency. Didn't know a thing about it, but I learned a hell of a lot about research and implementation of programs and things that I'd never, ever thought of before. You do the basic research and then you have to plan how you're going to get this out to the masses of this country and how you're going to fund it. You can do some great research, but if you don't have some excellent ways of implementing, it's not worth a damn. Well, I learned an awful lot about those kinds of things and got to rub elbows with some very high-level people.

But it was exactly why I was there. Simmons and Edwards would want to know just what was going on in this task force to be sure it was solid and that there wasn't somebody just doing something to feather their nest and had nothing to do with what needed to be done.

RO: How long did that assignment last?

MS: Well, it was for several weeks. I was actually on leave and got called back here to go down when we made the presentation. I don't know; it must have been six weeks or so.

And then I came back and, boy, I mean to tell you, I was even more dedicated to get back into Food and Drug into the career position, because I could see that no way

could I possibly stand any part of that department. I'm a compliance officer and that's where I wanted to stay, because that's what I know. Every time I'd get thrown into these other assignments, I could do okay, but I didn't feel comfortable there. It's a totally different ball game and I didn't want any part of it. But that experience was really something to go through, to witness all these things happening by these people. And, as you can imagine, it was so political that I was always afraid that I was going to get put in a position where I professionally could not accept it. But, you know, that never happened. I think they always felt, particularly Dr. Simmons -- he always felt that I was a kind of Mr. Clean. In fact, sometimes people said that to me.

I must go back quite a long time before I worked with Simmons. Actually, I went to Simmons about this business of people soliciting free lunches from industry representatives. Bob Bartz worked in the Office of Scientific Evaluation, and he was outraged about what was going on. He told me about it. By that time, I had a good rapport with Simmons. I went to Simmons and I said, "You know, I don't know if you're aware of it or not, but whenever there's a meeting with industry, some people in this bureau -- high-level people -- always set the meeting

for eleven o'clock with the clear understanding of industry that they're going to be taken to lunch, and to the best lunch you can get. And when they go to lunch, they invite anybody and everybody within earshot with them. I find that absolutely degrading."

He did remove Marv Seife from office director because of that and some other things. It was just unbelievable what they would do. And what disturbed me is when an office director does it, that's bad enough. But then they invited everybody including GS-13 reviewers to accompany them, and it's a big joke. Everybody knows it. What kind of an image does this project of the Food and Drug Administration? How can you be representing the public interest and engaging in that kind of activity? Just gross. That was just one of many.

I related another thing that I probably should say before we leave that bureau. I was involved in several personnel matters that were extremely tense, involving medical officers, primarily. There was a person by the name of Dr. Nestor, who had the reputation in the center of having never, ever in all of his career of, I think, over ten years, approving a single drug. The drug industry was an absolute enemy. They were all crooks, and you approve nothing. He had that reputation.

I had nothing to do with him personally. But I had a few encounters with him, one of which was a meeting that Chief Discipline Officer for Chemistry Dr. Armond Casola, who I have the greatest respect for as a professional. He was absolutely beyond question. But he did not like conflict, and he had two chemists. An issue that a company had come to him on that involved two divisions where there was a fundamental difference between the reviewers and, of course, that would then be for him to resolve, because it involved two different divisions. He had the supervisory chemist, reviewing chemist, up to his office. At the appointed time, in comes the reviewing chemist and the supervisors. But, in addition, Dr. Nestor and his division director, Dr. Alan Lidd, urologist, invited themselves. And I could see that Dr. Casola was visibly shaken, because he was not anxious at all to try to have to handle these guys on something like this. Very comfortable in the science, but not at all comfortable having to deal with these people.

So I went over to the secretary and I said, "Do you take shorthand?" She said, "No." I said, "I don't, either, but I'm going to take notes." So I walked right over beside Dr. Casola, because I could see he needed support, and I said in a very loud voice, "Well, since this

has expanded beyond chemistry, I think I'll join you folks." And I sat down, and very obviously and deliberately took explicit notes of everything discussed, and then wrote it up afterwards, in effect, chastising, on the record, them for having come and expanded this beyond chemistry, which complicated the decision very much. I put it in the record and sent them copies. I got a note from Dr. Nestor. He didn't appreciate it very much, but I didn't back off. Far as I was concerned, he had been conducting himself in an outrageous manner on many occasions and never once had there ever been a record made of that. I felt that if there was a record made of his conduct, over time it would be crystal clear this man was not operating in a professional manner.

One other incident was where I came into work in the morning, and Dr. Leong, who was a Ph.D. pharmacologist from California, was the office director. Maybe the deputy office director. But anyway, he was the office director. He was the power without question in that he was part of the administration -- Finch. He said to me as I walked in, "Merv, I want you here to this meeting. I've got a problem here." It was Dr. Nestor, complaining formally and bitterly, about his division director, Dr. Winkler; and Dr.

Winkler counter-charging him with unprofessional conduct in a meeting with industry.

I walked in and I just plain sat down and I took notes. I mean, detailed notes. It went on and it went on, and, I mean, it got negative. The used some pretty damn foul language. And I, again, was wondering, "Is this really a professionalism that ought to be here, or what is this?" But Dr. Winkler was just distraught with the way this guy had conducted himself. At the conclusion, Dr. Leong had kind of got the thing settled so that it settled down and they weren't shouting at each other and there weren't going to be any formal actions filed. So I said in a loud voice, "Well, since all of you have seemed to come to an agreement here in this meeting, I don't see any need for these notes, and I'll just tear them up and get rid of them." I tore them all into bits and threw them in the wastebasket. Went to lunch.

Came back from lunch, walked in my office, all of those notes were on my desk, all taped back together, with a note from Dr. Leong that said, "See me." I have those notes to this day. I said, "Well, what in the hell's going on here?" I walked in there and he said, "Merv, I want you to write up these notes." I said, "No, I can't do that. I tore those up in the presence of these people, and I can't

write those notes. That would not be proper. Unless they get caught?" "No, they'll not get caught." I said, "Well, then, I can't write it. If you want to write it up and sign it, that's your business, but I can't do that. I'll take them over the weekend and I'll make some sense out of them as best I can, but I'm not going to write the memo." I will not write the memo." He said, "All right, that's fine. I'll write it." That's what happened. They put those notes back together. Now to me, that was an indiscretion that I wouldn't do professionally. I have a duty, if I'm going to write up notes when I told somebody I wasn't, to inform them, and to give them copies.

RO: What caused him to change his mind about that?

MS: Well, I think they had clearly in mind disciplinary action, and that's what they wanted those notes, for see. They were going to initiate some disciplinary action and, as a matter of fact, they did.

RO: It was surprising that he wouldn't have said that before you tore them up.

MS: He couldn't, because I did it right in front of everybody. He couldn't have then. But he had in mind disciplinary action. Interestingly enough, as an aside, and then we'll end this segment, that was it. Years later, I don't know how many -- three or four -- I was at work in

the office of the ACC, assistant commissioner for compliance, in a totally other job, and I had this guy come into my office who introduced himself as a special counsel for the secretary to investigate FDA. He's a lawyer from the IG's (Inspector General), and he asked me a few questions. Had I been in this Bureau of Drugs? Was I aware of a particular meeting at which Dr. Nestor, and Dr. Winkler, and Dr. Leong were present? That he interviewed all of them and they'd each given a totally different story, and he had been told that I had been present at that meeting and he wondered if I could shed any light on it. I just quietly opened my desk drawer, pulled out the file, and handed it to him. That guy, being a professional investigator, couldn't believe somebody could have notes. It was a great thing for him.

So he questioned me rather closely about Dr. Simmons, because he had summarily moved Dr. Nestor and Nestor had filed a grievance, and they'd gone through the whole grievance proceeding. The allegation was that Dr. Simmons had . . . I don't know if he'd engaged in fraud or what, but anyway, it was a very serious charge. I could see where he was going, and I said to him, "Wait a minute. I don't know exactly what you're going to, or what evidence you have. But let me tell you something. I worked for Dr.

Simmons for several years. I know him I think as well as anybody in the Food and Drug Administration. I can tell you he is a person who had a difficult job to do. He had to try to get people moved in a way that he could make that bureau function, and he had people that were just resisting any change. I can tell you, he was totally naïve as to any personnel matters. He didn't know how government worked. He probably did things that were improper. But I can tell you, having known him, he did not do that with the intent of violating any law or regulation. He was doing that in good faith to do the best he could to make that bureau function. So I don't know what you've got or where you're at, but I can tell you I really don't think he was a criminal in any stretch of the imagination. He was trying to do the best he could." I think I probably had a lot to do with getting him off the hook, because they clearly had in mind to prosecute him. And I think maybe Dr. Leong as well. He didn't follow the rules; he didn't do any of those things. He moved people summarily.

I remember another instance, and then I'll quit. We had a Dr. Gyarfas that was an extremely terrible character, in my opinion. He liked pornography. He not only read it, but he typed it. Dr. Simmons called me and Dick Terselic into his office and he announced that he had no choice,

he'd had so many complaints from industry about this man's conduct that he was going to have to do something about it. What he intended to do was to make him a special assistant to the bureau director, because he didn't know what else he could do with him at that level. "What do you think about it?" He asked Dick first. Dick was a very power-hungry man that wanted to be commissioner as soon as possible, and so he knew what the boss's decision already was and he completely agreed with him and went right on and told him what a great idea that was and everything.

Then Dr. Simmons turned to me and he said, "And what do you think, Merv?" I said, "I think it's the worst thing that you could possibly do, Dr. Simmons, because you've gone a long way to upgrade this bureau and this office to manage this bureau. And it's my opinion, to just have him physically located in this office will do tremendous harm to you as to what you're doing and what you're trying to do. I cannot see what this man can do. He can't do anything unless he has people working for him, because he's not able to do anything himself." "Well, I had in mind he could write the bureau staff manual." I said, "No, not unless you've got six good Food and Drug officers who can help him, because he can't do it." "Well, I don't have any choice and I'll have to do it." So he did.

That guy was unbelievable. He was in the office next to me. He told me -- and we may have to put these notes under lock -- that he had gone to his senator in Kansas to get the job. He was totally secure when he came to the agency. He, in effect, bought his job, is what he did. He had a guy by the name of Joe Mamana, who you know, as his personal attorney. They talked almost daily. He was constantly being advised as to how he could file a grievance or do this or that. We would have a staff meeting. He would type up the notes of that staff meeting, and a time or two I saw those. They weren't even close to what had gone on in that staff meeting. They were slanted; they were biased. It was unbelievable what this person was. But Simmons was willing to just let him sit there rather than be a division director, where he would have a program responsibility.

But that, coupled with what else I have said, is why I have such a negative feeling about the top-level M.D. managers. I have to say another thing about M.D.'s, and that is, it's my strong belief that their training is not toward management. There are exceptions, of course, as there always are. There are some good managers, but they're not trained. You reward them in the management positions, and then you wonder well the place isn't well

managed. They're not managers. So that's why I was trying to build the role of compliance officers to assist them in the management, but I didn't have the horses to do it. So the first opportunity that I had to get back into compliance, boy, I took it.

I think we'll close there and then we'll pick it up next time.

(Interruption in tape)

RO: This is a continuation of an interview with Mervin H. Shumate, which was started on March 11, 1987. The date is June 18, 1987.

Merv, I believe we stopped the interview before about the time in your career when you had accepted a position with Sam Fine, the associate commissioner for compliance. Or was it regulatory affairs at that time?

MS: It was associate commissioner for compliance. As I indicated earlier, I believe, I was very happy to get back into a real compliance position after having had the experience in the Bureau of Drugs. I hasten to add that that experience in drugs was very beneficial to me. And I think it would be very good for all field people in FDA to have an experience in the center, because you are exposed to a lot of scientific and policy issues that are so much more gray than what you tend to be involved in in the field

organization, particularly as an investigator. So it makes you think a little more carefully about what's right and what's wrong, and particularly how best to carry out a particular policy or to develop that policy. And as you got involved in trying to create policy, you found it was a very difficult thing to do. It's just not as simple as a lot of people would like to think.

So anyway, getting into this, I took the position as director of regulatory management staff. It was a GS-15 position, and I was really happy as far as my career was concerned, because that was a good grade to have to wind up my career to get a retirement annuity. So I was pretty happy about that.

RO: Was that a new position, Merv, or had someone vacated it?

MS: No, it wasn't. It was a fairly new organization. The person that was in charge of it was Will Swain. He retired; that's why the position was open. It might be interesting to note why this office was created. The cases were backlogging in the office of general counsel, and Hutt had tried to get positions from the department and could get no positions. So he went to Charlie Edwards and told him that there was nothing he could do; he would have to have some support positions from FDA or the backlog on

cases would just get impossible. So Charlie Edwards gave him ten slots. Those ten slots were FDA slots, and they were FDA personnel that staffed these slots and started to review the pleadings and to do, really, legal processing work. All the cases were typed, for example, by this unit. There were only two compliance officers, Joan Davenport and Howard Schloss, and they were trained by Francis McKay, who was head of the pleading section, in reviewing pleadings. Basically, that's what this organization did when I took it over. But I really got quite an education right away. I might tell you the first day that I went in the office, the shock that I had.

RO: Before you do that, Merv, you mentioned that those ten positions that Charlie Edwards gave were FDA positions.

MS: Right.

RO: General counsel is really a part of the department, right?

MS: Yes. Maybe I should explain. The Office of General Counsel is in the Office of Secretary, and they don't report to FDA; their budget is totally separate. On occasion over the years, the general counsels have advised FDA. They report to the secretary, and they're very independent as far as the agency is concerned. There have

been efforts over the years to get them within FDA so that they're working for the commissioner. Well, you can see why the department wouldn't do that, because as long as FDA's in the department, they want control over the agency. I might explain a little bit later how I noticed the general counsels in the department and the more and more control they got over FDA. Actually, when I was in the field and when I first started in this position, the general counsel's office was totally autonomous from the secretary's office as far as I could tell; the decisions were made by the chief counsel, and that was it. But that wasn't so later on, and I might get into that a bit.

But at any rate, the first day I walked in that office . . . It was very, very small quarters in G.C. space, on the sixth floor. I stepped through the door and I could barely get by the secretary. Very nice-looking gal, and she was sitting there in cramped quarters where she could hardly turn around. I noticed cases, prosecution cases, stacked all around the room. I think there was a backlog of some eighty cases. And I have two compliance officers that are quite independent, because they'd been doing this for some time. I thought, "My God, what have I got into here? What is going on here?"

There was a part-time gal that was seated clear off in general counsel somewhere else. And these gals were typing on typewriters. They didn't have the automatic equipment. The amount of work this gal was turning out -- her name was Jean Knight -- you cannot believe the amount of work that woman could put out. I just had a call from June Stevenson at Jeff Springer's request just last week, asking me to give my opinion on Jean Knight. She's applied now for a job in the General Counsel's Office. I said, "There isn't anything I can do but highly recommend her, because she is one individual that is what I would call a workaholic. You don't ever have to tell her that there's work to be done and 'would you please work overtime, because we need to get this out.' She will work seven days a week, ten, twelve hours a day, whatever it takes to get that job done, and it'll always be done perfect." The only person I've ever seen that could type very complex legal documents and have somebody talking to her at the same time. She never even misses a beat; just keeps it right on going. And as I found out very soon, it was a blessing that I had this person working for me, because there was no way that we could have ever got the work out there without somebody that was that dedicated. And then, of course, I had Joan Davenport, who was equally a workaholic.

And I would say for the first two years we worked seven days a week. I went to Sam Fine on more than one occasion to ask for help, because I told him, "We can work overtime, but I can see where that's getting close to counterproductive," because when you work people long hours six, seven days a week, they begin to get owly. You can just sense that things are not smooth; people get tired, is what it is.

But I noticed right away that you had to work the weekend if you wanted to have any business with Hutt. You never could talk to him during the week, he was so busy. But he always worked every Saturday and Sunday, and you could call him anytime Saturday or Sunday and have a meeting with him. So that's what we did. But I found out right after taking the job that Hutt expected much more of that office than what had been going on. In fact, he came up to my office and met with me, and he congratulated me on getting the job. But in the process of that discussion, he made it clear to me that he wanted my signature on every case and he wanted assurances on the record from FDA, from, for example, veterinary medicine, because he'd gotten a couple of cases that were so bad they hadn't even considered what was the industry practice in forwarding a case. He demanded that the senior compliance officer have

a separate memo that would address that specific question on every case from veterinary medicine, because he'd been burned so bad. And then he instructed me that he expected me and my office to have reviewed that and satisfied ourselves that it was credible before it went to him.

Well, now you can see the dilemma I was in. My boss was Sam Fine, but every document I produced was signed by Peter Hutt. Peter Hutt was entirely different from the traditional Food and Drug Administration, and it didn't take me too long to figure out that I had to respond to his desires or he wouldn't sign the documents. So here I'm caught in between. I know Sam Fine is looked on as some hero figure, but he wasn't as far as I was concerned in the management. I never noticed Sam Fine to ever counter anything Peter Hutt ever said, and he never, ever really got into any case with me. Now, people can say, "That's great. He was a good delegator and you could just go do your thing," but let me tell you, when you're the one responsible for sending cases to the general counsel's office, you need support on the more controversial cases. So I had a totally different feeling about Sam. I didn't feel I got hardly any support from him in handling these really controversial cases.

RO: Merv, would you mind explaining a little bit the process that these cases like from the field, etc.?

(Interruption in tape)

MS: Now, Peter Hutt had made it clear to me that he wanted a policy overview in that position there. Well, as I said, up until then it had been simply a processing office, just processing cases. Now he wanted a policy review to assure him that this represented FDA policy. The reason that this was necessary is that a reorganization had just occurred not too long before, where each center became a program center. That you were left, for example, with all of these centers operating independently, sending cases directly to the general counsel with no policy overview to see that there was consistency between centers -- or if there were disputes between centers, who was resolving them. That didn't happen, and that's why these cases were piling up. If they were just a routine case with no questions involved, that was easy. But if there were issues sitting there, there wasn't any office or staff to get into that and to give assurance to the general counsel's office that it was sound. So that's what he wanted. Well, that was something I was very happy to get into, because as a compliance officer with all those years' experience, no way did I want to be head of a processing

office. I didn't want any part of that. If I wasn't going to be in a policy-making position, I didn't want any part of it. So I was happy to take on that role and really jumped right into it.

So what we had is, you had districts, for the most part, generating cases. Not always, but almost always. They would develop the case. It would be developed by the investigations branch, and then the laboratory branch would do whatever analysis was necessary. Then it would go to the compliance branch, and the compliance branch would be the people to put together the package and make a recommendation to headquarters. And usually the district director was involved and would sign off. Because we wanted some consistency and really wanted to get the regional directors involved in the decision-making process, we required regional Food and Drug directors to sign off on injunctions and prosecutions and mass seizures.

That meant those cases had to go through the regional Food and Drug director's office, and there was a big variation as to what that office did. In some cases they had an individual it was delegated to that did whatever they did. In other cases the regional Food and Drug director would get involved. This became important particularly after Paul Hile got in the senior position,

because he wanted them to be more involved in what was going on. Also, there is a regional consideration that needs to be put into a case, and it shouldn't just be a compliance officer looking strictly at the facts and making a recommendation. There needs to be that additional element of: what's the milieu in the locality? What does the governor's office think? Where are the pitfalls? What about state and local organizations? What did they do or didn't do and how do they feel? There needed to be that. Some regional Food and Drug directors would get into that role and would participate; others would totally delegate it to the district director and they'd sign anything that was sent to them.

I don't want to get too far ahead, but then that case would be sent to the program center, whatever that was. Then it would go through that compliance operation, would be signed off by the senior compliance officer, and then to the Office of the Associate Commission for Compliance, at that time, which was my office, come directly into my office. We would do our review and then forward them to the Office of General Counsel. There was a pleading section at that time, and they would just look at the legal. I noticed right away that Francis McKay was an absolute professional as far as pleadings. There wasn't

anything he couldn't figure out in a pleadings manner. But if he got into a policy question, he just simply didn't know what to do and couldn't proceed; he was out of it there.

RO: He was a good technician.

MS: Excellent technician. I remember, for example, going down there a time or two to consult with him on some problem, and he would reach down and pull out of his personal file some of the most yellowed legal papers you've ever seen and then recall what he had done in a particular situation to get around a problem. That's why I say he could figure out any problem you had on pleadings, that you could present the case somehow.

But there was a problem in the Office of General Counsel, because he was in the pleading section and he never, ever went to court. So you had the litigating attorneys that were quite uptight about that pleading section because it wasn't developed, in their opinion, the best possible way to present in court. That's what was giving them problems. And that's about the time we were bringing in the Arthur Levines and the McNamarras and some pretty bright young attorneys that were very much wanting to know and have a part of what kind of a pleadings case was going on out there. You put that with Peter Hutt, who

is a very bright person that's not bound to tradition, and he was very responsive to that kind of . . . He wanted it to be much more like a law office run, and that's how he ran the general counsel's office.

Billy Goodrich and Al Gottlieb, they just absolutely ran it with an iron hand. There wasn't anybody winked without their personal involvement. I'll never forget a few meetings I had with Al Gottlieb that were just shocking to me, because he would treat these young attorneys just in the most outrageous manner. I recall one Friday we had a pleadings problem, and Francis McKay and I went down to see Gottlieb. He was the deputy chief counsel, and we wanted his advice on how to resolve this particular thing. He tore into Francis McKay like you couldn't believe. Poor Francis had emphysema. He just chain-smoked and he had emphysema, so if he got at all upset, he went into kind of a medical dilemma. And he did, in this session. I just jumped all over Gottlieb because I didn't think it was fair the way he was treated. Here's a man that is as professional, as knowledgeable, and as responsive to higher management as anybody, and he's being dressed down like a little boy. I just thought that was outrageous, so I just jumped all over Al, and we went back and forth for a while.

The next day I had to meet with Peter Hutt. It was a Saturday. I went in and we were talking about whatever case I had. He spoke to me about the session the day before and the noise in Al Gottlieb's office, and that he ran a professional office and he did not tolerate that kind of conduct on the part of professionals. He wanted this to function like a law office, and you just don't conduct yourself in that manner. I said, "Well, Peter, I learned long ago as a Food and Drug investigator that if you're having to talk with a shouter, you have to shout or there's no communication." He said, "I understand, I understand. That's fine. But that doesn't happen here." Peter had nothing to do with Al Gottlieb. Now, you can imagine the dilemma that posed for me with all my documents going forward. Gottlieb, for the most part, managed the trial lawyers, and so he would get involved even though he never saw the case before it went out. Peter signed them. But he did not agree with hardly anything Gottlieb did.

RO: Gottlieb was at the time the deputy . . .

MS: He was a deputy to Hutt. But, as I say, Hutt did not permit him to function; he had nothing to do with him. So here I am, in between. It didn't take me any time to recognize that Peter Hutt was the boss and that I had to comply with him, and I even consulted with Sam Fine on that

one time. He made it crystal clear: "Yes, that's correct. He is the chief counsel and he is the person that you will satisfy," so there wasn't any question about that. Also, Al Gottlieb was trying to hang onto the past and was very close to Tom Brown, who was another staff director in ACC. And they would be together every day of the week. Tom would have compliance meetings once a week and I would go to these compliance meetings. They would sit there, for the most part, and bad-mouth Peter Hutt and everything he was doing. I'm sitting there trying to have a little input into it, but thinking in my mind all the time, "It doesn't matter what you gentlemen have to say. I've got to satisfy Mr. Hutt." So I was just confused; it was a frustrating experience.

It also came up later, too, that I can mention an incident with Taylor Quinn. Maybe I might as well just say it right here, since we're into that. I had four or five cases that Peter Hutt had sent back to me. I had sent them forward, and they were consistent with Food and Drug actions in the past on filth cases. But Peter had a rule that if those cases -- and these were all prosecutions -- reflected very serious conditions, that he would not sign them unless he had assurance that those conditions were under control. He demanded from me that I tell him in the

transmittal memo to him that the Food and Drug Administration has this under control. If I did that, he would sign the case. And on many occasions I would call the district director and say, "Now, I have a problem with the chief counsel. It appears this company is just totally out of control and the rats are knee-deep. And he will not sign this prosecution unless he has assurance this place is under control. If you can't say that today, you've got to get out there and find out and get a report back to me before I can send it forward."

Anyway, there were about five cases that he sent back to me, and he said, "This is exactly what I . . ." And he was not playing around when he would come up; he'd come right up to my office and throw them right on my desk and would say, "I've been telling you now, I'm not going to sign these cases. I want you to tell me these companies are under control or I'm not going to sign them. Prosecution is not the appropriate enforcement action where there's serious continuing conditions. It's not appropriate. It's been one year since you've been in this place. I want you to tell me." I had had it. There were five cases. I had been talking to Taylor and I wasn't getting any change from the way they'd always done business. So I went down there.

RO: Taylor Quinn, now, was director of the Office of Compliance and Bureau of Food.

MS: Yes. He was the associate director for compliance and food, the senior compliance official. I actually went up and talked to Sam before I went down there and told him I had this problem and I was going down to talk to Taylor, because we had to do something about it. I couldn't send any more of these cases forward. So he said, "Fine, go right ahead." I went down, and Taylor, he did not want to talk to me in the first place because it was his opinion that this was just fine, it's the way we've always done it and it's the way we're going to continue to do it. I explained to him that we can't continue to do it that way because it's not acceptable to the chief counsel. Well, he didn't care too much for Peter Hutt's views, either, and he promptly jumped up and called Sam Fine. They were very close friends from back in Dallas. Sam just checked out. He just left it hang without making any decision at all.

So I go back to my office with no decision, and I've got these damn cases and what am I going to do with them? Sam never did address it. There was some kind of a study going on, and he'd just say, "We'll just wait until that study's over and then we'll look at it again," but we never

did. He retired. He did not want to take Peter Hutt on, as I told you earlier; he would not take him on. And, frankly, I agreed with Peter. As a matter of common sense, when you look at it, what he was saying was not unreasonable. It was perfectly reasonable for somebody to take the position he was taking. But it didn't make a whole lot of difference what my personal opinion was, anyhow; I still had to satisfy him.

So, as I say, the way I would get around those is . . . I remember calling up Bob Bartz on one of those kinds of cases and asking him to get out there and to find out what is the current status and to get back to me so I can make a representation to Peter that we're in control; and if we're not in control, get an injunction in here just as fast as you can. Or a mass seizure, whichever. And that's what would happen. They were usually just as bad. I mean, they were not cleaned up. But I had that happen a few times, and that was not a lot of fun to be caught in the middle. And as I say, I wasn't getting what I felt was the kind of support I needed to deal with this. Here I'm getting beat from both sides. But it was very, very challenging professionally.

Another thing that was a most unpleasant thing was the Regional Food and Drug directors' meetings and district

directors' meetings, because Sam would always have me on the agenda. But he never discussed anything with me before, and he'd just leave me out there as a turkey shoot. I got some pretty unmerciful treatment in some of those meetings until I just dreaded to go; I really dreaded to go. I remember one classic meeting that I went to which was Regional Food and Drug directors' and district directors' meetings, and I went to this meeting. I was sick that day; I almost didn't come to work. And it might have been in part because I hated to go, because I knew I was going to get chewed up, see. Anyway, I went, and I was sitting in the back of the room with my head down, just trying to keep as low a profile as I could, sick, feeling terrible. Tom Brown made some outrageous remark about my office. And Dick Merrill was in there, and Dick Merrill made the most positive statement about me and my office that anybody had ever made. I was just dumbfounded. He and Sam Fine were both up in front. He simply made it clear that "Merv Shumate performs a function for this agency that is absolutely essential, and I endorse whatever he does. And whatever concerns he has, I just endorse everything he does." Well, I straightened up and I took a deep breath and I looked around and I said, "All right now,

you sons of bitches, let's go" (laughter). I was just whipped about that time.

RO: Dick Merrill came after Peter Hutt.

