

History
of the
U.S. Food and Drug Administration

Interviewee: Gary E. German

Interviewer: John P. Swann, Ph.D
Robert A. Tucker

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Interview with Gary E. German

January 26, 2010

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. The interview today, January 26, 2010, is with Gary E. German, who has served FDA for a number of years, and is currently the Director, Division of Human Resource Development, Office of Resource Management. The interview is taking place in Rockville, Maryland, and includes the participation of Dr. John P. Swann and Robert Tucker of the FDA History Office.

Gary, if we could begin with a brief overview of your personal and educational background, where you were born, raised, educated, and then move into your career, eventually, of course, to the FDA career. We'd like to also cover your service with the State of Pennsylvania.

GEG: Okay. One clarification. My title is the Director of the Division of Human Resource Development.

RT: Okay.

GEG: All right. Background.

I grew up in western Pennsylvania. I grew up in a town called Uniontown, Pennsylvania, which is 50 miles south of Pittsburgh.

My father was a civil servant also. He worked for the post office. And, interesting, why I wanted to be a civil servant.

I recall my dad grew up during the Depression, trying to take care of a family, and he happened to work in the coal mines. Then he had an opportunity to go and be a civil servant, and the story goes that my grandfather, who had emigrated from the old country, Czechoslovakia, said, the wisdom of man, saying, "There'll always be mail, but there won't always be coal." So, therefore, my dad chose to make less money, but to get paid every two weeks, and that's one of the reasons why I have spent 41 years with the government, 16 with the state, and my 25 years with FDA, is because of that piece of wisdom from my grandfather and my dad.

As I sit here getting ready for retirement, it's a nice statement that I think -- and I've chatted with my wife -- to say, it's been pretty nice to get paid every two weeks and not have that concern about, in today's environment, having a job, and the security has been good.

I went to high school in Uniontown, and then I didn't go very far from Uniontown. There's a school, California University of Pennsylvania, that is located in California, Pennsylvania. It's part of the state school, state teachers' college system. California used to be a normal school. It used to be one of those systems where they used to train teachers. And then, as the system grew, it became liberal arts. I tried very hard to be a biology teacher, and my wife didn't want to be poor like a teacher, so she said, "Can't we be something else?" And I was dating her, and, "Yeah, okay, fine." So I get a

liberal arts degree in biology. But then I said, “Okay. Now what do I do?” And this is during Vietnam. I was not the smartest college student. The guys came back from Vietnam, they had seen the world and I had not, and they knew why they were in school, I didn’t. So I barely made it through school.

But at that point in time I took a civil service test, again following the wisdom of my father, and I get a chance to become a sanitarian with the Pennsylvania Department of Health.

In today’s environment, in the environmental health world, the word sanitarian is poo-pooed, but I like it. The reason why I like it is I look back at this career. The first time I was ever introduced to the word sanitarian was as a teenager. I was cleaning out some papers recently and looked through my Boy Scout books, and there was a merit badge in public health. And in the back of that was careers in public health, and they had public health engineers and sanitary engineers. And then it said, in one sentence, very short sentence, “And there are inspectors called sanitarians.” Also, I have this idea that everybody has a calling, and I think that was the beginning of this calling, this public health, even as a teenager.

RT: Gary, what year was it you got your liberal arts degree?

GEG: In 1969.

RT: Then you were employed by the Department of Health of Pennsylvania.

GEG: Right.

RT: Shortly thereafter?

GEG: Yeah, within a week or so. My wife-to-be and I were planning to get married in May, so having a job seemed real important at that point, and having a job and getting a job. So I think I graduated in January and I might have started at the end of January or early February 1969.

The job, the first job was an inspector. I inspected restaurants and camps and campgrounds and schools, and I did dog-bite investigations, rabies, that kind of thing.

In the old days, in the Health Department, the left side of the building, in the building we were in, were the sanitarians, and on the right side were the public health nurses. In fact, there was this, I don't know how to explain it, esprit de corps. And that relationship between the sanitarians, the environmental people, and the nurses -- I still use this today -- that is, as we teach epidemiology and foodborne-illness investigations, one of the critical things is to get the nurses and the sanitarians and environmental health specialists, whatever it is, together. And we were talking in 1969 and 1970 together; we had a good relationship. It amazes me in today's world, where in fact the nurses and sanitarians don't get along. So, I learned that.

