History

of the

U.S. Food and Drug Administration

Interviewee:	**Gary Pierce**
Interviewer:	**Ronald Ottes** **Robert Tucker**
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RT: This interview is being conducted by Ron Ottes and Bob Tucker. It is another in the series of FDA oral history interviews. Today, the interview is with Gary Pierce, recently retired Regional Food and Drug Director, Southwest Region in Dallas, Texas. The interview is taking place in the Parklawn Building in Rockville, Maryland, and the date is May 8, 2003.

To begin, Gary, would you briefly cover your education background, where you were born, and any experience that might be relevant prior to your coming to FDA and, then, of course, we'll move into the FDA career.

GP: Thanks a lot. I grew up in a small midwestern town in Iowa. After I graduated from high school, I joined the service. About that time the Vietnam War was beginning to pick up, and so I spent three and a half years in the Air Force, including a tour in Vietnam.

When I got out of the service, I did a little bit of kicking around in different jobs. What quickly became obvious is, unless you wanted to work at a packing plant or some other job, you really needed to end up going to college. Of course, coming out of the service, I had the G.I. Bill behind me, and so I started college at the University of South Dakota.

RT: What year was that, Gary?

GP: In 1969. So I started in a science field at the University of South Dakota.

RT: Is that school in Vermillion?

GP: Yes. It's a very nice, very nice campus. I recently visited, and it's really, really expanded.

I always had a love for science, so I majored in biology, with my minor in chemistry. Then I met my wife, who has now passed away, and I transferred to Briar Cliff University, which is a Catholic college in Sioux City, Iowa. I finished my science degree there.

In the senior year in college, you start thinking about being gainfully employed. I was going to end up with a science degree in 1972. Of course, I wasn't quite sure where I was going to apply that science degree. In my senior year, I took what was called the FSEE, which was the old Federal Service Entrance Exam (FSEE), which was eventually replaced by the PACE (Professional Administrative Career Examination), and then it was replaced by something else. The FSEE was basically kind of a shotgun application for government service in certain areas, science areas.

So I took the FSEE and continued my senior year. Around April or May, I got a call from FDA. It happened to be the local resident in charge in Sioux City, James Egenberger. You guys probably both know Jim. Jim asked me to come in and interview for a job. Of course, at that point, I knew very little about Food and Drug and what they did and what their role was, other than just, well, it must be the pure Food and Drug Administration.

So I go in for an interview, and Jim hands me a couple books. I think it might have been the *FDA Consumer* or the magazine that preceded the *FDA Consumer*, and said, "Well, here's what Food and Drug does." So I took a look at the magazines, and Jim and I talked a little bit. Then I was offered a job in Kansas City. That District ended up being a training ground for

people from up and down the Midwest.

RT: What was your entry-grade level?

GP: I started out as a GS-5, making $7,300. When I started in Kansas City at 1009 Cherry Street, I still remember there were about forty of us who were hired, predominantly men. There were a few women with the group of new hires. All of us showed up over a period of about a month. I reported in early July, and I think the last group came in mid- to late August of 1972.

RT: Who was director then? Was that Charlie Armstrong?

GP: No, it was Lloyd Claiborne, actually. Lloyd swore us all in.

RT: Who was the chief inspector?

GP: It was before Ted Rotto.

RT: I can't think of it right now.

GP: What prompted this significant hire, Project Hire, and, of course, it was remembered for years as Project Hire. It was associated with a problem in the canning industry back then, Bon Vivant Soup, botulism, a couple of deaths, and so that was where FDA apparently got the

funding and the authorization to go ahead and do a significant hire of new personnel, and it was a significant hire. In Kansas City, we had about forty people who started with the period of a month.

Back then, the Kansas City office was an old Rayfield-style building, with an open bullpen and desks all lined up facing the front wall where the supervisors set. The chief inspector or the director of investigations was off to the side in a little room with a glass window. Most of the remaining Rayfield buildings still have that same style.

I had a chance to go back and see the old Cherry Street Building. It must have been about a year ago, when I was up in Kansas City, and I had Bill Sedgwick take me in. I had to go down to see it, just out of curiosity, because that's where I'd spent my beginning years with Food and Drug. It was really kind of sad. The building had been deserted for years, the windows were all knocked out, the roof had caved in, and the only way you could even focus yourself and orient yourself in the building was the flagpole outside on the lawn. You knew that right next to the flagpole was Gene Shevling's office and John Parker and Roger Flesch and all these folks who have long since either passed away or retired.

A lot of us were family people and ex-military. This was our first professional job coming out of college, and there was a lot of nervousness coming into the building, not knowing what to expect. I'm sure there was probably nervousness on the part of the new supervisors, because they had promoted a lot of operational folks into supervisors to deal with the influx of new employees. So a supervisor might have ten or twenty or so brand-new people right in off the street, and there would be one or two trained senior people, to take out three or four investigators at a time.

RT: What was some of your initial training? What did they start you out doing?

GP: The trainer assigned to all of us was Jack McGrath. John McGrath, actually; he went by Jack. I don't know if you've ever met Jack, but he was an interesting individual. Back then, the operating grade was GS-11, there was a smattering of 12s, no 13s, and no operational 13s. I think Jack was a longtime GS-12 canning expert.

We had an old training manual, and you had to keep track of what training you had, both on-the-job and formal training. Each week there would be two or three classroom-type training exercises where you'd look at collecting samples for filth and documenting evidence and photography and evidence development and affidavits and the basics of how to be an investigator.

At the same time, they hired a lot of analysts, but I grew up on the investigator side of the house. I'll never forget Jack. He would lay out a directive to us, and it was called a McGrathism. So a lot of us coming out of Kansas City grew up with the McGrathisms of Jack McGrath, what to do and what not to do according to Jack McGrath.

RO: They had a training facility out at TWA (Trans World Airlines)?

GP: Breech Academy, yes. About a month into our training, they brought everybody from around the nation, and I believe it was probably both investigators and analysts, into Breech Academy in Kansas City. They also had a training facility out in Ft. Carson, Colorado, and some

of the new hires went out there, but the lion share of them went to Breech Academy.

Back then, the training organization had an individual by the name of Dr. Harold Post. Dr. Post was in charge of the overall training and orientation of all of us, and the basics of how to be an investigator and how to be a government employee in the large setting. A lot of the operational people who became supervisors came to that training, and it was set up in group breakout sessions. It was kind of a dual training. The new supervisors got exposure to new employees and all the problems that come with dealing new employees.

RT: Do you remember, Gary, what your date of entry was in FDA service?

GP: Yes, I believe it was July 10th, 1972.

RT: Thank you.

GP: Back then they came on board over a period of a month because there was so many people being hired.

One of the first real operational work problems that we got to do in Kansas City involved the Bon Vivant Soup case that had taken place a year or so before we were hired. One of the first activities that all of us in Kansas City were working on involved a recall of Bon Vivant, and the product had been warehoused in Kansas City. The warehouse had gone bankrupt, and the canned goods were sitting there. So the auctioneer came along and auctioned all this Bon Vivant. We spent about a month running around either solo or with trainers, trying to recover

this auctioned-off Bon Vivant Soup. Back then there were a variety of Class I recalls, and we typically did 100 percent recall effectiveness checks.