MS: He came after Peter Hutt as the chief counsel, and Dick Merrill was a different person entirely than Peter Hutt. He was an academician. Bright. Oh, he could write beautifully. But he wasn't all that personable. But I respected him; he was smart. And got along really good with him. But I never dreamed that he'd make such a statement as that in front of these people. I remember we had a break right after he made this statement, and I stood up and I walked right straight across that whole room between all those district directors and RFDDs, and I walked up to my good buddy Bob Bartz, who was a district director in New Orleans, and I said, "I feel a whole lot better, Bob" (laughter). Because up till then I'd been beat so much that I just felt like, "God, I wish I could get out of this job. It's just not worth the pain I'm having to go through."

Another example that caused me a real problem was, we had a prosecution against Norwich Pharmaceuticals. The president of that company, Red something or other, I can't remember -- it could have been Red Kennedy, but I can't remember for sure -- came in to meet with Commissioner

Schmidt, and for some entirely other reason, and then in the meeting brought up the question of the prosecution that was out, which is a no-no. But anyway, there wasn't any substantive discussion about it. But after that meeting, Commissioner Schmidt asked Sam, "Shouldn't I know more about those prosecutions? I mean, Jesus, this guy brought up this thing, and shouldn't I, as the commissioner, know about this?" And Sam called me. Sam didn't know anything about him, either, of course. He was letting me do the whole thing. He called me and he said, "The commissioner wonders if he shouldn't know about these. You decide which ones are likely to be politically significant and you send them up so I can keep the commissioner informed about them." Well, you can imagine what that did to me. I mean, I am not about to decide what's politically significant and what isn't; that gives an appearance of some kind of selective enforcement or something, and I absolutely couldn't do that. So I didn't know what to do.

But Peter wasn't there. So the first time Peter came back, I went right down to see him and I said, "Peter, I've had requested to me to pick out those cases I think are significant so that Mr. Fine can keep the commissioner informed. I frankly don't know how I can do that, because as far as I'm concerned, any prosecution that's recommended

is significant, and I don't want to have to decide which one is . . ." How can you decide, anyhow, which one is likely to cause some political, or any kind of a problem? I couldn't. He said, "Well, Merv, I understand your dilemma and I'll tell you how you do it. And if you have any problem at all, you just let me know and I'll talk to him." He said, "Rather than you putting together any pickings, making any selection of any case, you just report weekly every case that goes through your office. And then if they have any question about it, of course, they can ask about them. But you don't have to then select things to give to them. Just give them the name and the date forwarded and that's it." So from that day forward, I prepared a weekly list of cases that went forward from general counsel to the Justice Department so they would know what the names of the companies and individuals were, but never anything additional. And that worked fine until I retired. I never had any more question about it.

But anyway, Sam had me up there after that, and he told me in no uncertain terms that it's my personal responsibility to be absolutely certain that every individual name is appropriately named: "I want you to be certain that we're not just naming people because they're on an organization chart." So you see, that was kind of a

different signal than what the district people were getting. You pick them because they're on the organizational chart. Now I'm being told, because this president of this company raised the question with the commissioner, "you be sure that it's reasonable to name those people."

He didn't have to really tell me that, because I took that as a serious part of my responsibility. The way I told my reviewers to review cases -- and I told anybody in the field that asked -- is, "What I want you to do is, for every individual you name, I want a separate paragraph with the rationale for naming them. And if you go through that exercise, it'll be readily apparent whether you have any basis to name them or not." Because, you know, you would get case after case with six people named and absolutely nothing, nothing at all, with respect to three or four of them as to why they were even in there.

Well, we never permitted anything like that. We would require some rationale as to why they were in there and, quite frankly, I had a case or two where they named the wife because she was on the board. I inquired as to why was she on this. Why was she listed here? There's nothing apparent that she is ever at the firm or has anything to do with it. Well, if you name the wife of the president of

the company, it's certainly going to be very serious. You know, I absolutely would never accept anything like that. But you had people, because of this act, strict liability, that didn't feel they had to have any basis for naming somebody. And that's why I think this act is kind of, it's very good on the one hand, but on the other hand, if you don't have very responsible people administering the kinds of cases that go forward, you can really name people without any basis whatsoever. Fortunately, our judicial system is such that you can't get away with naming too many people. But I have seen some people that have gone right on through that probably shouldn't have. But at any rate, that was one of our main functions, and I don't think many people would have known that Sam Fine was the one that reminded me of my responsibility. But he had nothing with me in my daily work.

One other significant thing happened during Sam's tenure as my boss, and that was the Searle Task Force. We had congressional hearings that revealed that some animal test data that Searle had submitted to the agency was fraudulent, and it became the subject of a congressional hearing. Senator (Edward) Kennedy was the chairman of the subcommittee that held the hearings. He had an assistant by the name of Horowitz who was absolutely all over FDA,

and an individual who is famous, Bob Sheridan, who was Bobby Kennedy's investigator that got Jimmy Hoffa. He was the investigator that was out all over FDA, looking into our files and trying to dig up anything he could that they could have a congressional hearing about.

So one day I get a call from Sam Fine to come to his office immediately, and I went to his office. He said to me, "Merv, we've got this very serious problem with this Searle case, and I have to designate you as the ACC representative on a Searle Task Force." You know, at that time I was working six and seven days a week, and I couldn't keep up. I said, "Is there any way I can get any relief, because I can hardly keep my office going without getting into something else." "No. You'll just have to do it above and beyond what you're doing now" (laughter).

Searle, being such a highly controversial and public matter, I didn't want to go into it partway. If I was going to be involved, I really wanted to get involved.

RO: Do you remember what drug that was involved?

MS: Yes. It was aldactone. There were many other drugs, too, but aldactone is one of the more famous drugs. It was a blood pressure medicine, and allegedly there were animal data that revealed it to be a carcinogen, and they had not given this information to FDA. Therefore, we

conducted a full-scale investigation of Searle. That's kind of interesting, too. The Bureau of Drugs named the task force chairman, and that was Carl Sharp. Now, Carl Sharp is a compliance officer in Drugs. He is excellent as a compliance officer in supporting a case, but he had never managed anybody. He's the kind of person who doesn't like to manage anybody, and he wants to manage himself and himself only. He just avoids any management role. Which, of course, I've tried to get him over the years to do, because I know he'd be extremely competent because he's good; he's just a good compliance officer.

Anyway, he was named chairman of this committee, and he didn't have any idea how to manage it or to do anything. Well, I had been very actively involved in setting up a coordination system in Drugs and had, because of the executive development training, learned a lot about project management and product management, and had been the methadone task force manager for the commissioner, which was a highly controversial matter. So I had a few sessions with Sharp, telling him there was no question but what he could do it, and he's a good person, and, "I'll tell you how to do it, and you just go ahead and do it." And that's what he did. He sent out memos and the things you have to

do to get that thing underway, and to get meetings and get issues and get things going.

So we went ahead and got the investigation going, and I strongly recommended -- there were other people recommended, but I strongly recommended -- Phil Brodsky as the senior investigator on that case. He was scheduled to go to Egypt on a trip. And we went to the commissioner and got that trip cancelled so he would chair this investigation team. And the reason I did that is, I knew this was so politically sensitive that I wanted somebody who was straight, and I knew Brodsky was as straight as an arrow. I also knew he could retire if necessary, and it might well be that he would have to retire going into something like this. That's what I wanted, was somebody like that. He took it, and he took it really serious, and, I think, did an outstanding job on a very tough, tough case.

But anyway, we went to Chicago a couple of times, the task force did, to be on site, to know what was going on, to give direction. It was an excellent concept, I think, in that we were set up in such a way that we set up the investigation and then were available on a daily basis to address any kind of issues that might come up. That's an excellent thing to do, because investigators on site are

always going to be confronted with confidentiality or whether you ought to pursue a certain avenue or not; it's so huge you have to have it. This functioned beautifully, because we could meet any time and address those kinds of problems.

We got all the investigational data, and there was a room full of boxes of data on many different studies. We went over to the Chapman Building because we had a hearing coming up, and this report had to be done by that date. Here we had eighteen boxes of data that was just a mess, and had to go through all of that and make decisions and write a report as to what was significant and what wasn't and what our recommendations were.

And I remember, when we were over in the Chapman Building we had Bob Sheridan coming by every day, just making sure he was around. It kind of gives you a little chill as to "what in the hell has he been told now that he's going to . . ." See, because he had a very close link with Dr. Adrian Gross. Dr. Gross was not on the task force, but he was always present. And he is what I call a "junkyard dog": totally biased and won't even make any . . . There isn't any question but what he feels that it's perfectly all right to overstate the case on your side, because that's what corporations do.

RO: Now, he was with the Bureau of Drugs.

MS: He was with the Bureau of Drugs and he was a pharmacologist. He's a pharmacologist-statistician-cancer expert. But he is not a person who has reason in evaluating data, and he was giving us stuff that you can't believe. But we were fortunate. We had Dr. D'Aguanno, who had been a chief discipline officer for pharmacology as I had been chief Food and Drug officer in the bureau. So we knew each other very, very well, and I had absolute respect for the man. He's kind of an unorthodox person, but in his science area, he was tops. He would always been very conservative and not just say something just to say it. He always was very sure about what he was saying. So we had him to give us a good scientific judgment as to whether this is significant or not. And, as I say, if we hadn't had him, we couldn't have functioned, because Gross was just giving us . . . His name is perfect, frankly.

Anyway, another person showed up in that meeting over there -- we worked seven days a week, day and night -- was Jerry Halperin.

(Interruption in tape)

MS: Jerry Halperin showed up. I'd never heard of him before. I was very suspicious of him because he wasn't a Food and Drugger. He'd come out of Rad Health or some

other area, and we didn't know him. Of course, I thought he could be a ringer that was there by some top management in the bureau that wanted to be sure that we were not doing anything that would cause them a lot of difficulty. Well, as a compliance officer, that gave me some concern because I intended to call it as I saw it; it didn't matter what. I certainly didn't want to have Adrian Gross causing me to do something outrageous. But on the other hand, I was certainly wanting to call it as it is if it was significant.

But it turned out Jerry Halperin was absolutely super. He would take a recorder, a Dictaphone, and he would dictate with the rest . . . It was Carl Sharp, Dr. D'Aguanno, and myself, and that was it that was doing this report. He would dictate and the three of us would sit there and talk to him and give him information or judgment calls as to what he should or shouldn't say, and he would convert that right into dictation. Then we got it typed and, of course, as you can imagine, we had to go over it an awful lot to get the report done.

But as I recall, we were just having an awful time getting that report done by the hearing date, and there was tremendous pressure from the commissioner's office to get it done. I remember also one other significant thing: my

friend Al Gottlieb again. He was supposed to be on this task force, but he never, ever got involved in any of these boxes of data. That was below him. He only wanted to see our report, and he shows up at the last minute and he is trying to tear us all through hell to make us write this or that or something else, and he had never seen anything in the facts at all. I know it was the last day that we were trying to get this done, and I was exhausted, just flat-out exhausted. I lit into him that I thought it was really something for him to show up at the eleventh hour and then be making all these recommendations when he didn't know anything about what he was talking about. We had it out right there.

As a result of that, I went to Same Fine and to Dick Merrill, and we got Arthur Levine assigned as a member of the task force and Al removed, simply because we needed a lawyer -- as we needed a pharmacologist -- to be intimately involved to give us advice as to what we should do or not do. I mean, we really needed some legal assistance. As a result of that, Arthur did get involved in the matter.

Carl Sharp and I went together to make this presentation. We were just plain frustrated because we didn't feel we were getting the help. You see, I think it was Dick Merrill had assigned Al as a member of the task

force because he's recognized as a very senior, most knowledgeable, Food and Drug lawyer. I don't know but what he might have done that just to give him something to do other than being deputy to him. But nevertheless, on something as controversial and as critical as that case, he didn't do us any favor, and we were just having an awful time. To give you an indication of how far we were pushed up against the wall, we had gotten to the point where we didn't care anything more about our personal careers or anything. You get so tired from working so hard that you finally say, "Whatever you do to me, I don't care. I've had all I can take." And Carl Sharp was particularly that way. We went up just before Christmas. I'll never forget that.

RO: Remember what year that was?

MS: That must have been 1976. I'm not sure, but either '75 or '76. To give an interim report on what our findings were, and we were just then getting into it really good. We had gotten some data that would indicate some really serious questions about their studies. We were briefing Commissioner Schmidt. They had a steering committee above the task force, and that was the commissioner, the deputy commissioner, the chief counsel, the associate commission for compliance. It must have been

'76, is when that was. And all the bureau directors. I mean, the whole policy board almost.

We were giving it. They had from Foods, oh, one of the old-time toxicologists down there. Gosh, I can't think of his name at the moment. But at any rate, we were giving our report to Commissioner Schmidt, and this doctor -- God, I can't think of his name -- the commissioner asked him what was his impression of these findings. He said, "Commissioner, it's just toilet training; it's just sloppiness. They just didn't take care in the way they reported their findings, and I don't see that it's anything all that significant." The commissioner turned to Carl Sharp, who was the chairman of the task force, and he said, "And Carl, what's your opinion?" Carl turned absolutely beet red, and he said, "Commissioner, my impression is that they've put this in beautiful binders, but the data's all based on shit." The commissioner leaned back. And he had on his country-doctor sweater as he often did. He leaned back in his chair and he rubbed his hands up his sweater and he says, "Ooh, you make my palms sweat" (laughter).

In that steering committee meeting, Horowitz called the commissioner, and the commissioner went out and took the call and came back. He was just ashen. I mean, they had him just terrorized, because, of course, he had to feel

that if this is an indication of what industry science is, then we are in awful trouble in this country. Also, when we got our report done, the steering committee wanted to rewrite, wanted to edit our report. We went to a meeting on this and we didn't have much time to get it done. We had talked about it and it was our conclusion that this was a task force report, and if it's a task force report, then it's just like we write it and no one else should be doing anything with it. And that's the way it stood. I mean, we stood our ground. There wasn't much they could do because there was so much congressional interest that any change at all would have been immediately picked up. I don't think they intended to make any significant change; it was just editorial is what it was. But still, there was a principle involved that really caused some trouble.

I remember, in putting that report together, we had to have it by eight o'clock the next morning. In the middle of the night, we were putting that report together and we couldn't find a Xerox. We finally found one in my office and, God darn, I had never used the damn thing and I couldn't find the paper. So we finally got somebody down in the general counsel's office to come in and to get theirs going, and we just got that report in just that next morning to get it out. That report is still used to this

day in courts all over this country on suits against Searle. I'm told Adrian Gross is a professional witness now that is almost continuously in court. Even though he's a full-time employee at EPA (Environmental Protection Agency) he's testifying as a consultant in cases all over this country.

RO: Remember how long that investigation lasted? It seems to me like it went on . . .

MS: It went on for a long, long time because it had humongous stuff. See, that's a classic example of how not to conduct an investigation, in that there was congressional interest which, of course, locked up the firm, naturally. Because they'd been called to that hearing just like Food and Drug. So then they hired a former U.S. attorney that they gave six figures to to come into that company, and that was the same U.S. attorney that we were trying to work with in the first place to get the case there. They just hired him as their chief counsel and he advised them.

I have to tell another little story, too, and that is that the whole foundation for this case was that the findings in these animal studies were alarming and, as such, should have been reported to FDA in less than fifteen days -- maybe five days, I forget -- and that they had

failed to do so. Of course, their position was that they were not alarming findings, that they had analyzed those findings before they reported them, and that, in fact, they did report them in due course. But it was a long time before they reported them. But at any rate, we were aware that is the requirement so we had top scientists in the center with signed memos in the file that these were alarming and that they had the report. There couldn't be any question about it.

After the U.S. attorney's office had this case forever, it seemed, Arthur Levine had to go out there to talk to them, because they had done their own independent analysis and it was their conclusion that this was not a case to prosecute. Now, I suspect there was heavy politics involved. But anyway, Arthur went out there, and one of the basic questions they raised was whether or not these findings were alarming.

So Arthur comes back and he calls a meeting. It was Carl Sharp and myself and Adrian Gross, Ted Byers, and Marian Finkel. It was a serious meeting in that Arthur put directly to Dr. Finkel, who was the director of the Office of New Drug Evaluation, and that's who he wanted on the line so he could go back to Justice and say, "This is the FDA position." Nobody even thinking there was any question

about our position. So he put right to Dr. Finkel, "Dr. Finkel, on the basis of these findings . . . The Justice Department has raised a question as to whether they are alarming. I need to know from you, as the senior official of the Food and Drug Administration, what is your opinion? Do you find these findings alarming?" She says, "No." Oh, I'm telling you, we almost fainted. After having all this publicity and having all the agency's credibility on the line with the U.S. Justice Department, she says this?

I'll never forget it, because Carl Sharp slid his chair back and he's turned beet red -- he had high blood pressure anyhow -- and he says, "Pardon me folks. I think I'll step outside and puke" (laughter). He had dedicated his entire life for years on this case. He knew every single animal and every single finding of every animal. He had that case memorized, and never in his wildest imagination would she say that. Well, you know, that destroyed us, because if they ever got her out there and she testified, which they very well could do, it would be curtains for us. Anyway, they dropped the darn case.

But I feel good about that exercise. And I don't even feel bad they weren't prosecuted because, as I say, when you get into this high science, 20/20's always clear. But if you were the one sitting there with that data, there's

room for a lot of judgment as to what is or what isn't significant. It's not always crystal clear. A But at any rate, from that moment, it prompted a Good Laboratory Practices program that I think really, really had major impact on the quality of laboratory data coming to the FDA. It was certainly sloppy, but I learned an awful lot in looking at that case and others -- and I was in other cases as a result of that, too, on task forces -- that the companies were . . .

See, this is the benefit I had at having been in Drugs. I was working real close with Dr. D'Aguanno, so I had an understanding of animal studies and how you can skew the data by what animals you select, how long you run them on tests, what dosages you give them. You can control quite a lot the outcome by how you design the study. There was an awful lot of that going on, where companies, with substances that had great promise, they didn't want bad news and they did everything they could to not get bad news. Not unexpected. But I felt so strong in the middle of that task force assignment, I really felt very, very concerned, as I'm sure the commissioner did, that there isn't a fundamental conflict to expect an applicant to submit data on something they have such a major interest in. Aldactone, for example, was selling at the rate of

\$100 million a year. For them to find bad news is not something very realistic.

So I was really thinking very strongly, and I still think it's something that ought to be considered, that it's okay for companies to generate data. But I think something like Sweden has is something that ought to be considered, and that is, if it is an extremely important drug and there's any possible toxicity, it ought to be conditionally approved and then the government or somebody else perform very fundamental, basic tests to confirm what the company has submitted before you make a final approval and let it go to the world. Because it's just, I think, asking too much for a company to generate extremely credible data. Now, I'm not saying that it isn't done; I'm sure it is. But I'm also sure, having had that experience and having been in that bureau, that there are many, many instances of where data was withheld, or it was colored in some way in how it was submitted, or studies were designed to avoid the more serious data. And I can tell you, I learned an awful lot about safety and efficacy, and those are so ill-defined. It's all judgment.

RO: During this conditional approval, are there more animal studies as well as human studies?

MS: Yes. What I'm saying is -- and it would be a judgment call -- it would be conditionally approved. Let's say it's something that's a very important drug for a large percent of the population, but it's a very important drug for a very serious disease condition. But there are still nagging questions as to long-term safety effects. Then I'm saying you may do animal or human studies but have those done by third parties totally disinterested in the monetary gain. You see, that could be done in Sweden or in England, where you have heavy involvement of government in health care, but it can't be done here because of the free-enterprise system. But I still think there's some good middle ground that ought to be considered.

I could expand that a little bit. I think also in another area there ought to be strong consideration. It has to do a little bit with these treatment INDs -- I'm thinking of laetrile -- where there are substances that are widely used for which there isn't adequate scientific data. But it'll never be resolved, because it's not in the interest of anybody in the free-enterprise system to develop the data. First of all, they don't have any proprietary interest in it. I think those are candidates where the government ought to design excellent studies and carry them out just so that society can have a straight

answer. Because it's never adequate for the government to say, "Well, there's no data to demonstrate its safety and efficacy." If it's something intended for AIDS or for cancer, the government has no credibility when they say that, absent data as much as the proponent of the product, see.

RO: Couldn't this be a part of the Orphan Drug Program?

MS: It could be, but the Orphan Drug Program is usually . . . I don't think it should be, because that would bastardize the Orphan Drug Program, I think. That's intended for developing drugs that are really needed for that segment of the population where there isn't money.

RO: There's limited use for it, where it's essential for a small minority of the population.

MS: I mean, maybe you could expand the charter program and fund it to do this, but I think it's entirely separate from what they're doing.

RO: I guess I misunderstood what you meant there, because some of this there was probably little monetary gain to a sponsoring drug firm because of the use of the thing, and I thought that's what you were saying, which fell into the Orphan Drug.

MS: That is what I was saying, but it's a different animal. It's really almost quackery but it has a potential. That's what I'm talking about. A substance that has gained some recognition by whatever means but there is no good data to make any reasonable public policy position, I think it would be well for the government to fund good, first-class studies to answer once and for all whether this is or isn't. Now, they did something like that with laetrile, and I think they could do it . . . Because otherwise, you really get beat around the ears and you don't have any good data to say anything as the proponent doesn't have any good data. But because the law requires data before it's approved has no meaning where the substance is widely available and is being used all over the country and you can't control it. You really can't. I see in this treatment IND very similar kinds of problems, too.

RO: Shall we stop here?

MS: Let's do.

(Interruption in tape)

MS: I'd like to wind up my discussion of that time while working for Sam Fine with one other little story that I think might reflect Sam's status in the agency at the time. That had to do with an injunction that we were

proposing to bring against the City of Washington, and against Mayor Washington personally, a very controversial case having to do with methadone. At that time, methadone was a very difficult thing to manage. We didn't have good authority. We were taking these people on the basis of new drug authority but, really, it did not fit exactly the situation. But we crafted a means to enjoin them if they were seriously out of control. This is one that was seriously out of control, and it was run by the City of Washington.

Well, that is highly political, to take on any counterpart government agency, and particularly the nation's capital, and particularly Mayor Washington, who was of the same party as the party in power, as I recall, at the time. So I went up to brief Sam on this case. There was no way I was going to forward any such case without him being aware of it, because I knew there could be some very serious political repercussions. So I went up to brief Sam, and Sam said, "I'm going to call the commissioner, and we'll see if we can't get a meeting with him right now, and we'll just go down there and make sure he's aware of this." I said, "Sam, I think I ought to tell you about the case first." "No. No, that'll not be

necessary. We'll just go right ahead." I forget his secretary; she'd been there forever.

RO: Marie McNulty.

MS: Marie. That's it, Marie McNulty. She called, and we immediately got a meeting and went down there. It was Commissioner Schmidt, Dick Merrill, and myself and Sam. Soon as it started, Sam said, "We've got this case against this city and Mayor Washington. Merv, you go ahead and brief the commissioner." When I proceeded to brief him, the commissioner said, "Sam, have you read this? I'd like to have your opinion." I could sense right then that Schmidt was aware that Sam had that tendency to just bring his staffer in. But he recognized right away it was a very sensitive political matter, and he wanted Sam's personal opinion. Sam had not read or had known anything more than just a couple of words I had told him in walking from his office down to the commissioner's office. Sam kind of fudged it that he was aware, and, "Let Merv proceed here. He'll give you the facts."

Anyway, I had a sense right then that the commissioner wanted Sam's input on political problems, and he wasn't absolutely certain that he was fully into whatever the concern was. I could sense a little tension there. And, of course, I could sense that the commissioner was a little

tense about this case going forward, too. He directed me after I had briefed him to go back and prepare a letter for Sam's signature to the mayor as one last effort to get their attention to something before we proceeded to federal court. So that's what I did. That night I went home and drafted the letter. The letter went off. But they still didn't do a thing. They didn't respond, as they hadn't in the past. So we did bring the case against the city. And it stuck, too. But, of course, they had a very serious track record. We wouldn't have brought any such case without clear record of failure to conduct an operation the way they should. I think if you read the papers at all you can see there's continuing investigations of the City of Washington. They seem to have a difficult time managing different programs, and the methadone program was no different than any other.

Sam was, in my opinion, an excellent soldier. He did whatever the commissioner said without question, and he was very, very efficient as a manager. I mean, he made decisions pronto, and often strictly on the basis of his subordinates' recommendation without any independent review by him at all. And I thought, sitting there as an associate commissioner for compliance on some of these really sensitive matters, had it been me, I would have kept

that case overnight to read it to be sure it sings before I would say anything to the commissioner. But Sam didn't do that. He just made a snap judgment.

I remember another incident maybe I can talk briefly about. It had to do with a case that caused us unbelievable difficulty. It was Baxter Travenol, and it was their plant in Hays, Kansas, where we had an injunction recommendation to close down and to completely recondition a tremendous amount of inventory that they had at that facility because of GMPs (Good Manufacturing Practices) and low-level bacterial contamination. As you recall, we had some difficulty about that time with low-level contamination in our laboratories as to whether we could confirm or not confirm. There was a lot of controversy about it.

RO: This is large-volume parenterals.

MS: Large-volume parenterals is what it was. And Abbott, of course, triggered this whole interest in large-volume parenterals because of the really serious problems with had had with some deaths that had occurred a few years before in their Mt. Airy, North Carolina, plant. So this company, being pretty astute, they came rolling right in and they wanted a meeting with Sam. Sam wasn't here. He was on a trip or a vacation or something, and so Bill

Randolph, as his deputy, agreed to the meeting. We had the meeting. The case had already been forwarded to the U.S. attorney's office, but they wanted this meeting. Sam would not hesitate to have a meeting. He would meet and he would make some summary judgments right promptly whenever he met with these people. Usually he'd say, "We're going to have this injunction," and he'd get up and walk out, and, "You go ahead and figure out how you're going to do it." It's amazing how many times this occurred before anybody really challenged that.

But anyway, this time we had this meeting, and it was Arthur Levine and Bud Loftus, Bill Randolph. Now, there's a cast of characters to be dealing with a major corporation. And the chairman of the board was there, a guy by the name of Hall, I believe. The chairman of the board and his chief counsel and a lot of other people, and they were wanting an agreement in lieu of any legal action; they did not want any legal action. I could recognize, as I had experienced before, that in a setting such as that, you can get far more from these people in an agreement than you could ever get in court, particularly low-level contamination, because then you have to convince a court that it's a GMP violation and it should close them and take

all their product. This company was ready to destroy everything, no questions asked.

I remember their chief counsel was challenging the chairman of the board: "You don't have to do that on this. They have a burden of proof here that I really don't think . . ." And he cut him off, in effect to say, "Either you shut up or I'm going to tell you to leave this office. We're going to do . . ." It was supposed to be Bill Randolph at the head of the table, but he didn't know beans about this case. Bud Loftus, as only Bud Loftus could do, was going on in the most outrageous manner about "I, me, my, me, and myself," until it was embarrassing. I cut him off; I just cut him right off. He was going through a long history of who struck John, and the chairman of the board is sitting here and he's not interested in that kind of thing. I cut him off.

I had the injunction in front of me, and I said, "We're not here, rally, to discuss anything in the past. We're here to discuss what you're prepared to do today, because we have an injunction recommendation out there and we have to know what you're prepared to do in order for us to consider whether or not we'll do anything short of that." And I read off the . . . "And what are you prepared to do about all stock on hand?" "What are you

going to do about getting your facility into compliance?" He didn't even blink an eye, man. He was willing to do anything and everything, right down the line. And he wanted to sign an agreement to that effect. So after we had gotten assurances they were going to do that, I said, "Okay. We'll convert this to an agreement this afternoon." He said, "Well, I've got my corporate jet here and we're leaving this evening. It's going to have to be pretty fast."

