

History
of the
U.S. Food and Drug Administration

Interviewee: John Scharmann

Interviewer: Robert Tucker

Date: June 17, 2003

Place: Oak Brook, Illinois

RT: This is another in the series of taped interviews for the FDA Oral History Program. Today is June 17, 2003, the interview is being held with John Scharmann, retired director, Denver District. The interview is taking place at the Oak Brook Hills Resort and Hotel, Oak Brook, Illinois. Robert Tucker of the FDA History Office is conducting the interview.

John, we'd like to begin the interview with a brief review of your personal and educational history. Would you please start by telling where you were born and educated, and something about any previous experience you've had prior to joining the FDA?

JS: Thanks, Bob. I was born in Springfield, Minnesota. I was the first child in my family born in a hospital. I was raised in Sanborn, Minnesota, which is about twelve miles away. It was a rural setting on a farm where I lived until I graduated from high school in 1950. After graduation, I worked in the food area for about six months in a Land-O-Lakes creamery and determined that wrapping butter was not something I wanted to do for a lifelong career.

I enlisted in the Air Force in November of 1950 and served nearly four years in that organization, serving in Japan for nine months during the Korean War. After leaving the Air Force in '54, I attended the University of Minnesota for two quarters, and from there I transferred to South Dakota State University in Brookings, South Dakota, where I graduated with a B.S. degree in agriculture in 1959. I planned originally to be a teacher, but after hearing experiences of student teachers, I decided that was not another career goal that I was looking for, and interviewed for a job with the Food and Drug Administration in Minneapolis. Armond

Welch, who was an inspector in Minneapolis at the time, interviewed me, and I was hired and came onboard with Food and Drug Administration in July of 1959.

RT: What led you to FDA? Was there an announcement of vacancies?

JS: My knowledge of FDA prior to the interview was limited. I had seen an announcement of various government jobs, among which was FDA. I took an examination to get consideration.

RT: Is that the FSEE [Federal Service Entrance Exam]?

JS: Federal Civil Service Exam, something like that. After having passed it, I made contact with the FDA, which resulted in Armond's interview. So I knew nothing about FDA, really, until I talked to Armond Welch that day. As I say, the interview was successful and I was hired in July of '59 into the Minneapolis District Office.

RT: You entered FDA at what grade level?

JS: GS-5 inspector.

RT: Who was the director of the district up there at that time?

JS: The district director was Maurice "Bud" Kerr. He was there for about six or eight months, and then a gentleman by the name of A. Harris Kenyon arrived. I think he came from Boston, to be the district director.

RT: Who would the chief inspector have been at that time?

JS: Well, there really wasn't a chief inspector, but I guess the senior supervisor would have been Joe Durham. He may have been called chief inspector, but I'm not sure.

RT: Probably not at that point.

When you came in, what kind of assignments did you get? I suppose you had training trips for a time, didn't you?

JS: I traveled with a senior inspector for six months, and you traveled two weeks in and two weeks out, and training involved making inspections with the senior inspector in all of the program areas that FDA was involved in at that time. One of the requirements, before you could be promoted to a GS-7, was you had to make inspections in the majority of those programs and collect a number of samples in those programs. Once that had been completed, which usually took a year or a year and a half, you were then eligible for a promotion.

RT: Was the eligibility for being promoted contingent at that time on a transfer?

JS: Not necessarily. It just happened to work out that my eligibility coincided with the opening of Dallas District, and in November of '60, I was transferred to the Dallas District along with a number of other people from Minneapolis. I think there were probably seven or eight people from Minneapolis, both inspectors and chemists, that went to Dallas.

RT: Sam Fine was the director?

JS: Sam Fine was the original director there. Jim Anderson was the chief inspector.

RT: Before you went to Dallas, you had had pretty much of an overview experience of the inventory in Minneapolis?

JS: Right. We were exposed to the majority of the product lines that the FDA was responsible for and those available in Minneapolis, which were pretty well across the board.

RT: I was wondering, that being an area where there was a lot of food production, was there opportunity to get any drug training at that point?

JS: Actually, my drug training began in Minneapolis district with FDA, becoming more involved in the veterinary drug and medicated feed area. I worked on that while I was there, and one of the trainers who I worked with was Tenny Neprud. Other trainers included Bob Jacobson, who was the dairyman. Horace ["Maj"] Allen. Maj was the flour mill expert who trained everybody in doing flour mill inspections.

RT: When you got to Dallas, did you encounter a different scene as far as inspectional responsibilities are concerned?

JS: Well, yes, to a certain extent. There wasn't a whole lot of dairy plants that we were involved in, in the Dallas District. It was more or less a general run of the inspections, again in the food and medicated feeds.

RT: At that point you had been promoted to a GS-7?

JS: Yes.

RT: A journeyman inspector.

JS: Yes.

RT: And at that point were you given any additional training, formal or informal?

JS: At some point shortly after arriving in Dallas, I was given some formal training in egg-smelling.

RT: Organoleptic.