RT: This warehouse where the Bon Vivant was stored was right in Kansas City, did you say, Gary?

GP: Yes, it was in Kansas City itself. There were probably Bon Vivant warehouses and recalls all over the nation. Wherever the stuff was stored was kind of at the mercy of where it was being distributed. That was one of the first real good operational pieces of work that I got to work on.

Another one that we all worked on was the Diapulse machine. Everybody worked Diapulse back then. I don't know if you've ever seen a Diapulse machine, but it's kind of like a big washing machine with an arm on it that has the diathermy application, and typically there were in the hands of chiropractors and some M.D.'s. That was where you first got the experience of finding out that you were not liked as a government employee in a lot of cases. You also found that these professionals, the medical doctors and chiropractors, could actually treat you pretty tough.

RO: Did you do any spieler work there, or didn't they record spielers then?

GP: Later on we did, and we did a lot of that work in the area of Laetrile, where you'd go out and listen to a sales presentation. It was always kind of a difficult time. Laetrile was another problem on which we'd worked after I'd been in the agency for a few years. It was one of these

issues that you tried to balance caveat emptor versus the public safety.

I stayed in Kansas City from 1972 to 1974, and there was about a two-year training period, or one to two years, in the district office, because almost everybody was hired into the district office, and then they were spread out to the resident posts. Most of us got a chance to go to a resident post. I ended up going to Omaha, Nebraska.

RT: Did that post at the time have a small staff?

GP: It was a large office. Carl Larrick was the resident in charge. It had a consumer safety inspector and a public affairs specialist, although back then it was a consumer affairs officer. Julia Hugley; I don't know if you guys know her.

RT: Yes.

GP: Julie was the consumer affairs officer back then.

So, two of us went to Omaha and added to the resident post up there. Most of us who were hired back in '72 in Kansas City were consumer safety officers or investigators. The fact is, I think we were probably called a Food and Drug inspector at that point. So, yes, I think when we first started we were known as a Food and Drug inspector. Then it went to the CSI (Consumer Safety Investigator) and CSO (Consumer Safety Officer) categories.

Most of us got farmed out to the resident posts. After about a year or so, we started receiving formal FDA centrally sponsored courses like microbiology at the University of

Wisconsin in Madison, canning courses, LACF (low acid canned food) courses, and basic drug inspection training at the University of Rhode Island. After about a year, if you made it past your probationary period, you began to get into some sort of specialization, but specialization really didn't hit until probably a good ten years later. For the most part, everybody started out as a generalist.

Your career path, if you wanted to be promoted, was relatively narrow. If you wanted to be a GS-12, your best option was to become a resident in charge. You typically moved for a resident-in-charge job, or you became a supervisor. We were a very mobile organization then, probably much more so than now.

RO: Were you doing OTC (over-the-counter) work there?

GP: The old BDAC [Bureau of Drug Abuse Control] days?

RO: Yes.

GP: That was just winding down when we came onboard, and a lot of the senior people had gone through the OTC days, the bennies and the uppers and downers, before parts of the agency had split off to BDAC, the predecessor to DEA [Drug Enforcement Agency].

People like Jim Reeves would tell stories. Jim was the resident in Oklahoma City and retired about seven, eight years ago. Jim would tell stories about how they would go to Denver and they would get a truck and they'd drive all the way to Dallas and try to stop at every truck

stop and see if they could make buys, and they would sit in bars at night trying to make buys of amphetamines. That was probably not a fun job.

RO: Although a lot of the people who did that enjoyed it, and when you'd ask them to go out and collect pesticide samples, that was demeaning.

GP: A few people in the agency ended up going to DEA. When I was in Dallas the first time on one of my jobs, I came across some people in DEA who were former FDA'ers long ago, so there were a few people that went over to BDAC and then on over to DEA.

One thing that hit us early when I was still in Kansas City was the transition to the Consumer Product Safety Commission. When I first started with Food and Drug, in addition to the FD&C Act and some of the other laws we enforced was the Federal Hazardous Substance Act. Mixed in with that was the work with hazardous toys and paints and paint thinners and batteries.

RO: X-33.

GP: Yes, X-33, and the NEISS (National Electronic Injury Surveillance System) accident investigations, N-E-I-S-S, or NEISS, however you pronounced them. You would go out on investigations where kids had been injured with a consumer product, like pajamas that would catch fire.

One of the inspections I made was a paint plant over in St. Louis, because St. Louis was

part of Kansas City district. I still remember going over to this paint plant in St. Louis. Of course, I'm trained in Food and Drug stuff, and so I'm sitting in this paint plant looking around, thinking, "What the heck am I supposed to be doing in this paint plant?" Except maybe look at the labels.

But it must have been right around 1974, CPSC (Consumer Product Safety Commission) split off as its own organization, and I remember there was a period of trepidation where people worried about, are you staying with Food and Drug? Are you going to CPSC? I knew some people who went to CPSC, and initially they probably did better under the new agency. There were quicker promotions and that sort of thing. But then, of course, CPSC ended up being a relatively small organization.

RO: Out in that area, you had a lot of medicated feed work, didn't you?

GP: Yes, a lot of medicated feed. DES [diethylstilbestrol] was still being used, and I think what quickly became obvious was you couldn't mix DES in the feed mill and ever get it out of the system. There was just too much carryover. Then eventually, it must have been 1980, somewhere in there, '79, '80, the DES implants became banned because of the concerns about DES.

RT: Did you get involved in the contamination of grain with mercury, mercurial additives to seed grains?

GP: To a limited extent, because of the reprocessing of seed grains. We found that there was a lot of seed grain, each year, that's unused. Then you had just people selling seed grain or byproducts from seed grains that ended up going to animal use. So, quite a bit of work on that.

RT: There was apparently at one point in time some plugging of lots of grain with mercury-treated seed, blending it and then actually sending it to human food processors.

GP: Yes, I guess that's the one real wakeup call you got when you became an investigator in FDA, which is that there really are some unscrupulous people out there. After you've gone through investigations on some of these quack medications, you find there are so many fraudulent products being marketed that it is a billion-dollar industry. It's probably much greater now.

RO: Back then, there was an awful lot of the farmers who didn't consider wheat as a food, and so they had pretty well cleaned up the Clean Wheat Program, because that was earlier when they had rodent pellets in wheat all the time. The same way with them dumping off their seed-treated wheat. What the heck is a bushel of seed-treated wheat into a carload of wheat.

GP: Because there were so many of us starting in Kansas City, they were always looking for something for us to do independently. Probably in the early seventies, somebody decided we would do an elevator survey, and it was probably because of treated grains. So you would get four or five counties in Kansas, Nebraska or Iowa, and you had to go down the road and stop at

every grain elevator. That's when you got a lot of experience riding up in the lifts and carrying the grain examination torpedoes up, and that was always an experience, ninety-foot grain elevators in Kansas, and getting up on top or having to go into the railcars and probe grain.