So we broke up and we went to meet with Merrill to tell him what had transpired, and he said, "Fine. That's fine. I don't see any problem with doing that. What we need to let Mr. Hall know is that if there's any hitch whatsoever in their carrying out what they're committed to do, it's Park II, and we need to make sure he knows that." Well, Arthur Levine came up to my office, and the two of us, with my staff, put together an agreement as fast as you can imagine under the most stressful conditions. We put in everything we could think of to get everything we wanted and more, because we knew this guy would sign. We did it, and got it up there to the commissioner's office. Unbeknownst to me, I went home that night and they negotiated all through the weekend without us present, with

the commissioner and the chief counsel. I didn't know anything.

(Interruption in tape)

MS: That action, because it had gone forward to the U.S. attorney's office, was perceived by the field to be some kind of a fix, and it was generally disliked by field managers. I recall every meeting we had for several that came up, and they were very intensely opposed to it. They felt that if it had left the agency, there was no way that there should be any reconsideration, that the matter was solely in the U.S. attorney's office.

But we were having emerge, because of Hutt and Merrill and others, a philosophy that you were to engage in these kinds of agreements if you knew you could get a meaningful agreement and it would do what you wanted done. And I remember Merrill, specifically, endorsed this and had the answer to it. But he was encouraging this kind of thing. Sam wasn't having any problem with doing it. The only difference is, it was Randolph sitting at this meeting making these commitments. If it had been Sam Fine, there would have been no question by the field, because he was perceived to be straight as an arrow, and if he made a decision, it was in the best interest of the agency and you don't worry about it.

And he did make those decisions. I remember he would make them, just summary judgments, snap. He didn't even want to listen too much to what a company had to say. He'd just listen a few minutes, and whatever he concluded, he'd make a decision and out he'd go. "Now you carry it out."

RO: One of the provisions of that was that if the company failed to meet any of the provisions of the voluntary agreement, you'd file the injunction. Is that right?

MS: Yes. As a matter of fact, there were all kinds of questions that came up from the field and others as to, "Well, how are you going to enforce this agreement?" And that's where Dick Merrill, who was chief counsel, said, "Well, if there's any slip-up whatsoever, I'll personally tell the chairman of the board myself." Graham was the guy's name. "If there's any slip-up whatsoever, it's Park II. He will be prosecuted, and I want a provision in there that says, 'I've been given notice and have waived all my rights in the event there's any violation of the terms of this agreement.'" But it was generally accepted as a thing to consider by the chief counsels, and it was not well thought of by the field.

I personally did write a draft policy guidance to the agency because I resented very much agreements that were

only available to certain corporations and certain law firms who were very knowledgeable of the Food and Drug Administration's actions, namely George Burditt. So what I wanted to do is, if this is what we were going to do, I wanted to write a policy document that would make it agency policy so that we weren't giving what appeared to be somebody some opportunity and somebody else we'd go directly to court.

I put that to Paul, and that was another one. Because of the field adverse reaction to that Baxter Travenol and others, he would never cut on it. He said, "It's a good idea and we ought to follow it, but I'm not going to sign anything." You see, I felt that if you're going to do something, you really need to get some policy out so people know and can be guided by it, because you had some districts -- Seattle, for example -- that were leaders in this area. They were negotiating agreements on things that other districts were never even thinking of. I didn't think that was right to have one district out there doing one thing and another district that's adamantly opposed and wouldn't agree to any kind of an agreement. It didn't matter if they agreed to kill themselves; they wouldn't agree to anything.

RO: A minute ago you mentioned . . . Did you say "Part II," or "Park"?

MS: Park II. I better explain that. Park is a famous case on strict liability. It had to do with a Baltimore company by the name of Acme Warehouse, whose headquarters were in Philadelphia. Norm Kramer was the compliance officer, whom I had the greatest respect for. He was one that had worked this agreement business, by the way, to the maximum. Dr. Kramer, if he had a problem with the company, he didn't play games with developing a case and sending it in to Washington. He'd have the president of the company sitting in front of him, and there'd be some very straight talk about what the problems were. And if the guy wanted to make commitments in the form of a letter or an agreement or something, he could do it.

Well, in this case, they had a warehouse and they had some rodent problems. Norm Kramer had them in and he'd written a letter to the president in Philadelphia putting them on notice. By gosh, sometime later they were filthy, and they prosecuted, not only the local people, but the president in Philadelphia. It became a very, very important case. I remember Peter Hutt writing the brief for the (United States) Supreme Court, and I still think it's an excellent brief to read on enforcement policy with

respect to prosecution. The thing Peter didn't know is he didn't know some of the things we were doing that he had written in this brief; but nevertheless, it's a good brief. It was because Norm Kramer had set the record in the manner he had that it resulted in a successful prosecution of this guy very remotely removed from the place of filth. So that was Park I. It was called the *Park* decision, a Supreme Court decision that reaffirmed strict liability as an appropriate . . .

But it wasn't, as some field people interpreted it, strict liability because the guy's the president of the company. You had to overcome several hurdles to really name somebody; and in this case, of course, Norm had done an excellent job at setting the record. So there wasn't any question that this guy had been on notice, and it wasn't as if he was prosecuted just because he sat there. So anyway, that's why Merrill said, "If there's any slip-up whatsoever, it's Park II." I thought that sounded pretty reasonable to me, and in fact was quite shocked with the adverse reaction that came from the field to this action.

I think with that maybe we can get to Paul Hile coming in as the associate commissioner for compliance, and maybe carry on that a little bit. I was really shocked at the time that Sam Fine retired and Commissioner Schmidt came in

with Paul. I'll never forget that meeting in the EDRO conference room when he announced on the red phone and to all of us that he had selected Paul Hile as the associate commissioner. And he had Mary K. Ellis with him. It gave me a real chill, because Paul had been very much a critic of mine at these RFDD meetings on cases over the years and had made some really cutting remarks about my particular role and performance. I thought to myself when the announcement was being made, "Well, that's it for you, Shumate. You're going to have to find some other work, because there's no way that you're going to be able to work with Paul Hile."

Well, what I didn't realize was that Paul is pragmatic above everything else. I must also say that Mary K. Ellis made some remarks to me right after that announcement, something to the effect that, "Well, we've got you now and we'll see that things change around here." I went home that night really feeling bad, thinking, "Oh, man, this is going to be rough."

RO: Paul at that time was executive director of regional operations and Mary was his special assistant.

MR: Yes. And looked at as somewhat of a political being herself. I'll explain in a minute here. It turned out that that was placed on me rather soon after Paul took

over. But at any rate, I have to say that within a very short time, Paul had changed roles. He had a totally different job now, working immediately for the commissioner, having to be a lot more concerned about public perceptions and policy and politics. And he changed rapidly into that role.

He also needed my support on legal matters, because I had a great rapport with the general counsel's office; and he had to have a rapport with that office, too. There wasn't any way that he could direct them as to what they were to do. So within an extremely short time, Paul was relying on me in the most professional manner. As I've explained, under Sam I was just operating totally alone down there, and it was very uncomfortable in some very controversial things with no support. Now I had support plus, and Paul was as opposite a person of Sam Fine as you could possibly find. Rather than snap, summary judgments or quick actions or delegations, he personally wanted to know intimate details of cases. That was quite a shock to me, because now I have to really keep him informed and keep him involved in things, and I'd never done this before. But I found out right away that that was an excellent thing, because as I kept him informed, he would not only understand, he would give me support and assist in the

political dimension of cases. Not big "p" political so much as the little "p": conflicts within the centers and center directors and districts and regional directors. It was very helpful to have that kind of support.

But I was quite concerned about Mary K. Ellis. I didn't have too much personal knowledge of her, but there'd been some stories around about how she was a problem and why he had her as a special assistant, all kinds of questions about that. Paul hadn't been on the job hardly any time at all and she called me up and asked me to take her brother on detail in my office, it would be great for his career development.

RO: Her brother was an investigator?

MS: He was an investigator in Cincinnati, I think going to Buffalo. Kiessling was his name, I think. I don't know his first name. I didn't know him; I'd never seen or heard of the man. But I found out later, when I did get to know him, he's a very nice person and, I think, very competent, probably. But anyway, I rebel at any smell of nepotism. I flat out just don't want to be a party to it, because it begins to make me feel like somebody's getting something because they know somebody. I had never gotten anywhere on the basis of who I knew and I resent anybody else trying it. So I thought to myself when she

called me, "All right, I'm going to have to find out right now. If I'm going to be forced to do things like this, then I am going to have to go somewhere, because I'm not going to do it." So I just declined. I didn't hear any more. She told me Paul was in support of this. I said no, I didn't think it was proper and I wouldn't do it.

Not but a week or two later I get a call from Paul, asking me to meet with Tom Davis, a good friend of his in the Bureau of Drugs that was having some difficulty. He wanted me to meet with him as to whether he might come on my staff. I'd heard of Tom Davis as a total zip as far as any professional compliance officer work, and as I've described, I had cases up to my ears. So if I had any slots at all, I wanted to get the very best person I could find, because I needed help. I couldn't manage the caseload I had. Oh, I resented that, you better believe it. But he asked me to do that, so I called up Tom Davis and I made it very clear in no uncertain terms on that phone call that Paul had asked me to call him, and what I would like for him to do is to submit to me a 171 with particular emphasis on his compliance experience, because I needed somebody that had substantial compliance experience in my office. And made it real clear to him that he wasn't just coming in because he knew Paul; he's going to have to

have something to justify it. If he'd send that to me, then I would arrange to meet with him.

Well, he sent his 171 and, my God, he had no experience at all, absolutely none. So I wrote Paul a note stating that I had reviewed the matter, and in my opinion he was not qualified and that I really needed some help. What I wanted to do was to announce the job and to try to attract the most qualified person I could get out of a center that could help me move some of these cases. He never gave me any problem at all. He said, "I agree with you." That gave me a signal right then that he wasn't going to force these kinds of people down my throat. But I was fully committed that if he did, I was going, because there wasn't any way I could run that office if I had to take these kinds of people. I found that to be a weakness of Paul over the years. He is extremely loyal to individuals, and sometimes he's so loyal that it overcomes his careful judgment on best qualified people. He had a record of attracting people like that. I was determined not to have that happen in my office if I could, because I couldn't see how I could survive if I had it.

Incidentally, just as an aside . . . Later I'll discuss, but just because we're talking about it, at the time Tom Brown retired, and between that time and I took

over his staff combined with my staff, Paul transferred Tom Davis on that staff such that when I took it over I had him and I had nothing to say about it. Paul had him designated as health fraud and he had all the records and things on it. Every time a really serious, controversial health fraud case would come up, Paul would ask me, "Who do you recommend we assign to this?" I would always say, "Tom Davis." And Paul would always point his finger at his head like, "Gotta have brains on this job" (laughter). I never let him forget that he gave me this man to keep for the rest of his days until he retired.

But at any rate, we got along just fine right off. But there was continuing difficulty in that Tom Brown headed a counterpart staff. I think at that time it was called Compliance Policy Staff. Her was constantly having policy meetings, and I was constantly in conflict with him on policy interpretation and implementation with cases. And it was obvious the field was going to Tom as their advocate, and I was having to put cases . . . He had sitting right at his right arm Al Gottlieb, who represented all of the traditions of the Food and Drug Administration. Yet I had to get cases through Peter Hutt, who didn't necessarily agree with some of the old policies of FDA and was forcing change. He insisted, for example, as I said,

when I first took the job, that you had considered the status of the industry before you recommended an action. You didn't just pick somebody and take them on. You knew something about the status of the industry, and if it was an industry-wide problem, you developed a different strategy. You don't just single out somebody and prosecute them.

Well, traditional Food and Drug, that's what you did: you singled out a company and you prosecuted them, and then you got the ripple effect on the rest of the industry. He was adamantly opposed to that. He wanted things done by class action. I had listened to Peter speak a few times, and he was really impressive because he spoke as a practicing attorney on the outside in bringing his philosophy in the inside, and that is, Food and Drug attorneys -- and I've learned since I left Food and Drug that that's true -- represent their clients as to what resources and commitments FDA's got. If you take them one by one, their client's safe for years, because Food and Drug'll never get to them. Well, what he was doing was developing class actions to make it more fair and to get more bang for the buck. I agreed with that; it sounded reasonable to me. The OTC Review and some others people could highly question, because they never, ever get there.

But that's only because the lawyers are preserving interests. It's still probably more fair, and it's a fact probably more has been accomplished through those class actions than would ever have been accomplished in lifetimes if we went just by single firm by single firm.

I think I did describe -- I know I did -- back at the time I was a field compliance officer, having people come into hearings and line products all across my desk of competitive firms that were doing the same thing they were, and "Why are you singling us out?" It was a big issue.

RO: Let's make sure, for the record, anyway, that we understand the differences between those two staffs. The compliance policy staff and the enforcement, which was your group . . .

MS: Right. No, it was regulatory management staff.

RO: But anyway, you were supposed to make sure that the enforcement actions were consistent with agency policy. But the agency policy was supposed to have been set then by this compliance policy staff?

MS: That was right. But it was a conflict at all times, because, as you know, you're in a case situation, which are often controlled a lot by the facts. You're confronted with policy decisions that you have to deal with in order to get a decision. Now, I referred some to Tom,

and he didn't have all that much experience on his staff. So there was no question; we were in conflict.

This came to a head before Paul all the time, and Paul had to decide between us. In fact, I recall one time when Paul must have been getting a little unhappy with Al Gottlieb and some of the things he was doing in beating the drums and getting the field to force certain things to go on in headquarters that Paul wasn't very happy about. But always if he had a question about what Al was doing, he would ask Tom to look into it. One Friday afternoon I get a call from Paul, and he asked me to go down and see Gottlieb, because something had happened on a criminal search warrant in Wisconsin, Mosinee, that had caused a big slap. He wanted to know what was going on, because it didn't seem anybody in the agency knew what was going on. So I said, "Well, Tom is the one that's always followed up on these kinds of . . ." "I'm asking you to do it. I want somebody to go down there to find out what's going on." I said, "Yes, sir."

I walked right down to Al's office. He was still deputy chief counsel then. I walked right in and I said, "I'm here at Paul Hile's direction." Gene Pfeiffer was with him, who was the senior attorney. "And he wants to know what's going on with respect to this criminal search

warrant, because there's a lot of publicity going on and he just wants to know. Apparently the action just went through with nobody topside even knowing about it; and it seems they ought to know about something as controversial as this." And Gottlieb looked me right straight in the eye and he as much as told me straight out that whatever he'd done, he'd done, and "you can do whatever you want, but I intend to do that in the future just like I have in the past." And Gene Pfeiffer piped up to say, "Merv, you ought to know about a case we've got going down in Arkansas. We've got another one going down there that's going to go off in the same way. No problem at all, and we're working with DEA (Drug Enforcement Agency) on that one." I said, "Well, I think in things so controversial as this that there ought to be somebody keeping topside informed about such matters, just because they need to be aware." Gottlieb said to me as I turned to leave, "Merv, if I were you, I'd go write a memo to cover your ass." I turned around and paused the appropriate seconds, and I said, "If I were you, I'd do the same."

I went right up to see Paul and also went in to see Dick Merrill, and advised them that these people are acting with impunity and they don't give a damn what the concerns are of the agency; they're going to do what they're doing

anyhow. That was the beginning of the end of Mr. Gottlieb, because he wasn't paying any attention. In fact, he was enjoying doing his thing. Then, as a result of that, procedures were developed to be sure there was a much more formal approval of such things as criminal search warrants and inspection warrants, because, really, once you issue those, you've committed the agency to an unbelievable course of action. It should be treated the same as any other regulatory action, and that's really what it was.

I got to administer it, and I got right into a hell of a mess on many of those, because I found out it was a separate organization that was doing these things. Paul Sage was one of the key people that was generating all of these things, and they were whipping them right through Al Gottlieb. Tom Brown was involved, and there wasn't anybody else that knew anything about what was going on. I found even a couple of them here these were being done without even the district knowing about it.

Al Hoeting, on one, I recall. I had a recommendation for a search warrant and it was a conflict. So I called up Al Hoeting to ask him, since it was a search warrant in his area, if he knew about it. He said, "I don't know a thing about it." I called a meeting and put him on the speaker phone, and had Sage and Levine. I cut Gottlieb right out

of it, because he's not the one deciding on those things at the time. It was an intense meeting, believe me. Sage just had written memo after memo, and there's no need for anybody else to know about it. I mean, this is the way it's going to be, and it's going to happen.

RO: What were these in connection with, Merv?

MS: This had to do with a quack outfit up there. I can't remember exactly the product, but at any rate it was a quack outfit that they wanted a search warrant. And Sage had a thing. He wanted to issue search warrants as a form of punishment, whether you got anything or not. I just disagreed with that kind of thing and wanted to be sure we were doing things responsibly and that field people were consulted. After all, they should be the first ones to endorse something of that sort, because they know best what is this person. Al was telling me, "Oh, we've inspected this firm over the years, and if we go out there and ask them something, they tell us. There isn't any problem. We don't need a search warrant. We can get anything we want." But when you had a Sage involved, with a Gottlieb and a Pfeiffer and a Brown supporting them, you had yourself a big problem to keep it controlled.

So I remember one time the whole darn bunch insisted on speaking to Hile and walked right up to his office.

Then Hile called me to his office, and when I get there, there they are, all in this session. And I think, again to myself, "Well, that's it for you, Shumate. You're not going to survive this." After a very brief discussion, Paul said, "And I agree with Merv. We're not going forward with this." Well, again, just like when Merrill had endorsed my conduct, I felt about ten feet tall, because it indicated to me that Paul was much more serious about matters now and that he wanted somebody to very carefully evaluate these things. He didn't want things to just whip through in a quick and dirty fashion. So that made me feel really good. It makes it more easy for you to handle those kinds of matters when you've got that kind of support, too.

But that was a continuing thing, and I recall one other incident and then we'll quit for today. That is a geatrichum mold case up in New York. The company was General Foods. We had forwarded an injunction recommendation to the general counsel's office. It was the first case that had gone forward to Rich Cooper, and Rich Cooper was a brilliant trial lawyer, in my opinion, and a very bright guy that required absolute excellence in all documents going to him. He had a thing about grammar that was unbelievable to me. I was entirely frustrated, because I would get cases back and he'd want them redrafted because

they didn't fit his requirements on grammar, and I could not understand what his requirements were.

One time he sent me a nasty memo, really nasty memo, about a case we'd forwarded. And Joan Davenport is one of the most sincere, sensitive persons you can imagine that was trying to write precisely what the general counsel wanted. But he kept sending them back. Finally he sent me this nasty note, and with it he sent me a little book on grammar (laughter). I was just livid, because here we are, overwhelmed with cases. We can't get them through in a timely manner, and this guy is forcing us to write Supreme Court briefs. I went to Paul, just at wit's end, and I just said, "I don't know what we're going to do. We can't satisfy this guy, and I, frankly, am not a grammarian and I can't freely understand, or anyone on my staff can understand, what he wants. We just can't do it. And I want to know if you won't go down and talk to him. It's not that important, anyhow, on the average case to do that." Paul quietly opened his center drawer of his desk and he showed me his little grammar book, too (laughter). And he said, "You'll just have to do the best you can." So I went back and we just did the best we could.

Anyway, we sent this injunction down there, and he sent it back up to me because of inadequate notice. I

looked at it and I agreed with him. There hadn't been very good notice. So I called some meetings of people and, boy, I ran right smack into the old Food and Drug. I had Tom Brown just ranting and raving that this case should go forward, there is nothing wrong with it. And Taylor Quinn was saying, "It's got to go forward. I don't care what he says, this is it." Celeste was involved, too, on the side. I did not agree entirely with Cooper, but at the same time, I could see he's chief counsel and he's got a different standard, and it's not unreasonable.

What had happened is, Buffalo, as only Buffalo could do, had sent a reg letter, but it was drafted in such a manner that it wouldn't generate any kind of a meaningful response. And what Cooper wanted is, he did not want the top corporate officials of a corporation where their home offices are at some distance and they are named, to find out for the first time in court papers that they were violating the law. He, as a trial attorney, simply did not want to have to go before a court with that situation, and he wanted to be sure they specifically and personally were given notice before any such action was forwarded.

Anyway, he sent that case back up to me and his attorney told me we had to change it. I sent it back down and said, "I am not changing it until I have some rationale

as to why, because it is consistent with what we've done in the past." Well, Cooper didn't have any problem doing that. He called Hile and me both to a meeting with him and he proceeded to give us instructions on how we were to handle such a case. I can remember, because Paul was smarting and he hadn't been in that position too long. He was still smarting over the Travenol case, and he proceeded to tell Cooper in pretty detailed terms why he was concerned about that. Cooper wasn't impressed one bit, and said, "I'm sorry, but I'm telling you . . ."

(Interruption in tape)

MS: Cooper listened to Paul's concerns about notice and the adequacy of the case, but he made it crystal clear he was not impressed with what Paul had to say and that that was his requirement. And henceforth, any case coming to him had to have on its face adequate notice to the principals of a corporation before they were named in any action before the court. He wanted that because it was just good business. Otherwise, you would constantly be before U.S. attorneys and district judges that would be questioning such a practice. It wasn't that it wasn't legally sufficient; it was just not good strategy to go forward. That was what he was bringing to bear.

Anyway, I was having a terrible time with the people at FDA and trying to satisfy Cooper. I was consequently calling meetings with Paul, and Paul wasn't wanting to make a decision one way or the other or to go forward with any forceful decision. Finally, I had not slept for a couple days and nights because I was just uptight as heck about this, and I got a meeting with Paul, Tom, and myself. It was that continuing conflict. Here Tom has all the wisdom in the world about something he's never even seen the file and he's making all this noise, and here I'm sitting with this file and I can't move it unless we satisfy the new chief counsel. I was at wit's end. So I proceeded to tell Paul what my assessment was of the situation and that it was my opinion we ought to do what this man said we should do. "But I have had it. I've done everything I can, and I've had it. I can't do anything more. It's your decision." I'll never forget the look on his face, because he was caught between two staff directors.

And by the way, Paul was not looked on favorably by the staff directors in ACC when he took over. Tom Brown was one of the leaders that wanted . . . I think he wanted that position, and he was doing everything in his power to make Paul fail. I had been solicited by Ernie Brisson, Tom Brown, others, to join them. Every time Paul would walk

out of a meeting or something, they would bad-mouth him. I absolutely refused to do that. I said, "Look, the man's got the job. It's a tough job. I'm going to do everything I can to support him, because I don't see how I can ever succeed if I don't. Sure, maybe I could do better. But he's got the job." So I signaled to Paul real early that I was going to work with him, that I was not going to be one of these guys out there sniping him. Tom was not making any bones about it; he was doing it. And he was doing with Gottlieb and others.

RO: Or course, there was such a contrast between Paul's and Sam's management styles.

MS: Yes, that's part of it. But also between Paul's and Tom's, because, see, Tom was also very superficial. He would shoot from the hip without reading the underlying document. And Paul is absolutely opposite; man, he wanted to know every detail before he'd make a decision.

But at any rate, on this geatrichum mold case, I just left it right on the table, because I'd had it. "I've just had all I can handle with this," and Paul made the decision in my favor right there. He had to, because he had Cooper that he didn't have control over he had to satisfy, too. Well, again, that gave me some feeling that I was getting somewhere with Paul and that he was respecting my judgment.

That pretty well took care of Tom, because that just about made it clear to him that he's just beating his gums in the wind; he's not going to anywhere with this.

We went forward with that case, and, by gosh, we got beat because we didn't have any good standard out there. Geatrichum mold, in case somebody doesn't know, is natural to soil. It's not something that's added, like rodent filth, in a facility; it's something that's naturally there. And it was difficult to demonstrate that it was filth, per se.

RO: This was in green beans.

MS: Green beans. I remember the attorneys that were assigned were Mike Taylor and Bob Brady and, boy, I mean, they worked hard on that case; and they were devastated when they lost. George Burditt won the case, and he got tremendous mileage out of it. Well, there again, we would have been far better off to . . . And we didn't fully inform Cooper of some of the pitfalls of that case. In other words, we should have given a clear notice to the industry of the policy, because that judge made it crystal clear that he resented having such a matter put before him to rule on, that that was something the agency should have ruled on and issued some policy to the industry. It was a very significant case, but I'm not giving it because of the

case, per se. I'm giving it because of the internal conflicts that I was having to live with and how Paul and I were beginning to develop a rapport with each other that served me very, very well.

I want to add just one thing about this mold case that I think is of some significance, and that is, when Cooper first raised the question about this case and I was trying to get the agency's act together to respond to a brand-new chief counsel that had very strong feelings about what we had to do, I had a visit by Pitt Smith. He informed me that he had a compliance officer by the name of Steve Kendall on this case who I was going to like very much. "He's a new compliance officer, but he is a good one, and he is really going to be excellent." I said, "Well, fine, thanks. I can use all the good help I can get."

Some days later, Paul Hile called me and said that he'd been to a meeting in Drugs having to do with Bristol, and at that meeting was one Steve Kendall. Steve Kendall had informed him that I was an obstructionist on this geatrichum mold case and he'd like to have me do whatever I could to get this case going. So that afternoon I was in an office with another Food and Drug officer working on a case, and my secretary came in to say that Steve Kendall was out there to see me. I said, "Fine," and I went back

to my office and I signaled Howard Schloss to come in, because he was a case officer on the case. I then buzzed her to tell him to come on in.

As soon as he walked in my office, I stood up and I said, "You're Steve Kendall?" He said, "Yes." I said, "Well, I just had a call from Paul Hile, and he's informed me that you advised him that I'm an obstructionist on this General Foods case. What you need to know is that not only is Mr. Hile involved in every decision that's made with respect to this case, so is Mr. Cooper, the new chief counsel. Therefore, I think it's a big outrageous for you to be making such remarks, and I hope you have a safe flight back to Buffalo." I walked around my desk and stuck out my hand and said, "Get out." He started, "B-b-but I wanted to talk to you about this case." I said, "Not today you won't. You can leave."

I didn't know Steve Kendall. That's the first time I'd ever met him. But I found out that that had a devastating effect upon him. But I didn't have any problem in doing that. I looked over at Howard Schloss and his jaw dropped down on his chest, because he'd never seen me dress down a person like that in the past. But what I was trying to signal to him was, if you're a grand-new GS-13 compliance officer, it's a bit out of your place to be

going to associate commissioners and complaining about senior compliance officials' conduct when you don't know anything about what's going on. I found out later that he is an outrageous character that we had many troubles with, that he personally didn't care whether the chief counsel had a problem with the case or not. The case is to go forward, period. But at any rate I thought that was something connected with that that I ought to have on the record, because it's one I won't forget right away. And I think with that we'll stop for now and continue later.

RO: Fine.

(Interruption in tape)

RO: This is a continuation of an interview with Mervin H. Shumate. Merv, I think when we ended the interview last time, we were talking about some of the internal conflicts that we had in the agency with some of the major cases we'd had. You'd mentioned about the geatrichum in green beans case and some of the problems we had there.

MS: Okay, what I would like to do is to pick up with a couple of situations I would put in the category of crisis management that I was one of the principals with Paul Hile in working on to reflect some of the key officials at FDA.

One I can think of first off had to do with a DES; this is diethylstilbesterol. It was late one afternoon that Max Crandall called me, who was the chief compliance officer in the Center for Veterinary Medicine. He told me that they had learned in the last day or two from an informant in Texas that a large ranch was maintaining two sets of books, and that they were using diethylstilbesterol implants in these animals, which was illegal, in that DES had been banned for such use many years before. Well, I recognized right then that that was an extremely serious matter and that topside ought to be aware of it. So I called Paul Hile and I suggested that this is something that I recognized as so significant that I thought he and I ought to go directly to Crandall's office and just get a briefing on just what's happening.

