

History

of the

U. S. Food and Drug Administration

Interviewee: Ballard Graham

Interviewer: Robert Tucker

Date: June 17, 2003

Place: Oak Brook Hills, IL

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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CASSETTE NUMBERS: 1 & 2

GENERAL TOPIC OF INTERVIEW:

DATE: June 17, 2003

PLACE: Oak Brook Hills, IL

LENGTH: 90 minutes

INTERVIEWEE:

NAME: Ballard Graham

ADDRESS:

INTERVIEWER(S):

NAME: Robert A. Tucker

ADDRESS: 5600 Fishers Lane
Rockville, IL 20857

FDA SERVICE DATES:

FROM: November 2, 1970

TO: June 20, 2002

TITLE: Director Atlanta District Office

(Last FDA Position)

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RT: This is another in the series of taped interviews in the FDA Oral History Program. Today, June 17, 2003, the interview is being held with Ballard Graham, recently retired Director, Atlanta District. The interview is taking place at the Oakbrook Hills Resort and Hotel, Oakbrook Hills, Illinois. Robert Tucker of the FDA History Office is conducting the interview.

Ballard, we usually like to start these interviews with a brief personal history of your personal background and education, so if you would please start with where you were born, educated, and a brief coverage of your employment history prior to joining FDA.

BG: All right, Bob. I was born in Bartley, West Virginia, on March 14, 1947. My parents moved to Indianapolis, Indiana, when I was baby. I don't remember much about West Virginia, other than it was a coal mining town. We moved to Indianapolis when I was a baby. I was educated in the public school system at Indianapolis, went to several public schools there, elementary and also went to high school there, went to Crispus Attucks High School in Indianapolis, Indiana. I graduated in 1966 from Crispus Attucks High School.

I took a break from school and I joined the United States Navy out of Indianapolis. It was on the, I guess at that time they called us 1-A, in the draft. At that time they were drafting. Anyway, I decided rather than to be drafted, to join the Navy. I went in behind my brother. I had an older brother who joined the Navy. I decided to join the Navy as well, so I joined the Navy and entered into the service in Indianapolis. I went through boot camp in Illinois at the Great Lakes Naval Training Center there. I was in the training center from, I think, November of 1966 until—it was like a thirteen-week training course, so I think I finished up there in sometime in

January or February of 1967.

From the training center, after I finished my initial boot camp training, I went on into the Naval Hospital Corps School. I was a hospital corpsman, so I had to go through school there. The school was also located at Great Lakes, Illinois, so there was a training center there for the hospital corpsmen. That was about a thirteen-week training course as well. That was the Medical Service Corps for the Navy and Marine Corps. They would train a bunch of young sailors who had the aptitude for medical areas and that kind of stuff. Apparently, my testing showed I had that kind of aptitude. So I went into the Hospital Corps school, graduated from Hospital Corps school, in '67.

My first duty station out of Hospital Corps school was Bethesda Naval Hospital. I was stationed at Bethesda Naval Hospital for only a couple of months. I worked primarily in the medical records section and maybe a little bit of work on the hospital wards, not much. Most of my time was spent in the medical records section.

I was only there for a few months, and then I was transferred out to the main naval dispensary down in Washington, D.C. The dispensary was on Constitution Avenue. It was like a medical emergency room for just the military service and congressional representatives and senators would also visit there as well. I spent about a year and a half or maybe two years at the main naval dispensary, primarily doing emergency room duties, taking care of dependents and other military people that would come through the doors. I assisted the doctors and nurses with medical treatments, injections, and testing and various other medical treatments.

I was there until 1969, and then I was transferred to Adak, Alaska, in another hospital

setting. It was a small hospital. It was a naval station in Adak, and I was there for about a year. I worked primarily on the ward, delivering newborn babies, and so I took care of newborn babies on the medical ward. So I got some experience in working with infant formulas and medications and things like that, and also doing some minor surgery with the physicians.

Then from there, I was transferred to the USS *Chicago*. It was a guided missile cruiser out of Coronado Beach, California. I was only there for about six months, because from there I mustered out of the Navy in August of 1970.

I went back home to Indianapolis, and I was looking for a job. I visited the Veterans Administration. They had a program called the Veterans Readjustment Program. They put you on a list to find jobs that would be comparable to what you did while you were in the service.

So in the interim, while I was waiting to hear back from the Veterans Administration, I got a job working in a hospital in an emergency room, Winona Memorial Hospital in Indianapolis. It was an internal medicine hospital, primarily in the internal medicine area, but they also had an emergency room. I worked in the emergency room there. I ran the emergency crash cart, for cardiac arrest patients and other emergencies. I worked with the doctors, assisted the doctors, with orthopedic types of surgeries and other kinds of emergencies. People would come in who needed to have stitches or other emergency things or a bone set, and I would assist the physicians.

I was only there for a couple of months, and then I got a call from the VA telling me about a position that they thought would fit my military background working as a corpsman, and it was with the Food and Drug Administration.

At the time, the Indianapolis office of Food and Drug Administration was looking for a person that didn't have a college degree but had some kind of background in the medical area, and they wanted someone that could come in and assist the inspectors as far as collecting samples and assisting the inspectors on inspections or other assignments.

I got a copy of the job description, and it sounded interesting to me, so I applied. At that time, they had the PACE exam [Professional Administrative Career Examination]. I had to take a PACE exam for that position. So I took and passed that exam, and was hired.

I was interviewed by Ray Stutzman, who was the resident in charge at the time. He came by my home and interviewed me and also interviewed me at the office. I was also telephone interviewed by Cliff Shane, who was the director or chief inspector at that time, as they called them, but it currently is the position of director of investigations.

RT: Was Shane at Chicago then?

BG: He was in Detroit. He was the chief inspector of Detroit District at that time. I learned that Ray Stutzman, David Duncan, Larry Boyd, and Joe Stegner were the inspectors at the resident post at that time, Ray Stutzman was the resident in charge. They also had a consumer affairs officer or consumer affairs specialist there by the name of Lynne Goossen. So those were the people in the office, and Betty Bogan was the secretary.

Anyway, I got a chance to talk with them, and they decided they'd like me hired. They passed my name along to Cliff Shane, who telephone-interviewed me. He agreed with them.

They brought me onboard, although it took a while for my PACE exam to clear. So they brought me in under the Veterans Readjustment Program as the VA had authority where they could bring me in without the test score. They brought me in as a GS-3 on November 2, 1970. That was when my FDA career began.

Shortly after sometime in 1971 in March or April, they finally got my PACE exam score back, and I passed. So then they moved me up. I was promoted to a GS-4. Then they moved me, instead of into an inspector's aide position, to the position of inspector technician.

RT: At one time the Indianapolis resident post was in the state health department building, but by the time you joined, they were probably downtown, right?

BG: Right. The resident post at the time when I joined was in the Wulsin building on Ohio Street. It was 200 Ohio Street, in Indianapolis. We were on like the sixth floor of that building. It was a small office, just us. An office big enough to have inspectors, and I had a desk.

