History

of the

U. S. Food and Drug Administration

Interviewee:	Gerald E. Vince
Interviewer:	Ronald T. Ottes and Robert A. Tucker
Date:	December 2, 1998
Place:	Parklawn Building Rockville, MD

INTRODUCTION

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

The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source, along with written and pictorial source materials, for present and future researchers. The tapes and transcripts are a part of the collection of the National Library of Medicine.

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INTERVIEW INDEX

General Topic of Interview: History of the Food & Drug Adm.

Date: December 2, 1998 Place: Rockville, Md

Interviewee(s): Gerald E. Vince

Address: [redacted]

Last FDA Position: Director, Office of Regional Operations

FDA Service Dates: July 1960 to July 1998

Interviewer(s): Robert A TucKer and Ronald T. Ottes

Number of Tapes: two length: 120 minutes

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RT: This is another in the series of FDA oral history interviews. This morning, December 2, 1998, the interview is with Gerald ("Jerry") E. Vince, former director, Office of Regional Operations, Food and Drug Administration. The interview is taking place in the Parklawn Building in Rockville, Maryland. Present in addition to Mr. Vince is Mr. Ronald T. Ottes and Robert A. Tucker.

Jerry, we'd like to have you begin, if you would, with a brief biographical sketch of where you were born, raised, educated, and any significant work experience you might have had prior to joining FDA.

GV: All right. Robert and Ronald, thank you for the opportunity to share this awesome occasion with you all. If I go on or babble too extensively in the wrong direction, just wave, holler, or throw something at me.

Let me start off with, as you suggested, where and whence I came. I often tell people that I'm an Ohio farm boy, having been born in Cleveland, Ohio, in 1938. Only child of my mother and father, Eugene and Agnes Vince. That's where I got my middle name, I guess--Gerald Eugene Vince. I was raised in Cleveland, moved to a suburb about when I started junior high school, graduated from Brooklyn High School in 1956, and went on to the Bowling Green State University in Bowling Green, Ohio. At that time it was one of the five state college campuses in the state of Ohio.

My work experience during college years--where I supported myself a good portion--was at the Cleveland City Hospital. Since I was majoring in the sciences, I happened to wander down there my first summer after the freshman year and learned that they were hiring a technician in the pathology lab for the summer. I spent almost three months working there, went back to school, and for the next two Christmas vacations and two summers I was reemployed by the hospital in the same general capacity with slightly increasing responsibilities.

When it came time to graduate four years later, having not achieved a magna cum laude or a Phi Beta Kappa academic rating to gain admission to a medical school, I

thought I probably better look for a job. It seemed the right thing to do at the time. So, among other options that I considered was the fact that there was a bulletin board in the placement office, and it mentioned that there was going to be a recruiter from the Food and Drug Administration on campus the next week or two. I said, "The F&DA, I think I've heard about them and cranberries." But that was the extent of my knowledge about FDA at the time.

In any event, I signed up for an interview, and a guy named Charley Dickinson--does that ring a bell, Ron?--came down from the Detroit District and interviewed myself along with a couple other people. I expressed some reasonable interest in this opportunity again. So as it turned out at the time, there was the requirement of taking an FSEE. Federal Service Entrance Exam, right?

RO: FSEE, yes.

GV: Right. And Charley came back a couple of weeks later and administered the test to several of us. I still believe, frankly, that in the process my name became intermixed with another candidate who passed the test, and he got my failing score. But I was fortunate enough to achieve a passing grade on it. So, lo and behold, I was offered the opportunity to come join the FDA in what was then the fairly new Detroit District office.

RO: What was your degree in?

GV: Bachelor of Science with a double major in chemistry and biology. The reason for the double major was simply that I started off to major in chemistry, but my grades were even less impressive in that than in the biology courses, so I switched over and still had more than thirty hours of chemistry along with the forty or so of biology.

In any event, I accepted the offer to go work for the agency in Detroit and arrived, I believe, on July 14, 1960.

RO: As an inspector.

GV: As an inspector, indeed, thank you. Yes, we were inspectors at that time. One of the things that happened between my signing up for the agency, I was supposed to begin work on the first or second of July, but between the time of graduation and about the month off that had been scheduled, my father had a minor heart attack, so I thought I better stick around home and help on that. So I delayed my starting date by two weeks with the compassionate understanding of the management at Detroit District. As a result of that, there were only three individuals that reported for duty that day. There had been about fifteen that came on board the two weeks prior to that, the pay period before. And having been "V", at the end of the alphabet as usual, with the Vince last name, another gentleman named Nethery . . . I remember that one because I shared a half a desk with him the first two or three months, because all the other desks were occupied by the twelve or fifteen new inspectors that had come on early in July.

RT: Who was the director then? Ted Maraviglia?

GV: No, actually at that time George T. Daughters was the director of the Detroit District. Ted was the chief inspector, as they were called at the time. So I wound up the first two or three months in the process of trying to figure out how we could share one desk with just two chairs and only one hole to put your legs underneath it. We tried to work it out so that we were both either out of the office at different times or other places at the same time. It eventually got to the point where I finally achieved the high honor of having my own desk and chair.

The first six months were very typical. At that time, one had to do everything from collecting wheat from bulk grain cars to examining hazardous substances to assure proper labeling, collecting samples of food products, drug products, and beginning to realize that medical devices might be an important aspect of the agency's operations. They had a variety of things that one was obligated to do in the first six months to assure that he or she--notice that sensitivity, that "he or she" even though there were no she's at that time--was capable of moving on to the next level of experience. So you were obligated to keep a very precise training record of the commodity codes you had experience in. I happened to find that when I was looking through my papers several months ago upon retirement, and I was amazed at how productive we were in those days.

RO: Was there much formal training at all?

GV: A good question, Ron. At that point it was almost a total absence. It was primarily on the job with whoever you were teamed up with that day. You were given your sets of manuals and told to read them, which didn't make a very big impression, obviously, but nonetheless it was something you could learn a little bit about. Shortly thereafter, as a result of this, the training need out there was obviously recognized. The Office of Regulatory Affairs conducted what I believe was the first of several of the "new hire" training courses. At that time I recall that we used a facility, the TWA training facility in Kansas City. The reason I recall that specifically was simply by the virtue of the fact that at that time there were only female flight attendants, and this facility was constructed so that the shower heads hit you in the chest. It was designed solely for females. That happened later in the year.

I do have one thing I'd like to share with the office with regard to a prior colleague, and that was my first road trip, which I was very anxious to go on, of course. As I said, I started in July of '60, and this was about six weeks later, perhaps about the end of

August. I was assigned to go on a two week road trip with Merle J. Ryan, the old Pat Ryan, to do a series of tomato canneries in northwest Ohio and northeast Indiana. If you've ever done a tomato cannery inspection in August in Ohio, it is indeed a challenging task and a very down-to-earth beginning of what one learns about tomato processing in that after the two-week inspection trip, I never drank tomato juice for about five years, because that's where all the tomatoes that were unfit for anything else went--down the juice line.

The other very memorable aspect of that trip was the fact that during one of the inspections of a cannery, Mr. Ryan, the very experienced and well-versed inspector in tomato canneries, and I noted a heavy drosophila infestation from all the rotten, moldy tomatoes being used. So Pat says, "OK, you trainee. Get your butt over there and grab some of those cans coming out of that machine, and we're going to collect a sample of these, pack them up, and send them back to the district office for filth examination." I, being the obedient trainee, said, "Yes, sir, Mr. Ryan, sir," and ran off to grab these cans which were hotter than heck coming out of whatever this machine was called at the time. We put them in a bag, and we took them back to the motel that night. He properly monitored my preparation of the collection report, and identification of the cans, sealing the bag, etc., and placed them back in the trunk of the government car.

This was all fine and well until about two days later when we were writing up the inspection report, and Pat said, "Let me see that collection report." I said, "Why?" He said, "Where did you collect these samples?" I said, "Where you told me to." He said, "You big damn dummy! That was out of the scalder, or whatever it was called, before they had gone to the retort." (Laughter) So we gingerly opened the trunk and found this bag that was already bulging. We drove down a country road, a very vacant and desolate country road, and very, very, *very* carefully took this bag of bulging cans, dropped them in the drainage ditch along the road and drove away like crazy. (Laughter) I guess that

made an impression on me by virtue of the fact that you can't always trust the judgment of your trainer. (Laughter)

In any event . . .

RO: Did you ever go back and collect samples, though, from that cannery?

GV: I believe my trainer made a judgmental decision that it would be best not to lay one's soul bare and make us look stupider than we already did to ourselves. So without the factory sample to show that there was indeed a potential filth problem with this cannery in wherever it was in northwest Ohio, we just figured, well, next season we'll get them to do it the right way.

(Interruption)

GV: One of the other earlier experiences that, unbeknownst to me at the time, eventually wound up as one of the precedent cases with the agency was my assignment to monitor a series of lectures by a gentleman named Lelord Kordell, who was at that time either famous or infamous, as far as the FDA was concerned, in respect to his oral and physical misbranding of various and sundry quasi-health foods. I attended a series of lectures that Mr. Kordell presented at a public facility somewhere in the Detroit area over a week or two's time. These were transcribed later, a lengthy process at the point.

RO: You went in with a tape?

GV: I was wearing a wire recorder. A box. Not a wire, as they call them nowadays, but the typical recorder. I was extremely nervous obviously. Fortunately, I had a very loose-fitting sport coat on and sat over in the corner so I could fumble underneath my shirt

and ignite the button to allow it to begin recording, but I always had flutters in the tummy. The recording and transcript then were eventually used in a seizure of products at several of the retail stores in the Detroit area and at a point later in time, resulted in the citation of Mr. Kordell and the eventual trial that took place. I actually was called as a witness in that trial, probably about two years later, as a result of that. The appeal process became one of the precedent cases, *U.S. vs. Kordell, et al*, as far as the oral misbranding of a food product.