JS: Organoleptic. Examination of frozen eggs. We went to Kansas City, Lloyd Barber and I, for, I think it was a two-week training, and then we covered the frozen egg industry in Dallas District, which included Oklahoma and Texas at the time.

RT: I suppose in that assignment you became more or less experts for the district in that area?

JS: We were considered the experts in organoleptic examination. If it was done, it was done by Lloyd Barber or I, or both of us.

RT: Did you get into import surveillance in terms of illegal pesticides from Mexico?

JS: We did very little, or at least I did very little border work. The imports that I was involved in came in through the port of Houston, and the bulk of this work was coffee. With a little experience in examining imported coffee, you learned pretty quickly who was importing the good coffee and who was importing the lower-quality material, and, of course, you concentrated on that.

RT: In terms of those inspections, were they focused on quality of product or sanitation considerations?

JS: The imports were on the docks for a short period of time, so this was a quality exam as to whether or not to release the lot of goods which was there. There wasn't really a sanitation inspection, because it was just temporarily on the dock. So it was purely quality determination.

RT: So it wasn't, then, insect filth or problems of that nature, is that correct?

JS: It didn't stay on the dock that long. There were a number of coffee roasters and blenders in the Houston area, so the coffee moved pretty quickly off the dock once it was released.

RT: When you were in Dallas, did you again experience the road trip thing of being in and out on alternate weeks?

JS: It was the same as in Minneapolis; two weeks in and two weeks out. Most of the trips I took were to Houston.

RT: At that time the geographical border of Dallas District was that still quite extensive? At one time it took quite a swath of states out there.

JS: As I recall, we just had Texas and Oklahoma. Louisiana and Arkansas belonged to New Orleans. Back then, Arizona and New Mexico belonged to California or Denver District.

RT: At Dallas, John, do you recall being involved in any significant seizure or litigation actions against unfit products?

JS: The only action that I really recall was an injunction I worked on which involved Elevator B in Galveston, Texas. The firm was enjoined from shipping out of the country. I worked with E.

Pitt Smith. That's really the only one that comes back to memory. I'm sure there were a number of seizures, but nothing that would stick with me very long, because back then, if you didn't get at least fifteen or twenty seizures a year, you weren't doing your job. That's not said in jest; that was fact.

RT: Yes, that's right. And that had quite a bit to do, I'm sure, with your progress gradewise.

JS: Absolutely, it was almost sole determining that if you didn't get regulatory actions, you weren't doing your work, and consequently you weren't promoted.

RT: While you were at Dallas, did you remain at the field operations level, or did you get into any first-line management responsibilities?

JS: No, I was an operational inspector the two and a half, three years that I was in Dallas. I was there from November of '60 to June of '63.

RT: What was the next step in your career?

JS: The next step in my career came about when Sam Fine called me into the office and told me that it would probably benefit my career if I took a lateral transfer to Cincinnati District, and being somewhat—well, I'm not sure how to put this. Being somewhat foolhardy, I told Sam that I had taken a lateral transfer to come to Dallas, I wasn't taking one to leave. And Sam said, "Well, I took a lateral assignment to come here as a district director."

“Yes,” I said, “but that was at the GS-13 level at the time.” And about a week later, I found myself transferred to Denver with a GS-11 promotion.

RT: Good. Well, it paid to speak up.

JS: Yes, it did.

RT: Sam was the kind of a man, I think, who probably respected it, if it was not a malicious comment.

JS: Yes. Sam was very straightforward, very honest, and I think he probably seriously meant what he said about advancing my career. But I wound up in Denver, anyway.

RT: You went to Denver at a higher level. Were you still doing primarily investigational work in the field?

JS: Yes. I was a GS-11 investigator [title changed about this time], but I kind of specialized a little more in Denver in drug work and in special investigations. This was at the time when silicone was being used for a number of cosmetic enhancements, and I did a lot of investigations of one particular doctor there who was using silicone for breast augmentation.

RT: Was that investigation prompted by adverse reactions?

JS: These were all prompted by complaints from people who had gone through the procedures, a number of which resulted in mastectomy. We seized from that doctor a fifty-five-gallon drum of silicone which he was using as his source of medical silicone. I forget whose product it was, but it was labeled for industrial use.

RT: So it was being utilized for an off-label use.

JS: Absolutely. And in fact, after I had gone to Kansas City, I went back and testified at a trial involving one of the civil suits against the doctor.

RT: What was the penalty he incurred from that? Was his license revoked?

JS: I don't recall that his license was revoked. I think he received some probation and some type of fine.

RT: You mentioned drug investigation. Were you addressing inspection of pharmaceutical manufacturing and processing or the distribution of the drugs?

JS: Both. We had a couple of what were called generic drug houses. Western Pharmaceutical was one, and it was a loosely run operation. He had a multitude of products and was fairly good-sized. I also did some work on the illegal sales of prescription drugs under the Durham-Humphrey Amendment.

RT: Did you ever get into the bennies and amphetamine truck-stop investigations?