At that time we had the old gray desks, the old gray vehicles, no radios in them, no air-conditioning or anything like that. But anyway, I started my career there, and did things such as collecting samples, just assisting the investigators or the inspectors at that time with doing inspections. Whenever they would need someone to come along, maybe they had a lot of samples they were collecting, or there were these quota samples they were collecting, agricultural samples, import activities and things like that, I did that kind of work to assist them.

RT: How long was it, Ballard, before you got some formal training and were able to do regular field inspections yourself?

BG: Normally, they bring you in and you go out with a number of the inspectors at that time. I went out with Larry Boyd and Stegner and Duncan and Stutzman. I don't remember the names of some people from Detroit. They would come in and they would have me go out actually on-the-job training where you go out and actually do an assignment, show you how to collect the samples, show you how to do a kind of a simple routine sanitation inspection. So it took about six months to nine months to get that experience under my belt to be able to go out and actually do some of those assignments on my own.

I went out. The first inspection I did was a little small warehouse. It was like a little candy warehouse, where they had candy stored. I went in and did the inspection. Didn't find much of anything. It was just a relatively clean place, no infestations of any kind. I got a chance to go out and do some actual sanitation inspections of actual manufacturers, candy manufacturers, where they actually manufacture candy. These were what they call the minor routine easy types of inspections to do, where it was just a routine sanitation inspection and looking at ingredients at the packages, writing down ingredients, seeing if there were illegal colors being used.

RT: When was it or did you somewhere along that early part of your career get an opportunity to attend or participate in formal training, classroom or whatever?

BG: My first opportunity to actually have formal classroom training was in 1972 when they had the Project Hire training, where they actually took us to the Brinks Academy in Kansas City. I think that was where they trained the airline stewardesses. Anyway, that's where they brought all the new hires in, and I was amongst one of the classes that went there, and went through the formal training.

RT: Cliff Shane, as I recall, was assigned as a project leader for Project Hire, so he had left Detroit, of course, by that time.

BG: Yes. He was at Cincinnati, I think, at that time. He moved on to Cincinnati. Yes, he was one of the project leaders, and, I believe, Jim Simmons. Let's see. They had a number of people that were involved in that training. They had Homer Ransdell from Chicago. I'm trying to think of some of the names that were there. E. Pitt Smith, he was there. He was on one of the project leaders.

RT: That was a national hiring program, wasn't it?

BG: That's right.

RT: We increased manyfold the field personnel of the agency. Do you recall what was behind

Project Hire?

BG: The reason Project Hire came along was because of the incident in 1971, I believe, when they had the Bon Vivant vichyssoise incident, where they had a Bon Vivant vichyssoise, cold potato soup, that had been contaminated with botulism, *Clostridium botulinum*. That was the reason for the additional hiring. There was concern that we were not covering the food areas as well as we should be as an agency because we were understaffed. So that was one of the reasons. That was the big reason we had Project Hire in 1972.

RT: Did the aminotriazole cranberry problem come to pass when you were there? Maybe that was before your time.

BG: That was before I came. That was in the late sixties. I came in just about on the tail end of that. I tell you what, when I came in, the inspectors were telling me about the IDI [Intensified Drug Inspection] Program. That's where they did the in-depth drug inspections. That's prior to the current GMP [Good Manufacturing Practices] regulations that we have now, but a lot of those guys, like Stutzman, would spend almost a year, or two, in a drug firm thoroughly reviewing on a daily basis the drug manufacturing records. That's what they were doing prior to my arrival.

RT: While you were still in Indianapolis, did you get any experience in drug manufacturing?

There were a number of major pharmaceutical firms in Indiana.

BG: I did. I got an opportunity to do some sample collections in some of the pharmaceutical companies, actually go along with some of the inspectors at the time, and at least get a glimpse of some of that special activity, with respect to a pharmaceutical inspection operation. So I got some of that at Eli Lilly, Dow and Pfizer, as well as at some of the other smaller firms. Central Pharmacal was there, and a couple other small pharmaceutical operations, independent generic-type operations.

RT: How long were you in Indianapolis before you were transferred to another post?

BG: I have to back up a little bit, because while I was in Indianapolis, I didn't have my college degree. In 1971, we had a supervisor arrive. His name was John W. Davis, John W. Davis, Jr. He was the first supervisor there at that resident post, and he encouraged me to pursue my college degree. I guess he saw I had great potential for the organization

At that time I was married, or I was just getting ready to get married, so I had to work. I wasn't where I could just not work. At that time Indiana University and Purdue University opened up a campus in Indianapolis called IUPUI, and it was more or less oriented toward adult education. I was able to take what they called evening classes, after work. What I did, I signed up and registered for school, got in, was accepted, and I went to school under the G.I. Bill there in Indianapolis at the IUPUI campus. They had three buildings there at the time when I started

my college education.

I took like six hours a semester. They had semester hours then, so each semester I would take as much as six credit hours. Sometimes I'd push it up to nine. But that's the way I started out in 1971 under the G.I. Bill.

Then in 1975, the Stride Intern Program was established by the agency, and out of that, I think I completed like about twenty-four hours credit hours toward my college degree at that time. The Stride Intern Program allowed you to work part-time and go to school part-time, so I applied for that. I think it was like three or four or five us in the region, but that was Region Five. I applied and was accepted into the program.

I did Stride from 1975 until 1977. I think at that time they were trying to send you to school to get a degree, but then they found out it was illegal to do that, so you were only able to get the credit hours you needed in order to move into your professional series. So I was able to get the thirty hours of science required to move into the investigator position. But I was so near a degree that I decided to go ahead and finish my college degree or get my degree. So after the Stride Intern Program, I went back and completed my degree program under the G.I. Bill in 1978 from IUPUI.

RT: At that time, after you got your degree, were you able then to advance in grade to, what, a journeyman inspector?

BG: Before I got my degree, I had been converted from an inspector technician to a full-fledged

inspector, a GS-7. When I met the requirements of hours and experience, my supervisor promoted or transferred me over to the Inspectors Series 696.

RT: That's rather an interesting and unique entry into the agency. Are you aware of that opportunity being provided at other locations at that time, or were you unique in that respect?

BG: I think at that time we were amongst a unique group, because I think that was the initial phase of the Stride Intern Program. Then I think from there it went on to the coop program. It went on to another type of series. But we were the initial group. It was like, I think, four or five of us who initially started out. They picked two, and I was amongst those two. It gave me an opportunity to expedite my progress, to get in the necessary credits I needed in order to move into the professional series for the grade.

RT: Of course, the other experience you had in the military was a good background to move into this area of work, and no doubt stimulated your interest in this kind of activity.

BG: Absolutely, absolutely.

RT: Prior to that time, had you been familiar with FDA?

BG: That's a very interesting question, because prior to that, I had really not paid any attention.