So that's what we did. We went right down to his office, and they were kind of handling it in a nonchalant manner without really seeming to be too concerned and without any real sense of urgency. As soon as Paul and I were briefed on the thing, we recognized this as really something that's got a potential if it's beyond this ranch; it's got a potential for being really a national disaster. Paul went from there right up to brief the commissioner, and we really, in effect, took over the management of that

DES fiasco from that moment on. I personally was involved in holding an awful lot of meetings to just flush out what was being done and what needed to be done, and then was consulting with Paul, who had heavy input into what the field organization was doing, and he was really putting them on a fast track.

I recall that very shortly after this investigation started, we had a major meeting down in F.O.B. 8 with Carol Tucker Forman and Don Houston and all of their staff, and Commissioner Goyan and Nancy Buc. With a lot of other people, like Paul Hile, Taylor Quinn, myself, and other people. Don Houston had requested to meet with us in advance of Carol Tucker Forman coming to the meeting, and he proceeded to brief us that she would have her General Patton's helmet on, with six guns strapped to her side, and that she would come in blazing, just wanted to tee off on anybody that had anything to do with DES implants.

Well, FDA was a lot more concerned about how many animals might be affected and how are we going to dispose of all this meat. If we're talking about thousands of animals, you've got a major public health problem, because how are we going to dispose of all this? And how are we going to determine whether or not it can be salvageable, or are they going to all have to be buried? And where are you

going to bury a million cattle? So, I mean, they were much more cautious and conservative about what they were going to do.

Sure enough, later that afternoon Carol Tucker Forman came in. I remember Tom Grumbly was her assistant and was right with her. She did come in with Patton's helmet on, and she's really talking tough. Now, this is kind of a strange thing for Food and Drug, because Agriculture is well recognized as being very closely tied to the agricultural interests of this country. And for her to come in there with such a strong, strident position just didn't seem to be consistent with that entire tradition of the U.S. Department of Agriculture.

So after we'd gone on through the entire briefing and there'd been an awful lot of give and take, all of a sudden she announced a much different position, much more conciliatory and much less confrontational. I recall Tom Grumbly was trying to sum up just exactly what their position was, and it came off that they were not going to destroy any of the animals; they didn't think that was necessary. I recall Nancy Buc, who was sitting right straight across the table from Carol Tucker Forman, she says, "Excuse me. I'd like the record to show that Mr. Grumbly is blushing profusely" (laughter).

And Goyan, I recall, immediately after that meeting, went to the secretary's office, which was Pat Harris, went over to brief her. We were there; we'd been there all day and we were there into the evening, and they came back from there. When he came in, he was just ashen gray, just looked like . . . And I understand it was really some kind of a meeting, that Secretary Harris had also come off, "We're going to prosecute every one of these people," and had really taken a hard-nosed position, which was somewhat contrary to what we were coming around to. We didn't know exactly how big a problem it was yet. We did know by then, though, that it was a much wider problem than we'd ever dreamed and that we were going to have some difficulty in managing the thing.

So it was decided right there that there were going to be six people from FDA and six people from USDA that were going to get together the next day and were going to hammer out a policy and how we were going to handle this, because we had to work together. I recall it was Bob Brady and myself and, as I recall, Tony Celeste, I believe. I don't know who others from FDA. There must have been somebody from CBM, probably Max Crandall, but I can't recall for sure. But anyway, I know we stayed late that evening. Then the next day we met with USDA counterparts, and these,

for the most part, were old-time veterinarians. We started the meeting, and they didn't agree with what Carol Tucker Forman and Don Houston had been talking about.

RO: What was her position, Carol Tucker Forman?

MS: I think she must have been an assistant secretary. I know she was Don Houston's boss. I don't know exactly her position, except to know that she was clearly in charge of that delegation. And, as you remember, she was very high up in the Democratic administration. In fact, I think she was in there in part to change the way USDA did business.

But at any rate, we got sat down and we'd already gotten outlines of how we were going to proceed. But, of course, there had to be some kind of a risk assessment on the record that would make some recommendations as to how we were going to dispose of all these cattle and how we were going to control all of them, how we were going to get them all under control. In setting up a strategy, it was recognized that it was in the public interest to get these animals and farmers identified as quickly as possible and under control. In order to get people to come forward to identify, you had to create a situation that would be an inducement for them to do this, because if every one of them was threatened with prosecution, as the secretary was

talking, they'd go underground. They wouldn't come forward, and you wouldn't even know where these cattle were. That was worse. We figured it was a first-class public health problem, and we had to take care of those cattle first; and then later we'll step back and think about prosecution. But the first goal was to get those cattle under control.

RO: Merv, for the record, as far as DES was concerned, why was it used in the cattle and at what point was it used?

MS: Well, it was used as a growth promoter, and there had been a contest ongoing. I recall, for example, as soon as this hit, I immediately got hold of Ed Ballich and got everything I could get my hands on to learn as much as I could about the status of DES, because I didn't know much about it. I recall that when I got right into the record, *Federal Register* documents and other things, it wasn't just exactly crystal clear as you would like as to how that should have been disposed of. In other words, hindsight's always 20/20, but when that was banned for use, there should have been a recall of all outstanding stock and there should have been a policy issued to control it.

But nothing like that happened. It was appealed up to the commissioner's office, and in the hurry-scurry . . .

And if I recall right, it was one of the last things that Sherwin Gardner did before he left the agency. He handled it as sometimes commissioners do: just at the last day or two that they're in the agency. In questioning people that were involved, it was people handling it in the commissioner's office, and, as you recall, we had a separation of functions. Because of that, there wasn't good communication, and the thing just dropped through the cracks; it wasn't handled in a good manner.

So anyway, here we were, faced with unbelievable quantities of this DES. They were implants that were implanted in the ears for growth promotion. One of the reasons that it was banned was that there was no data that would show that it ever left the tissues. It stayed in there for long periods of time, and the withdrawal periods that had been set forth in the past just couldn't stand up.

RO: Because it had been used extensively in chickens.

MS: It had been used, but it wasn't used at this time. It's a unique substance in that, if you recall . . . I remember when I was in Drugs, that came up as one of the very few carcinogens that was a carcinogen in animals that turned out to be a carcinogen in humans, where you had data that one would extrapolate to the other. Because, see that's always the argument. You do tests in animals, and

you don't know whether it will cause cancer in humans. But, of course, FDA's always taken a very conservative approach. But I remember this rare cancer in female children was caused by mothers having taken DES during their pregnancy. So it was well known as a very potent carcinogen, and it was for that reason that it was taken off. But the industry had fought it all the way to keep it on the market, and so FDA had thought as a result of that action it was no longer in use; it was off the market; everything is fine. Well, this investigation showed it was being used widely throughout the country. And if I recall, there were some 350,000 animals in I don't remember how many farms and ranches; but a very large number came forward.

As I was saying, we got together the next day. The veterinarians from the USDA were the old crew of USDA people, and they didn't agree with Forman and Houston's position. It looked to me like we were just not going to be able to work out anything, if that's the way it was going. I remember, after a little while and a lot of frustration, I said, "I really don't think we have to debate what we're going to do. We've been given instructions on what we're going to do. What we have to figure out is how we're going to implement." And we were

prepared to go to Houston or whoever we had to go to, because it wasn't going to work.

But if you have people like Bob Brady around . . . I recall it was probably Fred Degnon or another attorney, they were absolutely excellent in drafting policy statements and getting things going -- with our help, of course, assisting. What we did is simply wrote a white paper or a position paper that would serve as the policy pronouncement. Of course, concurrent with that, Foods was coming up with a risk assessment on what could be done with all of these animals, and it was concluded that there would be a certain level set with respect to the kidneys and liver, and there'd be nothing permitted in the tissues itself. Bu there would be a certain amount permitted in these other organs where the DES concentrates, and, within specific limits, they could destroy those organs and the meat could be used. If it was over certain levels, or if there was any DES in the meat tissues generally, it would be destroyed.

I'll never forget that meeting, in that we went up to -- this meeting occurred with Don Houston there -- the commissioner's office at Parklawn after this had been flushed out and they were looking at it to see if it was satisfactory. As I recall, Goyan came in. He was normally

a very low-key kind of guy; he never showed much emotion or upset on anything. But he walked into this meeting, and this conference room was loaded with people, including Don Houston and Novitch and Hile and Buc. What had occurred was, they had come up with an assessment, but one of their scientists had made a mathematical error and had come out with a figure like tenfold more than what it should have been; and that had been leaked by Agriculture to the industry. So it was outside. And then Sanford Miller, the center director, had to come forward and get it straight; they'd made an error.

I remember Goyan walked in, and he was ashen gray again. He said, "Your commissioner's backbone is as straight as a ramrod, and I want some answers and I want them now. I can't understand how anything like this could happen, and we've got to get this thing straightened out." Well, Miller had to explain what had happened, and things calmed down and the meeting continued. I have great respect for Don Houston, because he seems to be a very calm, collected person under very stressful conditions, and he kind of helped in keeping things to a little bit of a cool. But there was so much pressure coming on the agency from all sides that it was extremely difficult to manage. And I'm sure that's what Goyan was experiencing.

But at any rate, from there we came up with a policy that we would permit anybody to come forward and identify themselves. We would sign an agreement with them. And I must say that my office was working extremely hard to prepare an injunction such that if anybody didn't come forward and volunteer, we were going to go slap an injunction on them just as fast as we could; and we well recognized we were into low-level diethylstilbesterol here that would have been a difficult case to present in court. But we were prepared to do it; we had to be in order to back up our policy.

As you can imagine, we had all kinds of interest groups coming in. I remember in the EDRO conference room we just had meeting after meeting, and it was late nights, weekends, you name it. But I remember one group that came in was a livestock association, the American Livestock Association, I believe. Now, they came in and they were angry. They really thought that this was going to just devastate that industry. Paul Hile was very effective in these kinds of meetings in that both he and I had a farm background. And that couldn't hurt anything, because at least there were people in the room who understood their language and their concerns. If you had had people there that didn't know beans about a steer or a ranch or a farm,

that would have been a problem, I'm sure. But they could sense right away that they were talking to people who understood something about their operation. Actually, before it was over, they were pretty much supportive of the FDA in that they recognized there were these fringe groups that were putting the whole meat industry into jeopardy, and that maybe there should be some very effective way to control it, because if there isn't, it's going to put them in a very bad way as well.

They came into the meeting ready to take somebody's head off, but by the time they left, they not only were pretty much supportive, they were very helpful in helping us later on in some of the questions we got into about I remember ranches in Texas and how these cattle were moved from Florida to California through the process. These were things we knew nothing about, and we would call on them to give us some assistance on what this is all about, because that is a real problem in this country. You have these cattle going through these sales barns, and they're hit with so-called cocktails; a cocktail is a whole array of drugs that they give them just as a preventative to protect any cattle coming in. Well, sometimes they go through three or four sales barns, and every time they get hit with all of these drugs. So you really have a pool of

drugs by the time they get out to a feed lot somewhere. Even to this day, there isn't any real good, effective way to have any kind of a trace on this animal all the way through; and that came to our attention, which I don't think we'd ever fully thought about.

But we found out that there were all kinds of distributors that had continued to distribute this DES stock after they were supposed to have been destroyed. There was close interpretation, and they interpreted in their interest. We interpreted it a different way as to what was the cutoff date. And I remember that got to be a very central problem when we were trying to consider whether to prosecute some of these distributors. Because early on, it became quite clear that the average farmer out there didn't have any kind of criminality in mind when he was engaged in this. He was buying it through his local distributorship and didn't have any idea there was anything illegal about it. It was pretty clear the distributors should have known, if they didn't know, that there was something wrong, because there were a lot of prices, deals, and all kinds of things going on that would have led someone to know that there is something suspect about this substance. But it hadn't been given as widespread notice as it should have had.

But at any rate, we could see right away that if we could get appropriate control of a particular bunch of cattle in a farm somewhere, that was in the public interest to do and there wouldn't be anything pursuing that. But you can imagine, with some 250 farms and ranches, and then all of these distributors, even including manufacturers, that we had an immense problem as far as deciding whether or not to prosecute. So we had -- and my office managed that -- numerous meetings where for the first time we set criteria up that all districts were to follow in deciding whether or not to forward . . . That's the first time we ever did that en masse to try to get some consistency in the process. As a result, we finally wound up prosecuting this ranch in Texas where this had come up first.

(Interruption in tape)

MS: The fact that they had a double set of books and that they had other things going on, that pretty much would lead anyone to conclude that they knew something was wrong or they wouldn't be doing that. And then distributors were charged, and others; and actually there have been some prosecutions that have gone on through to termination as a result of that. But very, very few, considering the magnitude of the problem that was out there.

It's one of those situations that I think the agency doesn't receive enough credit for, in that it appeared, when this became known to us, that it was a completely unmanageable problem and that we were going to have great difficulty working with USDA, for example. We each had different missions, and how we were going to match up. Well, as it turned out, they matched up quite well. We worked together very well, and I think that thing was handled very well considering the magnitude of the problem. It was from California to Maine and from Minnesota to Texas; it was just everywhere.

RO: Merv, do you recall how we handled the stock that had been impregnated with this so that they wouldn't have to be immediately slaughtered and disposed of?

MS: Yes. We had an agreement worked out that anytime any rancher or farmer came forward and said he had some cattle that had been implanted, we would immediately send out the investigators and they would sign this agreement and they would identify those cattle that were affected. FDA would be responsible all the while in the feed lot up to the point they offered them for delivery to a USDA plant. And they had to offer them to a USDA plant. At that time, then, it would be turned over to USDA; and that's how we worked together.

But our few people managed all of those animals -- kept track of them, followed them, traced them, and at the same were going out there to try to trace the implants back through distribution channels to its origin. That was a big job in itself, too. And as you know, as I indicated, there was a lot of hanky-pank going on so that you didn't have always have the good, clean record that you'd like to have to just know exactly how things went. I mean, I remember a salesman down in Texas that was just carrying thousands and thousands of dollars worth of cash and was just delivering these out of the trunk of his car. So there wasn't any effective way to trace things back. It took an awful lot of work to nail that down. But at any rate, I think it was an example of an outstanding process that we went through with a lot of different people involved.

RO: So really, there was an established kind of a withdrawal period from the time of implant until they could go for slaughter? And then, when they went to a USDA plant, the tissue was examined first?

MS: Absolutely. They were quarantined and examined before they were released, and either they had to be tanked in hold if they were a certain level or the kidneys and liver had to be set aside for destruction and the meat go.

But that was all under the supervision of USDA, and they did all the sampling and control of that. They actually did, on several occasions, find implants right in the ears of these steers, even at the time they were offered for slaughter. And I think a time or two where they were offered without notice, and they found implants. Of course, there was a very good candidate for careful scrutiny as to what was going on.

We found one or two 4-H animals out in small farms -- couldn't even call them a farm, really -- in Iowa that had been implanted. I'm convinced that most of those people didn't have any clue that they were doing anything wrong when they implanted these animals; they didn't know. But I'm convinced equally well that the manufacturers knew something was going on. But they very vigorously disagreed with the court decision that banned DES, and they were doing everything they could and were continuing to fight to try to keep it on the market.

In fact, we had one very celebrated case out in Kansas where we didn't get a favorable decision from the judge because of the extremely low levels. We were concerned about that because we knew if we got into court out in cattle country, and you're talking about extremely small levels in parts per billion, that we would have difficulty

convincing a judge. And that's where experts were absolutely crucial to us to be able to articulate to a judge and a jury how this was adulterated and posed a real safety problem. We did lose that one case out there in Kansas, but it didn't stop the overall. I mean, that was turned on the facts in that particular case. It didn't have to do with the legality of the substance; that was illegal. So, I mean, that was quite an experience of where an awful lot of people had to work for a long time to get that under control and then finally conclude it, and I think maybe these prosecutions only concluded within the last year. They've gone on for years.

RO: Well, following that, didn't we encounter a problem up in New York state?

MS: Yes, we did. That was a precedent-setting case, too, up there. What happened is that there was DES being smuggled into the United States through Canada, originating in Belgium, I believe. They were using them in veal calves because apparently the use of DES in veal calves gives a very white color to the meat, and they then are absolutely top dollar in the New York market, particularly. They were bring it in just in plain bags in bulk, and farmers were buying it in restaurants and livestock barns around New York and then taking it home. They claimed they didn't

know what the substance was. It's possible they didn't know, but they certainly had to know by the way they were purchasing it and handling it in an undercover sort of way that there had to be something suspect about it. But anyway, there were quite a few farms up there that were using it, and we got injunctions against those farmers.

That was the very first time we were able to prove in court that a live animal was food under the Food, Drug, and Cosmetic Act. That had never been done before. And that was a very significant finding because that was one of our difficulties back through that entire process. We'd never faced up to some of these questions before, and there were some very novel laws being . . . Like, I recall we were trying to figure out that this DES was misbranded by implantation into animals contrary to any approved labeling. There were some strange kinds of things trying to be figured out as to how we were going to charge it, because it's in live animals on farms. Is that food? It stretches the imagination to think about it as food, but then, on the other hand, if you're going to have control over this from . . .

And you just stop and think about a pesticide; a pesticide is permitted on vegetables at certain levels; it's perfectly legal. It's simply you've got to have it

through a withdrawal period such that when it's offered for food, it's within tolerance. So it's not illegal to dose something, and there were a lot of novel kinds of questions coming up. But throughout that entire DES affair that I spoke of, it wasn't a problem because everybody came forward and agreed. It did complicate very much our prosecution of some of those people. We recognized that, that if something had to give . . . We had to control this as a public health matter. If in doing that we had to give up some prosecutions, well, that's the way it would have to be.

But it did complicate things, because you had some very good lawyers coming forward saying that the fact that we set up a voluntary program where people came forward and identified themselves that that would be improper to then prosecute them for having come forward. And they made quite a brief on that. But it wasn't our intention to prosecute people where there was any question at all about their knowledge. What we were looking for were people who clearly were flagrantly abusing. And, really, if you go back up through the distribution channel, those were the people that created the major problem, because they distributed hundreds and hundreds of thousands of these implants all over the country.

But even there it wasn't a piece of cake, because there was some disagreement as to just exactly what the cut-off dates meant. It meant one thing, for example, to a manufacturer. Did it mean exactly the same thing to a distributor and a subdistributor? You got into some really tricky questions as to just exactly what was appropriate. And, as I said, we didn't handle it well at the time we came out with the ban, in that we should have given it precise, detailed information on cut-off dates so there couldn't be any question about what we meant. Sometimes you don't do that as well as you could, and we didn't do it there.

RO: We did prosecute one distributor.

MS: Yes, we did. I'm trying to think of the one in California that came up right away. I'm quite sure we did prosecute them. I know I remember Max Crandall almost got us into some difficulty there, in that the president of that company called him and he, in effect, said it's okay. Of course, when we started to focus on this company and gave them a notice, they came up with this discussion they had had. I remember calling up Max and telling him to be sure to make a memorandum for the record. "If there isn't one, we need to know precisely what you said, because these people are saying that they contacted you and they were

told that there's nothing illegal about this," or something like that. So that shows you how, in discussing something with somebody, you've got to be very mindful of where this might wind up. You might want to be very concerned and responsive, but on the other hand you have to be very careful you don't get yourself involved in some situation that could compromise the agency's actions later.

I know there was a grand jury and I think we actually got something out of that in Vineland Laboratories up in New Jersey. That became a real problem because, if I recall, they had offices in Boston and Vineland, New Jersey; and we had some problems getting it to the appropriate judicial district to bring the case. It took an awful lot of effort. And, of course, as you can imagine, it was difficult convincing the Justice Department that they ought to put all the resources that would be necessary on such a case, because it was getting a long time after all this had happened, by that time. But at any rate, that was one heck of a big job that took an awful lot of our time for that year.

I'll just mention one more thing about Nancy Buc and maybe Gere Goyan, in that I recall right shortly after Nancy Buc came on board as chief counsel, Paul Hile had set up a meeting with her to discuss fraud -- quackery --

because we'd had problems with the general counsel's office in that they were never very receptive to these fraud cases; they just seemed to gobble up all kinds of resources and you never seemed to get all that much out of it. They just were not very receptive to these cases. So he wanted to have a meeting right after she got here to brief her on the problem and to solicit her support. I remember we went down to the general counsel's conference room. It was Paul and myself and Nancy and several of her attorneys; I don't remember who, but several.

Paul was really prepared. As methodical as he is in such a thing, he started out in a very formal, careful, thoughtful process to tell her about quackery and how we wanted to do some things. He just barely got started and she said, "Paul," and he kept right on going, just as methodically as ever. She said, "Paul!" Finally he looked up and she said, "I don't know what the fuck you're here for, but we've already spent more time on this than this is worth." Holy mackerel, Paul backed off and he looked up. "Well, what in the world am I going to do now?" Well, he shortened up his presentation, but he still went through it to discuss. And Nancy Buc had a name that rhymed with that word which became synonymous with her, because she used it all the time.

I remember on one of the very first cases I was involved in -- it was on a Saturday -- and Nancy was down at the home of the chief counsel of the department. I can't think of the name off the top of my head, but I . . . Let's see, Jody Bernstein. She was at her home, and I was with Arthur Levine and whoever the assigned attorney was; and we wanted to talk to Nancy. We got her on the speaker phone, and she used that word that rhymes with Buc just every other word. Arthur was using similar language. I'd never heard Arthur use such language, and I was just dumbfounded, because it seemed so much out of place. After he hung up, I commented, I said, "My God, I've never heard such a thing. I've never heard you talk like that." He said, "Well, when your boss talks like that, you have to talk that way, too" (laughter). But it was quite a shock, and I found out later, though, that was just common to her; she never even thought a thing about it when she used the word.

I think she was one of those people that had come up . . . She was Jewish and from New York City, and I think she was one of the first female Jewish law students at the University of Virginia. And having to come through that institution, you can imagine she had to be extremely aggressive. I think she carried that right on over into

her professional life. But there was never any question: when you were with Nancy, she made darn sure you understood that she was an important person to be reckoned with, and she had some very clever techniques to make sure you knew that. I've seen her do it on many different occasions.

Have I discussed the Rely Tampon thing? I must have.

RO: No, you haven't.

MS: I haven't?

RO: She was involved in that. But one other thing I'd like to do -- you've dealt with a number of chief counsels -- is how her role in that office, you know, differed from Cooper and from Hutt and things. Every one of those counsels had a little bit different philosophy on how they were going to run that office.

MS: Oh, yes. Maybe I could just spend a little time talking just about chief counsels and then call that quits for today and come back later, because it's getting on to eleven.

You're absolutely right. The chief counsels were very, very different individuals. But with the appointment of Peter Hutt, who was the first chief counsel to come in from outside the agency, it was a much different situation. They were representing the secretary's office, and it became very clear that they had a much more dominant role.

As I recall, Peter Hutt was often referred to as "the commissioner." And, in fact, he was the commissioner in many different matters. But Peter Hutt had such a fast mind, he could handle things in such rapid fashion and was so articulate, both orally and in writing, that he could overwhelm just about anybody just because of his sheer abilities, his work. He could work. There wasn't anything that he couldn't solve.

He, for example, immediately got the agency into the class-action approach on lots of things, and was very concerned about due process, and put out tremendous numbers of regulations with long preambles that described policy in great detail. Which was a totally different way of enforcement than what the agency had been used to. The agency had traditionally plowed new ground through Billy Goodrich by bringing legal actions and establishing through the courts. They were as different as night and day. So it was a completely new era for the agency, and he brought in an awful lot of bright, young lawyers. And a lot of them were dedicating their time to working in the regulations area and working for the commissioner on all kinds of special assignments that were different than what had been in the past. For example, all centers had a lawyer assigned to them, and they worked right intimately

with that center on policy, law. So they got much more dominant. I was very much impressed with Hutt.

Following Hutt was Merrill. Now, Dick Merrill was a very much different type of person. I would call him an academician.

RO: Which he was.

MS: Yes, which he is and was. Didn't, I don't think, like too much vigorous confrontation. He was kind of a quiet, retiring person, but a very knowledgeable and very competent person. I remember one time we had a case on a dairy farm up in Vermont, and he had turned that case down. It was a very old man that was the farmer. Darby Farms, I think was the name of the farm. I didn't too much disagree with him, in that it was a case that we had gone with before and you could make the judgment call that it was up to the judge and jury to decide whether or not the guy was a criminal. But at any rate, he turned that case down, and I kind of had a feeling there might have been a little bit of political influence somehow, but I couldn't say for sure.

But at any rate, Friedlander, who was the chief compliance officer in Veterinary Medicine, wrote a blistering memo that criticized Merrill very severely for turning that case down. He had me down there, and he was

so much out of character in that he took that personally. He really resented it. He just simply said to me, "As a professional, I believe it's my responsibility as the chief law enforcement officer of this department that I've made the decision. People can have different opinions, and I wouldn't even mind it if people had different opinions if they wanted to come to me and discuss it on substance. But to come up with such an emotional tirade as this, which I suppose has been distributed widely, I resent it. I don't like it." I agreed with him. I thought it was not right myself. But what you were seeing was a different mindset on the part of a chief counsel as to what was appropriate to go forward with and what wasn't.

I don't know if you remember, But Merrill was one of those people that was constantly trying to get the agency to be much more clear in setting up criteria as to when you should or shouldn't prosecute. I always thought that was an excellent thing myself, but every time we tried it, it is so difficult to do. And, in fact, his own attorneys didn't like it because it would cause difficulty in trying to bring cases. They would be forever bringing up these criteria as a reason why not to, and anybody who's ever been involved in the prosecutorial process knows that

there's so much judgment involved that it's not easy to put down one, two, three, zip.

RO: As far as the public is concerned, if you brought a case that didn't fall in that criteria, why, immediately, then you . . . It's difficult to have criteria that you are going to meet every situation.

MS: Exactly. But on the other hand, it's hard to argue that good criteria isn't appropriate so that people know clearly what standard of conduct they're being held to, because when you start talking about strict liability and GMPs, it's extremely broad as to when the agency could proceed. Now, we have a system in place that's been pretty good to make sure we just don't come with a marginal case. At least, it's designed to prevent that from happening. But at any rate, he was a gentleman and a scholar.

I'll never forget also the day that we had the meeting with Travenol, chairman of the board. Hall was his name. They were willing to sign an agreement, and it caused tremendous furor in the field. They thought we'd cut a deal, because the case had already been forwarded to the U.S. attorney's office. The chairman of the board came in. He was to meet with Sam Fine, and Sam Fine was out. But it was Arthur Levine and Bill Randolph and Bud Loftus and myself that met with quite a large delegation. That

chairman of the board, right in that meeting, committed to do everything and more that we had asked for in the injunction. He agreed to destroy everything that had been produced in that McPherson, Kansas, plant. I knew, and his chief counsel kept trying to tell him, "Sir, we're talking about extremely low-level contamination which I don't think really is that serious as to warrant total destruction. I just don't think that there's any judge in the country that's going to require you to destroy all of that inventory and all of that that you have on the market."

And the chairman of the board, I have a feeling, was almost on the edge of firing this chief counsel right there. He, in effect, said, "You shut up. I'm going to decide what to do and this is what we're going to do." What he was trying to do was to avoid a court case. But in doing that, he was going to give us far more than I knew we could ever get if we went into court on low-level contamination.

Anyway, immediately after that, we agreed we would sit down and hammer out . . . It was just an extremely difficult thing for us to do, because he was here with his corporate jet; he was going to be leaving town that evening. He wanted to sign it before we left. So I remember we took that thing back to my office and we converted that injunction to an agreement, slapping in

everything we could to make it as tight as we could, even more than what the injunction required, and get that typed and back up there for him to sign. And we did it.

But he was a man with a lot of clout, and I remember after that meeting we went down to Merrill's office and we presented to him what we had done. He said, "Well, I'll tell you. I think what you've done is absolutely correct, and if they don't adhere absolutely to everything they have agreed to, it's Park II." Well, that really impressed me that he was in tune with what was going on and he totally agreed with it. But this chairman of the board was meeting with the commissioner, and there were continued meetings going on throughout the weekend without any of us who had worked on it involved. Of course, you always wonder, then, what is going to happen here? How is this going to get watered down? But it essentially came out just like we prepared it.