RT: How long were you in Kansas City?

GP: In '74, I transferred to Omaha as one of the residents, not the resident in charge. I stayed in Omaha until 1977. Again, back then, the operating grade was basically GS-11. To get a promotion, you really had to transfer. That was kind of the bottom line, we were an agency that you moved to advance yourself, and it was kind of expected that if you wanted to advance, you moved. If you wanted to be a 12, you either specialized, and there were limited numbers of 12s, or you became a resident in charge.

In 1978, I moved to North Dakota. I was a resident in Fargo in 1978, and I stayed there about a year. Some interesting experiences in Fargo at dead of the winter when it's forty or fifty below zero without a wind-chill factor.

RO: That was probably a one-person post.

GP: One-person post, yes. I had the entire state of North Dakota. In fact, not only the entire state; I covered eastern Montana. Because that's about the point where we started picking up blood banks, when they picked up the Bureau of Biologics from NIH [National Institutes of Health]. We picked up blood banks and plasma centers to inspect.

RT: Did you have many of those operations in your territory?

GP: Yes. In North Dakota, well, in most states, almost every hospital drew or packed cells. They really hadn't come up with the big regional centers like the regional ARC (American Red Cross) centers or UBS (United Blood Supply) or some of the others, so almost every little place drew or at least packed cells. So every hospital was an obligation then, and we would just go town to town. Back then, most of these smaller towns had hospitals. A town of 10,000 or 15,000 people could seem to support a hospital. Of course, they can't do it now.

RT: You mentioned both elevators and blood operation. Just going down the line, do you think there was some communication between those that the FDA discovered?

GP: Yes, I'm sure. In the elevators, they obviously knew we were going through a certain county, road by road, and the blood banks, unless they were really naïve, they realized that we were on a twenty-four-month inspection schedule, and that we typically tried to be out there in twenty-two months from the point that we were there last, so it was fairly simple math for them to realize we were coming.

RT: At that point in time, with a large territory, this probably involved one- to two-week road trips?

GP: In Kansas City, we actually shared a government car with other investigators. So it literally was, I would take the car out for two weeks, I would bring it back on Friday, and the other person would take it out on Monday for two weeks. So we were in two and out two, and in two and out two. Kansas City has a city earnings tax, and for the amount of time that you were out you could deduct from paying the city earnings tax. I know in Kansas City, I was out 52 percent of the time one year on road trips.

RT: Did you happen to know, when you were in Kansas City, a fellow by the name of Vernon Shrover?

GP: Yes.

RT: Vern was a pharmacist, as I recall, and he went to Cincinnati, and literally was on the road most of the time.

[Begin Tape 1, Side B]

RT: —Sam Alfend, who was director at Cincinnati, really liked him because he'd just live in a motel and do truck stops, and apparently he'd been used to that kind of travel, I assume, in Kansas City, as well.

GP: We had old Olivetti typewriters, and multicopy forms, CRs and FD-483s and that sort of

thing. If you wanted to come home on the weekend in between the two weeks, you did it after 4:30 on Friday and you were back to work at eight o'clock on Monday. That was the rule of thumb. Typically, you were given seven or eight firms to do, and you were expected to have them all done, which is a little bit different from the family-friendly organization we have now, but you would typically, in some of these cheese plants and dairy operations, be in there at three or four in the morning, and you'd still be wrapping up samples at seven or eight at night, to move on to the next place down the road. That was just the kind of the philosophy of work at that point.

RO: It must have been kind of an accounting problem for you on that earning tax thing so that when you were out on the road you didn't have to pay earning taxes.

GP: Yes.

RT: I was going to say that my admiration for FDA was prompted as a state person by this work ethic, because I used to work with people from the Chicago district, particularly during the tomato canning seasons, and these guys would work all day, maybe early in the morning, and then they'd work in the evening in their hotel, getting the samples ready to go. I thought, "Boy, it must be tremendously interesting work to get that commitment," something I don't think you probably see too many places today.

RO: North Dakota surely didn't have many drug manufacturers.

GP: No. Medicinal gas. Almost every gas place that did industrial gas usually did medical gas, and of course, medical gas has really kind of expanded now because of the aging population, but more than anything, the drug industry in my travel area was medical gas.

RO: Problems with medical gases, did you ever really find anything as far as the quality of the medical gases? Most of the problems were on mix-ups, wasn't it?

GP: Yes. I think it took us a long time to come to that realization, and we now have de-emphasized medical gas, single medical gases. They would rather have us do multiple gas facilities. But you're right, it was seldom a production issue. It was typically a mix-up and sometimes a mix-up at the hospital.

Back then, as an investigator, you really were a generalist. You did a blood bank one day, a feed mill the next day, a rendering plant the next day, and the next day a medicinal gas place. Then as a single person resident, you handled all the consumer complaints. Plus you were the liaison to the state typically, and so you worked with various state agencies. I worked out of Denver District when I was in North Dakota and worked with John Vodnick—I don't know if any of you know John.

RT: I know John.

GP: John would fly out to Bismarck, and he and I would meet out there. We'd work with the

state agencies, and he'd fly back. It was always interesting having John come out, because as a single person resident post out there, at times you'd get a little lonesome for Food and Drug people, and so it was kind of nice to see John come up from Denver.

Some of the facilities we used to cover were on the Indian reservations in North Dakota.

RO: Where did you move on to from North Dakota?

GP: In about August of '78, I was at basic drug school in Rhode Island. We had lived in Fargo for about a year now, and my wife and family liked Fargo because of clean air, no crime, a small city, even though it was cold. I get a call from Ted Rotto and Roger Flesch. Ted was the DIB (Director of Investigations Branch) in Dallas, and Roger was the supervisor. I had known them in Kansas City, because Roger was a supervisor in Kansas City and Ted was the DIB in Kansas City. So they called me and said they were going to have a supervisor job open in Dallas, and they wanted to know if I was interested in applying.

I went home and told my wife, "You know, I really don't want to transfer, but it looks good to put in for jobs once in a while," not expecting that I would get it.

So I went off to drug school, and I got a call in drug school that they're offering me this job. Of course, my wife was along, because that was one good thing about drug school, you could take your family along. I remember going back to the house we had rented in Narragansett, Rhode Island, and said, "Our next job, and our next paycheck, is in Dallas."

So in August of 1978, I moved to Dallas as a supervisory investigator. It was a good move, actually. It was my first stint as a supervisor/manager. Of course, it was the only way to

get to a GS-13 at that point, because there were few if any 13 specialists. If you wanted to go higher than a 12, you had to go to a manager job.

RT: How large of a cadre of people did you supervise?

GP: As I remember, I had about twelve or thirteen people. Typically, everybody had one support person, which is kind of now a thing of the past, and usually one CSI (Consumer Safety Inspector), and then the remainder were CSOs (Consumer Safety Officers).