RT: As an aside, Jerry, I worked for the state of Indiana at the time, and two clerical staff were sent down to record Mr. Kordell's presentation, and as they were transcribing it back at the office, it was clear that he had almost won them over, he was such a charismatic talker.

GV: He was indeed. Very impressive and very convincing.

Another area that I had the opportunity to delve into at the time--this was again as I mentioned earlier, we were still enforcing the Hazardous Substances Act--some product safety issues and controlled substances. So I thought this was a neat thing to get involved in and spent a little bit of my time in the second and third year on the job in cahoots with a couple of other investigators doing the OTC (over-the-counter) investigations involving purchases--illegal purchases, as they turned out to be--of amphetamines, antibiotics, Seconal, Nembutal-type products, the quasi-narcotics, etc. I worked a number of truck stops with another investigator, a fellow out of the Cleveland resident post named Norman Deffner. Norman eventually left the agency and went on to become a dermatologist up in Wausau, Wisconsin, with whom I still communicate.

I eventually got my big break, so to speak, to wind up in a situation in Cleveland where an informant agreed to set us up with a meeting of a gentleman who operated out of his attic, a large, old mansion near Lake Erie in downtown Cleveland--Mr. Everett

Cross. The informant took me in the first time, introduced me as a college kid, which I still was fairly young and had a flat top and all that, made a small purchase of amphetamines and suggested that this was a new customer that Everett could trust and that I might come back. So about a week later, I returned to the facility, told Everett that we enjoyed his product a lot. I said we were going to have another big party this coming weekend out at the campus and purchased a bottle of a thousand bennies, as they called them at this time.

This was a good deal for me because now my supervisor was happy, and they were pleased with the activity and the opportunity here to perhaps bust a large dealer, and Everett was happy because he had a new customer who paid cash money. Couldn't use credit cards then, of course, that would have been a little silly to use an American Express government credit card. But nonetheless, I just paid the amount, whatever it was, for the bottle of bennies and went off in a happy way.

About a week later, according to schedule, I called Everett up and reintroduced myself--he remembered me--and placed a substantial order for perhaps 5,000 or 6,000 amphetamines and a couple hundred Nembutal, Seconal, and another bottle, just in case we needed some antibiotics, penicillin, after the party if somebody perhaps had a let's say social disease problem. Covered all the bases here. So Everett was good enough to arrange for a time and place to deliver it. This was a big order now.

But in the meantime--and I'm getting to the point here gentlemen--we were working with the Cleveland Police Department Narcotics Squad. In order to assure that we were doing the right thing here, they arranged for some surveillance and undercover activity. The initial thing that the narcotics guys wanted us to do was to record the transaction. I said, "OK. That makes sense, I guess. How do we do that?" This was where I had another one of these body wires, but this was a more sophisticated one. This was not a thing you just hung on your body; it was actually a unit that you strapped around

your chest and transmitted within a short distance, so they had to be fairly close to the house.

As we turned out for the appointment, I had placed the buy order and had the money ready to make the sale, and we were down at the police station in downtown Cleveland getting ready for me to do my pickup at about 10:00 at night and strapping on the transmitting device. One of the detectives, I don't remember his name, but I remember him by virtue of his demeanor and his size. He was probably about six foot, two inches and 250 pounds, short haircut, and looked like the typical bully on the block.

As I was putting my shirt back on and my sweatshirt that I was wearing that said "Bowling Green University" to make it more authentic, he looked at me and said, "Where's your heat, boy?" I said, "Excuse me, sir?" He said, "Where's your heat?" I said, "What heat, sir?" He said, "Your goddamn gun, you dummy! Where's your gun?" At which point I was shocked and said, "But sir, we're not allowed to carry firearms." I will not repeat the expletive that he shouted at the time, but he suggested these kids in FDA were a little bit stupider than he thought.

In any event, they accompanied us down in their undercover car near the house. I went upstairs, up the flights of stairs into the attic with Everett. Sure enough, Everett was there in his little attic area, his worktable, and already had the bottles set out on the table, scraping the labels off, of course. And on the table was a .38 and a long pig-sticker, as he called it. I said, "Well, this is a very interesting," you know, about an eight-inch dagger. So I was rather a little bit alarmed here, and I kept looking down to make sure there's nothing bulging through my sweatshirt or anything like that. We went through the process, the business and what have you, and I didn't get a receipt, of course, but I paid him his money, and we parted company. I told him how pleased I was that he could be of assistance to me and walked back toward the stairs of the attic.

As I had not paid attention on the way up, because I was a bit nervous, he had closed the trap door and apparently locked it somehow. As I turned around with the box

of five or six bottles and what have you in my hands, I noticed that Everett walked back to the table and picked up the dagger or the knife and walked toward me. At that point I didn't know whether to scream down into my chest and say, "Come get my ass, guys," or what. But it turned out that somehow or another the lock had slipped underneath the trap door, so he just reached down with his knife and flipped it up and opened the door for me. And as I peed my pants going down the stairs (Laughter), hoping this wouldn't short out the transmitter, I wished him a good evening and said I'd be in touch again.

So I guess that's one of the things that led me to believe that that along with the climbing into bulk grain cars at about 10 degrees Fahrenheit in the Toledo rail yards, and collecting samples from grain elevators in Port Huron, Michigan in a less than better climate was an opportunity for me to delve into the pharmaceutical inspection area, because there you worked indoors. It was a nice, clean, quiet atmosphere, I thought. So from that point on, we take a time out here.

(Interruption)

GV: Let me go back and finish up Everett Cross, because that has sort of an interesting ending. At the time, keep in mind that FDA was just tangentially involved with the over-the-counter drug sales, illegal distribution aspects, but in competition with what then was the Bureau of Narcotics--and eventually came to be called BNDD, Bureau of Narcotics and Dangerous Drugs several years later. Most of the inspectors who were heavily involved in the OTC business at that time transferred over to BNDD.

In any event, going back to Everett, after I had made my successful fairly large purchase and got untransmitted by the police department, and wrote up the sample on that, we decided we'd really go big time. We waited about ten days. Didn't want to get him too nervous or suspicious, because I had bought a large quantity--5,000 or 6,000 bennies, etc., and some sleeping capsule preparations.

About ten days later I called him up--we recorded the telephone conversation from the police department offices--and ordered a substantial sum, suggesting that I had a schoolmate friend of mine who was also attending college at a different university. He was interested in perhaps using some of my product, and I could certainly arrange to be a subdistributor. So I ordered a large quantity: 20,000 or 25,000 bennies and a number of other things to make the process look valid. And I arranged to pick it up directly from Everett in his car Friday or Saturday evening--I can't recall. Probably a Friday, because we were going to have a party on Saturday at this other campus.

So that was a reason to be all prepared with several of the big guys from the Detroit District came down--the chief inspector, the supervisor, and a couple other inspectors, along with the two people I had been working with in the Cleveland resident post, and about three undercover cars of narcotics detectives. Everett had told me he would be back around 11:00 at night with the delivery. I would just pick it up directly from his car and pay him his fair share of the profits and be on my way.

Well, we were staked out around the neighborhood, and I was parked directly across, actually in front of Everett's large house, because I told him what my car looked like, and I was expecting him. I sat there very nervously for about forty-five minutes past whatever the time was, 10:00 or 11:00. Eventually Everett's car showed up, pulled in the driveway very slowly and stopped in front of his garage. As arranged, I got out of the car and walked toward his car. At the same time, the narcs had quickly vacated their vehicles and surrounded the building on all sides. As I walked up to the car . . . And there was a prearranged signal. I forget what it was. Maybe I was going to drop my pants or something. But indeed there was a couple large cartons on the front seat by Mr. Cross, along with his .38. Again I got a little bit nervous, and I said, "Hi, Ev. I see you've got my stuff, but also you've got your gun out," at which time about five of these narcs jumped out and stuck their .38s in Everett's face through the windows, suggesting it would be good for him to get out of the car.

As it turned out, Everett was a good guy. He wanted to cooperate and agreed to provide us information to his source. So the next morning, perhaps only half a dozen of us at the time that were left, went down to a local Cleveland drug wholesaler, a rather large operation--we got the small private operation--and awaited the arrival of the presidente. The presidente eventually showed up and opened the building. We went in with him. He felt obviously uneasy. In the process we were able to find very similar bottles to the ones that we had purchased the night before. Of course, there were no labels on them. Also, we happened to find a wastebasket that contained a number of scraping labels, at which time the 6'2" ape-like narc detective gently went over to the proprietor of this establishment, grabbed him by his suit coat, physically lifted him from his feet, and I quote this--I remember these words exactly, almost like about the heat--he said, "Congratulations, you son of a bitch! You're under arrest." At which time, again, I thought, well, this is fun and interesting, but I think it's time to go on to a more challenging area of Food and Drug work, which again led me to the fact that shortly thereafter the '62 or '63 Kefauver-Harris Drug Amendments were passed, and we began getting heavily involved in pharmaceutical inspections.

The Detroit District at that time was a heavy drug district. I sort of developed an aptitude for doing this kind of work. It was a lot warmer and cleaner than crawling around in grain elevators and collecting samples of cucumbers from the field, so I thought this is perhaps the best thing for a young man who wanted to advance in the agency to do. I progressed in that area and actually became somewhat proficient.