You read things, but you never think much about the FDA, because you hear the name and it kind of flashes, so you're not actually intimately involved. It was like when they came to me, and I said, "Food and Drug who?" [Laughs] I started doing some research on Food and Drug, and I said, "Wow. This is really an important organization," prior to joining. But before that, I really didn't really have much knowledge about the organization. You heard about the cranberry thing around the holidays, and that kind of stuff, back when it happened, but otherwise, you just didn't pay much attention to what the agency was doing.

RT: It wasn't a household word.

BG: No, it wasn't a household word, not at all.

RT: You spent some time then after being enrolled, if you will, in the full-time journeyman level at Indianapolis, and then you transferred, to where?

BG: I transferred to Denver District, actually the Sioux Falls, South Dakota resident post. Prior to leaving Indianapolis, I was able to attend some additional FDA formal training schools. I actually went to the one-month drug school in Rhode Island. I actually had an opportunity to do that, and I think it was in 1977. Shortly after I was converted, I went to basic drug school at the Rhode Island School of Pharmacy.

RT: Up to that time, it seems that you were primarily food oriented.

BG: Primarily foods.

RT: Was that a switch point in your career for involvement in pharmaceutical products?

BG: That was the beginning of switching over to the pharmaceutical area, but although when I was in Indianapolis, I worked in all the food area, all the veterinary drug, because I was out on farms actually doing the sample collections where you do tissue residue investigations, actually visit the slaughterhouses, actually went out and collected all kinds of samples, imports, domestic, agricultural samples, all kinds of things that I was actually involved in during my work in Indianapolis.

Then I went to the basic drug school. But then when I was transferred out of Indianapolis and went to Sioux Falls, South Dakota, which is primarily a farm area, so you had primarily veterinary drug work. That's what I primarily did quite a bit of.

RT: When you went to the resident post in Sioux Falls, were you the only resident person there, or was there other staff there?

BG: It was a single-person resident post in Sioux Falls. There was another resident post out in Rapid City. I was on the eastern end of the state, and they had another resident post at Rapid

City, South Dakota. There was another resident out there. Then there was a resident in Helena, Montana, and one up in Fargo, North Dakota.

RT: While you were in the resident assignment, did you get into any particular regulatory problems or issues that come back to you on reflection now?

BG: I remember one significant investigation. This was an investigation that the Baltimore District was doing on chloramphenicol. Chloramphenicol is a drug primarily approved for use in dogs. It was only approved for use in dogs at that time. Anyway, they had a case that they were looking into where they suspected the product was being produced and used in beef cattle. So they sent out an assignment for me in Sioux Falls to go out and do an investigation of a particular veterinarian somewhere in South Dakota. Big Sioux, South Dakota, I think was the name of the town he was in.

Anyway, I went to this veterinarian and started asking him questions about receipt of this product, and he admitted that he had received the product. He said he used it in his clinic to treat dogs. There was something that caught my eye there, because he had some bottles of this stuff. It was like some opaque plastic bottle. It was like a green substance in it. I noticed that some was sitting on a table, and there was an invoice there. It was an invoice to a cattle feedlot. It was unlabeled and it just had the invoice there.

So I jotted down the name of this cattle feedlot. I went out from there, and I had to find this place. It was way out in the boonies someplace in South Dakota. It was very close to Rapid

City. It was like in the middle of the state. I went out to this cattle farm and started asking this cattleman about this product he'd received from this veterinarian. He said, "Yes, I received that."

I said, "How do you use it?"

He said, "Well, I use it for my cattle. When they get sick, I use it."

I said, "What is it?"

He said, "I don't know what it is. I just get it in a green bottle."

I said, "Well, do you have any more?"

He said, "Sure."

I said, "Well, do you mind if I take a look?" So he took me down to his basement where he had it on a shelf, which was full of these green bottles. It was unlabeled, and so I said, "Do you mind if I get a sample of it?"

He said, "No. You can get a sample of it. I don't know what the stuff is." I think he really knew what it was, but he kept telling me he didn't know what it was. Anyway, I got some samples of the stuff and sent it to the laboratory. Sure enough, it came back, it was chloramphenical.

RT: So that was an off-label use?

BG: That was an off-label use of the chloramphenical. They were using it to shoot up the cattle. I got an affidavit from him, saying, "Yes, I used this product," and what have you, and made a

case for the Baltimore District, because it was shipped from apparently Maryland somewhere over to South Dakota and probably several other places. So they were able to make their case.

RT: Was any regulatory action taken against this vet?

BG: Regulatory action was taken against the shipper of the product out of Maryland. I don't know if they ever followed up on the veterinarian in South Dakota, but they did take an action against the shipper out of Maryland.

RT: You remember who the Baltimore, Maryland, firm was?

BG: I don't remember the name of the Baltimore, Maryland, firm. I know I probably have it somewhere in my records.

RT: I just wondered if it was a large company or a small.

BG: I can't remember whether it was large or small. But Janice Oliver was the director for investigations branch. She sent me a nice letter thanking me for my efforts and work that I had done in making that case for them, because it made their case. They couldn't figure out what this guy was doing with this stuff. They knew he was off-label using it, but they didn't know how he was doing it and what have you, because he was doing this clandestinely as far as shipping and

stuff. He wouldn't label it and what have you. So he would ship it, and then the people at the other end— [Laughs]

[Tape recorder turned off.]

RT: Besides the chloramphenicol problem, what other kinds of activities did you encounter in the resident post that were broader in responsibility than that one activity?

BG: Yes, when I was there in 1981, we had the first Tylenol incident where some perpetrator tainted Tylenol capsules with cyanide.

[Begin Tape 1, Side B]

BG: In 1981, they had the first Tylenol incident where a perpetrator actually took Tylenol capsules and put the cyanide poison in the capsules in the Chicago area. I think about seven or eight people died as a result of this incident. At the time when that happened, I was the resident in charge of Sioux Falls, South Dakota, and I was left with the job of contacting a number of my counterparts at the regulatory state and local level to assist me with going out to a number of distribution facilities as well as retail establishments, work with the local authorities, police and what have you, to make sure that all Tylenol were pulled from the shelves of these stores and also collect samples to send them in to the Denver District. The Denver District was working

around the clock. They had people in the laboratory working around the clock, taking tablets apart and examining them.

That was a really interesting case that took a while to work through, and I don't think we ever caught the perpetrator of that particular crime. But it brought about the tamper resistant packaging regulations because of that particular incident. But that case kind of put me out there, because a number of the news media in the area would contact me and actually interview me on the radio and TV to present the agency's point of view on a number of these issues and regarding what consumers and the public needed to do, as far as taking precautionary measures.

RT: Since this problem seemed to originate in the Chicago area, did you find anything in your area that occurred with regard to tampering?

BG: We didn't. All the samples that I collected in my area, there were no issues with tampering from the standpoint of actually finding anything that was tampered with in my area and in the Dakotas. I traveled about half of the state and was involved at some point in pulling these products from the store shelves and working with the local and state regulatory and law enforcement agencies.