I'm forever beholden to Arthur Levine, because in times like that, he was absolutely invaluable. He was right there in my office with us, and he was assisting us with the language and getting this thing done as quickly as we needed to. I remember Arthur coming to this meeting with the chairman of the board, not in a suit but in kind of scroungy clothes that I thought he was doing

intentionally to show them that, "I'm not in the corporate rooms. I'm not impressed with the people, with all of it. I'm an outsider." That was intent. But anyway, he performed well. But that was another example of Merrill.

RO: Getting back to Darby Farms, why was it that Dick Merrill declined to forward?

MS: Well, it was on many different things. See, that was one of the things he objected to, too, and I did, too. He turned it down for many different reasons, but one thing was, this farmer was like in his nineties. He couldn't see that there would be any real benefit to society in going ahead and prosecuting a man of that age. People immediately took that as a sole consideration. But Dick Merrill, as I recall, required us, in every transmittal -- because he had a U.S. attorney complain to him -- to give the age and whether or not someone was infirm in the letter to the U.S. attorney. Because he had a U.S. attorney that went into court, and this doddering old man came down the aisle, and he had never seen him before. And he raised absolute hell; he did not want to be surprised. So he required us to do that. That didn't mean that you wouldn't prosecute them, but it did mean it was a factor to be considered and it had to be part of the case presentation. People took that immediately as he cut new ground, that

everybody over seventy has got a license to do anything. That wasn't true at all. He wanted to be very sure you knew what you were doing and that it was part of the record.

Also, as I recall, there was some question about the evidence. It wasn't as clean and clear-cut as you might have. You had a farm manager. This guy was in Florida. There's a farm manager up there running the farm. The guy claimed to not know exactly what was going on, and the evidence wasn't crystal clear to show. So, I mean, it wasn't just an absolute open-and-shut case. It was one those, also, that was getting stale. So you took together the three or four or five things, he did not feel that was a case to go forward with, and he just made the decision. But it was not well accepted, because it was the kind of case the agency had gone forward with.

But this happened all the time in Hutt's era, too. He very much was personally involved. I think I've talked about this before, but I remember Peter Hutt telling me that . . . We had a showdown on cases, and in that showdown it was Sam Fine, Taylor Quinn, Peter Hutt, and myself. Taylor Quinn said, "I don't read these cases. I just don't have time to read all of those cases." And Peter Hutt said, "Well, I know how many criminal

prosecutions go through this agency each year. I read every one of them. I think you can, too. That's your responsibility. On something this serious, as to an individual's freedom, the least that top management can do is read the letters. If those letters aren't really sound, it's your responsibility to get into that."

Well, I was reading every single one of them, I'll tell you, because I was trying to meet exactly what I understood Hutt to want. Because if he got one and he didn't like it, he'd either come right straight up to my office or he'd call me to his office. And after you've done that a time or two, you try to avoid it. Because he was right. People thought he was soft.

He, I remember one time, came to me with a prosecution; it was in New Orleans. And he threw that on my desk. He came right up to my office and he threw it on my desk and he said, "Look, this place is filthy; and from what I can tell from this file, they are continuing to be filthy to this day. What I want the agency to tell me before I will sign this prosecution is that this firm is under control and is not filthy today. And if it isn't, I want an injunction, mass seizure, or whatever it takes to get that under control. It is egregious." So I just picked up the phone and called Bob Bartz and I said, "Bob,

you can get this prosecution through, but not unless I can certify to Peter Hutt that that firm is in compliance today. I've got to have that assurance before we can get this signed." Well, they came in with a mass seizure, like in the next ten days. It was embarrassing. He was right; he wasn't soft. He was saying, "You've got the wrong remedy here. This is continuing. I want it stopped, if we're in the public health service business."

So after you've been through a lot of those experiences, you begin to try to conform if you could. And that was one of the difficulties in the job I had. Everything I signed went to the chief counsel, so he was my boss on every product I put out. Yet Sam Fine was my boss in real-day terms; but I had hardly anything to do with Sam Fine on a case. Rarely ever. It was extremely rare. If I ever had anything to do . . .

(Interruption in tape)

MS: If I ever had anything to do with Sam, it was only at my initiative, because I felt something was so politically sensitive or something that he should be aware of it. But there was never, ever any involvement by Sam in any case, which made me uncomfortable, because I felt I had more weight on my shoulders than I really needed. I wasn't at that high level that I didn't need some kind of

assurance that I was in tune. I did notice, however, that in every single showdown I ever was with Sam Fine and the chief counsel, he always deferred to the chief counsel. I never saw him ever not. So that told me something, too, and therefore I was working for Peter Hutt, as far as I was concerned. But that's why I much appreciated Paul Hile, because Paul left it entirely up to me, but I had a continual exchange with him on all significant cases such that I knew he was comfortable. And that made me much more comfortable in what I was doing. So I found that to be a much more satisfying relationship.

RO: We were talking, you know, about the differences in the general counsels. So before we drift too far, Merv, we're on Dick Merrill.

MS: I wanted to leave Dick Merrill now and go to Nancy Buc. No, Rich Cooper was next.

RO: Other than being the grammarian that he was . . .

MS: He was a grammarian, and I've already discussed that a little bit. But, in addition, he really shocked the agency, which I've discussed, too, in that he required so-called adequate warning before any kind of an injunction or prosecution could be forwarded to him, which made good sense. But the agency had never gone to the degree that he required. Now, we tried to write a policy statement and,

in fact, we did, and we never did change all that much. When it really got down to writing it down, it got watered down, as often things do, such that we didn't change too much. Except he just required a very high level of notice before he would sign off on a case. And I've talked about that in the geatrichum mold case, so that's enough. He also did, for the first time, draft criteria for criminal prosecution, which we worked on, and actually got Goyan to sign off on it. Never got published, because before it ever got published, we had a new commissioner; Goyan was only here a short time. Who followed Goyan?

RO: Hayes.

MS: Hayes? There was so much disagreement within the GC, also, that it just created a problem; it never got issued. I think still to this day it would have been good had it issued, because, frankly, people within the agency needed this information more than anybody else so that we didn't have people sending in a lot of cases that had . . . I found out, being the person responsible for resolving the institutional decision as to whether you go or don't go, that that was the most time-consuming part of the job was on a case turndown, where there wasn't good, clear understanding. So if you could have articulated some kind of criteria that would have reduced that . . .

You had some districts that would just send it in as a flyer; they'd tell you they're sending it in as a flyer. Well, flyer or not, it's a case, and you cannot then just stand aside and ignore it. That's why I came up with the ad hoc committee process, by the way, to just simply have a mechanism to force everybody together at the earliest moment without a lot of paper around to make some of these decisions. Because they're judgment calls, and you can make an argument either way ad nauseam if you want to.

I remember Gottlieb, once he came into EDRO, was one of the biggest pains, because when I would get a memo from EDRO on an appeal, it would look like a Supreme Court brief. He had spent months working on this case, and here I've got cases all around me that I'm trying to move that there's no question about; and here I'm having to respond to some guy over here that's spent a month developing a brief. As you know, you can always make a case for going on a case; that's without saying. It just got very frustrating, and we finally did take care of that, but not until after the reorganization. And that was Celeste, Gottlieb that were crafting these things. It was just driving me crazy because to get the kind of people you had to get involved to deal with those really took more time than going forward with a good case. You only had a

certain number of resources, so it was hurting, trying to get cases going. All I wanted to do was to set up a process whereby we could reach a decision and get on with it.

Now, Cooper had trial experience; that was new. He insisted upon that kind of thinking by himself and his lawyers on every case. He wanted to be in the best possible posture before we went into court. He, I remember, was very upset about a ginseng case that we lost and apparently had gotten some heat from Justice. He called a meeting of Paul Hile, Taylor Quinn, and myself, and he was really steamed up and he was wanting to know if we had any scientific support on this substance as a food additive. Taylor Quinn said, "Yes, sir." I remember, I looked across at Taylor and I said, "Can he speak English?" Because I didn't feel that we had very substantive support.

That was another continuing problem that we had that Cooper was big on and he caused his attorneys to require it; and it's still not done well to this day. I met with centers trying to explain to the scientists as to what we needed. You can get scientific support to go on almost any case; if you want to search far enough, you'll find a scientist somewhere who will take that position. What I was trying to articulate was a standard somewhat like a

consensus position. In other words, the agency would try to take a scientific position that would be supported by the scientific community beyond Food and Drug. Because we were going out there with some of these cases that we were just . . . Judges were ruling against us on mercury; they were ruling against us on different things. Paul got very concerned and he wanted to be sure we had adequate support. We wrote up a policy memo, sent it to the centers that that was a requirement as part of their submission. We never got the kind of thing that we felt we should have had, and I think that's still continuing, based on one of the cases I've been on recently. They just don't really focus in on good, solid scientific support before we initiate an action.

Also, another case I remember Cooper was on was Mrs. Paul's fish cakes, and that was one where Taylor Quinn was adamant that we had to take them on. That's the only case that I'm aware of where the Justice Department refused to be a party before the court. If the government went forward, it was solely on the responsibility of the Food and Drug Administration. Now, that was a very shocking thing, because that had never happened before and, of course, they made that known to the U.S. attorney's office and even to the judge. Well, now, if you don't have the

principal department of the government in support of your case, you've got trouble.

I remember that was another meeting that Cooper called with us that he was really livid, because this company had come before the court and had claimed -- and there was nothing to refute it -- that they had marketed millions and millions and millions of these fish cakes without ever any question, and that the consumer had accepted that as the common or usual name of the substance. It was fish cakes that had been made out of particles and pressed into blocks and sold as fish cakes. We didn't have, really, anything to refute it. What we had to back up our position was a compliance policy guide that had just been whipped up in the Center. Nobody had exposed it to the outside world, and it hadn't really been given any kind -- we didn't have the support again, and that was a problem.

But at any rate, I looked on Cooper as being a first-rate general counsel, a very intellectual guy. He'd been a law clerk and, as I said, he is a very good writer and he required every single case to look like it was going to the Supreme Court. It caused the agency unbelievable problems, because we typed and retyped cases until we were blue in the face; and it's very hard to keep the staff geared up doing perfect work when they have to keep doing them over

and over and over. I just finally go to the point where I just wanted to get my office out of trying to write to their satisfaction because I was convinced we couldn't. I just finally said, "You write them. We won't even try."

See, we were the ones that we getting the flak from the agency people, thinking we were doing all the rewriting. Well, we were, but we were trying to do it to make it acceptable to this chief counsel. I mean, he couldn't effectively communicate it to me and a very few people on my staff. How could we communicate to the field to meet his standards? So I finally just gave up and said, "You just write them any way you want," and you can be sure they were written any way they wanted. Every attorney had their own product, and it became very much different as to how we were going. We had pretty much boilerplate up until all of this time.

RO: Well, was it under Cooper, then, that we had to arrange for expert witnesses before they'd ever forward a case? Before that we used to get the case and then we'd try to get our expert witnesses.

MS: Yes, that was during his time that we had a requirement -- which Paul required because of a couple of cases we got pretty well smashed on -- that the center had to assure as part of the case transmission that they had

experts. They didn't have to go get an expert. For example, if it's a GMP case on sterile drug products and it was similar to many other previous cases, they simply had to assert that as part of their presentation. But if it was a case where we didn't have any kind of a precedent action, they had to . . . And GC, then, developed a little technique that required it. And they still didn't do it. They'd say, "Yes, we have it and we're confident everything's fine," but they didn't have it. General counsel got to the point that they would require an affidavit of an expert attached to the case. That way, they would have certain knowledge that they had it. If they didn't do it, you had, again, all of these different attorneys, each with their own ideas, going out and getting their own experts. So it became a kind of an unmanageable situation. But, all in all, I think Cooper was an excellent . . .

Now, following Cooper, was Buc. Nancy Buc was a character like I cannot describe any other. She was a very domineering person, and she had absolute license from the secretary's office. Her good friend Jody Bernstein was the chief counsel, and they were both good friends of the secretary, Pat Harris. And she didn't hesitate to make that known in certain situations.

I thought the first exchange or two that I saw her taking a role that I thought was inappropriate . . . I watched Paul Hile, and I thought he was letting her get too darn dominant, pushing him around. And I think I even questioned him a time or two about that, that I just thought she was out of bounds. That's why I have such great respect for Paul. I recognized that he fully was aware of the clout that she had, and she had more clout than Goyan had, without any question. He just deferred to the power. He knew what the power was and he was just going to take a low profile and roll with the punches. And he was successful at it. I mean, he got her support.

But it was quite a shock, because she represented a new thing, a much more dominant role in cases. She also had a phrase that I like and I still use to this day, and that is -- and she read every prosecution injunction -- she insisted that every one of those transmittals sing. When you write up a case, and I read that case, if that case doesn't sing as a persuasive case, I don't want any part of it. Either you haven't effectively communicated it or you don't have anything. And so she required that. But she wasn't nearly the stickler on law review kind of requirements, but she was a stickler on substantive cases.

I recall she sent back a case to me on a slack fill, a container of candy that had a phony bottom or something, and she turned it back as being something the agency hadn't ought to be putting a lot of resources to. I'd had enough experience with her by then that I recognized it didn't look to me like something to fight, so I sent it right back. But I gave her full responsibility and accountability for the turndown. And Taylor Quinn, he was livid; he did not like it. I recall at that meeting with Carol Tucker Forman, a room full of possibly thirty senior USDA and FDA employees, Taylor Quinn took this container and walked right straight across the room to me, slammed it down in front of me, and said, "You want to take it up with Nancy Buc right now?" I said, "No, Taylor. I think right now would not be appropriate. We've got too many other things here today." And she mentioned that later, that she wasn't as adamant about turning it down.

But see, by this time, I was getting tired of being a "stuckee," too, because quite often I would write a memo transmitting the decision for the record because I felt that every single case deserved some rationale as to why the disposition. But often it came out as though I was the one who turned it down. I was being the flunky of the chief counsel, and I got tired of that. So then I

developed a little skill that if that's what the chief counsel said, even though it was just a scribble in a margin or something, I gave them full credit for it and flushed it out in some particularity. I think she regretted that later; but anyway, that's what she did.

But I had the greatest respect for her, and I think maybe . . . Well, who was the chief counsel following her, Tom Scarlett?

RO: Yes.

MS: Maybe I'll stop there and then pick up, I think . . . If I haven't talked about Rely Tampons, I'll pick up there, because that was Nancy Buc, and I have the greatest respect for her for the manner in which she handled that thing. It was unbelievable.

(Interruption in tape)

RO: This is a continuation of an interview with Mervin H. Shumate. The date is May 13, 1987. The place is the Parklawn Building, Rockville, Maryland.

Merv, there are several issues that confronted the FDA that I would like to have your views on. One was when the Department of Justice required that our casework proceed through primarily the Civil Division in Washington. This, as I recall, pretty much prohibited FDA from working directly with the U.S. attorneys. You were involved from a

headquarters standpoint in that matter, and I would like your views on just what this meant as far as our field offices were concerned in proceeding with cases. There are also several investigations that I would like to have you discuss, such as the counterfeit oral contraceptive case, the illegal distribution of steroids, and the Herbalife issue. There are probably other cases that will come to mind, and there's no particular order in which they need to be discussed. But I didn't want to lose sight of at least these matters.

MS: All right. I might try to tackle the relations with the Department of Justice first, because they all do somewhat evolve into how we handled those cases that you mentioned. Our relations with the Department of Justice evolved over time with them always taking more and more authority. I recall, for example, under Dick Merrill, which was back in the seventies, that Justice kept asking for . . . At that time, the process was like this: the agency prepared seizures, injunctions, prosecutions, contempt actions, whatever, and sent them directly to the U.S. attorney. Simultaneously, as a copy went to the U.S. attorney, a copy went to main Justice. So they didn't have any opportunity to do anything with it, other than to be informed that something was going on. And then they would

routinely send a letter to the U.S. attorney indicating that they should be kept informed of any progress of the case or any problem. But they never asserted any kind of a dominant role. There were, of course, always exceptions, but that's the general process.

But back in the seventies, I remember Dick Merrill coming to me and our discussing the fact that the Department of Justice attorneys were not wanting all the underlying records. I believe maybe even before that they had requested them of Hutt. Hutt was a master at working out solutions to these kinds of problems, and what he was willing to do is, he would have the files available here, and if they were willing to come over here to look at our underlying files, they could. But that never satisfied them. And I know that from having been a reviewing officer, you like to have to access to the underlying documents and you like to get what I call the "essence" of the file. You like to know what's behind the outline that's in the criminal case. Is there really something there, or is there something that isn't quite so crystal clear?

So anyway, under Merrill, then, they kept insisting; they wanted those underlying documents. So what Merrill agreed to do is, every time, to provide them with such

things as the 483's and the inspection reports, but no underlying documents. So that was done routinely. All of this, of course, was for the purpose of heading off their insisting upon having a case, because it was obvious even back then that they were angling to the point that, "We're in charge here. We're wanting to see those files. And we'll decide whether the case goes forward or not." But until they could get in the process, there wasn't really anything they could do about it. And, of course, these things varied as dependent upon the attorneys involved. If we had a GC attorney that was extremely aggressive, he would retain dominance over the case just by sheer dominant power. But I fully believe the GC retained primary authority over the case by having all the files. It's difficult for somebody to take the ball if they don't have that underlying data.

It was extremely frustrating to me as an FDA official. I used to get so frustrated because it seemed to me that the public deserved something better than three law firms representing the agency. You had the U.S. attorney's office, who are under our system of government extremely independent. They work for the Justice Department, but they are appointed by the president, and they run their fiefdom with almost absolute authority under most

conditions. So if they wanted to keep that case, they could tell FDA to get lost and there wouldn't be anything they could do. They could also tell the Justice Department they didn't appreciate their presence. Now, they could not get them out of there because they were from headquarters, but there were very strained relations.

And there again, I experienced this firsthand as a field compliance officer. You would see the most embarrassing kinds of things going on between the different attorneys that made you wonder, "How is the public going to get well served here?" I mean, it was just outrageous. I always felt, as I think I indicated to you when we first went out to South Dakota there to handle one of those grain elevator situations, somebody has to be in charge of whatever's going on. Because, right or wrong, if you aren't, somebody'll pick that up and they'll exploit it. And that happens, too, with criminal cases. You'll have a George Burditt, for example, who knows the system better than any other person that I know. He will go to every single different constituent to see if he can't negotiate the best deal possible for his client, and he's very effective at it.

So that was evolving over time. It got on up, then, until Tom Scarlett became chief counsel, which would have

been under the Reagan administration, and it just kept getting tighter and tighter with indications that they were going to assert control over cases. Of course, I must say that usually whenever these initiatives occurred, it was because of a particular case that had just been forwarded to Justice and they absolutely had problems with it; they simply did not agree with what the agency was doing. Of course, they're much more attuned to the legalistic, law side of it, whereas we probably were considering public policy. There's a tremendous amount of judgment involved, so that anybody is entitled to their judgment; it's a question as to who's in charge. But at any rate, I remember, for example, the Abbott case, and the geatrichum mold case, the General Foods case, and a few of those cases that really caused Justice great concern about the adequacy of the agency's cases. Therefore, they wanted to assert more jurisdiction.

Now, I've just spoken about the Reagan administration. I have to say that for the first time, under the Reagan administration not only did we have to get the Justice Department's approval, we had to get the office of the secretary's approval. The chief counsel of the department had to be informed and sign off on every criminal prosecution and injunction. Now, that was quite a thing.

Tom Scarlett handled that very well. Of course, Tom Scarlett, the general counsel's office, is in the office of the secretary, and that had always been a role of the general counsel's office is to represent the office of the secretary on any FDA legal actions for the department. But here, all of a sudden, they were taking it. You probably recall the chief counsel's name; I can't think right now. Spanish or Cuban. Del Real. And that usually meant Tom Scarlett and the assigned attorney, with a brief memo setting forth their best judgment on the case, briefing the chief counsel and then him agreeing to the case.

Now, I remember a couple of cases -- one of them was Beatrice Foods -- where he actually turned that one down. And, I must say, not without some cause. It was a judgment call. But as you can see, here we had another layer introduced into the middle of a case going out, and it complicated things considerably. We were not really involved . . . I know Paul Hile did go down to meet with del Real on that Beatrice Foods case, but generally that was not the case; it was Tom that handled it.

RO: Was this on sufficiency of the case or more on the "politics" of it?

MS: Well, you always believe it's politics, but I prefer to classify it as prosecutorial discretion. In

other words, I am sure at the del Real level and at the Justice Department level, there's lots of discussion about the FDA and the adequacy of the cases because you know there's so much congressional interest. There's continual visibility given to a lot of our cases, and so I imagine there was lots of discussion going on at the higher levels of the departments; and they're saying, "We've got to get control over that agency." I'm sure there also is some politics involved. Of course, del Real would be looking at it as to whether or not it was consistent with the Reagan administration's regulatory reform agenda.

Of course, that always makes you very skeptical. If you've been handling something in one way and all of a sudden it's handled in a different way, you immediately conclude that somebody's getting involved politically. I cannot say honestly that I ever saw anything out of the secretary's office that was anything but an intense review as to the sufficiency of the evidence, of the case. I never saw any blatant politics. Now, maybe there was; maybe I'm naïve. But unless I personally experienced it or saw it, I wouldn't say there was, and I'm not aware of it.

But at any rate, that was going on. All at the same time, the Justice Department kept very nicely pressing, pressing, pressing for more control. I can't tell you the

year, but it was in the fall of probably '82 or '83 or '84, somewhere, when there was a memo came down. I know there had been negotiations with Tom and, I think, Assistant Attorney General Ford, where . . . And they have a very definite pecking order as to how things are handled. For example, Levine would be handling it at the level of Pat Glyn, next level down. There were a lot of negotiations back and forth, and I don't think anyone really thought they were going to take authority over it. But they did; they came right out with a memo that just made it crystal clear: all injunctions and prosecutions and contempt actions would have to be sent to main Justice.

Well, that was a real shock, and I remember the meeting that we had right following that that Tom Scarlett asked to come up to speak to the Compliance Policy Council just to inform them of this. He was really serious and concerned. I'm sure he didn't know at the time exactly what might come of this, but you can imagine the shift in roles it could have as to his office and what they'd done over the years. There was a great effort on the part of the department, which del Real, I believe signed himself, a memo responding to Justice, setting forth all the historical record and everything to justify continuing as it had always been. And I remember Justice coming back

with a brief that just slammed the door so tight that you couldn't even imagine, not only as to this department, HHS, but also as to the U.S. attorneys. I mean, they had a legal brief that clearly laid out . . .

I think we all understood over the years that the Department of Justice certainly had to have the ultimate responsibility for the United States government with respect to any prosecution; there couldn't hardly be any question about it. They were the people charged under the Constitution with enforcing the law of the United States in federal court. But they made this crystal clear: "No longer are you going to have it." So that meant, then, the cases had to be sent over there, and that also meant that they reviewed them very, very carefully, and they asked all kinds of questions. It was quite frustrating. But, again, I have to admit that they were doing it in a very professional manner, very pertinent questions that needed to be asked. But you can imagine the extra work it put on, trying to answer these questions. There were some very, very tense feelings.

I remember, for example, one particular case, and I think the attorney's name over there was McDade. It was the Syntex case. He had sent back a memo to the general counsel's office on his concerns about that case. I

remember Tom sending it up to me, and I prepared a response to it, because it seemed to represent considerations and criteria that were foreign to what we had historically done, and I questioned . . . A single attorney. See, that was the thing that outraged me. We, in this agency, were so careful to have a system that I call institutional. In other words, no individual, no matter how radical or how whatever, is going to ramrod a case. And we have some ramrods in this agency, such as the Sages of the world, that don't report to anybody, even including God. But we had a system that would control those people, and I call that an institutional process.

Well, it was obvious to me that that wasn't happening over in Justice. If you send a case over, it was the attorney who gets it, the attorney speaks for the Department of Justice and raises all these questions. And I'm thinking, "An individual? How do they have any consistency as between this attorney and the other five or ten attorneys that are looking at our cases?" So I was really frustrated about that, and questioned it. I think that eventually they were overruled; it did go forward. But it does about the same thing to the headquarters people that was so frustrating to the field people. And that was, you have so much going on after you'd done your thing that

you almost lose interest in it, because it's just gone and you don't know where or what or why or how or when it's ever going to get anywhere. And you're not even a participant in the discussions; that's frustrating, very frustrating.

But it was pretty obvious to me that we were going to have to recognize this, and I remember Pat Glyn coming over to a compliance branch chiefs' meeting, and he was speaking. It was right after this, and I was on the panel with him and with Levin. We had some very direct questions. He was so nervous. If you remember, he always smoked cigars about fourteen inches long. He actually consumed one or two cigars at the table. He'd take his knife and cut that thing off and he'd chew that thing. You'd think it would have killed him right there; it must have been toxic as heck. But he was nervous.

He went ahead, though, to explain in some detail the Justice Department's role; and in his opinion, the role was to look at the evidence and to determine the adequacy of the evidence to the charges. That means going right back to the underlying facts, and if they need to do further investigation, that is their responsibility to do that. Well, you could imagine. Here are all these old-timers sitting out there having this put to them. It really

raised a major difference. It also raised some very basic questions in my mind, because we were continually beat over the head because of the untimeliness of cases; and this is only going to make timeliness even more difficult, this additional layer that you've got to get cleared. So I'm thinking all the time, "How in the world are we going to cope?"

Throughout this time we were developing the ad hoc committee system, which was strictly for the purpose of trying to reach that institutional decision as quickly as we could so that we could put our resources to a common goal and to get that thing done, up or down, one way or the other. Don't leave a case dally for six months or six years just because you can't force a decision. You have very strong feelings in those kinds of things. I mean, I had some of the liveliest debates of problems to solve in trying to solve some of those cases as anything I ever did.

RO: Well, Merv, let me ask you this. When Justice did this, it kind of questioned how they felt about the adequacy of our review, as far as . . .

MS: Not just our review, but our investigation. And Glyn even raised the point in that meeting that they would look at it as to the adequacy, and if the investigation was not adequate, they would want to be involved in conducting

that investigation. Of course, that now raises all kinds of questions about how you're going to do it. I remember afterwards Arthur and I talking about it, and they were simply not going to agree to that. But now you have to understand, I was beginning to come around to the point that if what this guy says is true -- and I've seen the Department of Justice brief on this -- and they're going to run the case and they're going to start another independent investigation after the agency has forwarded it to them and concluded it's adequate, well, we might as well conduct a joint investigation with them. Why are we going to waste all of our resources only to find out we didn't answer the questions that they have? If you have had experience with a prosecutor running a grand jury investigation, you know there are some advantages to having that authority, because they have subpoena power of people and documents; they can plea bargain with people; they can bring one guy in and squeeze him and give him immunity if he'll testify as to others; and they'll start to make cases that the agency never could make because we simply don't have the subpoena authority.

Also, they were raising some basic questions about our ability to conduct criminal investigations. It was never well articulated, but I understood -- not as well as I

think we could or should have . . . It was started under Cooper, where there were a lot of questions in a case law outside FDA law that raised questions about evidence being tainted. In other words, if you're conducting a criminal and a civil investigation simultaneously, you could so taint the evidence that it would not be admissible in a criminal proceeding. And you know the fundamental policy of the agency was, if we have a problem and it's a public health problem, we're going to solve that problem. I think the DES case is the best example of that. We're going to get out and control whatever it is that's exposing the public to some hazard, and if in doing that we somehow compromise our criminal investigation, so be it. The number one thing is public health. Well, once you get over to Justice with criminal prosecutors, they're not thinking about the public health role so much; they're thinking about the criminal process. It's a different role, and that's where the clash occurs.