JS: I did some truck-stop work in New Mexico, but I wasn't particularly successful, because I guess I didn't look like a truck driver, nor did I look Spanish. I had an assignment to do at the New York Bar in Alamogordo, New Mexico. I was working in Las Cruces, so I figured, well, I've got this assignment, I'll just drive up to Alamogordo and spend the night. I was driving a '61 Studebaker Lark, and it was about 110 degrees driving from Alamogordo. I got into Alamogordo and I looked around to see where this place was, and then I went to the motel room where it was air-conditioned and spent the afternoon. [Laughs]

I went to the New York Bar that night and went in, sat down on a barstool. There was a bartender behind the bar, and one customer. They kind of looked at me as I came in, and they were speaking Spanish and looking at me, and I didn't really have any idea what they were saying. There was a heavyweight championship fight on that night that they were really watching. I finally approached the bartender and he had made no indication that they sold drugs. So I finally figured, "You know, John, this isn't any place for you to be at 9:30 at night," so I went out and got in my car and left. I never was successful at truck stops or bars or things like that.

RT: Well, some people are more comfortable and successful than others, but it was difficult for many field folks.

JS: It was difficult for a Caucasian to try and work a Mexican bar. [Laughter]

RT: I can believe that.

JS: But I did have some success over in Utah where I fit into the population a little bit better. I did an investigation of an osteopath there, and I made a number of buys. This was about the time the drug-abuse amendments went into effect. I had made a buy, and I told the doctor I wanted to buy 50,000 amphetamine tablets from him. "Well," he says, "I don't know." He says, "I'll try."

So we had the appointed time that I came back, and knocked on the door and he let me in and locked it behind me. He and two of his friends were there. One was drunk, the other one was playing the guitar. And he said, "Well, you know, I wasn't able to get the 50,000 for you because I had to sign some form because of the large quantity that had to be reported to FDA. But," he says, "I do have 5,000." So we had an agreement. I was wired for sound, and I gave the appropriate signal and opened the door. The U.S. Marshall came in and arrested the good doctor. The good doctor looked at me and he said, "Why are you making it tough on me? I was honest with you." [Laughter]

RT: He was putting the monkey back on you.

JS: Yes. That was one of the first seizures under the Drug-Abuse Amendment. The good doctor got two years in federal prison.

RT: That was in Utah?

JS: That was in Utah.

RT: Was that in a small community out somewhere?

JS: No, this was a suburb of Salt Lake. He and his brother were both osteopaths, and it was reported that both of them were selling. One would sell to me, the other one wouldn't.

RT: And those complaints emanated from consumers?

JS: I would guess they probably came from the local police. We did some work with the local police there.

RT: As I recall, it was Utah where there was some promotion of dietary supplements.

JS: Yes. Salt Lake City and the Salt Lake area was a hotbed for nutritional supplements. We didn't do a whole lot back then with them. We'd seize one now and then.

RT: As I recall, one of the members of Congress from out there, I don't believe he was directly interested himself, but had the interest of a constituent who was very active in this.

JS: Senator Orrin Hatch.

RT: Yes, that's exactly who it is.

JS: Yes, Orrin was a strong supporter of the nutritional supplement industry in the Utah area.

RT: So did that complicate your work, the Senator's interest? Did that compromise the investigational initiative?

JS: Not then. You have to remember this was back in '63 to '68, and we were not doing much damage to the nutritional supplement industry back then, and, of course, at the level I worked I don't know that there was any complaints from Hatch or not. But as we get further on in this interview, we will talk about the Salt Lake area again and the involvement of Senator Hatch.

RT: How was it working with state counterparts both in Minneapolis and in Dallas? Did you have support from those other levels of government?

JS: We did some work with state officials in both districts. And again, as an operating investigator, I'm not sure what the exact relationship was, but we did do some cooperative work with them in Minneapolis and Dallas. Denver was altogether different. The director there, when I got there, was Sam Alfend, and Sam was a very strong individual as far as management went, and he had a continuing, I won't say problem, but he had difficulty dealing with the State of New Mexico, and he worked very hard to try and get good relations.

But there was one fellow in the state office, and I don't recall his name, but I went to New Mexico on a road trip and I stopped in Santa Fe on the way down to Albuquerque to talk with him, and he was cordial and everything. So I said, "Fine. I'm going down to Albuquerque and I'm going to go to Mountainair and do a bean warehouse that's there."

He says, "Fine." He said, "Stop in Beline," a suburb of Albuquerque where they had a man stationed, and I did, and he said he was busy, so I should just go ahead and do whatever I was going to do. So I did. I went out to the bean warehouse in Mountainair and made an inspection, collected some samples, and I guess we seized some product later on.

By the time I got back to Denver at the end of that two-week trip, this guy in Santa Fe had called Sam and just read him off something terrible about the lack of cooperation from me, and, of course, I don't recall that I ever got an opportunity to explain to Sam what happened. He was quite unhappy.

George Goers was the supervisor then, and Don Martin, and they were in the office with Sam and called me in, and Sam was livid. I tried to explain, and George finally told me, "You might as well leave, John. You're not going to get a chance," so I left. And I guess whatever happened, they sorted it out.