Then in about '65, '66, the district announced a vacancy for its first drug specialist, a GS-12, unheard of at this time. I had been threatened with transfer at least twice before, once to achieve my GS-9, which would have been either in Baltimore or New York, and then for the GS-11, they would either ship me off to, as I recall, Atlanta or New York again. Not being smart enough at the time, I said, "Well, I guess if I have to go, I'll go." But because of either budget crunches and/or other issues that impacted upon transfer

funds, I wound up in Detroit as a GS-11 and obviously competed for this first GS-12 drug specialist, and lo and behold, I was the selectee. This didn't make too many other people happy, because many had already transferred twice just to get their elevens. But nonetheless, feeling not too unabashed about it, because I had been ready to transfer if I had had to, because that's the way you did business at the time, I said, "OK. I'll take the twelve and do my best."

I did my best, had a number of seizures, prosecutions, recalls, injunctions, etc. About a year and a half or two years later the Intensified Drug Inspection Program (IDIP) came about, and I was designated as the coordinator for that. So over the next roughly two and a half to three years I would make arrangements for training of the other inspectors who were involved in this process. I worked with a guy named Dr. Sereck Fox, who was a pharmacy instructor at Wayne State University in Detroit. He would come over and put on presentations for us and worked with the Center for Drugs, or whatever it was called at the time, and then provide information, etc. We had a fairly good team of inspectors doing our IDIP inspections. I would usually spend a week, two weeks, three weeks at each of the larger firms along with the teams.

Near the end of that process, I believe it was Mr. Ryan, Merle J. Ryan, and both he and Merv Shumate--the name is familiar to you gentlemen and to me--both transferred, one to headquarters and one to Buffalo, as I recall, leaving sort of a large hole in what was then called the food and drug officer ranks in the district. Shortly thereafter, Jim Simmons came up from Atlanta to take one of those vacancies, and I transferred over, laterally initially, to the position of a food and drug officer handling all the drug work while Jim did the foods. About a year after that, I became the first individual in the Detroit District to go . . .

(Interruption)

RO: Before we go into your experiences as a food and drug officer and the IDIP program, how successful do you think that program was?

GV: In retrospect, Ron, I believe it was probably the right thing to do, but I also believe that perhaps it was a bit overdone. There were a number of what I would consider now, at least, marginal or sub-marginal in some cases drug firms who were in business at the time and simply didn't see the light or recognize the fact that the newly enacted GMPs (Good Manufacturing Practices) for pharmaceutical production were real, and they applied to everybody who was making human drugs and some veterinary drugs. These firms chose to disregard what at that time was some of the very basic, essential procedures and controls that are necessary.

On the other hand, I also believe that perhaps the agency overreacted to that situation with the pharmaceutical industry and spent a little bit too much time and effort in the firms that were in fact acceptable at the time, just looking too intensely for problems or deviations or things that were not serious and were perhaps even in the process of being fixed or corrected, but management simply hadn't had time yet based upon the explosive technology and the application of the GMPs to that industry.

RO: Putting it simplistically, weren't we supposed to stay there to inspect them into compliance or determine that they couldn't get in compliance and then put them out of business.

GV: Yes. I believe that was the philosophy, and that was one of the reasons that in the case of some of the major firms that we had responsibility for in Detroit, Upjohn and Parke-Davis and later Eli Lilly, that the teams were in there sometimes almost a full year, just to cover all the operations and to assure that things were coming along. Then the medium-sized firms, of course, had a similar proportionate amount of time spent in them.

So it was a very intensive process, very expensive for the agency, because many of these firms were not in cities where there was a resident post, and it was an interesting and challenging time. But I believe, in many instances it was something that was the right thing to do by virtue of the very marginal operations and lack of voluntary effort by some of the firms who chose to continue doing business as they had for the twenty years prior to that.

RT: Are some of those points something that you'd like to get on the tape?

(Interruption)

RO: Wasn't that one of the first times that we tried to use a team approach. I remember we were supposed to take laboratory people along the inspections.

GV: I was just hearkening back to that. I was going to add that to my recitation. That is, I recall, even though initially for those of us who had backgrounds in chemistry, as I did majoring in chemistry, I was able to pretty much fairly, honestly evaluate laboratory procedures, because it was 90 percent wet chemistry at the time. But by the point in the mid-sixties, late sixties, the automated analyses, the gas chromatographs, etc., were coming on, I knew diddle-squat about the proper way to evaluate and assess the system suitability of an instrument like that, etc., reading the chromatographs and so on.

We did indeed--at that time, it was a first at that point--take some of our laboratory folks along with us on inspections primarily related to the labs. This was a practice that for some reason was sort of overlooked or disregarded for the next twenty years. It wasn't until again perhaps in the early nineties that management in ORA was reawakened and said, "Gee, we have a tremendous resource in our laboratories, primarily the drug analyst and in those cases of a sterile operation, a microbiologist. So let's get our act together and

make up a team and go out and really do this thing thoroughly and completely and adequately."

I never really understood why we got away from that practice. Perhaps just after the IDIP was over everyone was so exhausted, and it was perhaps a different mentality in the laboratory at the time then. Once you hired out as a microbiologist or a chemist, it was unusual, at least particularly for the chemist to move out of his or her ranks, as opposed to now a number of the foreign inspection cadre. The foreign inspection operation that I managed from my office during my six years in headquarters, a number of individuals on that foreign inspection cadre are analysts or microbiologists. Many are so proficient that they actually are assigned foreign inspections by themselves. So it's a transition, I guess, from the traditional "you stay in the lab and look at the four walls," to a more expansive view and perspective.

RO: Now we can move on to your experiences as a, as they were called then, food and drug officer.

GV: As I think I mentioned, I took over the drug program area. Jim Simmons came up and handled the foods. Eventually, all of a sudden I became a GS-13 food and drug officer, which was again unheard of by not having transferred anywhere in almost nine or ten years at the time. So I performed that task. We wrapped up the IDIP, concluded a couple cases, some seizures, recalls and such.

One of the other things I'm a little bit proud of is that I also helped develop, process, recommend and saw to its conclusion, with a lot of nervousness on the behalf of the Center for Drugs or whatever it was called at the time and our Office of General Counsel, the first GMP seizure of a drug product under 501A(2)(b) as adulterated by virtue of lack of compliance with GMPs. I believe the case is cited as *U.S. vs. White Quadrisect Tablets*. I don't remember the name of the firm, but it was a small pharmaceu-

tical manufacturer in Indianapolis, I believe. That was a precedent case. It was appealed, obviously, and was upheld, and it's one of the cases that's cited by the agency in its pleadings when it comes to adulteration under 501A(2)(b) charges in the litigation process.

After that, the IDIP kind of wrapped up and we had just some other things left over, I realized that I had been in the district for almost eleven years and would not probably go much further. I was happy, I guess, but then again, I sought some additional challenges. So I decided I would apply for a lateral transfer as a supervisory inspector in Baltimore. One of the main reasons was the supervisor I had worked for in Detroit had transferred there as chief inspector. I regarded him highly, and was grateful for how he had developed and trained me. So when Don Sherry had a vacancy in Baltimore, I applied and was accepted.

As might be expected, I was assigned the drug group and import operations, which were substantial in Baltimore at the time. As I walked in the door that day, in 1972 along with Project Hire, the second large hiring operation, I found that I was assigned seven or eight brand new trainees, with a staff of five senior inspectors and one technician. So obviously, this was another unique challenge as to how one efficiently and effectively trained seven or eight new people with only five core members who have from some good experience to about less than two years FDA experience.

So one of the things I would do in the morning in order to address this, and realizing you just couldn't learn by sitting at your desk and reading manuals and waiting for the training course to be available to everybody, was I simply lined these seven or eight people up against one wall near my little cubicle, got the other two or three or four people who were available that day and said, "What are you doing today and where are you going?" They would answer, and I would say, "OK. You and you go with him. You and you and you go with her." At least I got them out of the office and they had an

opportunity to get some on-the-job training along with some basic instructions that we put out along with the other supervisors and the staff.

RT: Let's see. What year was it that you went to Baltimore then?

GV: Late in '71.

RO: Who was the district director? Strait?

GV: Max Lee Strait. Right, M. L. Strait. And another colleague from Detroit District was there in the laboratory--Tom Welch. He had transferred back to Baltimore and I wound up in his car pool. I spent about not quite a year and a half, a little bit over a year and a half in Baltimore, at which time they had the big draft, as we called it at the time, where the field was all going to be consistent and have an investigation branch, a laboratory branch, and a compliance branch. So I threw my hat in the ring, and lo and behold, I guess I either won or lost and was selected to be the new Compliance Branch director in Kansas City District. So we moved out to Kansas City, to the Midwest, very late in '73, I don't remember the exact dates.

I spent a good deal of time in Kansas City, did a little bit of everything, obviously, as a branch chief. I had explained to the staff the impact and requirements of FOI (Freedom of Information), which was a brand new thing. I do remember the regional director becoming terribly nervous and irate and upset and concerned about the fact that we had to provide a copy of a compliance program to a person in the industry under FOI. I developed a very interesting group of folks there. A couple went on to be compliance directors and district directors, etc. That was one of the things I always enjoyed, helping mentor younger individuals or newer folks to the agency, to allow them to compete successfully for other more responsible jobs.

RO: Who was the district director, and who was the regional director?

GV: District director at the time I got there--he had just moved over from the investigation director--was Jim Adamson. And Lloyd Claiborne was sitting in the same building as the regional director for what was then Region VII of the HEW. I guess it was still HEW at the time. I did my thing there and was involved in a number of different type issues, of course, because it was a heavy veterinary drug industry. We did have a little bit of human drugs, which I still had a good grasp on, a fairly heavy food industry, a number of issues involving tissue residues. I got heavily involved in the DES (diethylstilbesterol) implant/explant process during that period of time.