Typically, in district offices, you were assigned a program area and some state coordination as part of your supervisory duties. I replaced Tucker Lightfoot. I don't know if you know Tucker or not. Tucker retired in Dallas, and he was kind of a legend in his own. I guess that was probably the one point that the decision I made probably directed the rest of my career. I think once you get a chance to be a supervisor/manager, there is real satisfaction in the job, and you never want to leave the job. That was kind of the direction that I went after that and I subsequently held a series of manager jobs.

RO: Who was district director at the time?

GP: Jim Anderson.

RT: He was the deputy director, wasn't he?

GP: No, he was the district director.

RO: And the RFDD was Phil White.

GP: Yes, the RFDD was Phil White, Anderson was a legend in his own time. "Papa Bear," he had a name, and he had literally been around about forty years, and he clearly could do just about what he wanted to do.

Unfortunately, he always had a pipe in his mouth. The pipe was kind of propped between his jaw, and he ended up getting a cancer of the palate and didn't live very long.

Then after him came Gerry Vince, Gerald Vince. I had worked with him in Kansas City. Gerry was the director of compliance in Kansas City when I was stationed there. Then after I transferred down to Dallas and after Jim Anderson had passed away, then Gerry Vince got the job.

RO: Was there much difference in the work in Dallas as compared to Kansas City?

GP: Some differences. You know, the similarities obviously were feeds and cattle operations and food plants. The real difference was seafood, because then you had the Gulf fisheries. And you had more pharmaceutical plants. We had a pharmaceutical plant in south Texas and a lot more device industry. Of course at that time, in Kansas City, the device industry may have been there, but devices were one of these areas that you regulated, but we had few GMP controls specifically for devices. We were trying to apply the drug GMPs (Good Manufacturing

Practices).

But by the time I got to Dallas, that district had a significant device industry, and, of course, then the device amendments came along in ’76, so we started regulating devices. So the big difference, I guess, between Dallas and Kansas City was the device and probably the seafood industries, plus, like I said, some larger drug plants.

RO: Do you recall any major regulatory activities at either Kansas City or Dallas?

GP: In Kansas City, because all of us were new folks, we worked on warehouse inspections. I mean, we were all involved in warehouse filth cases. The agency was actively taking filth cases back then, and so almost all of us starting in Kansas City ended up being involved in filth prosecutions and testifying in court. The fact is, that’s where most of us coming out of Kansas City and probably other spots in the agency got our exposure to court time. That, in itself, is a real eye-opener. You never really realize the ramifications of your work until you’ve actually sat in a witness chair and been grilled by a defense attorney. So in Kansas City a lot of the work we did were filth prosecutions.

RT: In Dallas, did you get much involved with surveillance of imports from Mexico?

GP: Yes. Imports back then, when I came down in ’78, were handled by a relatively small group out of Houston. Jim Jones was the supervisor of the import operations, which was relatively small. There was some work coming in through Houston, the port, and then there was

a little bit of work along the border. We had very few ports along the border that we staffed.

It really hadn't risen to the level of responsibility that it has now.

RT: Was that mostly with regard to excessive levels of pesticides?

GP: Yes, that was almost entirely that, filth work and some pesticide work. But then, of course, the world in 1978 is significantly different from what it is now. Now with 80 percent of our active pharmaceuticals coming in from overseas, that didn't exist back then, nor did a big influx of medical devices. So you're basically looking at food for filth or pesticide residues.

RT: Did you also get involved in any surveillance of lead or excessively leaded pottery articles from Mexico?

GP: Yes. In Mexico, a lot of that work took place along the West Coast, though, because of the influx of pottery from China and Japan. Yes, there was quite a bit of work along the Mexican border. Back then we really didn't have any quick tests for lead, and so it was basically collecting ceramics and sending them in for testing. It was kind of hit or miss.

RT: The testing would have been done where?

GP: Kansas City, actually. One thing about back when I started in the agency is to clear up that when we went through our lab reorganization, almost every FDA district office had a full-service

lab. It was typically micro, pesticides, drug, and a filth lab. There was some real benefit in that, because we were doing a lot of micro work back in the early seventies, salmonella in pizzas and a variety of pathogens in food. Typically, what you did was you collected a sample. Back then, FedEx or UPS hadn't come about, so your options of getting refrigerated product to the lab was either getting it there by Greyhound or try to catch some little local airport and convince an airline to carry it for you. But we had a micro lab in Kansas City and Denver and Dallas, and so it made it a lot easier, because you could get micro samples to the laboratories at these locations.

Probably one of the big investigations in Dallas was DES. After the ban on the use of DES implants in cattle, there was quite a clandestine movement of DES implants that were supposedly no longer distributed, but they had been distributed, and several large feedlots were using DES implants. We ended up doing an awful lot of work with DES.

RO: What was the purpose of using DES in animals?

GP: Growth promotion, and it apparently was pretty effective. I don't know whether the original clinical trials weren't good enough, but there was concern that the implant lasted longer than they thought. Then DES was banned for use in feed animals.

My resident investigator, Ralph Godfrey, and I went out to the feedlots on some interesting assignments back then. We had to go out and get some ex-planted DES samples. We had to convince the feedlot operator to bring in some of their implanted cattle, which, of course, weren't supposed to be implanted. They cut their ears open and ex-plant the DES. If you've ever seen an animal with its ears cut open, you know it was an interesting experience.

We conducted a series of interviews at night with cowboys who'd worked these big feedlots. They call them cowboys out there—and then with the management of one of these big feedlots, which in many cases meant management of companies that were based in Chicago and wherever.

On one of the interviews, we went into this room, and there were five or six managers of the feedlot, plus the corporation and their attorneys. One of the attorneys was relatively quiet. Of course, we were all introduced and everything. I find out about a month later, he ends up being FDA's chief counsel. Of course, I always wondered if he knew at that point that he was going to be in FDA. I'm assuming he did. You're one month dealing with this guy on the DES issue, and then the next month he's our chief counsel.

DES was a big investigation, and it ended up being almost a nationwide investigation. There were feedlots all over the country using DES. I always wondered whether the government had erred in some way, because some of the defense that the industry used was that the ban date wasn't widely publicized and there wasn't any real directive to bring the DES implants back. A lot of people just argued that, "Well, you know, we didn't really know the ban date. We thought you could use up existing stocks," and on and on and on.

RT: You spent quite a little bit of time in Dallas. Where was your next assignment?

GP: I was supervisor in Dallas for eleven years. That was the longest I ever held one job, and I was there from 1978 through 1989. I enjoyed the job. I enjoyed the hands-on supervision, the work with the states, and the responsibility for programs. A friend of mine, who is also a

supervisor down there, said, “You know, you really ought to try for another job.” If I probably wouldn’t had that incentive or encouragement, I probably would have stayed a supervisor. I enjoyed that supervisor job.

RO: Was Ted Rotto director of investigations?

GP: Yes, Ted was there. About the time that I left in ’89, he retired in either ’89 or ’90, because I came back down for his retirement.

So I started looking around for jobs, and the director of investigations job that Janice Oliver had then opened up in Baltimore. Of course, I’ve never been on the East Coast in my life, and I thought, “Well, I’ll put my name in.” Tom Hooker was the DD in Baltimore, and Tom came out and interviewed me. He offered me the job, and I’m thinking, “Whoa.”