RO: What about the role, though, of the U.S. attorneys in these cases? Did they like the fact that Justice and headquarters were kind of interceding in the middle of this thing?

MS: No, they didn't like it. But there wasn't a thing they could do, because they had the authority. There

were only two areas -- and that came to the fore right afterwards, and Glyn had to admit it to us -- New York and Chicago. You know, Fred Branding, who'd been the assistant for years, is a lawyer and a pharmacist. They were so strong and had lawyers of so much knowledge in the Food and Drug law that they could pretty much independently continue as they had, to some degree. But the others, they had no authority. And you saw a much less dominant role of the U.S. attorney.

Now, as in everything, that was some benefit to us, too, because you have lots of U.S. attorneys in this country who are so political they wouldn't file a case because a potential defendant is their nephew or the judge's nephew. Well, now we had someplace we could go to get the Justice Department to go ahead and file it and cut the U.S. attorney right out of it. You still had to have a relationship, though, because you have all these court proceedings and they're different in every jurisdiction. So there had to be some continuing relationship, but the Justice Department became much more dominant. They started to hire Food and Drug lawyers over in Pat Glyn's shop. We've got a lot of Food and Drug lawyers over there to this day that were there to perform a function of taking over these cases; and that was pretty obvious to everybody.

But I think maybe I can put this into best perspective by an experience that I had as to what the situation is today, and it'll then lead into the Ovulen and steroid investigations, which I had led, based on that experience. This case that I'm talking about is Richmond Plasma. It's a Richmond, Virginia, blood plasma facility, and the allegation was that there was fraud, falsification of records; they had two sets of books. They would overbleed patients, and then on the set of books that they left for the FDA to look at, everything's perfect. On their own regular set of books, they had overbleedings and all kinds of things that indicated some fraud.

We encountered that because a former employee came forward and gave it to us; so we know right early in the investigation that we had some fraud. But, being a blood case, having all the potential public health problems with blood, we went through this suspension/revocation process, and that takes forever to get that thing resolved. And did, in fact, I think, take care of the public health side. But that meant, then, the criminal investigation was set aside and continued for a long time. The district submitted a case with some eighty counts that the biologists cut back to twelve or fifteen counts, judgment calls on the adequacy of the evidence. I think that's

truly a place where you needed the technical expertise of the center as to what's really significant.

It then went to us, and we forwarded it to GC. GC looked at it and raised questions about the adequacy of the charges based upon some recent case law, and ultimately totally rewrote the case, completely rewrote the case. I got involved and held an ad hoc, because I could see this was one blood facility of many with national headquarters in Florida, and I had a reason to believe -- that there's often people didn't look at that. A district would bring their case, and it's our case. Another district might have something going on and wouldn't think about it. The center didn't think about it. But I could see what appeared to me a very strong possibility of criminal conduct at the headquarters. And if that were true, I wanted to get those people at headquarters, because they could serve you up a Richmond facility once every year and you would never, ever touch their . . . I wanted to touch their corporate operation and have an impact on it, so I had suggested that we pursue that through the grand jury investigation. So it went out of here, it was something like two years after the investigation.

All kinds of time went on; nothing ever happened. I get a call from Arthur Levine telling me that the Justice

Department had requested . . . The judge was very angry; the guy's name was Judge Dortch, I think. That he was extremely angry; that he was going to throw that case out strictly on the basis of the untimeliness of bringing the action. And that he, however, had set as court date for the agency to show cause as to why he should not toss this case out. "And we can't think of anybody. It's either got to be Mr. Hile or you, Shumate, that appears on behalf of the agency. Probably you would be the one, because it wouldn't be appropriate to put an associate commissioner out there in front of a hostile judge" (laughter). So I got nominated to go.

I reviewed that case with a fine-tooth comb, and concluded that, even though it was untimely, it wasn't all that much outside. To my relief, I couldn't find anything that would indicate anything that would be all that embarrassing in court, other than all the time. But I understood that it could take that much time, knowing our system and how many people are involved, and particularly where there's controversy of eighty counts in the district and twenty counts in the center and six counts in GC, and just all kinds of those kinds of problems, all of which takes a lot of time, because no one is sitting just looking at one case.

But at any rate, I then got to go down to Richmond, and we met on a Sunday night and met in the U.S. attorney's office. Cold. There was no heat in there, cold as it could be. There was Pat Glyn sitting there with gloves on, and a great, big cigar that would make you sick as a dog. And Ed Thomas, the compliance officer from Baltimore who was working on the case, he was taking after Pat's good leadership and he was smoking a cigar, too. And a former assistant U.S. attorney who was going to be on the pan, no longer in that court, but going to have to be involved. Of course, the GC attorney. I don't even think there was an assistant U.S. attorney there.

But anyway, we went over what we were going to do the next day. As Pat had tremendous experience at this, it went on and on and on, and I was freezing to death and shivering and pretty nervous about the whole deal, anyhow. I remember at the end of the evening -- it must have been after midnight -- I said, "I mean, there are tremendous records here. Is there any possibility of me having any access to these records on the stand? I can't remember everything." He said, "No, you cannot have any records. You're going to have to go back to your room and memorize everything" (laughter). I went back to the room and I went over those records, of course, into the wee hours. I

didn't sleep at all. And nervous as heck, because I hadn't testified in federal court for a long time, and I knew this judge was hostile. I'd never seen him before, but anyone ever having been in court knows that a hostile judge is not a good thing to have happen to you.

So the next morning I get up and I go down to breakfast real early. I'm having breakfast, and I've got my very best suit on, three-piece suit, and in walks Pat Glyn and the other Department of Justice lawyer; and they don't have any vests on. They asked if they could join me. I said to Pat I'd never seen Pat in all of the years I knew him without his vest. He always had kind of a ragged, old blue serge three-piece suit with a chain, kind of a formal-looking attorney, that he wore whenever he was in trial. He said to me, "Well, Merv, this judge does not like people wearing three-piece suits" (laughter). I said, "Well, that's simple. I'll just take mine off." Well, you know what kind of a character you're coming up with when the lawyers from the Justice Department tell you that this judge doesn't like three-piece suits; he doesn't like a lot of things.

(Interruption in tape)

MS: Anyway, we go into court. We had to have an assistant U.S. attorney at the table, because this judge

had a rule that there would be no proceeding before him unless the U.S. attorney's office was at the table. So we had to, at the last minute, go find an assistant U.S. attorney that would come and sit at the table. Didn't know anything about the case, had never heard of the case -- just had to be present. I mean, talk about a waste of time. It was very difficult to get one, in the first place. And in the second place, to have him sitting there all day long doing nothing but just being there I thought showed you somebody that's gone amok here, with power. But it was obvious he had plenty of power, because . . .

The defense, of course, was elated. They were extremely pleased, because it looked like this case was going to get thrown right out. There must have been six or seven different defense attorneys representing all of these different clients, from the corporate attorney, the corporate people charged, the individuals -- all kinds of them. But as it turned out, they didn't hardly have to question anything; the judge was cross-examining us as the defense attorney, practically.

I remember Pat Glyn. He was drawing on every ounce of experience he had before this judge and, I mean, he was taking some pretty strong licks. Pat has a problem hearing; he wears a hearing aid and he has a problem

hearing. And the judge has absolutely no patience at all, so he was doing his very best to hear and to do what the judge was saying. But there were times when it was really tough. I'm sure Pat will never forget that day.

But anyway, they put on first the district compliance officer, then the center compliance officer, then myself, then the GC attorney, and the assistant U.S. attorney. We were allowed to stay in the courtroom, which is unusual. Usually they don't permit witnesses to be in a courtroom. But at any rate, we started early in the morning. At about twelve-twenty, the judge said, "You know that my practice here is to break for lunch at about twelve-thirty. Today, we're going to run to about one o'clock, because we have a flutist who is going to perform in the lobby, and I strongly recommend that all of you plan to attend." Well, by this time, I'm so nervous about the whole deal that's going on, you think you've died and gone to heaven. If I went and listened to that flute music, I would have known I had (laughter). So I didn't go. Two or three of the FDA witnesses went down the street and got a bite to eat and came back.

I never got on the stand until like four-thirty that afternoon. You're just really tense by this time. We went on until seven-thirty or eight o'clock that night, and the

judge said that he was going to wind that case up in the morning. He'd continue in the morning, and that he would rule. Well, I know I left there, and Tom Bozzo and Mary Pendergast, the GC attorney, we went back to the hotel to get something to eat. And, boy, I think I drank three or four beers just one right after the other just to try to get myself off the ceiling.

Mary had to go back that night, but I had decided that I was going to sit there and look this judge in the eye no matter what his ruling. It wasn't clear what it would be. But to go a little bit further, he questioned us intensely on every single step of the way that that case went. He challenged me. He said to me, "As a federal judge, I think if I performed my job as the agency has performed theirs, I would be judged as totally malfeasant or completely incompetent." He went on and on like this, and he said, "And don't you agree?" By this time, because of having done all of this and being uptight and prepared, I had pumped myself up. I was also convinced there wasn't anything in this case to be ashamed about. These guys committed fraud over here. They're the criminals; we're not the criminals. Even so, it did take a lot of time, and I agree it did; there isn't anything in there that indicates anybody intentionally did anything wrong. It's

just that it didn't get handled in a timely manner. And I would agree to that; I would admit that.

But I was ready to wave the flag and not take any of this stuff from this judge. That was something. When he said that and he said, "Don't you agree?" I looked up at him. I wanted to explain our role, because I could see his mindset -- and Pat Glyn's, too -- was in the mindset of an FBI criminal case. And I wanted to make clear to him, and I did. I said, "No, sir, Your Honor. I am concerned about the time it took, but I do not think there was any intent by anybody. I think we did our job, and our job is different. Our job is to protect the public, and that's what we did; and it took us quite a long time to do that through the suspension and revocation process. But our first job is to protect the public health, and when we do that, we don't always get to the criminal as timely as we should." I had no idea what effect this might have, but the next morning . . .

And he went through that assistant U.S. attorney with the most excruciating detail you've ever seen, because it was like two years after Justice got the case before they brought any action, filed anything in court. They started, essentially, right from scratch, and conducted their own investigation, and took forever in doing it because,

obviously, they didn't have the knowledge of the kinds of technical aspects of it and they had lots of other things to do and they never got it done. And until Pat Glyn got involved and started doing things himself personally, it never got done. So, I mean, there was plenty of responsibility for the untimeliness. Only half of it was FDA; at least half was Justice. And there were some very intense feelings between the GC attorneys and the Justice attorneys, because, of course, they're wanting to make themselves look the best they can and it's making the agency look bad. So you had all of this again: the U.S. attorney's office, main Justice, and GC, all with different agendas and priorities, and the agency over here, somehow trying to relate to these people.

Next morning, go down there, judge starts right off by saying, "I have listened to and questioned the government witnesses. I can tell not only by the questions and their responses, but their mannerisms, their expressions. I can tell whether these people are telling the truth or not, and in my opinion, the government witnesses were all telling the truth. There isn't any question as to the credibility of the witnesses. And I have concluded, based upon their testimony, that this case will go forward." Goddamn near jumped up and cheered. We had an impact on this crotchety

old judge who had a track record, I think, with the FTC (Federal Trade Commission) and the USDA and others where he had thrown out cases in the past. He had some case law, so that was his big thing. But at any rate, boy, you could see those defense counsels now. They are wilting, because they didn't get off the hook.

So I came back from that, of course, so shaken, not only because of the experience, but because of what I had heard the Department of Justice say. It was my strong conclusion right then that never again was I going before a federal judge to defend such a long time, and that we had to do whatever had to be done, no matter who the lawyers are, to move criminal cases. In other words, if a grand jury is necessary and the Justice Department is going to be in complete control of how that investigation goes, then I want to get a relationship with them as early as possible to conduct one investigation, not two.

So right after that, we had the Ovulen case come up, which was a counterfeit oral contraceptive, a Lilly product. We had gone through the recall, of course, because again, a counterfeit drug -- and as I recall, one of the active ingredients was completely absent -- you had a genuine possible public health problem, and we went right full bore ahead to get it controlled as quickly as

possible. But it did represent counterfeiting. They actually had counterfeited labeling. Not too long before this, there had been a counterfeit law passed by Congress that gave the FBI a lead responsibility on counterfeiting. Not just drugs, but counterfeiting generally, and with some real clout. Heavy, heavy fines and some real authority.

So here we had a situation where there was dual responsibility. I contacted the FBI and talked with this young man and concluded that . . . And this was run from outside the United States; these drugs were coming from outside the United States. I knew that in order for us to conduct any kind of an investigation, we were going to have to have an awful lot of authority to subpoena people and records. So, having just had this experience, I wanted to get that there as fast as I could. Well, we did get it there in less than a month. Had that thing written up. I remember Rick Blumberg was the attorney, and there isn't anybody more intense about putting a case together than Rick, once he commits himself to it.

But it went over to Justice, and immediately we ran right smack into a Justice Department problem, because once the FBI is potentially involved, it's a criminal case. Our cases go to the Civil Division; criminal cases are handled in the Criminal Division. Immediately there's a problem

within Justice. I'm talking to the FBI and I'm trying like heck to get us to agree right up front on how we're going to handle this and see if we can't get together and work out our lines of authority and control. But I was going to make sure we got the ball to Justice as fast as we could, and then if they drop it, they drop it; we don't drop any investigation. And if they can't work within their own department, then that's their problem; it's not ours. We don't have to manage their department.

But Rick, as I remember, he's one of those very dominant attorneys I was talking about before, that he wants to run the case. And then we had Ed Atkins down in Florida, a compliance branch chief, who is also a very dominant type person. These two guys are going to run this thing as they always run it -- be damned to anybody else. Both very competent, though, extremely competent people. So it was very difficult and frustrating, because of trying to bring off these things.

I remember the FBI started to get out in front and wanted to grab . . . We got a hold of the plates for printing the labels, the counterfeit plates and those things, and the FBI was going to go out there and jump all over people. I was calling the FBI here and they would calm it down and we would work together and not get

somebody out doing their thing. But I found out the FBI, they operate much, much differently than we do in that we can, if necessary, control it from a focal point. But over there, they send TWXs back and forth and around, and, jeepers, there isn't any kind of central leadership to speak of. So you have difficult running a coordinated investigation over there.

But it took forever to get anything going because, as I recall, they had to go down and meet with the U.S. attorney. And I think at the very first meeting, the U.S. attorney said, "It's nice you gentlemen are here. I'm very pleased to meet with you. But we'll take care of this ourselves, thank you" (laughter). So you had some of the same old problems going on, but at least the monkey was on the Justice Department's back.

I have to give credit to Eli Lilly. They sent in, I think, a Dr. Peterson, and their chief counsel, John Holt, who were just extremely helpful in doing the kind of sophisticated analytical work and putting their entire company to work to nail down facts, particularly outside the United States, because they have a worldwide organization.

RO: They called this to our attention, first, didn't they?

MS: Oh, yes. They came forward and brought it to our attention, and that's why we got right out there and got the thing all recalled. It turned into some real intrigue. I think that case may now have been concluded. And they did actually get those key people that we were aware of but didn't have evidence on back in those early stages. There were people taking station-wagon loads of counterfeit steroids from Florida, which had probably come from Panama, to New York, going right into the legitimate drug channels through wholesalers. That was another thing that shocked you is how easy, based on price, you could put a product out into channels. Once in channels, it's gone all over the United States. But, I mean, I look at that as one of the first efforts to really try to coordinate and work this out.

The other case had to do with steroids. That's interesting how that started. We had this ad hoc committee process in place; it was working fine. I had a call from Al Hoeting. They wanted a criminal search warrant on a steroid operation up there in Michigan, but it appeared to be an extremely small, insignificant operation. I said, "Well, you send in your background information and I'll set an ad hoc committee and we'll talk it through as to how we're going to proceed." He did. Came in. He brought

with him Denny Degan, and they put on a presentation that was just fantastic. And I decided right there that Denny Degan was going to be the lead person to lead this investigation and to work with Justice and with others, because the guy is just one fantastic professional that knows exactly what to do and how to do it and to work with people. You know, normally, if you were doing things like that, you would pick somebody from the center or someplace like that to run a headquarters to headquarters kind of thing. But in this case, we picked Denny. He went on from there and, in working with the Justice Department, had just expanded this into a national investigation.

I did, because of having worked on Ovulen and having had some experience, set up a meeting with main Justice downtown and the FBI. I got the FBI in again, because, you know, lots of making things work is getting to know others and to know what they can do. That's part of it. You don't go and seek their assistance, because you don't know what they can do. But that's what you learn. Now, field people, generally, have a better understanding of that than headquarters, because they do occasionally work with each other. But that doesn't happen down here, so it was difficult to visualize how you could work this.

We had a meeting down in the FBI, had FBI agents in from various parts of the country, had Denny Degan there, and we had a thorough discussion on how we would work together to conduct a criminal investigation with the Department of Justice attorneys involved, which, it's my opinion, was the first that they'd really worked that way. I think I saw the other day where that has now resulted in a great many criminal prosecutions, an investigation that got started early and got to those people that were the kingpins and really has had an impact. I feel very strongly that if you're going to commit agency resources to these kinds of problems, you have to set up front a strategy that will actually have an impact on it or you shouldn't start it. If you just go out and show a little muscle here and there, they laugh, and it doesn't have any impact whatsoever, because there's so much profit. We saw in this steroid thing where people could just go to very wealthy people in just nothing flat.

RO: Merv, for the record, would you mind discussing a little bit the distribution and the use of the steroids and how it did get to be so profitable?

MS: Yes. There is a great thing in this country, and we were aware of it but had never really aggressively gone out to do anything about it because it was considered to be

kind of a local thing. But you have in this country, in the colleges and universities, and even in high school -- and that's what triggered our interest. We were starting to get quite a lot of complaints that kids in their early teens -- sixteen, fifteen -- were weight lifting and taking steroids to build mass.

We had some medical opinion that would indicate that was some very potential harm in doing such things, and also that there was quite a distribution network. I think everybody knew that there were professional lifters and athletes that were taking these things, and it was always an issue at the Olympics. They've got rather elaborate testing programs now that detect such things. But this ballooning out really started to take off, and so what was happening, for the most part, it wasn't prescription human drugs that were being abused; it was vet drugs that were available for animals that were being diverted for human use. And also from overseas. They were coming from Germany and elsewhere. Although as it turned out, I noticed, some of that that we thought was coming from Germany was actually being manufactured clandestinely in California.

But these people we found, many of them were weight lifters, world class, and they could travel all over the

world and did. I remember one guy from England. I wish I could remember his nickname, but he would bring it in over the Mexican border. These guys are so huge, they could attach tremendous quantities right to their body and come right across and nobody's ever even questioned them, because they're such bulky people, see. But he did get caught, because we worked with Customs and with the FBI and Justice, and they caught him.

There was another weight lifter in Cincinnati, world class, that we were getting search warrants on. I recall, after we had pulled the search warrant and didn't find a thing, he called up and asked to come into the district. The district called me and asked if they should talk to him, and I said, "Absolutely we'll talk to him. We'll take anything he wants to give us." He came in and he told everything. But he was in such business that he was shipping by United Parcel rolls of bills, cash. That's how they handled it so that it wasn't on the books or anything. They would ship cash, hundreds of thousands of dollars. It's just mindboggling, the money that was involved in this. It was just basically an underground network that was making these sales.

Now, what complicated it a great deal for us was, whether or not something is prescription and how it's

controlled by state law. And you have many states, particularly in the vet drug area, that absolutely have no controls whatsoever. So anybody, practically, could buy and sell these drugs with impunity, and that was, of course, making a great problem for us. In addition, you did have, as I think it turned out, physicians and pharmacists that were selling these in large quantities. Of course, that's where letters were sent out to all drug companies and to all wholesalers to solicit their cooperation in not selling unusually large quantities, and if they did, to make sure we knew about it. And there was some cooperation going on there.

RO: Do you recall what the primary steroid was?

MS: Oh, I don't right at the moment.

RO: We can insert it.

MS: Yes. I can't remember. There were several. But it's been quite a while since I had that, and I can't remember. I wonder if we couldn't take a coffee break here.

(Interruption in tape)

MS: I thought I ought to talk a little bit about the Rely tampon problem which gives some insight into the workings of the agency or the department at a particular point in time. The key players were: the commissioner was

Commissioner Goyan; the chief counsel was Nancy Buc; Paul Hile was associate commissioner for Regulatory Affairs; Wayne Pines was the associate commissioner for Public Affairs; Vic Zafra was the director of the Office of Medical Devices. This product, Rely, was a tampon manufactured by the Procter and Gamble Company. The CDC, Communicable Disease Center, I guess is what it is -- they were getting reports through their reporting system that young women, particularly, were dying or being very seriously injured because of an infection caused by Rely tampons, and they had data that would indicate other tampons may also be a problem. But there was no cause and effect established; it simply appeared to be an association.

This clearly gives you an example of the different roles between the CDC and the FDA. CDEC, as a public health organization, truly public health organization, would gather this data, put it into their mortality and morbidity reports, and send it out to the health professionals, mainly, but wide distribution, as kind of an alert to be aware, but not anything that would have to withstand any kind of court scrutiny. Whereas FDA could not take any such stand until we had evidence in hand that would withstand court challenge. That was causing us great

difficulty. They were really adamant that something had to be done and they were pressuring us; and there was a tremendous amount of press interest. We were trying to get our act together as best we could before we would take any kind of an action because, as I say, there really wasn't any evidence of cause and effect. It seemed to be an association, but it was a total mystery as to what was really going on.

It was at about that time that it was really getting very intense that I got a call from Paul Hile at my home on a Friday evening, eight or nine o'clock. Paul said that this toxic-shock syndrome -- and that's what it was called, TSS -- problem was getting so out of hand that there was going to have to be some better management of the problem or the agency was going to be in extreme difficulty; and that he and the commissioner had discussed it and they had agreed that I should chair a meeting in my office next morning at ten a.m., and that there would be lawyers and scientists and compliance people there. We would just simply have to get on top of this and figure out what to do. I said, "Well, I really haven't seen anything on this yet. I haven't had any involvement in this. But okay, I'll do the best I can."

So the next morning at ten o'clock, I came to my office. As I walked in the door, my office was full of people -- lawyers, scientists, predominantly. All around my entire office were Rely tampons taken out of their packaging and made to appear as little white rats. They were posted all around. I think this was mainly Arthur Levine's doing. But you can imagine I'm pretty much uptight, because I don't know any of these scientists; I had nothing to do with them before; I don't know anything about the issue; I've never had any exposure to it. And here I'm supposed to be in charge of this thing.

So my first thought was to get Vic Zafra on the phone to give us an overview of what was this problem so we could start to figure out what to do. So I dialed him up, got him on the speaker phone, and Vic started off as if we were all intimately familiar with it. Before he got hardly a few words out, Arthur Levine says, "Victor?" And Victor keeps right on. He says, "Victor. There are some of us in this room who wear these tampons and some who do not. That is the sum and substance of our knowledge of the matter. So would you start over and give us a better understanding of what you're talking about?" So he did. And after he had hung up, we really still didn't have much insight other

than to know we had an extremely serious problem that we had to sort out.

Of course, there was immediate pressure to get in touch with the senior officials at Procter and Gamble -- this is a Saturday morning -- because the pressure's getting to the point where somebody's going to have to do something or we're going to have to act. So I called, and I can't recall the official, but it was one of the high officials. It was an extremely careful conversation that I had to simply warn him that we were meeting and were considering the facts in this case and that the agency was going to have to act as promptly as we could, and that, hopefully, the Procter and Gamble Company would act as well, so that we could work together in trying to get on top of this problem. As a result of that, there was a meeting scheduled the very next day, a full-blown meeting with the Procter and Gamble Company.

I remember I called one of my staff assistants, Irene Kelly, who worked on device matters, a very bright girl and a person that I felt I needed to do staff work. If somebody had to start drafting things or whatever, I needed somebody that could do that. So I called her at home and asked her if she would come in. In telling her, I told her on the phone, "It's like a Chinese fire drill here." Well,

one of the doctors in the office was Dr. Lillian Wu, and she jumped up and says, "Chinee, Chinee, no Chinee fire drill" (laughter). I said, "I'm sorry, I'm sorry. I didn't mean to . . ." I didn't have any indication that I was getting involved in any ethnic problem there (laughter). "Whatever kind of a drill you want to call it, fine, but we're in a drill here."

Also, I remember as I was leaving the building that afternoon, I saw Commissioner Goyan down the hall. I was going to slip in a . . .

(Interruption in tape)

MS: As I was leaving the Parklawn Building that afternoon, I saw Dr. Goyan down the hall, and I wanted to slip out without talking to him because frankly I still didn't have enough in focus on the matter to talk to anybody. I was trying to get things sorted out. He saw me, and he asked me, "Merv, have you got this thing all under control? How are things going?" And I said something to the effect that, "Well, really, I just don't know at this point what's going on. I'm trying to get a handle on the thing and just don't know enough to say anything at this point." The next day, then, I had, of course, briefed Paul on what had transpired. He had asked me if I wanted to be at that briefing the next day, and I

said I absolutely did. The thing I was hungry most for was intelligence. I didn't know enough about this to really be in charge of anything, and I wanted to be involved in any and every meeting just to be informed.

The next day we had this full-blown meeting, and I must tell you the Procter & Gamble Company really knows how to put on a presentation because they had all their top scientists there, and they went through simulated uteruses and vaginas and you name it. They had done lots of research, all, of course, for the purpose of demonstrating that it wasn't product related; there was some other phenomenon involved. But the pressure was so intense that while we were in that conference room over in Silver Spring, in the Office of Medical Devices, there was the press out in the hall just pacing up and down. If you had to go out to the restroom, you just had to walk through these press people. So the pressure was building just terribly intensely to get the agency to do something. And we, quite frankly, didn't know what kind of a hook we had to do anything.

Following that day-long meeting, it was agreed there would be a full-blown meeting with the Procter and Gamble Company. We had concluded and were already starting to draft injunctions. We didn't know exactly what the charges

were or what the evidence would be, but we were going to be prepared so that we could say, "We are prepared to take legal action," and be ready to do it very promptly if we had to. But we knew there was quite a lot of work that would have to be done before we could really get it out. But that was going on, so that we were going to be prepared.

The company came in, and they had I would say a delegation of eight or nine, headed by Thomas Laco, who was executive vice president. They had with them the chief counsel, Jim O'Reilly, who was one of their lawyers and impressed me as an individual who has a photographic mind. He could cite guidelines and laws and regulations right off the top of his head. I hadn't seen too many people that could do that before. And their scientists. And their advertising people. They had a delegation of people that were top, top people.

We started to negotiate. It was interesting as to our delegation. I've told you who they were. But it seemed like Nancy Buc was getting extremely domineering, I would say, and Wayne Pines. Wayne kind of got out front first. Paul wasn't in the leadership role that I had usually seen him in. I was kind of wondering why he wasn't more in charge. I spoke to him about it. Well, as Paul often was,

he was pretty wise to read a particular situation, and it became clear later to me that Nancy Buc was talking continuously with the department people, particularly Jody Bernstein, who was the chief counsel of the department, and that she really had the power. She proceeded to use that power, as only Nancy could do. But Paul took more of a support role and it didn't appear to me he was doing what . . . I thought he ought to cut her off and take more charge, but it became evident later he was using good judgment in doing what he did. And she cut off Wayne Pines just almost instantly so that he wasn't getting too deeply involved here. Because we had a basic legal problem and, of course, that company knew it. Again, as a public health agency, we wanted them to stop manufacturing and to recall these products. That was the purpose of the negotiation.

RO: Merv, let me ask you this, because there's other tampon manufacturers. Was it predominantly Rely then?