I eventually got a little bit frustrated with what I was doing for eight or nine years and started competing for district director positions. Initially, I was reasonably unsuccessful for that. So it dawned on me, looking at the individuals who were being selected at the time, that one needed to have, as I called it, an expanded pedigree. FDA didn't have the formal development programs in the variety that it does now. I sort of tried to make my own or create my own executive development program.

I sought a lot of details. I got a thirty-day detail as acting district director in what was the relatively new Newark District, a number of thirty- or sixty-day details in various offices in headquarters. Finally, I guess the one that gave me the entree was a sixty-day detail as acting special assistant to a guy named J. P. Hile, and that was an eye-opener as far as the impact that Paul had on the agency and the way he did business--not that I agreed with it totally, as I learned later, but nonetheless, it was an entree.

So I competed for a couple of other positions, was interviewed, and came close on two of them. Finally they announced the vacancies in both Los Angeles and Dallas at the same time, and I made the best qualified list on that. I still think it was unfair, but nonetheless, because I happened to be on a detail in headquarters and both Mr. Claiborne, who was then in the Pacific Region, or Region X, as it was called at the time, and Mr.

Healton, who had then been working out of Dallas in what was Region VIII maybe--I forget, whatever it was--were the two regional directors for the two district offices that had vacancies.

RO: Six.

GV: Six. Thank you. It was Region VI. So Don and Lloyd asked me if I would agree to a joint interview, and being dumb, naive, and stupid, I guess, along with that, I said, "Why not." So here I sat in a motel room in Wheaton, Maryland, across from Lloyd and Don, for about an hour and a half answering a multitude of questions as to who, what, why, and where, and why the hell do you want to be a district director? We got all done with that, and I pointed out that, yes, I was certainly still interested even though I had been harassed and harangued for the last hour and a half and that I was willing to go either to Los Angeles or to Dallas, depending on who was the first to choose me or whoever decided that they would get second string.

I went back to my office about a week later in Kansas City and waited patiently. One day the phone rang, and lo and behold, it was Mr. Healton asking if I was still interested. I suggested that since he appeared to be interested in me, I would, let's say, repay his interest and say, "Yes, I would be pleased to accept his offer."

So in about June of 1986 I transferred down to Dallas District as the new director in a position which really had been vacant for well over a year and a half because of Jim Anderson's retirement, and Don basically ran both the region and the district. I learned a lot the first year. One of the things I've learned over the period of my career is that you should very intensely, carefully, and closely look at almost everything you can in your first year in a new job. Learn the nuances of it, the people, their processes, their abilities, those who you can count on, and those who you have to perhaps be more carefully oversightful for, and those who are nurturable and ready to move on to bigger and better things.

I was very pleased to have developed a good reputation for the district. We did a lot of innovative things. We were able to manage our small budget and our decreasing staff to accomplish the program priorities, and did a good job, and I think that was eventually recognized by both Mr. Healton and the guys that sat in headquarters at the time for ORO (Office of Regional Operations) and ORA (Office of Regulatory Affairs). I got a couple of awards and some bonuses, so I guess I must have been performing reasonably well.

RT: Were there any particular legal issues or actions that occurred during your time as director at Dallas?

GV: Nothing that really jumps out as a precedent case, Bob, but it was a process of nurturing the import program. We first started meeting, I guess, across the border with Mexicans, their representatives who were eager to learn more about how they could help their industry comply and decrease or cut down the number of detentions and refusals.

I also realized very quickly, along with my new colleague in Los Angeles, Mr. Gerstenberg, that we shared a roughly 1,000 mile border with that country, and it was very infrequently that anyone in Dallas District in the import program or the management spoke with the import program managers or district director in L.A. So we decided that we would have an annual conference on the southern border and get together with not only the L.A. FDA representative, but also invite some of the state people where appropriate and part of the time the Mexican officials. I think that was one of the more proper and positive ways of doing business at the time. We at least spoke the same language, so to speak, between the two districts that had the same responsibilities, had a much better communication process, and we were able to do a more efficient job of keeping the bad stuff out.

RT: The state of Texas, it seems to me like there was kind of a special conference relationship with the district down there with that state as well.

GV: Yes. I was very pleased to have that opportunity to not only step into that role, but also to expand it a little bit. We exchanged some details, some information, some data, actually excess laboratory equipment, etc., with Texas, TDH, the Texas Department of Health folks, who are probably one of the more aggressive state health departments in the United States.

I also had an opportunity to work with the state of Oklahoma, who eventually developed an MOU (Memorandum of Understanding) with the district as the first state to almost totally take over the food control work for a state when the agency's resources became strained and there was a very small amount of people and monies to do food work back in the mid-nineties.

On the other hand, Arkansas was a different matter, a rather unusual organization in the states where they had boards, the Plant Board and the Feed Board, instead of an official state agency, but we tried to do our best with them and got along reasonably well with the assistance we were able to provide there.

One of the other things that I, along with Don Healton, were responsible for in Dallas was to try to mold or to let's say remodel the micro lab, microbiological facility in the Dallas District which was being phased out, into a bio-tech lab, which was a partially successful process but never came to full fruition because of the eventual lab consolidation, which I'll talk about later.

RO: Who was the laboratory director when you first got there?

GV: Bill Graham was the lab director, only for about a year. He retired and I selected Darryl Brown, who was a supervisory chemist. By this time, of course, we were all

investigators, the investigation branch. Ted Rotto was the DIB, and Bob Hatfield was the compliance director.

Kind of a new look. We were able to, let's say, become much more efficient in the laboratory along with my managerial and monetary support and Darryl's management of the lab to become the ORA lab that was second most efficient in the country as far as time frames on samples. We developed a very good laboratory tracking system to assure that we were also very high, always in the top five, on the shortest time frame for analysis of violative samples. Good operation there.

We had twelve resident posts that we dealt with, so it was a very large district, a lot of people spread over space, and communication was very important. I implemented a weekly staff meeting where we would tie in the major resident posts by telephone and then reduce the significant notes of the meeting to writing by the end of the week with distribution to everyone.

I guess it was a good place to be because it had been sort of untended for about a year and a half, because Don had other things to worry about besides running a district along with a region. The fact that even though Jim Anderson had been a remarkable individual, Jim was the old school and hadn't adopted many, if any, of the new management tactics, techniques and practices. So I had a wealth of opportunity to do new things that were good things and the right thing to do but hadn't been done before.

RO: Was Houston a station at that time?

GV: It was a branch, Houston Branch. One of the other challenges that I had there was to arrange to, let's say, de-emphasize that and find Mr. (Tony) Whitehead another opportunity to work so we would have a more efficient and less expensive overhead process. Tony finally went up on the regional staff until he retired, and we simply provided the continuation of two supervisors there who reported to the DIB, as I believe

it should have been, as everybody else I believe felt it should have been except for a few people.

We also worked very closely, as I said, with the Texas Department of Health, had several of the first MOUs as far as work sharing, exchanged work plans and tasks of that nature before it became the right thing to do, before it was necessary to do, frankly, and set up a good training program for state counterparts.

RO: Did you have state contracts?

GV: Indeed. And that was an area that I had never had much experience with, but as a result of having that responsibility, and also at the same time changing states . . . As I recall, in '93 maybe it was, we gave up New Mexico to Denver and took on Arkansas, and I started looking at the state contracts very closely, at the food contracts as to what was being done and where. I realized that there was not a whole deal of foresight or planning going on as far as the fact that we were spending maybe $250 to have the state inspect a Frito Lay distribution warehouse where the product came in on a Tuesday and was all gone on a Thursday. So I said, "This needs to be looked at more carefully." One of the issues that I brought up at a regional management meeting and I think was also important in recognizing that management needed to be more active and oversightful in the state contract process to assure that we were getting our money's worth and that the consumer was benefitting from the inspections we didn't have the time or personnel to do.

RO: What was your impression of state contracts? Did we get our dollar's worth?

GV: Well, you know, that's a very interesting question, because I really kind of looked down my nose at it. I thought, Gee, what the hell are we wasting our money for on this stuff when we could be doing it ourselves and doing it better? Actually, I think it

depends, (1) on the state you're dealing with, (2) the oversight and management direction that's given to it, and (3) the ability of the state to accept criticism and/or congratulations. So now I have a totally different view. I think it is worthwhile and even necessary, but one has to be judicious and to select the program areas and the sites or the establishments in concert with the state and assure that they're done properly along with audit oversight. Trust, but verify.

RT: I think the view you had earlier was shared by quite a number of field managers, at which time I think Paul Hile more or less told the regional managers, district managers, "Well, you know, we have money, but we can't hire persons, so let's do the best we can." So that's kind of how the program was finally put on the road, if you will.

GV: It was probably put on the road, but I don't believe you had the direction and the speed limits associated with it at first to make it as effective as it could have been. That was recognized later on, and I believe now that it's even more important.

RT: Bill Cobb, who had left the Food and Drug Administration and went back to state work at College Station, Texas; was he down there at the time you were?

GV: He was. In fact, I had a chance to meet him once before he became ill. I do recall he and Mr. Healton were very close, and Don was extremely distraught when Bill Cobb passed away about a year later. He was a fine fellow from what I knew of him.

RO: So then . . .