But the state cooperation varied. We had pretty good luck with Utah. But, of course, the second time around when I was in New Mexico, things were better.

RT: You mentioned Don Martin being in Denver. He was also one of the first cadre of folks in Dallas, as I recall. Was he in a management position there?

JS: He was a supervisor in Dallas when I went there. It was Don Martin, Dick Glover, and I think Owen Lamb. Dick Glover, Don Martin, Owen Lamb, and I want to say Taylor Quinn, but I'm not sure he was a supervisor or whether he was in a compliance position.

RT: In Denver, did you encounter any significant problems? We've mentioned some in Utah. Did Denver include Wyoming?

JS: Denver included New Mexico, Utah, Wyoming, and the southern quarter or southern two-thirds of Idaho. It was sort of like you cut the Panhandle off and that went to Seattle.

RT: Probably in Wyoming, there wasn't too much of interest.

JS: There wasn't a whole lot in Wyoming. Up in Idaho it was primarily agricultural, bean warehouses, sugar mills and fish hatcheries. A lot of trout hatcheries on the Snake River.

RT: Was the extent of your travel different in Denver than it had been in Dallas?

JS: No, it was still two weeks in and two weeks out. But towards the latter part of my stay in Denver, I got involved in the compliance officer work. That kind of cut down on the travel. I worked with Don Taylor.

RT: They had two units or two organizational sections, one for compliance and one for investigations?

JS: Compliance, investigations and the laboratories. And, of course, the administrative function. As far as operational, it was those four functions.

RT: Where were you in the oncoming Project Hire? Was that after you had joined FDA?

JS: Yes. Denver hired about that time two lady investigators there, and I think that was part of Project Hire, plus three or four, five other people.

RT: That was a first for employment of women investigators.

JS: Yes, as investigators. There were a number of other districts that hired, too, in the same effort, but we had two young ladies that were hired as investigators.

RT: Women had been in laboratory activities for years, I think.

JS: Yes, but this was the first experience with ladies doing field inspections and they were expected to do the same type of work any other investigator would do and travel the same schedules. They were productive.

RT: The Drug-Abuse Amendments, we did touch briefly on that.

JS: Yes.

RT: Were these new hires involved in that work or were they into the more traditional ranks?

JS: They entered through the traditional ranks.

[Begin Tape 1, Side B]

JS: Usually only investigators at the GS-9 or -11, and there were a few GS-12 specialist investigators that did the OTC work, or the over-the-counter drug work.

RT: Did these new female employees encounter any resentment on the part of the male investigational staff as an intrusion in this "sacred" area?

JS: I don't know that they were really resented. There was some concern of having to travel with them, because, you know, but they were trainees and somebody had to take them on the road for training trips. As I said, there was still two weeks in and two weeks out. So I suspect if there was a problem, that's the only one that really happened.

RT: After you served in Denver, what was the next move in your career track?

JS: My next move or assignment was to a position in headquarters in Crystal Plaza, to the Bureau of Compliance. That organization handled all the compliance activities for the agency. There were no compliance functions in the Bureau of Drugs, the Bureau of Foods. I went to work there for a fellow by the name of Al Barnard.

RT: Al had been district director at Kansas City.

JS: Yes, it's my understanding he came to Washington from Kansas City. I worked in Washington for three years, and worked more or less across the product line, not too much in drugs. I worked in the food and hazardous substances areas. When they moved portions of the FDA function to Rockville [Maryland], the people in that Bureau of Compliance had an opportunity to make a choice; you could either go to Rockville or you could go to the Bureau of Foods, which is what I chose to do because I lived in North Springfield, VA. I worked in the hazardous substances area, again, and also cosmetics. Walter Moses was the head of the function there.

RT: Walter Raleigh Moses.

JS: Yes, Walter Raleigh Moses. A fine southern gentleman.

RT: He certainly was.

JS: I worked there for about a year and a half and had some involvement with Sam Fine again, who was there as the director, I guess. I'm not sure what his title was there.

RT: Sam at one time was sort of the precursor to the Associate Commissioner for Regulatory Affairs (ACRA).

JS: Yes, right. He was, you might say, the original ACRA.

RT: That's right.

JS: I did some work for him in the cosmetic area and sat in on some meetings with him.

RT: In the hazardous substance area, was that after the X-33 extremely flammable product episodes had occurred?

JS: Yes, X-33 episode happened while I was in Denver, and we did a lot of work on that. It was kind of spooky. We'd go out and collect samples of this stuff and haul it back in the trunk of your car. [Laughter] Fortunately, none of it ever went off. But, yes, that was after the X-33.

RT: In the hazardous substance area, when you were in Washington, what were some of the products you dealt with?

JS: We handled the labeling for all hazardous substances, the paint thinners and things of that nature. Part of the more exciting work in that area was with fireworks. Dale Miller was sort of the fireworks czar, had lots of contacts up and down the coast with people who were actually in the mafia and dealing in fireworks. They would come in and talk to Dale about labeling and things like that, and Dale would show them these terrible pictures where the kids had had a car full of cherry bombs that exploded and blew the roof off and the doors off and, of course, killed the kids.