So that was my move to the East Coast and my move to a director of investigations job. That was a fun job. I stayed in it until 1996. I probably would have stayed in that job had the next best job not come open here in headquarters. During my stay in Baltimore between ’89 and ’96, we were doing a lot of blood work. We were the home district for the American Red Cross, and we recommended an injunction for the American Red Cross, which is still going on.

Those were interesting times in the agency, trying to decide what to do with the biggest blood facility in the nation. We ended up submitting an injunction recommendation. There were some interesting meetings in the agency that I attended regarding the American Red Cross. The decision finally was that we had to do something with the American Red Cross.

We were also doing a lot of seafood work, so we had a lot of seafood injunctions because

Listeria then became the bug of choice, the pathogen that probably had been around for a long time but now because of finding Listeria in California cheese and the linking of Listeria with illnesses/injuries, Listeria became the pathogen of choice. So we began to do a lot of crabmeat plants and began to find Listeria in that and salad operations. So at the same time we were dealing with the American Red Cross, we were also pushing a lot of injunctions on seafood operations.

That period of time, the eighties, was when we probably made the subtle shift from seizures to injunctions. To that point, we had done a lot of seizures, a lot of regulatory letters, which are now called warning letters. But during that period of time, we began to do a lot of injunctions. I think now just before I left the agency, the realization hit that injunction may not be the best way to go just because of the impact it has on the agency to enforce the consent decrees.

RO: They're costly.

GP: Yes, very, very. One of the injunctions that we had over in Baltimore was against Barre-National. Barre was the largest liquid generic manufacturer in the nation. I always wondered who suffered more under that injunction, we or Barre, because we were out at Barre all the time. They learned from us, and then once they were under injunction, their clearances started going through on generics because you can still get an approval on an application even though you're on an injunction, as long as you're substantially in compliance with GMPs. So we spent a lot of analytical time, a lot of investigator time, with the firm.

RO: You had an antibiotic manufacturer there, too.

GP: Yes, we had a veterinary antibiotic company that we subsequently enjoined and put out of business.

RO: What was the name of that firm? All I can remember was Copanos.

GP: Yes. Up to the point that I left Baltimore, Copanos was still trying to get back in operation.

RO: Didn't the firm hire Ted Byers, who used to be the Bureau of Drugs compliance chief, to monitor that?

GP: One of the interesting things you encounter in FDA is the number of FDA people who end up working for the industry. One telling thing was that we had a big meeting with this one medical device company, and so there was our side lined up, the district director, and me as the director of investigations, and the director of compliance, on one side of the table. On the other side, everybody on the other side, except for one guy, had either been ex-GC (General Counsel) or ex-FDA. The president of the company was the only guy that hadn't been Food and Drug. So it was like old home week there sitting at the table.

One of the things that I did in Baltimore, right at the point that I transferred up there was the generic drug problem. We had a company called Pharmakinetics. There are only a few bio-

equivalence labs in the United States and Canada. I think at one point there were about five of them. Generics were just in their heyday at that point. All these little generic operations were popping up, and they had to demonstrate equivalency to the innovator drug. Of course, anytime there's a lot of money to be made, there are people who are willing to bend the rules.

We had this company called Pharmakinetics. Pharmakinetics was doing the bio equivalence studies for all of these generic companies, primarily capsules and tablets. Their role in it was that they were doing studies for some of these companies. Many of these generic drug companies had done their bio equivalence studies at Pharmakinetics.

So we spent a huge amount of time with Pharmakinetics collecting innovator samples and looking at records and on and on and on. It took us a long time to recover from that.

In the thirty years that I was in the agency, there were only a few times when the agency really took some black eyes. The generic drug issue was one. We had some incidents where imports and import inspectors in a couple of districts had got too close to the industry. For the most part, though, I think, as an agency, we were ethical and aboveboard, and we were moral people who did what we needed to do. But we did have some histories, some isolated events that took place in the agency, that didn't give credit to all of the good, hard-working people in the agency.

[Begin Tape 2, Side A]

GP: I guess it was probably late '95 when Bob Fish retired. The agency's headquarters was looking at how should it be reorganized. Of course, we love a good reorganization. There was

one or two studies on FDA headquarters, and the decision was reached coming out of one study. It might have been the Tolen Study or it might have been the study completed by another individual. There were two reorganization studies that were completed here in headquarters. The decision was to combine field investigations. By that point, imports had split off into its own division, the Division of Import Operations. So the decision was to split off imports from DFI (Division of Field Investigations) and then combine emergency operations under Dick Swanson with field investigations, which was under Bob Fish, and combine them into one division. So when Bob Fish retired, probably late '95, Dick Swanson then took over the combined division, although Dick retired in early '96.

So the job came open. I guess I always told myself the only job that I would ever take in headquarters would be director of DFI. So this combined division job came along, and I applied for that. I came over here to Parklawn April 1st, which was April Fool's Day, 1996.

RT: Your title then?

GP: My title was Director of Emergency and Investigational Operations. Subsequently it's been reorganized and made into separate divisions.

It was an interesting time. I had two huge divisions and ended up having almost sixty people. So I had international ops and domestic investigations, plus I had emergency ops. It made some long days, and I spent a lot of weekends down here. Even so, it was an interesting time. It was a good office. There was never any lack of things to do. The days flew by pretty quickly.

RO: Can we back up a minute, Gary? I think it was while you were still in Baltimore when the Office of Criminal Investigations was formed.

GP: Yes. I think they were formed right about ’85, ’86, somewhere in there.

RO: What impact did that have on the regular investigator?

GP: Initially, OCI was trying to feel its way through what its job was. It came about primarily as a result of the generic drug scam, and some of the people who came into OCI were current ORA investigators, such as Jan Longnecker and Tim Rice out of Seattle and some other folks who came in with FDA investigator experience. They had to work closely with district employees, because the district people had the knowledge the drug operation. The OCI people brought the criminal investigations element to it. It was a transition period where both organizations within ORA were trying to feel their way through, you know, how to interact.

RO: They got their own territory.

GP: Yes, and initially there was some concern. I wouldn’t want to call it turf, but you know turf exists in organizations. It was trying to feel out what role each organization played in sharing of information.

Right about then, there was a chief of the Office of Civil Litigation (OCL) in the

Department of Justice. His name was Theroff, I think it was. Anyway, he came up with the position that you can't mix 704 authority with criminal investigations authority, and so that kind of muddied the waters a little bit more, because whatever we gained on our 704 authority, we weren't supposed to use that 704 authority to gather criminal information that we would then turn over to OCI. In working with the OCI people, if you had the OCI people side by side with the field investigators, it was a question of how much could the field investigator share with OCI, and vice versa, without crossing the line and supposedly misusing our 704 authority? So that was some more of the delicate dance in dealing with criminal investigation.

RO: Was that ever resolved?

GP: It was resolved to a point. But whatever information you gain under your 704 authority, you can share with the OCI people. After a while, it kind of got worked out.

RO: What authority does OCI have to go in?