GV: So then I got again a little bit, oh, I won't say dissatisfied, but another philosophy I had, and I'll share this with you gentlemen--and the recorder. As I progressed through

my management responsibilities or career milestones, whatever you want to call them, roadblocks, whatever, I recognized after I spent too long in Kansas City as a compliance director that after four or five years, you lose your enthusiasm for doing the same job. Not the energy, because I never got bored.

I never had a chance to be bored, because one of the things I did in Kansas City that I should have mentioned, the last three years I was there I had the opportunity, if you will, to be nominated as the management chief negotiator, when it was the beginning of negotiations and union contract talks with the NTEU (National Treasury Employees Union). I learned more about personnel issues in that three years than I ever cared to, frankly. It came in handy later on in my career, but that was one of the things that was at the time stressful and undesirable but very valuable later in my career.

But anyway, back to Dallas. After about five years, again I got sort of the wanderlust, and this five-year thing set in saying, "Well, you're doing a good job. You've done about all you can. You've about run out of ideas. Things are well. Let's see if you can go somewhere else and screw that up for five years."

So I started applying for some positions in headquarters, and one of those was at the time when Mr. (Ron) Chesemore moved over from ORO to the ACRA (associate commissioner for regulatory affairs) position.. So I competed for that and barely passed the interview, and eventually Ron asked me if I might be willing to come down laterally. I said, "No, Ron, but thank you." You know, I'm working here in Texas with no state income tax and already at a GS-15 level, and figuring out what and where, I said, "I'd lose money." He said, "Well, you're going to get your SES (Senior Executive Service) eventually." I said, "Eventually when you can tell me it's there, I'll be down," because I had talked to a number of people about it, including Gerry Meyer, who was sort of my mentor when I was at headquarters.

You know who Gerry Meyer is. In fact, he's one of my colleagues now, believe it or not, at AAC (AAC Consulting Group, Inc.). He's part time like I am, except that I spend more than part time there.

So Gerry had recommended, and I listened to him carefully, that this was indeed an opportunity, but you should pass it up unless and until the SES is waiting for you when you get here, because once you're here it's too late, and who knows how that process worked at the time.

So after my usual Friday afternoon phone call to Ron Chesemore every Friday for about seven or eight months and him saying, "It's close. It's soon. Don't give up," finally in early June I said, "Ron, come July 4th we're going to take a three-day weekend, and I won't care whether I get a call, because that's when I'm going to say, "Thank you. No thank you, I don't want the job." It's just not worth the frustration or let's say the financial impact it would have on me.

So about two weeks later I'm sitting at my desk, again on a Friday afternoon, Mr. "Cheesemore," as I had come to call him, is on the line, and my secretary says, "Mr Chesemore wants to talk to you." I said, "Oh, what did I screw up on now?" because I usually called him on a Friday afternoon. So Ron said, "Well, when are you going to get your ass down here?" And I quote those words, too. I said, "Why?" He said, "Because your SES is waiting." I said, "I'll be down there in early July, Ron." So, lo and behold, I came down on detail officially and then two months later or so moved the family down there, my wife, and bought a house and spent almost the next six years as the ORO director and went through a number of transitions, modifications, initiatives and things that I'll talk about after I take a small rest break here.

(Interruption)

GV: One of the few perks that I found that came with the SES position was an indoor parking spot, a very desirable activity in the Parklawn Building, so that was certainly a welcome surprise. And the other fact that along with the SES small salary increase, because coming from Texas, I believe it was a $19 every pay period raise, which was not quite consistent with the expensive cost of living here, but nonetheless, we could get along. But in any event, the other aspect that was a bonus, if you will, was that one could accumulate annual leave over 240 hours, but certainly after the first two years in the job as ORO I found that I was lucky to take forty hours a year. So that certainly came in handy eventually.

In any event, I arrived on the job, had four and a half divisions at the time, as I recall.

RO: What was the year there?

GV: This would have been . . . I arrived for official full-time duty September 1, 1991. Damn, that's a long time ago, isn't it? Again, I exceeded my five-year capacity, but it was still an interesting process. In any event, I inherited four and a half divisions, and a vacant deputy position. We had a number of actors in and finally wound up with the chance to select my own deputy, Debra Ralston, who I'm extremely pleased to have had the opportunity to work with and watch her develop over the last several years into what I consider a very competent and efficient manager.

Also, over the next several years, we were able to put in place a new Division of Import Operations and Policy and selected Tom Gardine as the director for that. Eventually, Mr. Tucker's leader moved on, Heinz Wilms retired, and we selected Richard Barnes, which was a shock and surprise to many of the people by virtue of selecting an outsider for an agency position, but I believed and still believe that Richard came very well qualified and enthusiastic and was a good man for the job.

Richard Baldwin was my DFS (Division of Field Science) director. He and I left about the same time. I retired, and he went on to become the regional director in the now Pacific Region, our old Region X. The other two division directors were Bob Fish from the Division of Field Investigations and Dick Swanson from DEEO, Emergency Operations folks, recalls, hurricanes, tornadoes, tamperings, etc. So I had both the opportunity to select what I considered several good people, and inherited several other good ones. That made my job much easier.

Things were always changing at headquarters: new initiatives, new procedures. One of the first major tasks I had--working closely with Don Healton on this--was to develop the laboratory consolidation plan. One of the things I became acutely aware of when I went to Dallas, having had a small branch to manage in Kansas City with a minimal budget, all of a sudden becoming a district director with almost a $400,000 budget, I quickly realized that over half of that went to the laboratory. We needed to keep state of the art. With the decreasing budget and what have you, there was simply no way that we could effectively maintain nineteen district laboratories and keep them adequately equipped and staffed. So it was not a pleasant challenge or assignment, but one that needed to be done. And it's now well over halfway into the process.

I worked on a number of other initiatives for the ACRA and for the centers. A Medical Device Industry Initiative, which is now being expanded to cover all program areas with some minor exceptions or modifications. A significant electronic monitoring process for the import program--the Oasis electronic entry screening activity, which was a very lengthy and expensive process, but was the only way to even try to keep pace with the significant increase in imported products.

RO: You say that's up and running full?

GV: It's as advanced as it can be. It still needs some fine-tuning, but it is as close to what is now available, state of the art and moneywise, as is possible. It's still not the best method or quickest system, but it sure is much more efficient than the old paper review and delay and other aspects of that.

RO: What was the Medical Device Initiative?

GV: That was a spinoff of what initially was known as the Grassroots Meetings, where we would meet--and I attended many of these as a headquarters representative--with the local industry, either as a unit or a specific program area, and listen to what their concerns were about the agency's way of doing business. The medical device industry was very, let's say, vocal and very active at the time because of the agency's close oversight of their activities, the impact of the device GMPs, the 510(k)s the PMAs, etc. They felt they were being overscrutinized by the agency.

It got started with a meeting that--who was it?--Ed, Mr. Esparza chaired I think either in Denver or Dallas as the regional director there at the time. We gathered a group of representatives from the device industry, and we met over here in the ORA conference room. Dr. Kessler spent about an hour or two with the group, along with deputy commissioners, and Ron, and Dr. Burlington, and a number of us from ORA, some of the senior managers. Ed came in. I can't remember who the chair of the committee was at the time. It might even have been Ed, come to think of it, before we changed to district directors.

We listened to their proposals, their twenty-some proposals, some of them crazy, that the industry suggested we could do to make things better and nicer and more, let's say, nonconfrontational. One of these we accepted was . . . Actually we accepted three of them, which became the Medical Device Industry Initiative, a pilot for about a year and a half whereby, (1) there would be a preannounced inspection if the firm was in

substantial compliance, was not a "for cause" inspection or didn't result because of a recall or an adverse event or something of that nature or data integrity. So there would be a five, six, seven-day preannounced telephone call saying we're going to be out there to inspect your operation, looking at particularly this phase, and perhaps wanting to see certain records. It would give the firm time to assure they had the right people on board, and the records were either readily available or already on hand if we knew what we wanted to see.

The second phase, the very controversial aspect, was the annotation of the FD-483s, which provided management the opportunity to have the investigator note on the Form 483 at its issuance whether either the observation, the deviation, the violation, whatever you choose to call it, was corrected and verified, was corrected but not yet verified because we couldn't spend forever waiting for them to do it, or that correction was promised or offered within a certain timeframe.

RO: So that was if the correction was done during the inspection. This was the . . .

GV: Right. If it was an easy fix, and it was demonstrated and documented, then it was shown as "violation corrected and verified." Others they would say it's either in the process of or that it will be fixed within 90 or 120 days because of the need to develop a validation protocol, something you just don't do overnight.

RT: This prenotification, if you will, of the inspection, that seemed to be a real departure from historical philosophy of the agency.

GV: About the only place we had done that in the past, Bob, was with the BIMO (bioresearch monitoring program) inspections.

RO: Well, in IDIP we did.

GV: Well, IDIP, yes. That was . . . We had already forgotten about IDIP. That was a thing of the past, I guess. The other exception, as I recall, was in some instances where some of the districts had a very positive relationship with their pharmaceutical industry that was in compliance, and they would sort of preannounce a PAI, a preapproval inspection, to make sure everything was ready a week or so in advance. But this was a formal process, across the board for the medical device industry, with the district's management exception if there was a violative history, a follow-up to a warning letter, a recall or some other reason to perhaps not be as comfortable with the firm's ethical status.

And the last phase, the third phase of that, was the eventual written notification of a firm's compliance status. If it was NAI (No Action Indicated) or VAI (Voluntary Action Indicated), they would receive sort of a standard form letter from the district management stating that the inspection had resulted in the agency determining a few violations, but because these were either fixed or minor, you were considered in compliance and there would be no impact upon future contracts with the government, etc.

RT: Was there ever any indication of device manufacturers using that kind of a prenotification to their advantage?