RT: But mostly under Al Barnard's organization?

JS: Yes. Well, Barnard, when they went to Rockville, the compliance functions then went to the bureaus. So Barnard was kind of—I'm not sure what Al did after that. He may have had some kind of transitional problem, but actually when I went from Barnard's organization over to foods, I worked for Walter Moses.

RT: Well, Barnard went into BDAC [Bureau of Drug Abuse Control] for a time.

JS: That's right. So I worked there in Washington for just about three years, and then I was fortunate enough to get a job in Kansas City as a compliance officer. I think to this day I owe Jack Evans, L. Jack Evans, thanks for that, because he convinced the district director in Kansas City that I should come out there and replace the fellow who went to Baltimore.

RT: Who was director at Kansas City at that time?

JS: Charlie Armstrong. When I reported in, Charlie called me into his office and we talked and he said, "Well, now, tell me, John, what do you think your job is here?"

And I went through the liturgy of, "Well, I review cases and I make recommendations and I meet with industry."

"Well," he said, "that's part of your job, but your big job is to keep me out of trouble."

[Laughter]

RT: He was being candid with you.

JS: Yes, he was. I worked for him for a while and then he left and went to Washington, and Lloyd Claiborne came in as the district director.

In Kansas City, as compliance officer, we dealt with all product lines. We seized vitamin products over in St. Louis, and actually had a couple of contested cases over there that we handled with the General Counsel's office. I guess if I had to be somewhat ashamed of any prosecution I ever recommended, it was a fireworks case against a couple in northern Missouri just on the Missouri side of the river. It was a man and a woman who were selling fireworks, and we put together a prosecution recommendation. The agency bought it and we wound up in federal court with this grandma and grandpa, if you will, with charges of illegal sale of fireworks.

RT: Was that adjudicated before a judge and jury?

JS: This came before the judge, and the judge looked at it and he accepted their guilty plea, but the fine was, I don't know, minimal, or maybe it was a lecture. I guess if I had to be ashamed of anything I did, it was prosecuting grandma and grandpa for fireworks sales.

RT: Yes, that's why I asked you if it was a jury trial, because sometimes a jury is pretty lenient on that kind of thing.

JS: It didn't go to a jury. They pled guilty and the judge understood the circumstances. I guess we're probably fortunate he didn't lecture us. [Laughter]

RT: Maybe so.

JS: One other case in Kansas City, there was an animal byproducts manufacturer, and this was at the time when Kenny Lennington was going to break the salmonella chain, and we inspected a byproducts plant a number of times and, you know, if you really stop and think about it, salmonella in a rendering plant is ubiquitous. But we inspected it, and during the process when you collected in-line samples, of course, they'd just cooked, so it was clean, but as soon as it went through the packing machine, it was re-contaminated again. So we enjoined the animal byproducts manufacturer for manufacturing a contaminated product with salmonella. In FDA, once you obtained a complaint or a consent decree, a permanent injunction, they never went away; you just got to the point where you ignored them.

RT: This animal byproduct, what was the destined use of that article?

JS: It was turned into a feed ingredient, so it was going back into animal feed. We're still dealing with that concern today. But we never did break the salmonella chain.

RT: Were you involved in investigations of these off-label foreign peddler distributors of drugs?

JS: Veterinary drugs?

RT: Yes.

JS: Not to any great extent. As I say, I was in Kansas City for about five years, and during the last year and a half, I had applied for and was accepted into one of FDA's Executive Development Programs. While I lived in Kansas City, I spent a lot of time in other places.

One of the assignments I had during that developmental program was to review the statutes the states had relating to food and drug law, to the FD&C Act. Ed Fry was a fellow who was with me in the program. We updated the code for the states through AFDO. We put together an updated code, and it was distributed. I guess a number of states, based on the updated code, did accept it. But that was one of the main projects.

RT: Was Ed a fellow Executive Development Program classmate?

JS: Yes, he was part of the program, which I think included about eight or ten people from various field organizations and some from headquarters.

RT: If I remember correctly, Burton Love was also in the program.

JS: Burton Love was in it.

RT: I think you two worked on some common projects at the time, is that right?

JS: We may have, I don't recall, but I do recall working with Ed Fry, because I know we went down to the [U.S.] Library of Congress looking for things that might be helpful in updating the

code and getting some background. But most of the assignments, other than that one, were working in various other divisions within headquarters just to see what they did.

RT: Part of that program was to broaden your expertise or your experience, wasn't it?

JS: Yes.

RT: Do I remember that as sort of a condition of being in that program, you had to find where you would work afterwards? There was no particular promise of job replacement, was there?

JS: No, there was no guarantees. You could conceivably wind up back in your own district. At the end of the program, I wound up in Minneapolis as the director of compliance. Henry Roberts was the director at that time, and somewhat later in my career, Henry explained to me the resistance he put up to having a director of compliance, but—

RT: He was overridden.