GP: Well, it's kind of been understood under FDA that 704 gives us authority to go in, and the courts have held that up. In certain cases, we had to get warrants.

The one thing that OCI did bring to the mix, which was really good, was the ability to go directly to the U.S. Attorney and the good working relationship they had with the U.S. Attorney. A lot of the OCI people were ex-Secret Service and ex-postal inspectors, and so they had a lot of experience working directly with the U.S. Attorney, whereas we had our GCS (General Counsel)

system and then through Justice and that route to the U.S. Attorney.

So after a period of time, probably two or three years in there, it kind of evened out. At the point when I retired, most of the FDA district offices had a pretty good working relationship with their SAC counterpart (Special Agent in Charge) and there was quite a bit of sharing of information. So that really worked out pretty good.

RO: When you were in Baltimore, you mentioned earlier about laboratory reorganization. During the course of events, a lot of the laboratories have been closed. When you were still in Baltimore, was the laboratory in Baltimore closed?

GP: It was closing. The Laboratory Restructuring Plan of 1994, I think it was called. I had a copy of it because I worked on the closing of the Laboratory Restructuring Plan. That was one of my last things I did. I guess the feeling was, we couldn't operate eighteen labs, I think at that point it was, because we couldn't staff them, we couldn't fund them, and so the decision was to go to regional laboratories and specialty laboratories. So laboratories like Dallas when I was there had a big lab. Kansas City had a micro lab for total diet work.

The decision was to phase some of them out slowly over a period of—I think the last one was supposed to be closed in 2015. Anyway, you had these laboratories that were actually pretty good laboratories. Baltimore had a crackerjack drug lab. They had a good micro lab. Dallas had a good pesticide lab. So these laboratories, through what they saw as no fault of their own, were being phased out. I guess the hope in this plan was that the majority of the analysts in these laboratories would transfer to the mega labs, the regional labs. Unfortunately, what happened is

that wasn't the case.

There were quite a few retirements. There were quite a few analysts who became investigators or transferred to headquarters. Baltimore was in that situation. Baltimore, the lab director, was a guy by the name of Bill Ment. Because of my investigations work, I had a lot of interaction with laboratories. Bill was a crackerjack lab director. He ran a good lab, a good tight lab, was good on timeframes, did good quality work, but the reorganization plan came along and Baltimore was destined to be closed. There was a lot of resentment among employees in the organization at that point as to why is this laboratory being closed when it produced good work.

RT: Did the agency actually lose to other employers a substantial number of folks?

GP: Yes, industry, state labs, there were a variety of places, other feds.

One thing I mentioned was that we actually were a pretty mobile employee group, but we were much more mobile as investigators than we were as analysts. So when I talk about mobility, it was understood as an investigator, if you wanted to advance, you applied and moved all over the nation, but that wasn't necessarily the same philosophy in the analysts. For the most part, they typically stayed in their own laboratory, unless they moved to a lab director job or a lab supervisor job. Then sometimes they would transfer.

So there was a lot of angst on the part of these analysts when their labs were closed, and, again, most of them felt that they ran a good lab and the lab was being closed without good reason. Baltimore has a big import area because of Norfolk and the port of Baltimore. They get an awful lot of cocoa beans and spice into McCormick, and a lot of medical devices and a lot of

seafood, and even condoms. So here's a lab that believed they're geographically set up to accommodate the industry. At that point, imports were becoming much more of significance at the agency than they had in the past.

RT: How many people would you say were really lost by FDA?

GP: I think there were probably less than 50 percent of the analysts who moved to new labs. I know some of the analysts.

So you lost IVD (in vitro diagnostic) expertise out of the laboratories, because, frankly, they didn't want to go to some locations. They just wanted to stay in the area, and they typically did what they could do to stay in the area, and a lot of times, it was not working the bench.

That was kind of a tough time in the organization. The employees exercised their right to go to their congressman in some cases. I think in some cases, it probably hurt the employees because the handwriting was on the wall. A lot of the senior managers, even in laboratories and districts, probably should have recognized that it was a futile attempt to keep these labs open, and probably could have done more to ease the transition of these employees, but it was a tough time for everybody and a tough time for laboratory directors to give up a good lab.

That sore remained an open sore for a long time, because the labs were expected to be phased out clear up until 2015. The last three labs that were to be closed were Kansas City, Denver, and Seattle. So there were three remaining left, and that was Denver and Kansas City and Seattle.

One part of my job as a regional director was, from time to time, we would get special

assignments. One of my assignments was to work with Division of Field Science and determine if we could declare the Laboratory Reorganization Plan of 1994 as completed. Of course, we still had three laboratories that were still on the list. Even though these labs were set to phase out in 2010 and ’15, the employees still found it a sore point, and you’re looking at seven, eight, nine, ten years in the future, some of them would probably long since be retired, but it was still a sore point with those employees.

I worked with Mike Olsen down in field science, and we drafted a plan to close out the reorganization plan, and submitted that plan to the ACRA’s (Associate Commissioner for Regulatory Affairs) office, who then dealt with the commissioner. The commissioner at that point might have been Dr. Schwetz. The decision was reached that we would consider the reorganization plan completed, and so we did. Then we subsequently notified the employees in the three laboratories that the plan was completed, and there was no future plans to close Kansas City, Denver, and Seattle. That was a nice thing to be able to do, was to be able to close out that plan.

RO: What difference did you note when you came into headquarters as a director of DFI as compared to the field?

GP: The first thing, I was pleasantly surprised. After muddling around through the field from ’72 through ’96 in a variety of operational jobs, you always hear “Headquarters never does anything. Headquarters never knows anything. Those bureaucrats up in headquarters in the Parklawn Building.” So that’s kind of what you hear as a field operational person. Of course,

nobody ever wanted to go to Rockville [Maryland]. You only went to Rockville to advance or some scenario like that.

So when I transferred over here in '96, the pleasant surprise was that they had some really good people here, really good, hardworking people. I'd be here sometimes until seven, eight, nine o'clock at night and on weekends, and there would be people in other divisions doing the same thing, field science, the import ops, DFSR—Federal-State Relations. So there were a lot of hardworking people here. That was a pleasant surprise.

The other thing was that up here you got things done through people, so you quickly learned to become a diplomat, because whatever was decided to be implemented here in headquarters, you had to get it done through field managers. Of course, field managers have a variety of things on their plates, five centers that they have to satisfy, and so it was interesting to be able to get to work and get things done through people.

The other thing that I encountered when I was up here is that it is so fast-paced, and it was probably fast-paced when you guys were up here. It was meeting to meeting to meeting to meeting, topic to topic to topic. You would literally just go from one meeting right to another, completely different topic, and you had to be reasonably versed in that topic to decide where you wanted to go with things. So that was always interesting, plus dealing with the congressional folks up here. I found that up here in headquarters you have an awful lot more dealing with the congressional types, and a lot of the staffers were not the most pleasant folks to work with. So I was pleasantly surprised that there is life in headquarters, and there are good decisions that are made up here by a lot of really hardworking people.