MS: No, but there was a closer association documented to Rely, and it was I think in part because of the tremendous . . . They had a fiber that was extremely absorbent, and it might have been the efficacy of the product that cause the problem. I don't think they've ever documented absolutely what was the real cause and effect. There was no absolute consensus within the scientific

community either. We had difficulty, I remember, with Minnesota and other states that were doing lots of work in this area. They were pulling the scientist's role on us, and that is, they were all preparing manuscripts to publish in journals, and they wouldn't reveal this information to us because, of course, of their publishing rights. It was creating great difficulty for us, because as I say, the thing we needed more than anything was good, solid data to base any kind of an action on. We were having difficulty getting it.

But anyway, we were talking in terms of a recall, and the Procter and Gamble Company wanted absolutely nothing to do with a recall, because in their opinion, as expressed by their chief counsel, that would indicate some liability on the part of the agency, and it would subject them to liability suits; and they really just weren't satisfied at all that they were liable for these injuries. This is, in my opinion, the classic example of how working together in a negotiating session you could work out something that's in the public interest that departs from the norm.

It began to evolve that we would not call it a recall. We never did call it a recall. It would be a market withdrawal, and there would be a consent agreement. So we would give them what they wanted, but they were indicating

they would give us everything we wanted; namely, they would stop production and recall everything, and they would do that within a matter of a month. They had like 350,000 cases of these out in distribution. There were an additional hundreds of thousands in the hands of consumers, and they would recall every one of those, right down to the consumer level.

Nancy Buc, I recall, wanted them to pay for every one of those packages out there as an incentive for them to come back. The executive vice president, Laco, kind of hesitated just a second on that, and Nancy, as only she could say it, said that the consumer would be screwed, something to that effect, unless they did that as a corporation. And he without even batting an eye said, "It'll be done; we'll do it." He would turn, then to whoever was in charge of advertising or recall or whatever, and they would call Cincinnati. We would break for caucuses all the time to give people a chance to go talk and come back. Things would just get done; I mean, just get done more efficiently than I had seen. I remember all these top officials flew in in their corporate jet thinking, I'm sure, they were going to be there for an hour or two, and that was it. They were there three days and three nights, same suits, and as I've told people before,

by the third day, those guys in all of their fine suits were beginning to look more like the government folks at the table (laughter).

But we negotiated every single phrase throughout the entire agreement, and it turned out to be called a consent agreement, which was the first time we had come up with such a document. This was in part because Nancy Buc had had experience at the Federal Trade Commission with consent agreements. And that is in part how this thing was developed. So she had a lot to do with the strategy of the document. Mike Landa was the GC attorney that worked on it that did an awful lot of the wordsmithing, and is an excellent lawyer in working out those things. Then we had to negotiate every single provision and comma throughout this thing.

As I recall, the third night we were working on it, trying like heck to get this thing done. It was about six, six-thirty in the conference room in F.O.B. 8 downtown. The senior executives from Procter and Gamble were concerned because the airport closed at, say, ten or eleven o'clock that night. They were wanting to know if they were going to be able to get out before the airport closed down. We assured them that it certainly looked like they would, because we were essentially done; it was simply getting

things typed and in proper form for signature, and that's what was happening. It was my staff that was getting the typing done, and to do it at F.O.B. 8 and to get that done under this kind of pressure was some kind of unsung hero, too.

At about six o'clock, Vic Zafra stands up and he says, "Gentlemen, I'll have to excuse myself. My wife and I have tickets for the symphony tonight at the Kennedy Center and we're going to dinner before. So I'm going to have to leave." Well, that was an absolute shock. I looked over at Paul Hile and I thought, "My God." I could not believe that a senior FDA official, having held these people there for three days and three nights, would get up and walk out of the meeting at that time. He did. And at the same time, the only remaining device person there was Anne Holt. Anne Holt leaned over to me -- she has a hearing problem, and I was sitting right directly across from Tom Laco -- and she said, "Merv, I've got my car parked in an unlighted parking lot. I think I'd better go." She said it loud enough that you could hear throughout the room. I turned to her, and I said, "Anne, I will take you to your car; you stay, okay?" God, it was embarrassing. It was hard to believe that somebody would do something like that.

But we continued. We got all the documents signed. And I remember when we left that F.O.B. 8, we were walking down through the guard checkpoint there, and I put my arm around Nancy and I said, "Nancy, you are one tough act." She had performed super throughout those three days, using toughness and giving a little as necessary to get this thing done, but to get it done that, as only she could say, would sing when it hit the public. That's what she used as a phrase: "The documents have to sing." In other words, you won't be embarrassed; it will look like we've done what's best for the public. She certainly had done that, and I thought really did a major job. But it was obvious she was an extremely dominant person throughout that entire negotiation.

I think it's a very good example of how FDA could work with industry to negotiate a satisfactory conclusion to a serious public health problem. This kind of a thing, because it was new and is a consent agreement, you would get particularly traditionalists within the agency that would object to it. They don't agree to anything other than an injunction, for example. But if they understood how weak any charge we would have made would have been, they would have thought this was a great solution to a very difficult problem, because there isn't any assurance at all

that we could have won had we taken them to court. And this company, it was clear, was going to fight everything to the hilt because of the liability problem. So unless we could have gotten our hands on an awful lot more data than what we were able to get -- there wasn't adequate data to support the charge. But in going into these negotiations, we had on our own made a commitment that even if it were weak, we were going to go with it just because we couldn't see any other way to handle this. It's very important that the other side be very much aware that you're committed and that's what you're going to do. That makes them, then, come forward to negotiate.

And Ron, I might talk just a little bit about that. It was this experience and some other experiences that led me to believe this could be a very effective way for the agency to handle certain situations. What I wanted to do - - and I even wrote a memo to Paul, which I still have -- was to somehow incorporate this into our enforcement policy with instructions. Because, quite frankly, I objected to the Procter and Gamble Company or to George Burditt coming in and negotiating a consent agreement only because they knew the system; they knew how to make that happen. Whereas some little company that might be just as committed and just as capable didn't have that option; they would

have to go to court. So, I mean, I wanted to regulatize this process. It was never, ever accepted by the field predominantly; they just didn't accept this approach.

RO: Well, didn't we have a similar thing with Travenol?

MS: Travenol was one I was thinking of, and as you recall, that was an extremely controversial thing. But in my opinion, it was not unlike this in that we got everything we could have asked for. Whereas, as the general counsel for that company told the chairman of the board, "There isn't any way that a court will grant what FDA is asking for because it's low-level contamination; there isn't any way they can prove any contamination at all in the bulk of our production." And we knew we couldn't as well. It was strictly a GMP case. And, you know, that a federal judge faced with a GMP concept would take out every single thing they manufactured is almost unheard-of. It would have then placed a tremendous burden on us to demonstrate that lot after lot after lot would have to be destroyed.

The chairman of the board totally dismissed his chief counsel and said, "We're going to recall everything, and we're going to destroy everything under your observation." So we got everything we could ask for. But it could never

be effectively communicated to the field or to others that this was an effective, efficient way to conduct the public business. They just flat-out considered it almost a sell-out. That was one of the real disappointments I had, that we never could get that accepted as a perfectly legitimate way to do what needs to be done. Here we were sitting face to face and negotiating an agreement that was being done within three days. They went out and hired whatever it took. They hired companies to go out to every single outlet to get these off the market -- promptly. If we had gone to court, and had to prove such a difficult case as this, it would have been months and months. And probably we may never have gotten these off the market. Because I don't know that we could have ever reached that level of evidence to satisfy a federal judge.

But anyway, it's one of those things I look back as a very, very positive way to handle a problem. Believe me, there was tremendous, tremendous difficulty in getting this thing done, because it wasn't just the Procter and Gamble Company. There were seven or eight or nine other manufacturers that had the same problem but to a lesser degree. Everybody was exploiting everybody else, and it was extremely difficult to get this resolved.

RO: Didn't they think this was connected to the absorbency of the tampons? And at one time weren't they going to try to label the tampons based on absorbency? Did that ever happen?

MS: Yes, they actually did come out with labeling requirements for tampons. And really, initially one of the main things that happened right off -- and we got Procter and Gamble to do a lot of the funding of this that the agency would have had to do otherwise -- to get out to women these potential problems so they would recognize the symptoms very early, and to get out to the medical profession to alert them. Because it turned out that if they recognized anything unusual and acted promptly, they could usually take care of it very readily. But if you didn't, within a very short time, this staph infection would just overwhelm the system and a perfectly normal sixteen-year-old girl would die. I mean, like one a week or something. So therefore, there was extreme pressure to not permit another death.

But on the other hand, it may have had something to do with absorbency, but that company had done tremendous research, and there didn't seem to be any rational explanation as to what was triggering it. I don't know that they even know to this day what really caused the

situation to occur. But if they followed the labeling instructions, the problems were very, very minimal. I think there actually have been cases of toxic-shock syndrome with Band-Aids and other things. In other words, men have had toxic-shock syndrome, so it's a phenomenon that's not easily understood. Of course, they know a lot more now than they did then. But anyway, I thought that company just performed in an outstanding manner.

(Interruption in tape)

RO: This is a continuation of an interview with Mervin Shumate. The date is February 5, 1988. Merv, when we closed at the last session, you discussed how FDA and Procter and Gamble worked together in dealing with the problem of toxic-shock syndrome in tampons. Off the record, I believe we talked about at least one other issue that you wanted to discuss, and that was the matter of how Herbalife was being promoted, and how FDA dealt with the problem. There may be other things as we discuss that you'll want to introduce. Does that sound reasonable?

MS: Sounds reasonable. I think it couldn't be more appropriate in that I met with the IG (inspector general) from the department yesterday in response to a request from them, asking me if I would talk to them about Mr. C. McClain Haddow. I had said yes, I'd be more than happy to

speaking about him. Because McClain Haddow was the chief of staff of the department under Secretary Heckler. The reason I mention him is that he is unique, in at least my experience at FDA, in that he had absolute power, and he also, in my opinion, operated in a very unethical or improper manner in his position as chief of staff. Now let me explain why I think that's so.

I think it's partly because he worked for a secretary who wasn't very strong. So she delegated an awful lot to this chief of staff, and he very quickly rose to the occasion and exercised an awful lot of power that I, at least, had never been aware of on behalf of the chief of staff. I don't think Food and Drug Administration generally ever heard of the chief of staff before this. I think there was another main reason why he was unique, and that was that he was also fresh off the staff of Senator Hatch, and therefore was used to serving as a senior staffer with Senator Hatch, and responded to the interests of constituents. When he came to the department, he conducted himself in precisely the same manner. He never changed roles. And since Senator Hatch was the chairman of the Appropriations Committee, and was very, very closely tied with the Reagan administration, he conducted his senator's office right through the chief of staff of the department,

such that any client raised a question about FDA, they could have immediate, line access to the agency. That is what I think gave rise to his inappropriate conduct.

I think most of the time he would go through the commissioner, or possibly through Tom Scarlett, to the agency. However, on occasion, he would go directly, as far down as a compliance officer in a district office. I recall one occasion where he went right straight to the district compliance officer and directed that compliance officer to a meeting with Senator Hatch. To me, that is completely inappropriate. Now you can say, "Well, he's the chief of staff of the department; he had line authority over the agencies," and of course, I agree that he did. So it's not a question of him having authority to direct the agency to do this or that. That I don't question. What I do question is the manner or the appropriateness of how he conducted business.

RO: Tom Scarlett is chief . . .

MS: Tom Scarlett is chief counsel. It's significant to note that both Tom Scarlett and the commissioner are political appointees and therefore have to be extremely responsive to the chief of staff of the department. But I wanted to talk about him in the context of Herbalife, and then about other things. Because I think it indicates

something that I really want to wind up this tape about, and that is the politicization of FDA. I think the agency has become so political as I think this discussion will indicate that it's extremely difficult to . . . It might even get to the credibility of the agency as a public health agency. I think that's serious, and that there ought to be something done to try to minimize that. I'll even discuss that a little bit.

RO: You're going to talk about how you thought this politicization took place?

MS: Well, yes, I'd be glad to talk about it.

RO: What caused it?

MS: Well, I've seen it for years. And I don't even argue against it. It's not that. I saw this happening for years, and I think it really started when we got the first politically appointed commissioner, Charlie Edwards.

RO: Goddard.

MS: Yes, Goddard was also. I guess that's correct. But Goddard was new, and I don't think was quite as . . .

RO: He didn't come from outside of the government. He at least . . .

MS: Yes, and he wasn't quite as hard-nosed a manager, I don't think. I'd say Goddard was the beginning of the new era; that's right. But from that day forward, it just

continually got more political. Although I remember some pretty tense moments about conflict between Edwards and the regents, he pretty much got a hold of things pretty fast and was able to protect FDA. He was a strong commissioner that could protect FDA. And as you know, he later became assistant secretary. I have a theory of this; I think as we had consumerism take off and freedom of information, you had FDA thrust into the limelight like they had never been before, and therefore became a very heavy political liability to whoever was in power. So naturally they would do whatever they could to control the agency.

I look at this totally bipartisan. I mean, I don't see too much distinction as between Jimmy Carter, for example, and Ronald Reagan. They both ran against the federal government, and therefore, the so-called professional bureaucrats were always on the defensive and having to defend whatever they ever did. And I know if you defended it too strongly, you could easily be on the outside looking in, just because you defended something. So, I mean, there was a steady progression of this going on. I remember Califano and the Drug Rewrite bill, and how he wanted that through. It was excruciating the pressures to get that out quick. And I remember people would go to Califano if they had a problem with the agency. There were

little questions about it because this had never happened before, really, and all of a sudden, you're being second-guessed about things, and immediately, of course, the suspicions were it was strictly political. And I'm sure it was very political.

Then, of course, you got the Reagan administration in. I see a difference between Reagan and Carter in that Reagan was much more effective in how he got control of, say, Food and Drug. Carter spoke the same philosophy, but he didn't have an effective mechanism to control us. Well, delegation of authority was taken away; OMB (Office of Management and Budget) was put in charge of the regulatory agenda and the agency had to submit them annually and get them approved; regulations had to be approved. So all of a sudden, you had not only the department but OMB making decisions, and those are very political decisions often. That means you have a much longer pathway; you have people involved that don't have an institutional understanding of what the agency's traditions have been. All of a sudden, everything's up for grabs, and it's a whole different ball game. Very, very political.

You recall as well as I do that as these changes occurred and they began to affect the agency, it could be understood by those of us here in headquarters who had to

interface with these people because you could see and feel and understand what was going on. But the field organization generally, they didn't understand it and they didn't want to understand it; and therefore, you had a problem within the agency because you had people resisting change. I know there was no way with the power these people had that you could resist it. If you resisted it, you wouldn't be part of it. So you had to learn to try to cope and to work with them. And hopefully, with such credibility that they would accept and modify what they did to some degree. But that meant you had to work like heck to sell everything that before was taken for granted.

RO: The field didn't even want FDA headquarters interference, let alone outside of FDA.

MS: Yes. And I have to say in my job, trying to handle cases, for example, I often had much more difficulty with the field than I had with others, at headquarters and outside. They resisted it and sometimes made things extremely difficult. Because there's one thing I don't disagree with, and I know Paul Hile doesn't either, and that is, these administrations do have a mandate when they come in. Reagan had a mandate to deregulate, and they laid down some pretty clear guidance on their philosophy; that is, you're not to do things that are theoretical.

(Interruption in tape)

MS: You're not to mess with things or waste resources on things that are theoretical or insignificant. Such things, for example, as safety. Well, Food and Drug has a mandate on such things as food additives and on OTC drugs and things that aren't really any question of safety; but they are subject to FDA approval, and they are proprietary. So you have to maintain a certain system whether there's this question of safety or not. But there was always that pressure, that friction. And you were to lay out a year in advance what your regulatory initiatives were going to be. You know, that's difficult as heck to do before you've done a lot of staff work. So I don't question that mandate. I think that's appropriate; that's what the people have done. Then we as professionals should figure out how we can do our public business within the framework of that mandate.

As you know, as the pressure got really heavy, Paul had his standard civics lesson that he gave. It was all for the purpose to try particularly to get the field to understand . . . And what he would do is he would give his civics lesson by showing the president and the secretary and the commissioner and himself; and the field, of course, could understand that he was in charge of the field and whatever he said they did. Well, he would make the point

that, "If the commissioner tells me to do something, I do it. And if the secretary tells him to do something, and if the president . . ." He was trying to say that. I don't question that; I agree with that. Where I had a real problem with these people is they politicized it. They didn't tell us to revamp our policy with respect to seizures. They would single out a specific company and product and try to force us to change what was agency policy. Well, that's wrong, and that really was difficult. Maybe I can describe that I'm not getting to Herbalife right away, but I will.

I can describe that in one particular case I had where I got a call from Tom Scarlett. He asked me if I had some seizures in-house of Sandoz. I said, "I don't know; I'll check." I did, and I said yes, I do. "I want you to hold those. Don't forward those until I tell you, because Sandoz is going to meet with Deputy Commissioner Norris." "All right, fine." Time went on and time went on, and of course, the senator is pressuring us as to "why aren't you processing these seizures? They're consistent with the DESI program; why aren't you processing them?" So I finally kept talking back and forth with Tom. Finally Tom came to me one day and said, "Well, we've done everything we can with the commissioner's office, and we're not able

to get them to do anything with this. I think it's time for Regulatory Affairs to go to them." Of course, you have to understand, you never had the benefit of a clear communication as to exactly what was going on. You simply were getting the conclusion of somebody. You weren't told who's got what political clout with who, but you know something is going on, or you wouldn't be directed to hold them.

Anyway, I went to Paul and I told him, "I talked to Tom and I've got these seizures. We can't move them. They're hung up in the commissioner's office, and we're going to have to talk to him about it. I think you should do it because you know these people better than I do and I don't know how I can press them or how much or whatever." He said, "No, you're going to do it" (laughter). So we went in that afternoon, late. I proceeded. Paul said that I had a matter to discuss with respect to some seizures of Sandoz products -- they were DESI drugs, is what they were -- and that Merv would do the briefing.

I started off and tried to allay any of his concerns in it by saying I had personally reviewed these files and had in fact discussed it with the reviewing division in the center just to be sure it was solid and that it was consistent with our DESI program. Because I have to

quickly add, when you get something that appears to be possibly political, you want to be absolutely sure you're credible. And I had had seizures, particularly DESI seizures, sent to me from Rudy Apodaca's shop that were often not credible. I mean such things as they're going to be approved tomorrow and they send you a seizure today. Things like that; there isn't any need to get into a contest. The company is not telling us to go stump it; they've got the data in and it's about to be approved. So there's no benefit to anybody to go out and go after them. But I had experiences of that happening. And particularly, if I thought the department was involved, I certainly didn't want anybody having us to lay our files out and find that to be the case, or I knew we'd look stupid. I had assured them of that.

Well, before I could really hardly say anything, he interrupted me and said, "What you need to understand is, I'm philosophically opposed to seizures" (laughter).

RO: This is the deputy commissioner.

MS: Deputy commissioner of the Food and Drug Administration. I sat there absolutely puzzled. Opposed to seizure? I mean, seizure is the foundation of the Food and Drug Administration, and here are the two senior enforcement officials of the Food and Drug Administration

sitting before the deputy commissioner, and he makes this statement.

So I kind of took a deep breath and I thought, "Well, I'll lay out the alternatives and give him a little lecture on what our enforcement strategy on this and what is the effect if we don't carry this through." So I proceeded to tell him, "Injunction is an option, but it really isn't an option because a federal judge is not likely to close down a company that's been marketing a product for thirty years on a DESI announcement. So we're likely to lose. You don't want to lose in a case like that."

"Criminal prosecution is an option, but you're not going to bring a criminal charge against somebody who has been legally marketing this for thirty years. And in fact, seizure has become a remedy that both parties completely agree with. We seize a lot; we don't stop their production -- they continue producing; the courts decide who's right; and everybody understands the process. It's worked fine. As a matter of fact, it's worked since 1962. And if we changed it now, it would be a major signal to the regulated industry that the agency has taken a change of policy. I don't know how we could explain it."

Well,

Well, he said, "But you don't understand. I'm philosophically opposed to seizure, and so are the other folks downtown." Well, what are you going to do now? No discussion of the merits, nothing. That's just all he said. Well, Paul said, "Well, John, we'll go back and we'll think it over and get back to you." I swear I couldn't figure out what we were going to do. But anyway, we left. We got out in the hall and I'll never forget it. I have to tone my language a little bit. But I was angry; I mean, I was really angry. To think that this guy was telling us this. Paul looked at me and he says, "Gee, I wonder if he includes filth in that?" I looked Paul straight in the eye and I said, "He doesn't know what the hell filth is and don't tell him" (laughter).

Paul told me later that he'd had discussions previously with him; so it was a philosophy problem with him. That was, he was opposed to the admiralty provisions, which say you can seize and then determine the merits. He was opposed to that. But now that to me is a perfectly appropriate thing to tell us in a generic setting. But for us to be discussing some specific company and specific seizures, without raising the question across the board is totally inappropriate. That's what I was so opposed to, see.

I had been told by the grapevine -- and I haven't any idea whether it's correct or not -- that Secretary Heckler had been to Sandoz in Switzerland and she was very favorably impressed with their company, and that there was a great and wonderful relationship. Well, those kinds of things just make you feel terrible when you're the guy sitting there with those seizures and no good rationale as to why you weren't doing anything with them. They were still there when I retired. I'm told they did finally go through after I retired. I suppose after Haddow left, because again, I'm quite sure -- although I don't have any direct knowledge -- that it probably came from Haddow or the department to Norris, and then through Scarlett, or maybe to Scarlett directly to me. I don't know. But anyway, it gives you an example of a philosophy and of a practice that was very political, in my opinion.

Well, that kind of sets the stage for the discussion of Herbalife because that was really a traumatic thing. The district had been monitoring this company. It was one of many companies similar that had an awful lot of vitamin-mineral products. They were making claims that were clearly drug claims. But they were not the most flagrant claims you've ever seen. Pretty much typical that you've seen.

RO: Out in California?

MS: Out in California. And I'm sure people at the time noticed there were Herbalife signs on mailboxes and bumper stickers. They had 100,000 dealers in the country or something.

RO: Almost a pyramid.

MS: Really what it was was a pyramid. So they made their money on the pyramid deal more than on sales, actually. The reason they were so unique is that this young man got into the cable network business system; and that's how he was able to really make this into I don't know how many hundred million dollars a year, but an unbelievable amount of money. And there was even one question, I think.

There were some deaths on some of the weight-control things. But the commissioner personally reviewed the autopsy reports, and there wasn't any way you could say with any certainty there was a cause and effect. People had other kinds of problems or something. There was just a little element of that, but I don't frankly think it was anything too credible; at least, they weren't able to pinpoint it. That's one thing that's been true with respect to the quackery program. If there was a question of safety, there was never any question in the minds of

anybody at FDA as to how you proceeded. Now, there was tremendous disagreement and dispute once you got in the economic area. That's where it really got difficult.

But at any rate, we had a hearing coming up. I don't know who it was before. I don't know if it was Weiss or who. I can't remember. But anyway, we had a hearing come up, and I got a clear signal that we were going to have to do something about this company. So I convened an ad hoc committee meeting. We really worked hard to figure out a strategy to take this company out. I mean head up. Of course, you can imagine what a massive investigation that would be.

That's another feature of these quackery cases. You have a tremendous investigational problem to tie oral claims on cable television to products and all kinds of things. It's hard to do, particularly where people are well counseled, and they had Kirkpatrick & Dillon who was the best as far as quack products. They're pretty slick on how they proceed. So it's difficult to make a case, very expensive. But we were prepared to do it, and what we had in mind is, we were going to make seizures in all of the regional warehouses around the country. It would have been a massive operation that would have really taken them out.

Well, as we were getting down toward the hearing, all of a sudden we get the word that there aren't going to be any seizures. I was told, and I don't know if it was Paul -- it must have been, but I can't be sure -- that Senator Hatch had had a discussion with the commissioner, and there were not going to be any seizures; there wasn't even going to be any Reg letter. I remember at the time I thought, "That's strange. How would a senator even know about such a thing as a Reg letter?" But that's the word I got.

Well, now we've got all this momentum underway. Boxes of paper are coming into the headquarters, all for the purpose of generating a big seizure, and here we are with other signals. So we were getting ready for this hearing, and I remember that was quite excruciating, because in getting ready for that hearing, naturally again, you have to be very careful of the credibility of the agency. Because you're going to put the commissioner before the hearing, and you've got department as interested as they were, you've got to be absolutely sure of what you're talking about. So Paul and I went through every single page of this evidence that we had, and we found some things that were not good, as far as backgrounds and warnings and some letters that went out. I remember one letter a

compliance officer in Los Angeles sent. Deborah Grell is her name.

She had sent a letter to the company, or Kirkpatrick & Dillon, chastising them about the illegality of a vitamin-mineral product. Kirkpatrick & Dillon had been the lawyer on the case that she cited. And it was pre-vitamin-mineral amendments, such that it no longer was an appropriate case. And of course, the vitamin-mineral amendment clearly set the tone which was drastic change as far as the Food and Drug Administration was concerned as to how we approached the vitamin-mineral business. So you know, we had a few things like that that was making the case a little weaker than what you would like.

But at any rate, the commissioner got prepared, went through all of these autopsy reports. And I remember the pre-briefing in F.O.B. 8 before he went over to the hearing. There was this young man sitting in the conference room I had never seen before. He was a good-looking young man, very well dressed. I asked John Taylor or somebody from legislative affairs, "Who is this guy? I've never seen him before." I thought I knew everybody that would be in a meeting like that. "Well, this guy is a young staffer right out of Mac Haddow's office." And he never said a word; he strictly sat there throughout. But

you can imagine what an effect that has on FDAers when Mac Haddow's got his own rep sitting there monitoring everything that's being discussed. Of course, I'm sure the commissioner knew exactly who he was.

But anyway, we went over to the hearing, and it was another one of these partisan political things, because the hearing was being conducted by the Democratic chairman. And here we have a Republican administration, and of course, then you get into the who-struck-John kind of thing. I know there was one food-additive thing that I think John Taylor really got worked over pretty good on. It was from Fiji, if I remember. John had been over to Fiji on a detail over there. I cannot remember what it was. But anyway, it was a thing that clearly needed to be taken care of and hadn't been taken care of. Of course, commitments had to be made to take care of it as promptly as possible. But the priorities or significance really loses in that kind of a debate; you're just really under an intense scrutiny.

Following that hearing, then what do we do next? We've got all of this going and the signals are, we're going to work this out. So we're going to set up a meeting with these people. We had to work to get an agenda up, and it was being coordinated with the department. I remember

that Paul was just uptight as heck. We were having to prepare talk papers and all kinds of things because the pressure was so intense to explain what we were doing. So you're really losing control of what you can do. One hand, you're being pressed to go out there and take care of this terrible problem, and on the other hand, you're being told you're not going to do anything.

So I remember I told Paul that we just absolutely had to have a session with the commissioner, because I just had to know. I couldn't hold an ad hoc meeting or anything and give instructions on what we're going to do unless I get some pretty clear indication of what we're doing. Because I just didn't want to go through this process again; you'd lose all credibility. "No, we're not going to go to the commissioner on this." So I said, "Well, then, you're going to have to be at this meeting, because I need to have some help here on what we're going to do." And I've of the mind that by this time I'm going to talk pretty straight. Because I'm losing all credibility and I'm not going to take this anymore. We had it down in the CVM conference room, and I remember Paul came; but when we walked in the room, he told me to sit down at the head of the table (laughter). Well, I knew he wasn't going to be there very long.

But I was ready and I started. I was very candid about the hearing, and how we were going to have to figure the best way we can to get the most accomplished we can. But it wasn't likely going to be any mass seizure campaign or anything like that. As I got really going, and I was pretty emotional, Paul put his arm around me -- and I'm sure he was trying to signal that he was supporting me and also to give them a sense of the difficulty of the problem, but not talk absolutely straight -- but he said, "Well, now you people here need to understand that we've got to handle this. This is a very sensitive situation and we've got to handle this just right. Because if we don't, somebody could easily be swinging slowly in the breeze. Now, if that's Merv, that's one thing, but if it's me, that's not going to happen." I put my arm around Paul and I said, "Paul, I've often thought it, but I never thought I'd hear you say it" (laughter).