GV: There was, Bob, but it was very rare. We did a survey of the--I forget what it was--600 inspections that were done over that period under this process, or 800, and there were only two or three instances where the investigators felt that they had been sort of manipulated by the process or the firm not being as kosher, perhaps, as they could or should have been. Then, as we pointed out, the district had the discretion of not preannouncing the next inspection.

But again, because of the nature of the animal, along with the pharmaceutical industry, you don't preannounce food inspection, because you can clean up and wash and make sure you have nice raw materials. But in the drug and the device industry, 90 percent of your inspection is predicated on a record review, and it's extremely difficult for anybody to go back and fix records for products that were manufactured over the last twelve months and make sure they caught all the little things that may be wrong. So it is really impractical for them to "cheat" in that area.

RT: I think that was a good clarification for anyone that may review this record.

GV: Yes, it is. Thank you for bringing that up.

RO: Is that program still in effect?

GV: That has become a formal program and is no longer a pilot. Starting January 1, a new pilot will be expanded to all four program areas, the other four, with the exception that there will be no notification or preannounced inspection of food firms, and there will be no prenotice of inspection to firms in the blood or plasma product area. But it will be extended to the pharmaceutical industry, to the veterinary drug industry, to . . . Who am I missing? Oh, biologics, with the exception of the plasma and blood firms. If it's an inspection of a biologic firm manufacturing a vaccine, a biological diagnostic, or an allergen, they'll be prenoticed. There will preannouncement of the inspection, but not for blood or plasma products. And, of course, foods will not be prenoticed. It's simply just the nature of the animal.

(Interruption)

GV: Well, I believe that 90 percent of the industry is ethical enough. It's the 10 percent you really can't trust that could do some damage by the process.

RT: During your tenure here, Jerry, you've operated under several commissioners and several management philosophies perhaps. Are there any that you would care to comment on your experience with?

GV: No, actually, Bob, because I had the unique opportunity of working only from one commissioner and one ACRA. Mr. Chesemore just moved upstairs, and he's still here for another month. And Dr. Kessler, or David, as they call him, had just come on board about a month or two before I arrived, and after his departure, we had Dr. Friedman as the acting interim lead deputy commissioner or whatever the title is. So there's certainly a tremendously different style between Kessler and Friedman. One of the things I was very pleased to see, and I sent her a note and got a little note back from Dr. Henney, because I had dealt with her very closely in my first couple of years here, so I was very pleased to see her nominated and finally selected as the commissioner. I think she'll do a very positive job and fill the void that's been open for almost two years by virtue of the absence of a permanent commissioner and, frankly, lack of what I considered necessary decision making in that interim.

RO: Under Dr. Kessler's organization of the headquarters office, the position of the ACRA was changed considerably from what it was in the past.

GV: Yes, and significantly.

RO: Do you care to comment about that?

GV: Well, my thought process on that . . . Go ahead.

RO: Well, you had served, you mentioned, on several details here, one of them, as special assistant to the ACRA under the old regime, so you knew how that operated.

GV: Yes. Well, first of all, I felt that there were too many deputies. With that many, what, five deputies, I don't know how one was ever able to get any consensus or agreement and who was in charge of what. There was a little bit too much, in my mind, infighting as to who is the biggest deputy and who is in charge of what and where.

But on the other hand, from the ACRA's position, the job had gotten so big and overwhelming by virtue of the new regulations, procedures, programs, etc., that perhaps it was time to take some of those things away from the ACRA and reassign them. But then again, I also would suggest that perhaps too many things were removed from the Office of Regulatory Affairs management oversight, and it created some difficulties. Of course, in the last ten years the agency has become much more politicized than it had been. So times change, and one needs to be somewhat flexible. It was perhaps not the best thing to do; but on the other hand, something was necessary. There was just too much to effectively manage and communicate.

RO: If you were asked to counsel Dr. Henney coming in as the new commissioner on her organization of the agency, would you have any comment on that?

GV: I believe that my very basic counsel would be to look at the size and organization of the Office of the Commissioner and consolidate some of that and have fewer managers and more staff available to do the work. I would very seriously consider how much money or resources I allocated to the tobacco process, unless and until there is some very clear statutory language or regulations.

One of the things that I--and I'll touch on this in a few minutes, too, in the MRA (Mutual Recognition Agreement) in the international arena--I would certainly suggest that even though there has been a study for two years that Dr. Friedman has been considering, I guess, the agency needs to do something very soon and very positively to address its role in the international arena by virtue of having three different offices all getting involved in it and in many cases duplicating each other and not knowing what the other is doing. I find that as something which could be very embarrassing for the agency and the United States.

RO: You mentioned MRA. That's an acronym for . . .

GV: I was one of two primary representatives from the Office of Regulatory Affairs to the team that met for over three years with representatives of the European Commission to negotiate the Mutual Recognition Agreement on pharmaceuticals for the agency. This was a major step for the agency. It was extremely lengthy, it was extremely frustrating, and it was extremely tense, by virtue of the fact that a number of us on the team--Mr. Joe Phillips from what was then the Mid-Atlantic or now Central Region and myself, along with Stephanie Gray, the primary rep for the Center for Drugs, Mike Dubinsky from the Center for Biologics, and several people at different times from CVM, who was not a major player--were almost consistently at odds not only with the European Union negotiators, or the European Commission who represents the European Union in this process . . . Not only were we at odds with them, but we were at odds with our chief negotiator, Mr. (Walter) Batts, Office of International Affairs, who worked for Sharon Holston, deputy commissioner for external affairs, who was always under constant pressure and urging by both the U.S. Trade Representative and the Department of Commerce to keep trying, go back to the table even though it seemed like a fruitless task, one we could never come to agreement on.

Many of us felt, as I believe both the House Oversight Committee and GAO are now determining, that the agency may have erred in giving away too much and promising to do too much with the minimal resources available. Not one of my prouder days, I guess, as far as a senior manager for the agency. Both Gary Dykstra, the deputy ACRA, and Ron Chesemore supported our position, but the political winds had their sails blown in a different direction. I won't say we were forced, but we were obligated to give up a number of things that we felt were extremely important to FDA and to the American consumer in order to come to some closure with the European Commission on the MRA negotiations.

I predict--not that I'm into predicting much--that this is something that will be very visible over the next several years as it moves through to the three-year transition period when it becomes effective as far as the agency having to rely on inspection reports from the regulatory bodies of the fifteen member nations in the EC (European Community) to make our decisions on new drug applications or export of pharmaceuticals to the U.S.

I certainly don't feel comfortable with it. I recognize the position that Walter had and that Sharon was under the pressure from the . . . I kind of got the impression that Friedman stayed out of this pretty much. Kessler was not involved in it. David was very selective as to the issues he got involved with.

I remember when I first came on the job, I spent many hours with him on conference calls with the field on the silicone breast implant investigation. And then he became very actively involved in some significant recalls and then much later, much heavily involved with the ephedra compounds in dietary supplements and the adverse effects of the ephedra products.

I always was and am still under the impression that there was extreme pressure from both the U.S. Trade rep, the Department of Commerce, and the White House, saying, "Get your butts back to the table, and try harder, and do this and do that." So I'm

not proud of the agreement, but on the other hand, we didn't give away as much as we could have.

RO: So the agreement now is in effect, in a sense, for a three-year transition period.

GV: The three-year transition period starts, I believe, this month.

RO: Then, if during that transition period . . .

GV: If the agency finds, hopefully--not if; I'm sure they will find--one or more of the European regulatory authorities equivalent to FDA, then we will be obligated to accept inspection reports from that country's investigatory body, inspectorate, if you will, to make decisions on NDAs, or at least the GMP aspect, the quality control aspect of the pharmaceutical houses in that country that export to the U.S.

RO: How do we determine that they're equivalent? I mean, are there . . .

GV: That's one of the things that was always said, "Well, we'll iron that out later," and never got into the nitty-gritty, except for the fact that there would be significant exchanges of information, regulations, programs, policies, joint training, and, if you will, oversight inspections or situations where an FDA representative would accompany the Brit, or the German, or the French, or the Greek, or the Italian inspector and see how they actually conduct a GMP inspection of their firms.

RT: Now the joint training, then, is an initiative of several participants, or would FDA be the lead on that?

GV: See, we never had the time or the opportunity to discuss this nitty-gritty on that, Bob, and that's one of the things that bothered folks like Doug Ellsworth, who was also the secondary member for the Center for Drugs at the time, Mike Dubinsky, Joe Phillips, myself, Stephanie Gray. There just wasn't anything very conclusive about how we were going to do all this stuff with a shrinking budget and the lack of personnel.

RO: What impact does that have on the foreign inspection program that we . . . ?

GV: That's another thing I should mention, too, Ron. Thank you for that. One of the things, a major achievement, I guess, that I feel of mine when I came on as the ORO was that we were inspecting perhaps 300 to 350 foreign firms a year. That process and the budget tripled or quadrupled over three or four years to the point we were making between 800 and 900 foreign inspections a year, over a $2 million budget, and expanded the inspection cadre to about 250 people.

RT: What is the relative proportion of inspections? Let's say foods vis-à-vis drugs or devices.

GV: Devices and drugs usually vie for the top, about 250 to 300. A small number, perhaps 25 or 30, of veterinary drug firms. Perhaps bimos in all three program areas--biologics, drugs, and medical devices--would be close to 100. And then perhaps 40, 50 food firms.

RT: Are there any other countries in the European Community that send their inspectoral personnel here to inspect out firms?