RT: In that light, you've served the agency for a number of years. From your various vantage points and maybe more particularly at the terminal end of your career, you've had direct contacts with the top leadership. Do you have any impressions on the commissioners or key leaders that you might share with us?

GP: Yes. The one thing about my job in headquarters when I came here was I had emergency ops and international and field investigations. I had a variety of interactions with a variety of senior managers on the international side because of the European Union Mutual Recognition Agreement (MRA). I worked closely with Bill Hubbard and a variety of other folks here, because we had to implement the MRA. We had to tell Congress what we were doing to implement it. I had a lot of interaction with the senior associate staff up here on those sort of issues.

On the emergency side, I had an awful lot of interaction with Mary Pendergast and Dr. Kessler on emergency operations issues around the world and the United States. Around 1996, '97, somewhere in there, '98, there was this obscure incident that happened in Haiti and there a number of children who died of kidney failure. Of course, I'd worked with Dr. Stu Nightingale, who was in international operations upstairs, and I had a lot of interaction with Dr. Nightingale on international issues. So we learned about these kids who died in Haiti. Their deaths were associated with the cough medicine with acetaminophen in it.

My job was emergency ops, one of the things that I had in my division. So I did what I figured was what I needed to do, which was notify import ops, make sure they're on the lookout for cough medicine from Haiti.

I went to the consumer affairs people, and we put out some notices in Haitian communities here in the United States that there had been this incident, and to be careful about bringing in on personal entry and passenger goods, any cough medicines.

I got a call to go see Dr. Kessler, and so I go up and talk to him. He decides he wants to help.

I said, "All right, so I'll send somebody down." So I get one of my drug investigators, Dave Pulham. It just so happened that Dave was bilingual, and he could speak French. French is one of the languages in Haiti.

The CDC [Centers for Disease Control and Prevention] had helped with the investigation. So at Dr. Kessler's behest, I sent one of the drug investigators down there to work with the Haitian government.

It never did lead back to the United States in very much of a manner. It ended up being a problem with glycerin and diethyleneglycol in glycerin. In fact, it's the same thing as the sulfanilamide issue years ago. But the glycerin had come through various traders and brokers in Europe, and as best we could determine, it came from China.

So I ended up spending probably the next six months, or maybe even a year, sending people to Europe and sending people to China. Dealing with the Chinese government is an interesting experience. We had people over there trying to determine the source of the glycerin, and, of course, there's no direct tie to the United States because it's glycerin that went to Europe, and they went to Haiti. But as a premier health organization in the world, we felt we should be playing a role. But anyway, so I did send people to Europe and China, several times to China, and a couple times to Haiti to help out.

Mary Pendergast was primarily the individual I dealt with on emergency issues. In the Olympics in Atlanta I was dealing with Dr. Frank Young, the former commissioner. Dr. Young was in charge of the department's Emergency Operations Group. So after he was commissioner, he went down there, and I had a lot of interaction with him and working with getting ready for the Olympics.

Our role in the Olympics was primarily the safety of food vended at the Olympics plus controlling what these athletes brought in, drugs and foods and pharmaceuticals. We had a lot of people at the Olympics in Atlanta, forty or fifty people. Then they had the bombing down there, so we're all scrambling in the middle of the night, trying to make sure that none of our people got hurt down there. So I had a lot of interaction with Dr. Young. I always liked Dr. Young. He was a nice guy.

RT: Dr. Young, I think, had a real interest in emergency operations. Were you involved with him? He used to come down when Dick Swanson was down there quite a bit.

GP: Dr. Young was going just as I came up here, and Dick Swanson was retiring.

RO: They reorganized the division that you came into. Was that good or bad?

GP: If you ever look at change and implementing change in organizations, there's a period of time where there's denial and then acceptance and then moving on. So it was a significant change to people to bring all these diverse groups, international and domestic and emergency ops

together, with very few managers to run it. So it took a while in this change to get people to accept the reorganization. It ended up being a pretty large operation. It actually ended up being a larger division than most of the offices here in headquarters, because we had about sixty people spread all over the nation and national experts in various district offices. So it was an interesting time, working with change.

At that same time that the reorganization was taking place, we were going through GPRA [Government Performance and Results Act], because that was the time of the [William Jefferson] Clinton and the [Albert] Gore [Jr.] administration.

[Begin Tape 2, Side B]

GP: So in addition to this reorganization of these diverse groups that were brought together in one division, we were also beginning to deal with the impact of the Government Performance and Results Act. I went to a meeting in downtown D.C. at, I guess, the Office of Personnel Management, and they brought in some speakers primarily from Gore's group. They began to talk about the change that they wanted to see in frontline regulators, and that was a term that I came away with from that meeting. We were frontline regulators. Frontline regulators was like a bad term there.

So not only were we reorganizing as a group and trying to bring this all together in one division, we were also dealing with the impact of GPRA, which ended up being a greater span of control, fewer supervisors, and empowerment of employees. So the entire agency, in ORA (Office of Regulatory Affairs) primarily, went through a significant restructuring that now after a

period of, I don't know, five or ten years, a lot of the organizations have returned to the structures they were before GPRA. So we were dealing with reorganization of this division, plus implementing all the aspects of GPRA in span of control. I had supervisors up here in the division that had twenty or thirty people in their supervisory groups, a span of control of twenty or thirty people. I don't know that you can do that, not in the diverse work that the agency does.

It was an interesting time doing both. A lot of teams, team leaders, team development. That was the big push in the GPRA, with a lot of teaming and empowering of individuals and self-directed work groups and so on.

Then about that same time came along Dr. [Donna] Shalala's efforts to improve the quality-of-worklife activities of the Department's employees. Also about this time, the national union came along. I don't know if they were all mutually exclusive or not. So we had worklife activities, we had a national union come along, and GPRA we were dealing with. I know there were some managers that were just shaking their head, just trying to decide what comes first.

RO: I imagine then when you left DFI or headquarters here and got back to your old homestead in Dallas, you were happy.

GP: Well, you know, it's kind of interesting. I was happy in my job. I was director of the DEIO Division from '96 through 2000, and, again, happy in my job, I'm within two or three years of retirement. I probably would have stayed in the job, but this regional director job came along. My wife had passed away in '99, so I thought I needed a change. So when the job came open, I interviewed for the job. Dennis Baker was the ACRA then and John Marzilli was the deputy. I

was upfront with them. I told them that, "Well, I'm only going to stay about three years, because I want to move on. But I'm willing to give you three good years if you want to take somebody for that short period of time." So they offered me the job.

It was an interesting time. It was good to be back in operations again. Of course, as a Regional Food and Drug Director, you're not nearly as close to operations as you are as a supervisor or a DIB or even a district director. You've got to be real careful that you don't meddle in day-to-day operations or you end up being a thorn in your subordinate manager's side. So it's kind of interesting. It's the one job that I had where I really had to make sure that I didn't mess with day-to-day operations, but where I delegated instead.

One part of the job I felt was really my responsibility as a regional director was to make sure that my subordinate managers had the people and the resources to get the job done, and then step back and let them get the job done, and if they didn't, then deal with it.