JS: He was overruled. I can remember, after having been there a short period of time, Henry was a pretty nice guy, actually, and we were having a district meeting one day, a compliance meeting. Henry was grumbling about something. Investigations was there and laboratory folk were there and compliance folks, and I said, "Look, Henry, you just stick with us. We'll make you a star." [Laughter] And he got this kind of strange scowl on his face, but he didn't say anything. But, yes, you had to find or more or less make your own job.

RT: Now you're back in Minneapolis. During that tour assignment, what were some of your noteworthy experiences?

JS: We had Medtronics [Inc.], a device firm, and we had made a number of inspections of that firm. They were having considerable difficulty with their GMPs at that time, and we had had a number of inspections. We had many discussions with them. George Burditt was their counsel. At some point in time we decided, well, we're not getting anywhere, so we put in for a 305 hearing and sent it into the center, and they approved it. So we called the management in, and George Burditt showed up as their representative counsel. We were talking to George before the meeting. There was so many people there, we didn't have room in our conference room; we went over to the Federal Building. They were getting ready to head over there, and George says, "Well, you're coming along to hold the hearing, aren't you?"

I said, "No, I've assigned that hearing to Ed Dee. He'll be holding the hearing." Well, George was kind of taken aback, that he wouldn't have the director of the compliance branch, at least, at the hearing. That was my first encounter with George.

We had a lot of doings with the state there. Tom Masso, in the latter part of my stay there, was the director of the state Food and Drug section. Before that, was Ben Stephen, who was a longtime person there. We had a good working relationship with them.

The only person in a sort of health operation that we didn't get along with real well was the director of the epidemiological section and his name was Mike Osterholm.

RT: He was a very controversial guy, wasn't he?

JS: Yes. He's still very controversial.

Yes, Dr. Mike Osterholm. Mike would have a press meeting at the drop of a hat, and we would be involved and we would always have to go to these meetings. Tom Masso would sit on his right, and I would sit on his left, and Mike Osterholm would do all the talking, and Tom and I would just sit there. Finally, one of the press people asked after the meeting, he says, "Well, who are you two guys? You never say anything at these meetings." We kind of explained to him what the deal was. Mike is still controversial. He's the director of the bioterrorism now of the University of Minnesota.

But for the most part, we had a good relationship with the state. When they were really short on funds, Henry would rent a van so they had transportation and could attend meetings of the Central States Association meetings, wherever they happened to be.

RT: I remember seeing that happen a time or two. Interesting.

JS: I worked in Minneapolis for fifteen years. When I first went there, I was director of compliance, and after about six years, George Goers had been the chief investigator and he retired, and I convinced Henry Roberts to assign me into that position. So the last seven or eight years or so, I was the director of investigations in Minneapolis.

RT: For chronology, you had come back to Minneapolis in what year?

JS: That was in 1976.

RT: And then you stayed there—

JS: Fifteen years.

RT: So you got pretty familiar with that whole office.

JS: Oh yes.

RT: And then after serving there, what was the next step?

JS: I guess I wasn't properly developed in the first executive program, so I had to go through another one. There were seven of us in this program. The fellow I mentioned earlier when I was working out in Dallas, Pitt Smith, he tagged us with the name "The Magnificent Seven."

[Laughter]

RT: That sounds a little bit like him, too.

JS: Yes. But I went through that program and I did an assignment in Nashville. Ron Chesmore was the ACRA then, the associate commissioner for regulatory affairs. He really wanted me to go either to Nashville or San Juan. We had just had a granddaughter born in Kansas City, and Marlene says, "There is no way I'm going to San Juan." So Ron and I had a number of conversations and I told him, "Look. If I really had my choice, I would like to go to a district

that has a laboratory.” And I said, “I ain’t going to San Juan,” and added, “Nashville doesn’t have a laboratory.” I then said, “Leroy Gomez is leaving Denver. I would take Denver.”

I wound up in Denver as a district director, and again I think it was much to the reluctance of a parting district director, Mr. Gomez. I don’t believe he had much choice in the matter. So any number of times I think I was more or less forced on people, if you will, but I think it worked out well.

I was in Denver for five years, and while there we had a number of interesting episodes. We still had Utah as a responsibility, and in Utah there’s a significant nutritional supplement industry. In fact, the Nutritional Supplement and Health Education Act—

RT: Oh, yes. Nutritional labeling in food supplements.

JS: Yes. That bill was sponsored in the Senate by Orrin Hatch and in the House by Congressman Richardson of New Mexico, and it put the onus on the agency, really, to show that these products were not effective, rather than the firm having to show that they did do what they say.

But earlier than that, I got involved with a group of people in Utah in the medical device industry. They had an annual meeting which they originally booked out as the Shing Prize for Excellence, which was given to a firm that they considered to be an excellent operation. The first one they had was shortly after Dr. Kessler became commissioner. and Dr. Kessler had been associated with Senator Hatch even before he became commissioner. I think Senator Hatch figured that if he got Dr. Kessler as commissioner, he would have a little more control. Well, I don’t think that proved to be true, but, nevertheless, for this meeting Senator Hatch convinced

Dr. Kessler he should come out and make the keynote speech, and then they would show him the medical device industry in Utah.