GV: Good question. The Brits do, the MCA--Medicines Control Agency, I believe is their official title--conduct foreign inspections. The Germans on occasion do. And I believe the Swedes may. Switzerland is not a member of the EU, the European Union.

RO: It isn't?

GV: No, sir. They're still neutral. They're beginning to feel the heat, because they're surrounded by fifteen countries that are. So they're thinking about maybe revising their philosophy on that. The only other country I'm aware of that does this same thing is the TGA, the Therapeutic Goods Administration from Australia. They'll actually conduct inspections on foreign soil. Canada used to, but they have had budget problems, as you know, and very infrequently do they make any trips now.

RO: So I guess under this agreement, we won't have individual memorandums of understanding or any agreements with those countries.

GV: That's correct. It would be a blanket agreement with those fifteen member nations and any others that join in the future theoretically. It's something that needs to be carefully monitored and managed.

Another aspect that I became heavily involved in during my tenure as the ORO was expanding the cadre of national experts to provide for at least two and in some cases three nationally recognized investigators in almost all program areas except for vet medicine. I announced and selected the first biotech national expert. I selected one of the individuals from the biotech lab in Dallas District as that representative, and he's performed very well. I'm proud of the young man, since he came across the Rio Grande on his mother's back many years ago and worked his up through a lab technician and now is a GS-14 national expert. Just a great example of success and achievement.

What else was I going to say about something else I mentioned earlier? Let me recollect my thoughts here and take a break from talking.

(Interruption)

GV: I guess this goes back to the laboratory consolidation process. One of the things we worked very hard at and recognized the impact it would have on the people, the laboratory staff for the district we were closing . . . Again going back to my concept and my actual reality and perception that there is a much greater difficulty or a much lesser degree of transfer, mobility, for analysts it seems . . . And one of the things we hoped or at least we projected, based upon the five mega labs, the multipurpose labs in New York; Atlanta; Jefferson, Arkansas; Seattle; and maybe someday Irvine, California, was that we would convince and take as many positive steps as possible to provide opportunities for these analysts to transfer to the new work sites as the old laboratories closed, because certainly that's one of the very important resources ORA had was an analyst or a chemist or microbiologist with ten, fifteen, twenty years experience.

We projected that we thought maybe 50 percent, 60 percent we hoped, but we thought 50 percent of the people would select the options of transferring, being relocated to an identically similar job in a newer, more state of the art, and perhaps better environment than the old beat up facilities we had in Cincinnati, New Orleans, Chicago in particular, and other sites that were not as desirable as Atlanta, as the new New York Regional Lab will be. Jefferson, a brand new facility. They remodeled and expanded Seattle Lab, and eventually, as I said, maybe one in Southern California.

But I guess maybe local management was not objective enough in many cases to push that or to urge or to spend adequate time counseling their employees, and we lost too many of the experienced, qualified analysts to local jobs, reassignment, program analysts, investigators screening imports eight hours a day on a damn computer just because they

wouldn't move or wouldn't relocate or transfer. It was their decision, but I feel badly that the local management allowed that to happen without urging them or making a more concerted effort to say, "Hey, you're valuable to us. We need you. We want you. All we're doing is going to ask you to transfer from here to wherever it might be at your discretion. You have your choice."

It just didn't happen in a couple districts, and I think that's going to have an eventual negative impact on the agency, because when these remaining labs do close and they're consolidated in the five sites, or at least four sites--I don't think anybody wants to go to Pico Boulevard, frankly, in L.A.--we're going to have to go out and hire new people and spend the time and money to train them. So that's just a shortcoming of the process and I think one point where local management screwed up.

(Interruption)

RO: Of course, getting back to the laboratory folks and the fact that they won't transfer, one of the things that we were always confronted with was the fact that a chemist was a chemist or a microbiologist, and they forgot that there was a bigger agency involved here. And it was hard to get most of them interested in the fact of a case, you know, of what do you need in order to develop a regulatory case. So they were scientists, and that was it.

GV: And the exception of those that did leave the laboratory eventually came on to become senior managers.

RO: Well, that's right.

GV: People like you.

RO: Yes, even like me. But you take a look. At one time, you know, we started to count up how many district directors came out of the laboratory, and it was pretty miserable.

GV: I did that, too, and I think one time there was as few as two. That's changed a little bit, but I frankly, on the other hand--and that's another thing that bothers me, Ron--I don't see, and particularly from what's happened in the laboratories, the consolidation and the lack of mobility, I don't see the opportunity or at least I don't see the competitiveness is a better word. I see the competitiveness of very few current laboratory directors being capable to successfully compete for a district or a regional management job. They've just become too ingrained, with one or two exceptions. Now there are some newer laboratory directors in the last two or three or four years that may have that ability. Right now I don't see anybody from the field that is capable of successfully competing for the next higher level management job.

RO: Having come out of a compliance branch and being a director of a compliance branch, I'd like to have your comment on the abolishment of the compliance branches.

GV: I'm not too glad you got me into this, but since you did, I'll discuss it, Ron. One of my major frustrations in the position here in headquarters was ORA 21 or reinventing the agency, and I have several people to blame--and I'll say, frankly, blame for it--as far as the degree of latitude that was given to field management to do things differently. Now there's nothing wrong with doing things differently, but within reason. One of the continual problems I had, one of my responsibilities and one of the very frequent criticisms I got--and I did a lot of programs, industry associations, grassroots meetings, public meetings, information conferences both foreign and domestic the last three or four

years--one of the major criticisms I received as the ORO director representing Mr. Chesemore and Mr. Dykstra was the lack of consistency or non-uniformity of the field.

I was in an extremely difficult position to defend that, because Ron and Gary had given so much latitude to the field management to go out and do what they thought was the right thing without thinking about, maybe, what was the wrong thing or going too far and trying too many different things and not realizing it wasn't working in time to either change it, modify it, or call it back a little bit.

RT: That was almost the other swing of the pendulum from the earlier years when there was such as strong, central control that no one really could take any initiatives that weren't a part of the module.

GV: And Bob, I can really empathize with the regulated industry in respect to a multi-site corporation that has plants in perhaps what's now called New England District vs. New Orleans District vs. Denver District and the fact that they have a uniform QA plan or standard procedures for the three sites that make similar products but experience totally different inspectional techniques or management responses in similar situations. There were necessary extremes.

In my mind, I always had an extremely difficult time dealing with the Pacific Nation, as I called it, or the Left Coast, because they were so far out in different areas and lacked the ability to marshall up forces and get priority programs done when they should have been done, because everybody was doing their own thing and nobody seemed to have any oversight or responsibility on what was happening as far as those things the agency had identified as priority.

RT: Well we even, in my work in Federal-State Relations, the state contract program was what I worked with, and it was almost the Nation of California. They were parallel

to what you said with regard to other states. They presented many problems in the national program.

GV: And the agency--and I'll be very candid--the Office of Regulatory Affairs listened too carefully to California's whining. They paid too much attention to that one state.

RO: Do you think it was a good idea of doing away with the compliance branches then?

GV: I don't think it was a good idea, but on the other hand, I believe it was necessary and appropriate to have a more, let's say, pragmatic or team approach to these issues. One of the things that I did as a compliance director in Kansas City early on was to assure that my compliance officers, as they were called then, instead of food and drug officers, got in on the ground floor, so to speak, with the investigators and even the analysts when necessary to develop a case that we could tell was building.

One of the things I started there was a biweekly compliance meeting with the lab director and some supervisors, the DIB and his supervisors, and the district director and I sat down in a room and went through a list of firms that were on our action list, determining what the status was, what we were doing, what the projected action was, and monitoring the progress and the things that needed to be done or say, "OK. We've done all we can. Let's cut bait. Let's not waste any more time and resources on this firm. It's not that bad or it doesn't call for regulatory attention at this point."

You asked, "Was it a bad thing?" It was in certain cases, because with the exclusion of, or banishment, or disappearance of the compliance branch, some management in the districts and regions provided almost no experience or oversight for the teams, as they called them--teams, I use that term very loosely--that were theoretically developing regulatory actions. I had many, many comments from my colleagues in the Offices of Compliance in the centers about the "trashy work," "crap," "junk," that's

coming in from the field with little or no oversight or assurance of the fact that it's even meeting outstanding policies. Direct reference seizures that shouldn't have been direct reference, or things that didn't require headquarters review that could have been processed directly.

RO: What about OE? Weren't they doing any oversight?

GV: OE was cut out as bad as ORO and the rest of the ORA world. It was an experiment that went too far. Some things were necessary and appropriate.

RO: Is that still going, or has it been pulled back now?

GV: In my view, it's been pulled back, but there's still a degree of disparity as to who is doing what and where. One of the things I could not believe--and I've always liked to look at statistics, not in depth but oversight--that after the first full year of ORA 21, a new way of doing business, we had several districts who went a whole damn year without one seizure, without a significant regulatory action, and a minimal number of warning letters. In my mind, you can't go from one extreme to the other without causing either some sense of uneasiness in the industry or lack of assurance of safety and protection of the consumer from that. Perhaps they were overusing it, but you don't go from one extreme to the other and say, "OK. I'm going to hold your hand and help you fix it," and go on like this and waste time and money and resources for six months, a year, or longer than that and still have nothing to show the consumer or to assure the firm is now in substantial compliance.

There are regulatory tools available to the agency. They are proper ones. They just need to be judiciously used. And in many cases, because of the attitude and lone ranger approach by some of the district management, and regional management, it's not being properly managed or administered. It wasn't; it's better now. It's still got a long way to

come back to let's say a meaningful compromise, but it's sure better than it was three years ago when there was absolutely no direction to what was happening and who was going in what direction. I didn't say that publicly, because I felt too strongly about the agency and ORA's reputation, but it bothered the hell out of me. My supervisors chose to ignore my whining and complaining about it.