RT: In that part of the country, did you encounter any operations like blood bank operators or blood sampling at hospitals?

BG: In that part of the country, you have the Indian reservations, so there are a number of Public Health Service operations there. They have a number of places where blood collections are done and hospital blood bank operations are conducted, so we actually did inspections of those kinds of operations. When you went into those, you looked at primarily the records, how they kept the records, whether or not they were drawing the blood properly when they did the phlebotomies and things like that. I went in and did inspections of those facilities to see how the blood was shipped and how it was maintained and properly labeled. This was a Center for Biologics activity.

RT: You mentioned Indian reservations. I guess that's primarily a responsibility of the Bureau of Indian Affairs. Was there any liaison between Indian Affairs staff and FDA in terms of problems of an FDA interest?

BG: Primarily the organization I worked with was the Public Health Service, because they were actually onsite and they took care of all of the issues even with the Bureau of Indian Affairs. When it came to any of the public health, FDA-type related activities, I usually worked with the Public Health Service folks. I would go to some Indian reservations because they had a cannery operation on the reservation.

RT: In the agricultural area, did you encounter work in illegal residues and drug residues in animal feeds?

BG: I did quite a bit of that work in South Dakota with regard to tissue residues, illegal tissues residues, feed manufacturing, and making sure that they properly manufactured the feeds, properly cleaned their equipment to assure there wasn't any residue carryover and things like that. I did a number of those inspections. I had some cases that went forward as far as regulatory letters at the time. Regulatory letters were issued because of inadequacies in operations.

One case I did in particular that turned out to be a big case was one involving PCBs, polychlorinated biphenyls, in chickens. What happened was they had a soup plant that used these spent layers. They call them spent layers because they were chickens that stopped laying eggs pretty much. So they would take these birds and slaughter them for soup, that is, for chicken soup. So they had a contamination of chickens with the polychlorinated biphenyls [PCBs]. So I was given an assignment to go out and do an investigation of farms around the area because the plant was actually in Minnesota, but they got chickens from all over, including South Dakota and North Dakota.

I said, "I'm just going to go out and look at several producers in my area," so I went out to a couple of farms. I went to this one farm, and this is kind of interesting. I had to get some chickens from the coop and some of the litter and things like that, as well as some of the feed. The farmer took me out to his chicken house. I said, "I need to get some chickens." I think I'll need to get about twelve or so chickens to send to the laboratory to be tested. I said, "I'm perplexed as to how I'm going to do this. I figure I'd have to slaughter them." I'd never done it before.

So the farmer went out, and he said, "Well, here's how you do it." He grabbed one of those chickens and just pulled his head off. [Laughs]

I said "My goodness," so I just grabbed a chicken, you know, and pulled its head off. So we got our twelve chickens and I got my chicken litter and feed. I didn't gut them or anything like that. I just put them in some dry ice there in a cooler and took them back to the resident post. I had a refrigerator there and a freezer. I froze them, packed them up in dry ice, and shipped them over to the district to be tested for PCBs.

RT: That was sort of unusual duty.

BG: That was most unusual, yes. [Laughter] It was really unusual.

RT: In that part of the country, we had a clean grain program. That may have already taken place by the time you were working there. Did you get into examining grain for rodent defilement or mercury treated seeding grain or that type of activity?

BG: Yes, I did. Of course, we always had to go out and collect sorghum and other raw agricultural commodities. We were looking for pesticides, illegal pesticides, any kind of other chemical contaminants. So I would go out and collect samples of raw agricultural commodities looking for rodent defilement. I never had a violative sample with an actual rodent defilement. We did find things where there was some chemical contamination such as mercury and things

like that. Then we'd have to try to track down the brand, where it went and what it was used for and that kind of thing.

RT: That was very difficult if a producer plugged a big load of grain with some unused mercury treated seed. It was really hard to track that down, wasn't it?

BG: Right. Let me digress back, back to Indianapolis. I'm going to go out of South Dakota and digress back to Indianapolis. While I was there as an inspector in Indianapolis, I had another interesting assignment. One of our inspectors was out. I think he had stopped someplace to eat lunch in a place called Rockville, Indiana. While he was there, this lady who was in the restaurant had apparently read an article about seeds, and any color of seed meant the seed was treated.

She mentioned to him that she had seen a truckload of a seed, it was colored seed, and she said it was destined to go to some feedlot. She told him about it, and so he went out and was able to find that truck and actually followed it to the feedlot and found out they were using this treated seed to feed beef cattle that were going to market. He got some samples, which were found to be positive for Dieldrin. It was a pesticide which wasn't supposed to be fed to feedlot cattle or to any animal destined for human consumption.

He did that investigation, found out that they had about 130-plus head of cattle up there they had fed this treated seed to, and they were all contaminated with Dieldrin. What happened was that he actually got a seizure of those animals on the hoof. The company wanted to come

back and claim the animals because they wanted to try to see if they could salvage them and still sell them to the restaurants for food. They worked out between the courts and the agency that the way to get this Dieldrin level down to an acceptable level in these cattle was to feed them charcoal. Apparently, charcoal absorbs the Dieldrin. They actually took seed and mixed it with charcoal and fed these cattle this charcoal treated feed, to bring the level of Dieldrin down.

Every two or three weeks, I would have to go out and actually get samples from the animals. They hired a veterinarian, and he would come out to check the animals. They had ear tags and I had to keep track of them by the ear tags each one of them had. I was able to identify the cattle by the ear tag. The veterinarian would run them in a chute, give them a local anesthetic in their spine, slit their hip, take some fat out, and place the fat sample in metal sample tubes, which were like toothpaste tubes. Then I had a crimper and I would crimp the tube closed. Then I'd put it into dry ice and ship it up to Wayne State University in Michigan. They would check the fat for each one of the animals, but I had to make sure I kept my numbers straight because as the levels came down to tolerance level, they allowed them to ~~ship~~ those animals for food.

So that was unique. That was probably one of the most unique cases perhaps that we ever did, as far as actually seizing the animals on the hoof and getting the pesticide level down to tolerance level. Some of the animals got too heavy, and so a lot of them died from heart attacks, broken legs, and other physical ailments.

RT: Were any of the lot salvaged and eventually put into the food channel?

BG: Eventually, they got the levels down within tolerance, but they weren't able to salvage all 138. I think they were able to salvage maybe about 110 or 120 or so, but as they got the levels down, each time I went out there, as each animal got to the tolerance level, they were allowed to ship the animal. They were allowed to ship one or two animals each time until they finally were able to get most of them shipped and consumed for food. [Laughs] So that was unique.

RT: That is a very unusual experience.

BG: That was in Indianapolis. But I was the guy who every other week or so would go out to Rossville, Indiana, to this place and work with this veterinarian. He would slit that hip of each animal.