Senator Hatch and the representative of this firm took Commissioner Kessler to the plant to show him what they considered to be a state-of-the-art facility; however, about a month or two later after this visit, we enjoined the firm for failing to meet the requirements of the device amendments. Senator Hatch wasn't particularly happy about that, but he never did say anything. We were doing congressional visits at that time. I would go and somebody came from the regional office and office of public affairs, and we would visit the senators and representatives from our district who would take the time to see us. Surprisingly enough, about the only two senators who would actually take time to see us personally were Senator Hatch from Utah and Senator Robert Bennett from Utah. But Senators Hatch and Bennett would take fifteen, twenty minutes and they would sit and talk to us and listen to us.

One time I remember being there and we were sandwiched in between a nutritional supplement firm and a Mormon family. We knew the firm and they knew us. When we were getting ready to leave, this family was there. It was the husband and the wife and three or four kids, and we were standing around talking to Hatch and a couple of his aides as Senator Hatch was welcoming them there. He made the comment, "You only have three children. That's a pretty small family."

And the fellow says, "Oh, no, no, we have eight. The other five are at home." [Laughs] That made the good senator very happy. But he's a very personable individual, and he does what the people elected him to do, which is to support their industries.

So from that involvement, we went to a couple of these Shing meetings, and they would beat up on us and we would go home. So the next time they called, I talked to Wendell Gardner.

Anyway, I told him, “We’ll come back, but we ain’t going to come back and get beat up on again. If you want to talk about some positive things that we can do to make things a little smoother between FDA and the industry, we want to do that, but we’re not going to come over there and be whipped because of the terrible things you say we do to you people.”

We went over and had a pretty good meeting, and out of that grew the original grassroots meeting for better cooperation for devices. It kind of expanded out of the Utah Valley over into Salt Lake with Wendell Gardner and a number of other people. We were instrumental in getting Ron Chesmore and some of the other folks, including the center people, to meet with these folks back in Washington in Ron’s conference room. Out of that came the things that Nancy Singer was talking about the other day at this AFDO conference. The annotated 483, the pre-announced inspection, were two of the things I remember coming out of that meeting. Those started in late and ’95, and then, of course, I retired in ’96, but it has continued on.

RT: Yes, the presentation at the AFDO conference here by Nancy Singer yesterday gave an update on what happened, and she mentioned, to your credit, the involvement of Denver District in trying to get that cooperative effort off the ground.

JS: It worked.

RT: Ms. Singer is general counsel for a device group?

JS: When I first met Nancy, she was the executive director and vice president of the Food and Drug Law Institute, which is a trade-type organization. She pushed pretty hard for some of the

changes that initially came out of the grassroots meeting, so she should get some credit for the things that happened there.

RT: She was speaking yesterday at this meeting about the reaction of both the regulated industry and the agency to some of these procedures that have been developed.

JS: Yes, some of those things industry really wanted. One of them was they wanted pre-announced inspections, and that has happened. They wanted annotated 483s, where if the firm corrected the item prior to the investigator leaving, that such a note would be made on that 483. There are a number of other things that have come and gone since that first started.

RT: The pre-announced inspection was really a departure from the agency's historic view of regulatory investigations, wasn't it?

JS: Yes, the agency, prior to that, always felt that to get a good evaluation of what a firm is doing, they shouldn't know you were coming. It was quite a departure from prior practices to even try to pre-announce inspections in the medical device area, because all the old-timers would say, "Well, if you tell them you're coming and you give them five days, you won't find anything." Well, I suppose if you're looking at a grocery warehouse or something like that, this might be true, but if you're looking at a complicated industry like a medical device firm where everything is—

[Begin Tape 2, Side A]

RT: John, we broke there for a change of cassette, so please continue what you were saying.

JS: I was saying that the pre-announced inspections were kind of a change in philosophy for the agency, because the old-timers would say, "Well, you can't find anything wrong if you tell them you're coming." That probably would have some truth in a sanitation-type inspection where you're looking for filth, where they get two or three days to clean up. But when you're looking at a sophisticated industry where a lot of the evidence you're looking for is documentation, it's pretty hard to sanitize a bunch of records in a short period of time and make them look like they're original documents.

RT: So from that basis, it seems, judging by Ms. Singer's remarks, both the regulated industry and FDA investigators concur in the advantages of this different approach.

JS: Both sides prosper from that approach, because, as Nancy said, it gives the industry a chance to pull together the documents that the investigator says he wants to see, and have the appropriate people onboard so the investigator doesn't go to the plant and have to sit and wait for all of these things to come together. So it works for both sides.

RT: John, we've covered quite a range of activities in which you've worked over the years. I wonder, do you have any impressions, personal impressions, of management styles or management individuals that were significant in altering the course for success of FDA's mission?