RT: Now, Jerry, you've recently retired. I guess we ought to put on record the date of that. You left FDA when?

GV: January 1, 2. (Laughter) July 2, 1998 was my last day on the job.

RO: Well, you aren't under oath. So if you lied a little bit, why . . .

GV: Well, it's close. January and July start with a "J", so I was half right there, Ron.

RT: You are now in a consulting capacity, and as such, do you look at the Food and Drug Administration in any significantly different perspective as an outsider than you did when you were here?

GV: Oh, in a couple ways. And let me point out, only three months experience in the senior consulting role, but I've certainly had a chance to observe and make some observations as to different sides of the fence, so to speak. First of all, I find it very interesting to note that in many cases a firm's management is willing to pay a consulting firm that has a good reputation and experience, as I feel AAC does, several hundred dollars an hour to give them almost the same advice that they would receive from the agency representative for free. Not recommendations, of course, but advice or pointing things out. And they'll act on this a lot more quickly and spend more money than if an

investigator brings it to their attention. I don't quite understand that philosophy, but on the other hand there is a basis for it, because certainly, not all investigators have the same level of experience or the same degree of, let's say, insight or ability to detect and bring to management's attention some things that may need fixing.

RT: Again, in the historical perspective, I think the agency's field representatives were often admonished that their job really wasn't to educate the industry.

GV: That's correct. And I don't believe that has changed that much, except that, by virtue of the way FDA does business now and the impact of FDAMA, it has become a much more, as I call it, user-friendly agency, more industry responsive.

RT: Now what is FDAMA?

GV: FDAMA. F-D-A-M-A. The FDA Modernization Act of 1997.

RT: Oh. (Laughter)

GV: You guys know that. You've just never heard it called FDAMA.

RO: No.

GV: It's a lot quicker than Food and Drug Administration Modernization Act of 1997, though.

RO: Yes.

GV: So that's been a major change in the way we do business--consultation, the public meetings, that sort of thing. And this is good in part, but again, it's something that there still needs to be a line between the regulator and the regulatee. So, I guess that's perhaps one of the reasons that the regulated industry is willing to do business with consultants and assure themselves of their perspective and the experience is usually available in these firms.

RO: Yes, because when our philosophy used to be "Gotcha!" and now you're saying that we give advance notice of when we're coming in, why . . .

GV: I like to think of FDA as still the cop on the block, but they have a little different uniform and are much more willing to talk and counsel people as opposed to grab and arrest. And it's in part the way it should be, but I'm also a little concerned it may go too far. I'm also very concerned--to be very, very candid with you--that the long-term impact of FDAMA on the agency by virtue of the guidance, the regulations, the procedures, the meetings, etc., will have a negative impact on the American consumer unless and until somebody in the agency, and not just the agency, but somebody in the administration is willing to go to Congress and say, "You can't keep giving us new regulations, new legislation, and things to do without more staff. How about user fees?" You know, an end point is going to be reached where we just don't have anybody to do anything.

RO: Do you think user fees have been helpful to the agency?

GV: They have been helpful, but only in a limited area, and that's obviously to expedite the review and approval of drugs and biologics, but that doesn't serve the entire purpose and responsibility of the agency. There's still three program areas that don't have user fees, and many parts of the program areas that do that aren't affected by user fees ORA

in particular has had to eat the resources and doesn't have the money and the people to do the things, the surveillance inspections, the post-marketing, the other necessary and let's say surveillance-type functions that we've been prone to do for many years.

RO: Are we meeting our statutory obligations?

GV: Absolutely not. Not even close, Ron.

RO: We're just forgetting them?

GV: We haven't forgotten them. We just don't like to see how far off we are.

I had an opportunity several times to testify before congressional oversight committees and appropriation hearings in my position here, and it always amazed me that we would be counseled when you go down, "Tell the truth. You don't lie, obviously"--and I wouldn't lie anyway--"But you never say you need more people and more money." I had to bite my tongue a couple times when the chair or acting chair of the committee would say, "Do you have enough staff for this, Mr. Vince?" And I'd say, "Mm hmm hmm," kind of mumbled a little bit, and tried not to answer or cough and let them interpret that as to what it meant. It was just silly to me, particularly in the last six, seven years with the additional legislation and responsibilities, and mammography, modification of the device stuff and things that nobody says, "Gee, you've got eighty-four new things to do, but you can still do it on the same or smaller amounts of dollars and people."

I have had "off-the-record" discussions with committee staff, and they'll ask me, "Why don't you say you need more people?" And I say, "Because I still have a family to feed." You don't go out and contradict. It's not a lie. You simply just don't answer the question responsively. Most of the chairpersons that I've dealt with are, let's say,

compassionate enough to not ask that question. They understand that you can't say it anyway, so they try not to embarrass you with one or two exceptions.

That's another interesting process, the political impact of a job in headquarters vs. that of the field. And that, I felt, was one of my major roles as the ORO, to try and not allow the political things that impact on us here in Washington or Rockville to be transmitted to the field. Let them have the time and opportunity to do what needs to be done. Some things you simply had to pass on, but in those cases where possible, I'd make them less onerous or to require different approaches to it. I did have that authority and responsibility as the ORO. No assignment could issue to the field that had major impact without my concurrence.

It was one of the things that I became very sensitive to, the fact that many centers and offices were issuing draft assignments, just did business in their one way and didn't realize there was a different world, so to speak, or a different environment in the field offices where you make inspections, investigations, collect and analyze samples, monitor recalls, and do your thing without having to worry about what this congressperson thinks or what the department feels is important or that sort of silliness, as I called it.

RT: Well, that certainly is an enlightenment that you've acquired by coming to headquarters, because having worked at the state level before FDA, I used to get the impression from some of the inspectors that FDA is absolutely devoid of politics. After having worked in the Legislative Office in headquarters, that doesn't quite ring true, but it's good that they can operate in that freedom of thought.

GV: In most instances, that's one of the things that we've been able to preserve. When I say "we" I mean ORA headquarters. Not in all instances, of course. There were a couple of occasions, where I won't cite instances, where I simply declined to pass on the

assignment, and my supervisor said, "OK, I'll do it." And I said, "Good, because I'm not going to." I'm fairly strong-willed in that regard.

RT: Sure.

GV: I didn't sign up for that.

RO: Anything else, Jerry, that you want to mention?

GV: Well, a couple of other things, since you've given me the opportunity now to go on my soapbox here. I have always enjoyed, even though I was many times at odds with the center representative, one of my major responsibilities at ORO was to represent ORA headquarters in the field advisory committees that are now chaired by district directors as opposed to RFDDs in the past. Even though there were many times where I was at odds with certain representatives in the centers, you almost always are able to work things out to mutual satisfaction, not being as unreasonable as they wanted to be, but being more reasonable than we thought we might have to be to get the job done.

There are very few people that I don't hold in high regard and respect within the agency. I think it has a high degree of integrity. There are some bummers, some losers, some cheats, but with 9,000 people, you're bound to have a couple. But I've always been impressed with the way we've tried to do business. I think it's a very close-knit family in many instances, particularly within ORA. You know, it's a first-name basis with all the regional and district directors, almost all the branch directors, many of the staff and the people here in headquarters. It's an important job. It's an important agency. I hate to think of us--and I keep saying "us"--being forced to do more and more with less and becoming less effective and less quality minded. That's one of the things that bothered me in my job the last couple years. I just had so much to do that we were sacrificing

quality for the minimal amount of quantity that we were able to garnish from the few people and monies we had left.

One of the other things we started that I still am very reasonably proud of, and on which I worked closely with Gary German, was the investigator certification program. That's continuing, but it's extremely resource intensive. I believe that will be a very positive milestone for the agency. It's being expanded now to biologics and to the Seafood HAACP area (Hazard Analysis and Critical Control Point). There are probably about sixty investigators now that are certified in the medical device program area, and that will continue. I think that was a very positive thing.

Another project I dealt with my last year was the development and management of Team Biologics--a totally different concept where we recruited a number of people, primarily from the field offices and a couple from the Center for Biologics, to be members of this team that worked very closely with its own ORA compliance officers and staff in CBER to assure the proper attention to biologic products that have been perhaps less carefully regulated by CBER staff. That was certainly a very challenging process that's ongoing now. But again, even though there was many an occasion where there was tenseness and argumentative issues between managers and myself, we always were able to work it out, and I think to the benefit of the consumer.

A very family-friendly organization. Big. You know, you don't know everybody. But nonetheless, when there's 130 people in your own office, almost 400 in ORA headquarters, and about 2,800 or 2,900 in the field, plus the individuals you deal within the commissioner's office, OLA, Public Affairs, the five centers . . . I think there were two days in my seven years in headquarters that I was a little bit bored. And that second day I was bored, I decided to hang it up.

RT: Well, your decision to retire then was more a matter of having been in the harness long enough rather than any particular dissatisfaction, then. Is that correct?

GV: Oh, a combination, Bob. I had done as much "stuff" as I thought I could, and it was time to move on and let somebody newer, younger, and with more ideas come in and take over. Plus, the body was starting to age. I started getting that CRS problem on occasion, but nonetheless, I also found that even after two months of retirement that I wasn't ready to *retire* retire. I was offered the opportunity to work with some of my previous colleagues on a part-time basis, which has become more than part time, but nonetheless, I find that I'm able to fulfill some important responsibilities there.

RO: Good. Well, Jerry, we want to thank you for the interview.

RT: Thank you very much, Jerry.

GV: I appreciate it.