I remember we had these gold jumpsuits. This was funny. One of the animals, as they'd shoot them up into the chute, while I was standing there with my clipboard and making sure I had the right animal and I was looking at the ear tag, this animal kicked up some of the muck on the ground. Some of the feces flew up in my face and all on my gold jumpsuit, so I had a black spot right on my gold jumpsuit that I was wearing. It was that charcoal feces. [Laughs]

RT: Let's see. We regressed back to Indianapolis. We were previously speaking of your Sioux Falls residency. After serving there, where were you next?

BG: After serving in Sioux Falls, then I went on to New Jersey in 1984. I was selected as a

supervisory investigator, New Jersey District, which at that time was Newark District. It was located in East Orange, New Jersey. I had applied for a supervisor's job, because I wanted to be a supervisor. I thought that I had gotten some pretty good experience and background that made me capable of doing that job. I applied for the position, got it, and I actually started working in New Jersey in January of 1985 as a first-line supervisor. Then I was able to put my drug experience and the basic drug school and things like that which I had gone to school for, and I was able to put that to work. Then I was able to use a lot of the Hospital Corps training as well in that district. Newark was primarily a pharmaceutical district. It was primarily all they did was pharmaceuticals inspections.

RT: As a supervisor, you probably were responsible for providing training to new staff, weren't you, in that discipline?

BG: Yes, I was. I was responsible for and I think I had like eight investigators who answered to me in the district. I was responsible for their training, for their performance evaluations, making sure that when we had new people coming onboard, they understood the policies and procedures of the agency, as well as the district policies and procedures. So I was responsible for all of that kind of training and evaluation.

RT: Had the drug GMP [Good Manufacturing Practices] regulations been developed yet?

BG: The drug GMPs were at full force at that time, because it was in '78 when the GMPs hit, and then it was in '80, in the eighties, when I went to work in New Jersey. So they were in full force then. We had a number of cases that came out of New Jersey District from the pharmaceutical arena, and particularly we had a few generic drug facilities there.

At the time I was there in 1990 is when the generic drug scandal hit, and we were part of the solution to that problem. We had a regional director at the time, and his name was Richard Davis. He primarily ran that drug program for the center after the generic drug scandal. He developed the guidance documents used in the pharmaceutical arena, across the country, not only for generics but for the Rx [prescription] drugs as well.

RT: Dick Davis, I think, chaired the field drug committee.

BG: Yes. It was the drug field committee, field committee, drug field committee, yes.

RT: Were you involved with him in some of the headquarters liaison with the field?

BG: Yes, at the time in 1991, I was selected for OPM's Office of Personnel Management's Executive Potential Program. It was a yearlong executive development program for people with a potential to move up to senior-level positions in the government, executive management systems. I was selected to participate in that. During the time I was involved in that, I was required to shadow a number of senior executive and executive people at the department as well

as the headquarters as well as in the field.

I had the opportunity to shadow Richard Davis as the regional director, and had the opportunity to sit in with him in a number of meetings that he had with the center for drugs and involved with the number of cases, of generic drugs, developing guidance documents and assisting with that, as well as training of the new investigators coming in, on doing inspections, drug inspections.

RT: During the executive development program, was your onsite experience broader than in drugs? Did you get into other fields, or were you primarily in the drug arena during that development program?

BG: In the Executive Potential Program, they want you to broaden your whole self, so they want you to get outside of where you're normally comfortable. So I got outside of that area, and had an opportunity to work in a number of different places to get outside of my comfort zone. I was comfortable in the drug area, but I had to get outside of that and actually work in the department in some jobs that I wouldn't normally do in the FDA where I actually had liaisons with department level people where we're giving presentations to the Congress and to participate in some of the hearings, although not as one of the testimony presenters. I would sit there and provide information to somebody who was testifying before Congress, and I was involved in those kinds of things, so that was good experience to have.

RT: During your executive development, were you given any assignments outside of the headquarters offices?

BG: I did. Most of my assignments were in FDA headquarters and actually over at HHS. I had an opportunity to go to HHS headquarters in Washington and spend time there. I was there for about sixty days in the Office of Women's Health. I spent time in the Office of Women's Health for sixty days, so it was outside my normal FDA work. That's when they were establishing that office, the Office of Women's Health.

RT: Do you recall who your fellow classmates were when you were in that program?

BG: Let's see. Kelly Sauer was in my program. She was in with me. Malcolm Frazier. Shelley Maifarth out of Denver. Those are the ones I can recall right off the top of my head. I may think of more as we go along, but those are the ones I can recall right off the top of my head.

RT: Usually there were several that came in at a particular time.

BG: Yes.

RT: Some folks we've interviewed have said when they came into that program that when it concluded, it was up to the trainee then to find the next step in their career. Did you have to do

that as well?

BG: That's correct. That is correct. That was the whole purpose of the program, for you to broaden your horizons and executive management experience level, to see what's out there, and see what jobs you may be able to feel comfortable in, in trying to move forward. They gave me the opportunity, and so with that I have spent some time, just like I said, working in various offices. I spent time working in Philadelphia in a detailed position as the acting director of investigations branch. About the time I was finishing up my program, that job became vacant, and so I applied for the position and got it, as the director of investigations branch in Philadelphia right after I finished my executive potential program.

RT: You actually moved into that job in what year, do you recall?

BG: In 1992. 1992 I moved into the job of the director of investigations branch in Philadelphia.

RT: That was the year I retired. I remember you being up there at that time.

BG: Right.

RT: While you were there, what were some of the highlights of your experience?

BG: When I was in Philadelphia, we worked on the second Chilean fruit episode. While I was a supervisor in New Jersey, we had the Chilean fruit crisis incident, where there was a threat in which some terrorist group threatened to taint fruit coming from Chile with cyanide. Apparently, our investigators actually found some grapes that apparently had cyanide in them. I wasn't the investigator that found those, but it was an investigator I knew who apparently was on the dock and collected the samples that supposedly showed the presence of cyanide in the grapes.

Anyway, I spent time there. I did a detail. When that was going on, I was in Baltimore District as the acting director of the investigations branch at the time that happened. Each district in the Mid-Atlantic Region had supplied investigators each week to go to the docks and examine fruit coming off the ships coming into the port. I spent a lot of time working, doing that, out of Baltimore, making sure we had our fair share of investigators to go up to Philadelphia.

RT: I think it was Commissioner Frank Young who made the decision to make an all-out effort there.

BG: Right, right. And sometimes we had like up to 125 people who were circulating in and out of there.

RT: As I recall, they never found additional lots that were contaminated.

BG: That's correct. They only found, I think it was, two grapes with cyanide in them, but other

than that they found nothing else.

RT: That whole episode cost a couple of FDA people's lives. They went down to Chile and were involved in a plane crash, unfortunately.

BG: That's right. That's correct. That's right.

Then when I was in Philadelphia, we had another incident that happened with Chilean imported food coming in. This was a situation where they had brought some fruit into a warehouse from overseas, imported. They apparently used methyl bromide to spray this fruit, and apparently it left a film on the fruit. There was concern this might have a potential health risk or health hazard. I got involved with trying to determine the risk, and we also had to get samples. A lot of effort went into investigating that situation, and the agency was very cautious about how the investigation was, that is, to make sure that it dotted all the i's and crossed all the t's to insure there wasn't any miscommunication.