JS: Based on what I've observed from the time I started with the agency till the time I left, the big change in how the agency operated was when Jim Goddard came on as commissioner. He was the first outsider to be commissioner. George P. Larrick was replaced by Dr. Goddard, and Dr. Goddard was somewhat of a free spirit who changed a lot of things. I'm not sure that all of them were good, but I'm sure all of them weren't bad either. But maybe they were just different from what we were used to seeing.

So since the commissioners have since all come from the outside, you saw various and sundry thrusts, if you will, of interest, because each commissioner seemed to have their own personal agenda when they came in. I think Goddard's was to enhance his position as commissioner and also build a reputation as a hard-line enforcer. There were a number of other commissioners who came in with their own agendas, whose names escape me, but I know one particularly spoke strongly against the use of salt.

RT: Was that Dr. Arthur Hull Hayes?

JS: I think it was Arthur Hull Hayes. Guests who dined with him were surprised to see the amount of salt he used.

RT: Dr. Goddard, as I recall, changed the modus operandi of management in the agency. For years and years, field managers processed their decisions through headquarters, and Goddard, I think, threw the responsibility back to the field, which made some field managers rather uncomfortable.

JS: Well, yes, this is true. I guess you could say his position was, "You have the job. Do it." And you're right, a lot of district directors and higher senior managers in the field didn't really like that responsibility. Some of them really liked the guidance that they had gotten in the past from people like Alan Rayfield and Kenny Lennington and Reo Duggan.

RT: There was a manager at about the time that I came into FDA in Denver, who was noted for never deciding anything without calling Washington. Then he retired and went to the State of Florida and worked for them in their food and drug program. He wrote into the Division of Federal-State Relations and asked many questions. He made a complaint one time that he wasn't getting an adequate answer, and my boss said, "Well, write him back and tell him again. He got the same answer the second time." But he was used to that old style.

JS: Yes. And it's strange there were those types of directors, and then you have the director that was in Denver when I went there the first time, Sam Alfend, who was reportedly the only director that would pick up the phone and call whoever he wanted in Washington and yell and swear and carry on. So you have both extremes.

RT: Sam is not the man I'm thinking of, and it isn't important that I remember his name. He's deceased.

JS: Yes, the commissioners have changed the way the agency operates, and I guess maybe Goddard is the most obvious because he was the first one that came from the outside. I remarked

earlier about how when Dr. Kessler came on, and I think that Senator Hatch felt that he would have some sway over the activities of Dr. Kessler as far as enforcement went. As I recall, about the first thing that Dr. Kessler did was seize a bunch of orange juice because of misbranding.

RT: Yes, he did do that.

JS: I think the agency has changed tremendously.

RT: Under Dr. Kessler, of course, the agency undertook an area of regulation that it had never really touched before, which was tobacco.

JS: Yes.

RT: And that upset a lot of folks.

JS: That may have been his downfall. But the new commissioner we have now, Dr. Mark McClellan, is, at least in my opinion, the most politically attuned commissioner we've had. He came out of the Bush administration. I'm surprised at some of the things he's done, but he has a chief counsel, Don Troy, who also came out of the Bush administration. I see the agency being much more industry oriented than it had been ever in the past, but the pendulum swings. I've watched the agency from the outside for eight years now because of what I've done since I've retired.

RT: You're not employed directly by industry, though, are you, John?

JS: I don't consult with anybody. I work on a contract basis with a trade paper. Jim Dickinson is the president of the organization, and it's called Ferdic, Incorporated, and I write for two of his publications. One is the *FDA Web* and the other one is the *FDA Review*, which is hardcopy. So I've kept in contact with a lot of FDA folks, and I see a lot of things that have changed in the eight years that I've been gone. It's been interesting and I enjoyed it.

RT: Very good. Is there anything you'd like to add as we close our interview?

JS: I don't think so. Like I say, it was an enjoyable career.

RT: That's what almost everyone in our interview program has said. It is a fascinating and inspiring field of government service.

JS: I think the one difference now between when I started back in 1959, and it's not so true in government, or particularly Food and Drug, but not too many people outside industry or in any industry start with a firm and stay with it for thirty-seven years. So I think that's been one of the changes, there probably isn't the attachment now, but—I can't think of the term I want to use. But the feeling of camaraderie which we had with the agency when we started. I don't know if that's still there, but it's better in FDA than I think it is in a lot of other places. But *loyalty*, I think, is maybe a better term.

RT: The employees of both industry and government tend to be more mobile today.

JS: Yes. I think they refer to that as the revolving door.

RT: I believe so.

JS: I think we have a deputy commissioner who has gone through the revolving door a number of times.

RT: Back at the time when some of the people who we knew years ago came into the agency, they were finishing college and seeking jobs during the depression. At that time the job was a privilege; it wasn't a right. It was a different mental mindset.

JS: Yes.

RT: John, I thank you very much for giving us the privilege of interviewing you for the oral history program.

JS: I appreciate it and I look forward to seeing the rough draft.

RT: Okay. Thank you.

[End of interview]