The regional director job came along because Ed Esparza retired. He probably retired, it must have been April, May of 2000. Then they announced the job, and then I moved down to Dallas in September of 2000.

RT: You had liaison with the states.

GP: Yes, I had eleven states. I had Denver, Kansas City, and Dallas districts, along with a new mega lab in Little Rock.

RO: Is that lab fully staffed now?

GP: Yes, it is, and it shares the facility with NCTR. That was an interesting lab. We were trying to get up and running a new laboratory starting completely from scratch, brand-new laboratory, bring everybody in. We had some really high-visibility programs. Dioxins are a tough animal to analyze. It's an expensive analysis. You've got a lot of really high-tech equipment, high-resolution mass specs at half a million a pierce and ion trap mass specs at $100,000 apiece, and you've got very few people who can actually operate that level of technology. So it was an interesting time getting these laboratories up and running.

RO: Were there many people that transferred from other districts there?

GP: Down to ARL, Arkansas Regional Lab, no. And that was the one difficulty. There were some reasons. But some of it was if you've been—have you ever been to NCTR, Ron?

RO: Yes.

GP: You're fifty miles south of Little Rock. You're literally out in the woods. If you're an outdoorsman and you like working in a campus-type setting, it is just great. But you had people in Baltimore and New York and in other places where these labs were closing, Denver and Kansas City, and to convince them to leave a mega city like Denver or Kansas City or Dallas and to move to Little Rock was not an easy sell. So there were very few trained people that transferred over, very few trained supervisors. So right now their staffing level is about eighty,

and probably 90 percent of the people are brand new off the street.

In fact, the one good thing is, we're a better-paying employer than anybody in Arkansas, and so we were stealing some pretty high-level folks from the Arkansas state labs and city and county facilities, because we could pay more than they could.

RO: Does the government pay to transfer to the first duty station now?

GP: No.

RO: I thought maybe that would have been an incentive for at least some people.

GP: Yes, only if you're a current employee. But one thing that came along, I don't know whether it was the result of Dr. Shalala, was the ability to get things done. You couldn't pay for that first transfer of an employee, but we had the ability to do what's called above the minimums. So we could say, "All right, we will hire you in our Arkansas Regional Lab, and you've got some expertise either from industry or the state, so we'll bring you in as a GS-11. Maybe we'll bring you in at 11, step 10." So we had a lot of negotiability in the salaries we could bring them in on. We couldn't pay them the relocation, but we could sweeten the deal so that maybe we paid them a little more than they were getting paid right now, to kind of make up for the transfers, so a lot more flexibility in hiring than we had early on when I was a manager.

We got the Arkansas Regional Lab up and running, but we had a difficult time period when I first got down there in Arkansas Regional Lab. We made a laboratory mistake, and you

never want to make a mistake as a regulator, but those things happen. We made a mistake that resulted in the company recalling product. One of the most difficult things in my career was to call this big company and say, "We made a mistake." The company had already started recalling, so there wasn't much they could do. You know, they stopped the recall at that point, but they already had the recall out.

So it was one of the most difficult things I had to do, and I figured that I had to do it because I was basically the CEO of that organization. So when we learned about it, I called the CEO of this big company, who happened to be based in Wisconsin. That made it a little bit difficult. But I had to call this CEO and say, "We've made a mistake."

RO: Well, the FBI made mistakes, and as a result, some of their cases were lost.

GP: Yes. But I figured we're an ethical organization, we're a moral organization, and when we make a mistake, I figured we had the obligation to deal with it. You know, we could have just let it go, the recall was already under way, and just swept it under the rug. But that's not the agency that FDA is. So I called him and I told him, and of course, now there's a potential tort claim that may or may not get filed against the agency, but those sort of things happen, especially in this high-tech analytical world we're in.

In running Dioxins, we're running down so low that you can't even imagine. We're running down in parts per trillion. And the same way with pathogens, you got all of these varieties of pathogens. We actually caught this one ourselves. We caught the mistake when we went back, the supervisors went back and looked at the analytical work and found the mistake.

RO: Did you say what type of product that was?

GP: It was a cheese, probably the second-biggest cheese manufacturer in the United States. We're an ethical, moral agency, and I would expect that anybody in a similar situation in the FDA would do the same thing. I mean, that's what you do to maintain credibility, and we probably end up with more credibility admitting that we make a mistake.

RO: How come you didn't go into consulting like all of your colleagues?

GP: You know, I talked to some organizations about a job, but the reality is, I wanted to try something entirely different. I've always wanted to know if I had what it took to be a teacher. I didn't get a teaching certificate in college or in grad school, because I didn't think at that point I was cut out for it. But I think we really underpay our teachers. We're sending our children to schools, and we're paying our teachers $23,000 to teach the kids of the future. So I thought, "Well, I'm going to get out and I'm going to see if I'm cut out to be a teacher." So this is why I've started teaching at a preschool.

Retirement from the agency, the annuity is pretty good. It's always there every month. It gives you the opportunity to do some other things, and so I'm currently doing the other things. I may, two years down the road, decide to do something differently, but I don't ever see myself consulting. They offered me a chance to come back as a contractor of the agency, and I told

them that I'd think about it in nine months or so. But I don't know. Again, if I wanted to stay, I could have stayed in the agency because I enjoyed the job, but I want to try something else.

RT: Gary, is there anything else you want to add?

GP: No, it's been a really terrific job working for FDA. I can't ever imagine myself putting widgets together as a career. Coming out of the service, I worked in meatpacking for two or three months, and I worked on a bridge crew all the way through college and on a road construction crew, so I've worked in a variety of industries and I've been in the military. I can't think of a better job than FDA because of the opportunities it's given me to deal with international agencies and to deal with governmental issues. Issues that most people only read about in the papers, you're actually seeing it from the inside.

So it's just been a tremendous job. There's always been that concern about the changing workforce and what drives the changing workforce, but we've recently gone through a significant hire because of the counterterrorism activities, with a lot of emphasis on imports. We brought on 820 or 830 people into ORA, but a lot of them are stationed at the borders now. We've also staffed up some of our laboratories. So I've had a lot of interaction with the new folks we've brought onboard. We're bringing a good crop of new employees onboard, so if you had any concerns about the welfare of the organization after you left, all you have to do is look at the faces of these young folks you're bringing onboard, and we're bringing quality people on. We attract quality people.

The other thing I've seen with the FDA managers is that we deal with our problems. We

deal with our problem in place, for the most part, and we have a good staff of employees. I had this supervisor in Baltimore, Lloyd McEwen. Lloyd's people were always really sought after. Lloyd was from Tennessee, so he was kind of a plain-talking guy. But he hired well, trained well, and he fired well. I always marveled at the quality of people that he developed and nurtured.

There are good supervisors out there like him, who develop and nurture good people.

I'm biased. I think ORA is one of the better organizations in the agency because of pretty decent managers, and the fact that we knuckle down and deal with problems when we have them.

RT: We thank you, Gary.

RO: We appreciate very much for affording us this interview.

[End of interview]