RT: Was there any regulatory action arising from that particular incident?

BG: No. Loren Johnson was the district director in Philadelphia at the time, and he and I were able to talk to the center and the particular company and brokers that were involved. They took a voluntary action, which precluded us from having to take a regulatory action.

RT: Did they actually take off the market then?

BG: The product that was suspect, they actually just did not ship it.

RT: Was that a considerable value shipment?

BG: It was for considerable value. It was up in the, I think, hundreds of thousands of dollars. It was of considerable value.

RT: You said it was on fruit. What kind of fruit was it?

BG: It was various fruits. It was like from bananas to grapes to berries. There was a variety of different things.

RT: Where did these come from?

BG: I think they came out of Chile, if I'm not mistaken. They were Chilean fruit again. That was why there was so much sensitivity to that, because this happened probably about '93 or somewhere around in there, shortly after the first Chilean grape crisis or fruit crisis. Those were very sensitive, both in the agency headquarters and the district.

RT: Philadelphia is a major import location. Were there other kinds of import problems that you encountered?

BG: When I was there, we had an incident where there was a question of food contamination on one of the cargo ships caused by stowaways. It was a sugar container, actually had sugar in it. Apparently, the stowaways were inside cargo containers and it got so hot in the storage below deck in the hole of the ship. Apparently there were two or three of them. It was found one had died in the sugar, and so we had to investigate that. We had a couple of our import investigators go out and investigate the incident. We had to decide what problems have resulted from this dead person or corpse being in the sugar. Then if they could, determine what kind of follow-up action should be taken.

RT: What was the conclusion?

BG: I think it was determined the sugar could be reconditioned. There was nothing that said it couldn't be reconditioned and properly used. So it was reconditioned. It was taken through a reconditioned process and eventually used for consumption.

RT: It was reconditioned satisfactorily, you say?

BG: Yes, it was reconditioned. There was nothing in the regs that said that it couldn't be

reconditioned. There was nothing that defined it was adulterated in any way. [Laughter]

RT: An unusual contaminant.

BG: It was a very unusual investigation and final decision.

RT: During your tenure in Philadelphia, is there any other experience that you'd care to share before we go on to your next assignment?

BG: Let's see. We did quite a bit of work with the state and local people there in Philadelphia. That was where I really got some experience working with the state, with our state counterpart, because we had—of course, you're familiar with the FDA official establishment inventory, the OEI. We were trying to see how we could avoid not duplicating each other's effort. The state and some of the local health departments conducted inspections at quite a few of the facilities that we were inspecting. We were trying to see how we could combine our OEI and theirs to see what they were doing versus what we were doing and thereby develop plans to avoid duplicating work and regulatory activities.

RT: While you were in Philadelphia, I think Dick Davis was a proponent of this concept. Did you get involved in any working agreement—

[Begin Tape 2, Side A]

RT: I was about to ask Ballard if Philadelphia developed any working agreements, or I think that's what they were called, wherein there was a shared responsibility for the exchange of information from one level of government to the other in order to avoid an overlap of coverage.

BG: Yes, we did. That was one of the things our regional director, Richard Davis at the time, was a proponent of. That kind of activity, I think the partnership activities that we're currently seeing now in FDA, were started in that kind of process, where we had the working agreements with the states for inspectional activities.

RT: I guess the term that was escaping me was a memorandum of agreement.

BG: Memorandum, right, MOU. Dick Davis was a big proponent of that, trying to stretch our resources as best we could to and see where we could best cooperate, because the states did quite a bit of food related work and quite a few of the food manufacturers, distributors and warehouses. They did a lot of feed mills and things like that. So a lot of such work was not something that made no sense to us to go out and duplicate it if the state/local work was comparable. We had people who were commissioned by FDA in the states to do that kind of work.

RT: I imagine that you may have encountered more intergovernmental cooperation there than you might have earlier in your experience with state agencies. Is that right?

BG: In South Dakota, I had a good working relationship with my state and local counterparts, because I needed them because of being the only FDA person there at my end of the state. I couldn't cover it all. There was too much out there. I had to use them to find out if there were things that may fall into a governmental arena. If they couldn't handle it, they would pass it on to me or vice versa. I found some work was more of a local issue and I would pass it on to them. So I got a good mixture of intergovernmental cooperative work, both in South Dakota and in Pennsylvania and Philadelphia.

RT: In South Dakota, I suppose it was with the State Department of Agriculture, wasn't it?

BG: State Department of Agriculture, and then they had the local health department there in Sioux Falls I worked closely with. Particularly in Sioux Falls, we also had the time, and I meant to mention that we had the Girl Scout cookie issue come up where they had report of pins being in the cookies. Apparently, a perpetrator had threatened and said pins had been put in Girl Scout cookies. This was a unique thing.

I have to go back and digress again. I remember these things. But this was unique, because we got this information through my Denver District office that some perpetrator had threatened or alleged to have put pins in Girl Scout cookies. We had a Girl Scout cookie chapter

in Sioux Falls. They had about four or five hundred cases of Girl Scout cookies that came from this particular plant where this supposedly had happened. In order to get these cookies tested, I was tasked to come up with a way to examine them without destroying the cookies and without actually sending them to the laboratories. It's too much for the laboratory to check.

I explored ways of trying to use as many resources that I had there. I talked to the local law enforcement, the police department. I went to the airport to see if we could use their metal detectors and finally ran across a meatpacking plant there called John Morrell's meatpacking, and they had a real sensitive metal detector could pick up a piece of metal in meat. These Girl Scout cookies were stored in a warehouse that wasn't too far from there. So I was able to work with the officers in John Morrell's to get them to bring their machine over to where the Girl Scout cookies were stored.

We ran some tests right out in the field, myself, along with some of my local counterparts, where we actually took some cookies and put pins in them, inside the boxes, and put just pins outside the box but inside the case and then ran it through to see if the metal detector would pick it up. Sure enough, this thing would pick up these cookies. We would bury them trying to see if we could fool it. It would pick up. Every time we put them in there, it would pick them up. We ran four or five hundred cases of cookies through the machine. We successfully examined the cookies, which led to the Girl Scouts being able to distribute all their cookies.

RT: Nothing was found in there?

BG: Nothing was found. Nothing was found in the cookies at all.

RT: But again, a test to the ingenuity of the inspectors.

BG: That's right. [Laughs] That's right.

RT: There are times you have to go outside our agency to get the facilities and so on that are essential to completion of these things.

BG: That's right, to get the job done. Like I said, it was one of these things where the Girl Scout cookies—they wanted the Girl Scout cookies, the Girl Scouts did, and we couldn't find anything in them. We couldn't test them. So I said, "I've got to figure out a way to get these cookies tested." It worked and the district was not going to allow them to be shipped until we got it some kind of clearance.