But you have to understand that by that time, you're getting so pushed up against the wall that you don't really care anymore; you're just saying, "Hey, wait a minute here; this isn't right. Here there's obviously political overtones and involvement. But nobody's communicating to those who have to do something. What the heck are you supposed to do?" And I think that's what happens when you

get into a political thing. They have to have the deniability argument like Reagan and the Iran-contra affair. They don't want to talk too clearly because then they would be clearly on record and accountable. But if they give signals and you're doing your thing, well, then, of course, they're free. That's one thing I objected to in a political thing. I feel that if you're going to politicize the agency, then you've got to make the political decision and be accountable for that. You shouldn't ask a professional who isn't a politician to be accountable for that. That's what I felt was happening, too; you were being forced to be responsible for something you didn't even necessarily agree with.

But at any rate, we went ahead and worked it out as best we could, and then got ourselves prepared for this And you have to understand, the field people there were not happy at all; they were wondering what the heck you're doing and why this. It's difficult. So we had a meeting. The way it was going to be worked out is, we would have a meeting with the president of this company who had requested a meeting. He had said at the hearing that he didn't understand all of these requirements of the Food and Drug Administration, and if anyone would tell him what was

required, he'd be glad to comply. And this kind of stuff. That meant we had to meet.

So we worked hard to get an agenda prepared. I remember when the meeting came off, we had no clear understanding of how the commissioner and the deputy commissioner were going to fit. We had worked out what we were going to do. I got the word -- and I must have gotten it from Paul -- that these people had met with Haddow before they came to the Food and Drug Administration. Well, you can imagine, again, what kind of a signal that gives. You don't have any clout. You know they've probably already agreed on what's going to happen. And you're having to face this Young Turk of a president who knows he's got all the marbles. That's a very uncomfortable situation for a regulatory agency, because in every situation, when the president of a company comes in, he's sitting across from you and you're the one with the hammer. Well, in this particular situation, this guy's got the hammer -- or you have reason to believe he does.

But it didn't turn out too bad, and I know I was relieved. As soon as he started to speak, he indicated he was going to do whatever was required to comply. Well, that was good news, because if he had said, based on his discussions with the department, "The heck with you," I

don't know what we could have done, really. I just don't know what we would have done. It would have been a very tricky situation. Well, I remember the commissioner got up, and here we had all these signals of accommodating these people and trying to work it out. He gets up and he gives a lecture like he's talking to the Kiwanis Club on the horrors of quackery. It was just a bizarre experience.

I know Paul told me that that night when he went home, he had a glass of Scotch; and when he took a drink, his muscles relaxed, and it was just like he'd been run over by a truck. He was so tense, he could hardly stand it. I remember I told him, "Well, Paul, if you were that tense, you've got to do something because you can't stand this kind of treatment very long. The body won't stand that." Paul started the meeting, and I remember he was so tense that he was having difficulty talking. So to relieve him a little, I just put my hand on his arm and I interjected to say something not . . . Well, it was intentional, too. I had carefully reviewed the file, so I knew exactly what the facts were. I wanted to signal them right away that I knew the facts, and that there were claims, and that they were significant. So I said something like that just to make sure they understood they were not talking to people who didn't know anything.

RO: Were these labeling problems, or was it promotional?

MS: They were labeling problems. See, by this time we were left with just labeling problems. And they were not labeling problems of really any consequence. Now, there had been in the past sometime some brochures that they claimed they didn't distribute that distributors generated; but I'm sure they were part of the scheme. But by the time we got right down to it . . . And let me tell you what we did. We had to be prepared -- and in an extremely short time -- to tell them what our concerns were about these products. You can imagine the difficulty of getting senators to review these kinds of labels. They're the most low-priority kind of thing you can get. That was following the meeting. We were under such tight constraints and so much pressure, I told Paul, "We just ought to take over the EDRO conference room, designated to Herbalife strategy."

RO: Command center.

MS: "Command center. Request centers and GC to designate people" -- because we had foods and drugs and whatever, a whole hodgepodge -- "into that conference room and they shall stay there until we get this job done. Because I don't see how we can ever do it if we don't."

And that's what we did. I remember it very well because we worked the whole doggone weekend. There was a Redskins game, a playoff game or something, we wanted to see so darn bad. We were able to turn on the set, but it was so snowy you couldn't see anything. But we did do it; we did get it done. I remember they were not all that significant, but we had to get them to them.

RO: Some of these products, I guess, were considered as foods, and some as drugs.

MS: Some were foods, some were drugs. There were some food-additive questions. I've got some here, for example. They were herbs, and vitamin minerals. One was Tangkuei; that might have been the one that from was Fiji. I'm not positive. Pollen and yeast tablets, I guess; it was a mixture of stuff. It's the kind of stuff that you see in health food stores.

We then had to meet after that for a long time with their lawyers here in town and work this out. I think I've heard just recently that they're still not done with this, to this day, on this mess. But I remember that the people who came in to represent that company were from a law firm here in Washington. Paul was told that this guy, Paul Manifor, was a lobbyist of the highest, absolutely highest stature. He could pick up the phone and talk to the

secretary of HHS instantly, wherever he was. He had entre to the White House anytime. It was clearly recognized that they were not Food and Drug lawyers, but they were extremely well-dressed. That has kind of an intimidating factor, too, when you hear this kind of thing, that these people are not really lawyers, they're lobbyists. I saw after that some time that they have such accounts as the Saudi Arabian account; they're lobbyists for the Saudi Arabians. So, you know, they're in the big leagues. It was a very intimidating situation, which further indicates the political ramifications of this. But the nice part of it is, this guy came in and agreed that he'd do whatever had to be done. So we at least didn't get into a head-to-head confrontation. But we had to work our way out of it.

Paul told me one other thing, and that was -- and I think that might have offensive literature, but it wasn't an effective recall; it was just asking people to destroy or something. So we wanted them to go back and get all that in, to recall it. They agreed to do it. So a very few days after this meeting, LA goes out to do a recall thing as normal. Paul says that they called Haddow and Haddow called and ordered him to his office, that the Food and Drug Administration is harassing these people. Paul said he went to Commissioner Young and he said, "I've been

ordered to Haddow's office, and I'm going to go. But I tell you, I've got a lot of years here, and I've got all I can handle, and I hereby offer my resignation."

(Interruption in tape)

MS: Paul offered his resignation, and the commissioner said, "No, I'll not accept your resignation and I will go talk to Haddow." So that's how it was resolved. But now, if you were sitting in Paul Hile's shoes and a guy by the name of Bob Weatherell has been summarily removed from his job -- and I am sure Mac Haddow was the one who was instrumental in his demise -- you've got to be very concerned about that. Here you are with thirty years of service, or twenty-eight years of service, and all of a sudden, you're totally intimidated on what you're doing. That's what it amounted to. So it gets really tight. Now you know Paul was probably one of the best masters at responding to these people's wishes. He and Weatherell both worked as hard as anybody to satisfy these people on anything they asked. There was never a question about it; they did whatever they were told. They were good soldiers.

But that's the Herbalife thing. It created all kinds of tension within the agency. But I think it clearly illustrates how political even a thing like that got, which

really affects the credibility of the agency. There were often the words made -- and I can tell a couple others, too -- is that all Haddow would say to some senior person? Is that all you've got to do down there is to work on these kinds of products? What are you wasting the taxpayers' money for? You see, if he raised that question in the generic sense, I think that would be completely appropriate.

For example, quackery. I truly believe from the secretary . . . And I've heard comments attributed to the secretary; she, I understand, lectured the commissioner one day about, "Aw, you M.D.'s are all alike. You're just never happy with anything. You want complete safety on everything. What the heck are you worried about?" on some quackery kind of a thing. It probably wasn't a genuine safety thing again; it was an economics, probably. But anyway, you had a philosophy. I think you've heard of the president carrying bee pollen in his Air Force One. You had a philosophy that went right through the administration that really pretty much said you don't regulate that kind of stuff; it's not worth the money. If they would have said that in a generic sense and directed us to come to that, I would have no problem with that; I think that would

be perfectly appropriate. But raising it in the context of a specific company to me was totally inappropriate conduct.

RO: Because there were times when, as far as strictly economic violations, we didn't do it.

MS: Well, we never touched them because we couldn't. We knew that. We always went right after any genuine questions of safety, and we went after those that were flagrant violations. But there's a whole range of things that we never touched because it was just not anything that you really could . . . I guess the best description the chief counsels have given in the past, and I noticed the commissioner gave it in a hearing before Weiss just recently on health messages, the question was whether it met the "Hee-Haw test": would the government look silly bringing this?

Now, you know, that's a judgment call that people have very differing opinions on. You've got some district and some headquarters people that feel that you have a duty to go after every violation. It doesn't matter how insignificant. Then you have others who say, "Wait a minute. We've only got X amount of resources. We can only do so much. We'd better do that that represents the most serious problem to our society. And also, in doing that, you'll have a little more credibility to the courts and to

Congress and to others," given the vitamin-mineral amendments and this administration and everybody saying, "Get out of people's affairs; they can make their own decisions."

RO: Getting back to Herbalife, the agency never did take a legal action against them.

MS: Absolutely not. There was no legal action to be taken. That could have come from the hearing when he made representations that he had never been told by the Food and Drug Administration. Really, when you got into looking at the file carefully, we never did really give any clear message of what we expected. I remember the district referred some matters to Foods and Foods bucked it over to Drugs, and you had a Food-Drug combination. Nobody got back. I think they did get a response on some from Foods. That was communicated, but the Drug part of it wasn't communicated. So there wasn't a good communication to the firm on the status of different products. That contributed to our problem, too. So I remember when Paul and I were going through that file real carefully, we didn't feel real good about where we were sitting in a regulatory setting, and that we really needed to get our act together; and that's why we did.

RO: I suppose that under that climate, you couldn't even consider a "voluntary injunction"?

MS: Absolutely not. There wasn't even any thought of it. I mean, when we're getting clues that there's not even going to be a Reg letter . . . Now, let me tell you, the letter that actually went to that company was a story in itself; I forgot that. Paul called me one afternoon, and he said, "Merv, you're going to have to come to my office right now. The department wants a letter drafted to Herbalife, and they want it this afternoon. You and I are going to have to craft the most careful letter that you can imagine. You just come up here right now, and I don't want you talking to anybody on your staff about it." "Okay." I went straight up to his office, and I hadn't been there five minutes, and I'm trying to get an understanding as to just . . . Because, you know, when you're writing a letter like that with all of this political, you want to be very careful. Normally you don't write something like that without staff support, because they have knowledge that you can't possibly know.

But anyway, I'm there; I'm going to do the best I can. And by gosh, within minutes, Paul goes to a meeting with the commissioner. So now I'm sitting there and we've got to have this this afternoon. I rewrote the first draft and

it was rough as heck, just rough. About three o'clock -- this was probably twelve-thirty or so when he called me -- he calls me and says he's talked it over with the commissioner and the commissioner said, "Don't worry about the department; I'll take care of that. You don't have to do that today. I'll tell them we'll get it there, but it won't be there today." I felt relaxed. He said, "But don't stop working on it." "Okay, fine, that's great. Maybe we'll have a little time to think this through a little bit." So I went ahead and I gave my draft to Lyn.

At about five o'clock, in walks Norris. "Where is this draft letter?" I said, "Well, Paul just talked to the commissioner and he said we don't have to have it today." "I want that now," and he took it right out of her typewriter. I hadn't ever seen the draft; Hile had never seen the draft; nobody had seen the draft, and he took off right straight to Haddow's office. Well, you know, to be doing business like that totally, totally destroys you, because then they can say, "Well, what kind of a crew have you got over there putting together something like this?" You never had an opportunity to do anything, see. And I never had a real good signal as to what is this letter supposed to contain?

Anyway, he took it down there, and about that time, Paul went on leave, and Jim Swanson came in on detail in Paul's job. He and I had to spend a few sessions with the commissioner and the deputy commissioner and Mary Francis Lowe crafting this letter. I remember on one of those sessions, I had a tremendous urge to stand up and say, "You can take this thing and do anything you want with it. I've had all I need of this." And I thought to myself after I walked out of there, "Geepers, cripes, you'd better out of here, because it's getting more difficult every day." Here's people working on a letter that have never handled anything like this. They're so careful about this and that that you begin to wonder, "What is this, anyhow?" It just shows you the political status.

I know Swanson had a tremendous education about that. But he got right in the system; he understood what was going on and got the thing done. I think, as a matter of fact, he might have worked over the weekend and retyped and typed and retyped. It was amazing to get that thing done and out of here.

But after a while, you get to the point where there's no credibility. I've talked to Paul a little bit about this, and thought about it, of course, having had that session with the IG yesterday. There's just a question in

my mind that you have to really think about, and that is, what amount of money did Senator Hatch or this administration get from the president of Herbalife to get the kind of response he got? You know there had to be something. There's no way he could have gotten that just as a citizen. So I didn't say, and I can't say -- I have no knowledge that anything occurred; but I have to believe something may have. So I'm just suggesting that if somebody could take a look at that, they might find a quid pro quo. How could you get these kinds of lobbyists involved, and this kind of conduct with Haddow personally involved, and the commissioner and the deputy commissioner, on a case like that without something. So that's just a question that I have in my mind, and always will have. But that's the Herbalife story.

Now there's a couple of other stories very similar to that. I can't remember the name; I think I would have never forgotten it. A very small company. They didn't have any technical staff. It was strictly a marketing-sales organization. It seems like Mountain View; some such name as that comes up. It was a Utah firm, fits the pattern: Hatch constituent; direct line to the chief of staff, the department. He had a me-too drug of a hand-wash preparation that was supposed to be antiseptic. I wish I

could remember the chemical, and I can't even remember that.

But anyway, it was a me-too drug and he wanted FDA to approve his ANDA, but he didn't have safety data to substantiate approval. It wasn't an ANDA; it was an NDA. He got session after session with the commissioner and all the staff. It was Novitch that sat in on it. And then with Hank Meyer and Bob Temple, and Dr. Finkle -- everyone explaining the New Drug process. There were regulatory people there. I was there representing ORA. It was a bit difficult because of the fact that there were approved NDAs and we were aware that there was a perfectly safe substance. There wasn't a genuine question of safety; but the safety data was proprietary. It was not something the agency could use in approving someone else's. They would have to either generate the data or quote the literature, and they couldn't do that.

So what we were confronted with was having to defend the drug-approval system. And if you change, you have a major problem because the innovators are going to be all over you. So you don't have a chance, really. But it was one of those very insignificant things that you couldn't justify. There again, it fits the pattern: "What are you

wasting all the taxpayers' money on something like this?"

(laughter)

Anyway, we had some seizures recommended. And by gosh, this guy came right in. I remember the words was, you were not to seize those. I don't know who the calls were made to, but I do know that's the only case that I'm aware of where Haddow had a staffer that was actually calling me and asking me about the status of these. That never happened any other time. I don't even remember exactly what he required. But I know I was sending over information to hm. I had to get the information together and get it over to them that would describe what we were doing. And again, that was the first time it came up that they were philosophically opposed to seizures; and the one way we were trying to work our way out was to go for an injunction. I think that might be what we ultimately may have done.

But this guy obviously had all kinds of clout and he was getting the highest officials of the agency to talk to him about things that, under normal circumstances, he wouldn't have had even a minute's time. It came out, for example, that he hired a chemist to formulate his product, and he made an error in formulation. Well, rather than reformulate, to have it formulated the way it was intended

originally, he simply amends his DNA to reflect the misformulation. Well, that begins to give you some clue of what kind of an organization we're talking about.

The reason that that case is a bit significant to me is that when the ANDA and Patent Restoration Act were passed and signed by the president, I remember looking the *Washington Post*. And who is standing directly behind the president but the president of this company (laughter). Someone had told me that they had ridden on a plane with him back to Utah or Denver and they'd overheard him say something to the effect that he could do whatever he wanted to as far as this agency was concerned. So that was the kind of thing that indicates another one. And all these have several things in common, that is, they're Senator Hatch's constituent.

There was another outfit out there, Nature's Way or some name such as that where they had a lobelia, another food-additive question. The district wanted to sample for seizure and had put it under state embargo. Well, if you put something under state embargo, you've really got the agency in kind of a bind, because if you don't seize it, you've embarrassed the state, and if you do seize it you're all right. But here again, in this particular situation, those people came in to meet with Haddow with a state

legislator. Haddow called Miller and they walked right across the street to F.O.B. 8 and had a real heads-up session with Miller and John Taylor. They would have to be the ones to provide the details, but that's the kind of clout that a constituent could get if they came in and wanted to talk to the top of the agency. That's what they did. We never did seize those things. The word was, you're not going to seize them. Here they were, under embargo.

I remember I was supposed to craft a letter to go the company to force the issue, but I was concerned about how to do it because I knew with that kind of clout, if you ask them to destroy, they're going to tell you to go pound sand. Somehow, we did get a letter out there. I don't know how we crafted it, but the regional director, Leroy Gomez, sent it to the firm; and somehow the firm did agree to stop selling or something. For the record, we got it cleared up. But under normal conditions, you would have seized a product like that. They had warning; they had everything set to seize.

The reason I bring it up is that when you have these kinds of things happen a few times, you have district people who even know less than you do really start to wonder how political are we getting, anyhow? I remember I

had to go out and speak at Denver, at one of those regional meetings, and of course, was pretty intensely questions about these kinds of things. I think I was pretty sharp in my response to suggest that if they had any direct connections to Senator Hatch, why, they could also get pretty good treatment (laughter). I mean, you get to the point after a while where you can't defend it. If you do, you don't have any credibility at all.

But that pretty much covers what I had to say with the IG yesterday about Mac Haddow. I was told by the IG he is now in jail, and the reason he's in jail is because something he set up and his wife was paid public moneys, which was completely illegal. Obviously it was, or he wouldn't have gone to jail. But my impression of the man is -- and I've never met him -- I know this, that he spoke at the FDLI in December of 1985, just two weeks before I retired. There had been a lot in the trade press about this administration causing an exodus of senior officials at the Food and Drug Administration. He gave a rather careful speech that that was not so, that he had had his personnel people review the data and the data confirmed that it was as perfectly normal as it always is. Well, at the particular time, I was retiring and Crawford was going to USDA, and Novitch had gone to Upjohn not much before.

But the significant thing is that within the two weeks, the day before I retired, Paul Hile called me into his office and said, "Merv, I have to tell you something that I find extremely difficult. I have been informed by Gerry Meyer, who was informed by Mr. Haddow, that they have withdrawn your SES bonus because you're retiring." I said, "I cannot understand that. I thought bonuses were for past performance, not for future." Well, that's the way it is. They've withdrawn it and I understand that Crawford isn't going to get his because he's going to USDA. Well, that shows you what kind of an operation we were confronted with there. He was miffed, I'm sure, because people were leaving, and one way to kind of take care of that is to just make it clear that you don't get any bonuses if you leave.

RO: Let's not reward anybody that's leaving.

MS: But as far as I'm concerned, a person that's eligible to retire can retire and shouldn't be in any way penalized for doing it. As a matter of fact, they ought to give incentives for some (laughter). But that was something that really, really made my last day here very, very depressing. I had really thought that was terrible. And, as a matter of fact, if I had been smart, all I would have had to do is not tell anybody and handed my papers in,

and I would have gotten it. But I thought I should tell them so they could make plans and do whatever they needed to do, which is the usual thing to do. But that was terrible.

Now, what would I say right quick as to how you might fix this? Well, I think it's terrible for FDA to be so political. I'm not saying, though, for a minute they shouldn't be sensitive and subject to the general public concerns about what we do. So you've got to carefully construct something, and possibly the way to do it . . . I remember Senator Gore actually spoke at that same FDLI meeting that Haddow spoke -- he spoke either right before or right after it -- wherein he put out there that he thought the commissioner ought to be subject to appointment, that there ought to be congressional approval, and also that they would be in for a set number of years. In other words, it would be taken out of the department and made an independent agency.

Well, I know other independent agencies, and I'm not sure that makes all that much difference. But I do think there would be something to a commissioner being in for a certain number of years. Because then they aren't quite so subject to the whim of a political situation, not quite.

If they're appointed, say, for four years or six years, or whatever you say, they're there.

RO: Yes, but Merv, look at some of these independent agencies. They're appointed, and they leave within two years of their appointment for an outside job. They go back to academia or whatever. So I don't think there's any guarantee.

MS: No, there's no guarantee, by any means. All I'm saying is, there really needs to be some way that FDA can be depoliticized because I think when you come to the public health mission of this agency, you really shouldn't have politics. I'm talking about the kind of politics I've been discussing here. I think the agency should have to be subject to the mandate of the administration that's in power, of course. But if you stop and think about it, just the congressional oversight of this agency is just unbelievable.

RO: Oh, well, you take the last fifteen years.

MS: The last fifteen years, the amount of time that has to be put in to going before hearings and preparing for hearings and following up to hearings. A lot of that is just raw politics. I remember Weiss had his staffer come out to see me. His name's Sigleman, and is pretty well known by the agency. This was just a few days before I

retired. I think he thought he was going to have a session with me and I was going to give him all the scoop that I could give him about this administration or whatever.

As he started off -- and I had never had any session with him before; I had never met him before -- but I said, "You know, you people have even less credibility. I'd be glad to talk to you about this administration and some of the problems I have with it, but you people are worse. You don't have any more credibility -- in fact, less. Because some of the investigations you've done, they are just political. They're not really an attempt to find out exactly what is the best course of action for the public. It's strictly partisan politics. I tell you the story and you turn it to your interest, and who winds up in the barrel? I do. And it doesn't matter whether the truth comes out or not." Well, that has to be addressed somehow, and I don't know exactly how you can do it. But you never will go back to the good old days, because we've become too much of the public.

RO: That's right.

MS: I remember when I came into FDA, my God, until I took that civil service exam, I had never heard of Food and Drug. I went and looked up what it was after I had taken

the test. Because I didn't know; I'd never heard of it. Well, now, everybody knows Food and Drug, I'm sure.

RO: Well, if they're going back years ago, the late Senator Humphrey determined that he could get some political mileage by holding some hearings. He was one of the first ones that really gained something by holding some hearings on FDA.

MS: Yes, the agency is an absolute goldmine as far as a politician is concerned.

RO: Before that, you know, like you say, we weren't even heard of. And we avoided it.

MS: Yes, we avoided it, and as a matter of fact, I think to a fault. Because some of the problems we had, say, with the field organization is what we trained them from the day they come in, politics is not your business.

RO: Don't talk to the press, either.

MS: And don't talk to the press. But really, politics is a part of our business, and you have to have people trained to figure strategies that will best fit a particular situation.

RO: Well, you've got to be sensitive.

MS: You've got to be sensitive to it. And you can't act as though it doesn't exist, because you won't exist if you do. But I'm just saying I told this IG that I don't

know that there's any evidence I have -- because I never had any personal contact with Haddow -- I don't have any personal knowledge or any personal evidence that I could give anybody that would provide he did anything illegal. But I would like to for sure see if they can't follow through to encourage somebody to put in places policies that this kind of conduct can't occur. I think he just came off a senator's staff; he conducted his business exactly as if he was on a senator's staff. That is completely inappropriate in the chief of staff of HHS.

We're just talking about Food and Drug. You can just imagine what must have occurred in HRSA, where he headed it up, and some of those other agencies. I am sure he had at least as much, if not more, clout there. Because FDA does have -- maybe not as much as they used to -- maybe a little bit more independence than some others, I think.

But anyway, I don't have any magic answers or magic bullets, but that was an experience that I think could be really serious if it's not controlled. And it didn't just occur in this administration; it's been going on for several administrations.

RO: Well, Merv, if there's nothing else you want to add to the record now, why, if after reviewing the transcript we find something, we can have another session.

MS: Well, I appreciate it, because there may well be; after I look at this I'll want to delete all of today's tape and put something else (laughter). But I'm inclined to say that it is very significant and it ought to be part of the record, really.

RO: Thank you.

MS: Thank you.

It is my privilege to speak here tonight to say farewell to Merv Shumate on behalf of the Office of the Chief Counsel. It is a sense of privilege mixed with a sense of regret, of course, because the Chief Counsel's Office has always had a special relationship with Merv, both as a top compliance official and as an individual. The presence on the program tonight of four present and former members of the Chief Counsel's office signifies that special relationship better than anything I can say.

In fact, as Peter recounted, Merv's first assignment in the Office of Regulatory Affairs was to assume responsibility for a traditional GC function, the preparation of enforcement pleadings, after Frances McKay's retirement from GC and that activity was reorganized to place it within ORA. A key element in that job was the review of enforcement cases for legal and factual sufficiency, for consistency, and for adherence to enforcement policy. Merv was exceptionally sensitive to the need for soundly based enforcement actions that represent a coherent, even-handed expression of regulatory policy, and he had the knowledge, experience, and above all, the good judgment to see to it that the cases FDA referred met that standard.

The Chief Counsel's Office benefited enormously from the smooth transition in the pleadings review function. Over the years, the Chief Counsel's Office, and the Agency as a whole, continued to benefit from Merv's wisdom and from his insistence on quality as he expanded his responsibilities to include more and more of ORA's regulatory activities. For example, Merv made his first post in ORA, the Regulatory Management Staff, into a focal point for all aspects of FDA's enforcement litigation, and in that way revived in important respects some of the central control functions of the old Bureau of Compliance. Merv's aptitude for synthesizing a rational regulatory position from disparate and often conflicting points of view led to his ever-increasing involvement in resolving issues outside the context of litigation, and, eventually, to his becoming the Deputy Associate Commissioner for

Regulatory Affairs. Merv's progressively expanded field of operations was the inevitable result of the reliance placed on him by Paul Hile and others as someone who could be counted on to get the hard job done when it mattered.

It is in the role of problem-solver and crisis-management pointman that I and many others will probably best remember Merv. Whenever the agency, in matters of major enforcement or regulatory significance, had to answer the unanswerable, solve the unsolvable, or calm the uncalmable – Merv always seemed to be presiding, quietly but implacably outwaiting the forces of confusion and dissension in pursuit of that frequently elusive objective, the institutional position.

From the perspective of Chief Counsel, one of the most noteworthy area in which Merv exercised his consensus-building skills involved the ad hoc case review system, which Merv both pioneered and led. The ad hoc review system was an initiative designed to overcome the delays inherent in level-by-level processing of significant and novel enforcement actions. The ad hoc review system was badly needed and it has worked well. Central to its success has been Merv's ability and willingness to immerse himself in internal controversy, to expose himself to all points of view and to participate actively in the give and take of discussion among all parts of the agency. Merv has always known that difficult solutions to tough problems do not arise spontaneously, nor can they be unilaterally imposed. Instead, they require the exercise of effective management by someone who believes that the paramount objective is getting the right answer, not toeing bureaucratic or jurisdictional dividing lines. In this environment of creative conflict, GC has always been assured of having a voice in the matter at hand, and the relationship between FDA's compliance staff and the agency's lawyers has always been one of healthy, mutual respect.

No list of Merv's accomplishments in the area of litigation management would be complete, or course, without mention of the direct referral of routine cases from the Center compliance

staff to GC. Even more than increasing one's involvement and one's responsibilities, giving up control when it is no longer necessary is the mark of a true managerial professional. The concurrent review and the routine referral procedures both have significantly enhanced FDA's enforcement effectiveness – and as head of the office that is last in line to receive the agency's enforcement output, I can sincerely say that the successful effort Merv has made in this area is something in which Merv can take great pride, something that will have benefits that will endure for many years.

The Office of the Chief Counsel is losing a valued colleague with Merv Shumate's departure. Each of us, as individuals, is losing a good friend. We all wish you well.