Fortunately, I had a good group of people over there I could work with to get this done.

We got the job done.

RT: As I recall, you next went to Dallas from Philadelphia?

BG: I next moved from Philadelphia to Atlanta. That was my final duty station, Atlanta District,

and that's where I finished my career. I went to Atlanta in 1994 and I left Philadelphia in December of '94, and actually arrived in Atlanta. I started my first day in Atlanta District on December 5th, 1994, as the new district director in Atlanta.

RT: Who did you follow as district director there?

BG: I followed John Turner. John Turner moved up to the regional director's position, and I went in as the district director in Atlanta.

RT: Now, of course, Mr. Turner was filling a regional post that was already established. It was already a region before John [unclear].

BG: John Turner, it was already a region before he—let's see.

RT: Was it John Sanders?

BG: No. I'll think of his name in a minute. The person that John took over for came up from New Orleans District. He was the district director in New Orleans. He was regional director there for about three or four years before he retired.

RT: Was it Jim Simmons?

BG: No, it wasn't Jim Simmons. It was Bob Bartz.

RT: Oh, sure. All right.

BG: Bob Bartz, that's who Turner replaced as a regional director. Bartz replaced Maurice Kinslow.

RT: That's right.

BG: Maurice Kinslow was there before Bartz.

RT: Yes, there's been several folks down there.

BG: Then Turner came in as the new regional director after Bartz.

RT: As you moved into that task, what were some of your early challenges there?

BG: I guess really the biggest earliest challenge was trying to replace someone. I think Turner had been the district director for about thirteen years. Coming in, he was going to be my boss and he was going to be down the hall from me. He ran that district for thirteen years. I think it

was probably the biggest challenge to not look like you were, I guess, shoot poo-poo in his programs and stuff that he had done and that kind of thing and still get your own agenda on the table. That took some ingenuity.

RT: That's tough. I'm sure that's right because usually when new managers come in, almost at any level, certainly at the top level, they want to make their mark.

BG: Right. It was one of those things that you did very, very cautiously and very, very carefully. You certainly did not hand off any programs that were in existence then. I'm more of an extrovert, and I think my predecessor, Mr. Turner, was more of an introvert. He was from the laboratory side, and I was a field investigator, loved doing field investigative work. I related very well to investigations branch, compliance and all that, so you know it was just right up my alley being in a position like that. I just went right in. Whenever things were going on, I went right in and got deeply involved in them. Being a first-line supervisor, a branch director, in my career, I've also been a field investigator, resident investigator, I understood the psyche of an investigator and understood how tough a job it is when it comes to doing it.

Doing that and being involved in that, I think, helped me as a district director to better understand, work with the people there, because we had a number of resident folks in that district. We had three states that we covered, North Carolina and South Carolina and Georgia, and a number of state people that we worked with. At that time we developed the partnership program.

RT: Did you implement any organizational or functional changes during your tenure as district director there?

BG: At that time, the agency was exploring the idea of combining investigations and compliance. Our director of compliance retired, oh, maybe a couple of years after I was there. I explored the idea of combining investigations and compliance. I tried to see if I could make that work, and combining the two branches and see how it would function.

We did a number of things. We wrote up a position paper and developed a process to transition over. It worked for a period of time very well, but then the agency started going through some organizational changes. When Henney came in as a new commissioner and the agency, as well as when Dr. Kessler had come in, they both wanted to make a number of changes to give the field more authority and direct reference authority and things like that. In order to make these things work, I felt like the separate branches were probably most important to have as opposed to having them combined, because you have that second view from an independent source.

RT: Somewhere along the line I seem to recall they made some changes in resident post, too, didn't they? Did that occur when you were there?

BG: The resident post, before I left, when we got the final hiring under way, there was the

terrorism hiring. What we were doing was opening up resident posts near seaports and border ports. We had resident posts down in Charleston and Savannah and we needed to put one in Wilmington, because that was another seaport in the Atlanta District. We added a resident post at Wilmington, North Carolina, to make sure we had full coverage. We already had the Savannah and Charleston ports covered. We just beefed up the staff. I actually spent a lot of time working with Customs and things like that in those areas to make sure that we were meeting their needs as well as they were meeting our needs as far as what we needed to be looking at. Things were coming through.

RT: When you went to Atlanta, did you encounter cooperation or any problems with your state and local counterparts? It's a different area. Did you have any different experiences working with other governmental agencies down there?

BG: Quite honestly, I must have been either fortunate or lucky in my career. I always seemed to work very well in my case with my state and local counterparts. That also holds true for down in North Carolina, South Carolina, and Georgia. I mean, we worked very well together. If they had an issue, we'd work with them to help them. We'd do that. If we had an issue they could help us with, they would do that for us.

So I never had any issues that came up. We had issues with salmonella in eggs in South Carolina, and we worked closely with the state people as well as the state veterinarians on that issue. We worked very hard to get that resolved as far as where the salmonella was coming from,

how pervasive it was, and that kind of stuff. So we were able to work through those issues. There was a lot of concern. We knew we had to enforce the law, but we didn't want to. We were just coming in being gangbusters over this thing. It was we tried to get them to work with us and tried to get them to see the significance of this problem, when you had these salmonella outbreaks in various restaurants and things like that, which were directly related back to the eggs coming out of that state. We had those kinds of issues to work through, but we were able to work through them without it getting out of hand. There was some contentious moments from time to time, but we were able to work through most of it satisfactorily.

RT: You've had a long and impressive career. I wonder if you have any impressions about management levels of the agency including even the commissioner leadership changes that occurred during your career. We've had more frequent changes of top leadership than we had early in the agency's history. That may have reflected down through the field. Did you have any impressions you care to share along that line?

BG: Yes. When I think of people who impressed me in my career, one of those persons is Paul Hile. He was the associate commissioner for regulatory affairs, the very first one, I think. He used to always talk to us about Civics 101 and understanding the governmental system and how it works. When you listened to him and what he was saying, it's absolutely true. Our country is run on the electoral system. You elect people into office who you want to see there when you want to see things done differently. When the people speak and elect who will run the country,

the FDA and all the departments are of course a part of that function and that electoral system, whether or not we as career employees agree or disagree with the process, that's the process.

It's worked quite well for 200-plus years in this country, where the elected party comes in and set a new agenda. This is the agenda we want to go with. But we also have the regulations and the policies that have been established over the years and have worked quite well. I believe you can work within the confines of those and still get the job done and also work within the current administrations and still get the job done and not be overt about not following their policies of what they wanted to get accomplished.

I was quite comfortable with working with that. There was maybe somebody you disagreed with but then that was the whole process. Every four years or every eight years, whatever the case may be, you were going to get a new elected official in the position who was going to say, these are my policies and this is how I want to see things ran and done. With the advent of having the commissioner confirmed by the senate and its process, I personally agree with that. I think it's the right way to go. I think it's the American people have spoken. This is the kind of government they want to see, and that's what we have to—like it or not, we make it work the way the American citizenry wishes.

RT: During your rather extensive time in the agency, you've probably experienced some differences in approach to enforcement, litigation versus voluntary compliance and other initiatives. What's your personal impression of those respective approaches to compliance?

BG: I think compliance can be brought about in many ways. You can take the litigation approach, which is time-consuming resource-intensive, and if you can get a firm to voluntarily comply fully with the law and do it and keep them on track. I mean if they get off track a little bit, you get them back on it and that kind of stuff. To me that's less resource-intensive than taking them to litigation, because litigations are long and drawn out. I think for the bulk of the industry that's pervasively regulated, I mean the industry that we're involved in, they understand the authority and the power the agency has. You won't find too many of them fighting the agency too overtly. They want to comply.

I think if you get the industry that wants to comply and you try to work with them within reason, you just can't keep giving them chance after chance after chance, and then after you've done. After you've worked with the industry to bring them into compliance and tried to keep them in compliance, the record shows that, and they continue to fall out, and there's actual deception and some fraud that's intolerable. I think that's when the agency must introduce and use all of its authority and power it has to go after those kinds of people or organizations.

RT: Ballard, you're retired from the federal agency service now, and you're now in the private sector. Do you see the Food and Drug Administration in a different perspective from your current vantage point working in industry, or do you still regard it in more or less the same way as when you were a bureaucrat?

BG: I still regard it the same way. I tell the people on the I'm currently in, "The agency has a job

to do. We have a job to do. We need to make sure that our policy and procedures meet the spirit of the law and that we're within the law." I see it no other way. The law has been tested and tried, and it's worked for a number of years. I believe in it, and that's the only way I talk. I believe in what the agency does. The agency has the responsibility to protect the public health. It has to do that whenever we in industry begin to look at it differently. Regulatory officials are going to look at it from the perspective of what problems could this product or this operation cause to the public health.

RT: You haven't gathered the impression from your comments, I suppose, that the current regulatory scheme is unduly burdensome on industry? Is that fair to say?

BG: I don't think it is. All the years I've spent with the agency, I always thought that the agency was reasonable and approached things in a reasonable way, a rational way, and I think that if a company came to the agency with a reasonable proposal, a reasonable approach to something, the agency would listen and try to work with the company to make sure. Because the agency doesn't have those resources to spend, and you've got to get a company that's going to work and do the right thing. The agency wants to get that accomplished without having to use all of the regulatory and the enforcement tools it has available to use.

RT: We've covered a rather broad range of things. As we come to a close of our interview, are there any other comments or remarks you care to make in conclusion that we haven't already

covered?

BG: I just want to thank the agency and thank you, Bob, and everyone who is involved in this process to give me the opportunity to share the stories of my work with the agency over the thirty-plus years I've spent with the agency. I found my career with FDA was quite pleasing. I enjoyed every minute of it, and from time to time, I think about the times I've spent, the good times I've spent with the agency, the opportunities the agency gave me to grow and to develop in my career and my profession, in something I've thoroughly enjoyed. This is just a culminating part of that experience to be able to be a part of the history of the agency. I really appreciate that.

I just hope what little bit I've been able to share with you today will go a long way to perhaps give somebody else maybe the impetus to do some things in their life that will move them along the career path they feel good about doing.

RT: That's very good. Now, I suppose in the course of things, you've received some recognitions along the line for work you've done. Are there any that you'd care to mention?

BG: I always felt like I was doing my job. I guess maybe some people would say you are just waving a flag, but I really mean this from the bottom of my heart. I wanted to give something back to my country. I felt like we are always looking and complaining about paying this or paying that or paying this. I don't think there could be any greater calling than to come in and do a civil service for your country and to do it with a good heart and trying to do the right thing. I

really never got really bent on getting this award or that award for doing my job. I said that was my job, and so that's what I wanted to do. To do my job and do it well. I always figured the reward I would get was that I was helping my country.

RT: Ballard, in our earlier discussion, you mentioned that you were involved in some of the Olympics investigation at Atlanta. Do you care to add something on that, please?

BG: Yes. During my time in Atlanta, Bob, you know we had the 1996 Olympic games. I think it was the centennial Olympic games that we had there in Atlanta. Of course, the agency was involved from the very outset of getting preparation for the Olympic games, particularly the Atlanta District, because we were right down in the heart of the city. That's where the district offices and the regional office are located. Some of the activities we did in preparation was working with Customs and making sure the Olympic participants were able to get their food, including any special food from their various countries and any particular drugs they may be taking from their country, and things like that. We had to work closely with our federal and local counterparts to make sure that happened.

We also worked with the haz mat [hazardous materials] team out of the department to make sure if there was any issues from the same part of hazardous activities or materials that, we were able to cover those. We had people actually in the Olympic Village who inspected daily the food supply, making sure the food was clean and served under sanitary conditions. We had an incident where some sandwiches were being made up, and these box lunches were intended for

some of the workers in the various Olympic venues. They were left out and unrefrigerated for a period of time, and so we got involved in that investigation and brought that to a final close where we actually—because there was some potato salad that was a part of this box lunch process. So we were able to get it down to at least find out the level of how many boxes may have been involved. We were able to find all of those and properly dispose of them so they wouldn't get to an individual and make them sick.

One of the things we felt really proud about was that our activities there in looking at the food and making sure it was processed and handled properly, throughout all the venues, no one became seriously ill as the result of any kind of food contamination or anything like that. So we really felt good about what we had done in the whole process. It was a once-in-a-lifetime experience that I was able to experience in Atlanta District as a district director involved both with headquarters a number of high-level federal agencies from the department all the way up to the White House and the Department of Justice, a number of various organizations. It was just a great experience, and one I always will remember as being a pinnacle of my FDA career. So thank you.

RT: Another item we may have overlooked in the earlier text which we might incorporate in the transcript is that as part of your executive training, you attended the Office of Personnel Management Federal Executive Institute in Charlottesville, Virginia.

BG: Yes, sir, I did.

RT: What kind of training was that, and how did it help you in your director job at Atlanta?

BG: That was the Federal Executive Institute in Charlottesville, Virginia. I spent the month of June there in 1996. I was there for the entire month, just working with other high-level or senior-level government employees from various other agencies. We spent time actually doing an assignment together, working out issues from the standpoint of how to resolve issues when it came up to anything that happened within a system, how to best resolve the matter, how to work with other fellow agencies to get things accomplished, also how to better examine yourself to see how you will work in a real tense environment or in a tense situation in order to better understand yourself and how you work with others in situations of that nature. It was an intensified thirty days, where we had to spend time together as a group, almost day in and day out, where we would have assignments together which we would work through.

It was a developmental program that the Office of Personnel Management developed, preparing high-level federal executives for senior level positions within the federal service. That was another experience I will long remember because it was a great experience as well.

RT: I want to thank you, Ballard. The History Office appreciates your participating in this oral history, and we'll make it a part of the record.

BG: Very good. Thank you very much.

[Tape recorder turned off.]

[End of interview]