JPS: Can you say something about the training you received as a state sanitarian for Pennsylvania?

GEG: Yes. It's also interesting how that all fits into this.

In the first year, the Health Department had a very, very good program, where in fact they would take all the new hires and they would send them off to residential training. It was 10 weeks or it was 12 weeks. It was a long period. Mine was at the Neshaminy Center in Bucks County, Pennsylvania, and I was in that training program with people from Bucks County, and sanitarians from around the state of Pennsylvania. Significant of that is I learned things in that class where, in today's world, FDAers are not taught things I learned. Example: individual water supplies and individual sewage systems.

Last week I had a conversation with an individual from the CDC (Centers for Disease Control) in Atlanta who has an interest in sanitarians and environmental health specialists, and he and I were talking about this training that we have. And I made the statement in front of one of the muckety-mucks upstairs here at FDA that says the FDAers don't know enough about individual water supplies. I could tell you a lot about individual water supplies 40 years later.

The significance of this class was, as I will tell you that two or three years after I started my career -- I guess I'll just keep on telling it -- while I was making these inspections and I had gone through that environmental health training for the state, all my friends from college were immediately going back to get their master's degree. One of my best buddies from college, I found out later, he was actually talking to my mom and said, "Why isn't Gary going back to school?" I tried to go back to school part time, and by then I was married; two or three years after starting my career, I had a child by then,

and I tried to go part time and I couldn't do it. I couldn't be a dad, I couldn't be a husband, a good inspector or worker, and then go to school at night. And out of the blue -- and I had this desire, this passion of some sort to be a professional, to further my career! Well, I couldn't get into dental school and vet school and all these other schools because my grades were terrible. I didn't really want to do that. So what profession could I get into? I thought public health sounded pretty cool.

So I was exposed to a journal, the *Journal of Environmental Health*, and in there was some advertisement or marketing for a public health program in East Tennessee State University, in Johnson City, Tennessee, and they had a master of science in environmental health. On a whim, I wrote to them. The professor, or whoever, sent me back some information, and I had it in my drawer in the corner of our kitchen. I was busy being a dad, I was busy trying to find my life kind of thing.

One evening the telephone rang, and there was this very Southern-sounding guy; it was Monroe T. Morgan, and he was the head of their department. He said, "Gary German?" and I knew he didn't know me because of how he pronounced my name.

I responded, "Yes, sir."

He then said, "You sent for some information for graduate school. I haven't seen your application." Then he started to give me a lecture about why I needed to go to grad school.

I said, "Well, sir, I'm very interested, but I don't have any money."

He replied, "If money's the problem, I'm gonna help you right tonight."

And I asked, "What are you talking about?"

He said, "If you can get me that application here by a certain date," whatever is the equivalent of overnighting, I had to get this application in, "we'll pay your way."

I exclaimed, "What?"

He said, "We are going to accept you into the program without looking at your grades. We're going to accept you on probation, and all you have to do is come down and maintain a B average."

I answered, "Okay," and hung up. I just still feel this wonderment of what had just happened.

I sent the application in. This guy courted me to get me to come to school, and this was like in April of the year, and school started the end of August.

What I found out later, once I got down there, is that Dr. Morgan, associated with the federal budget process, had so many dollars from the Public Health Service to spend on Public Health Traineeships, and somebody backed out on him; one of his students backed out on him at the last moment as part of his timeline, and he needed a warm body, and I was the warm body because I was willing to go.

I looked at my wife -- and I have a marvelous family and marvelous wife -- and I said, "We're going to Tennessee for a year."

She looked at me and said, "We are? Okay."

We went down there in August for a 12-month program, and once I decided to do this, I started getting some hard time from my employer. "Well, you can't just pick up." I had a boss at that point in time, he was a tyrant. He was a nasty man. But he taught me so much about public health. He believed in graduate schools and graduate studies.

He said, "If you want to get ahead, you need a graduate degree." He had an MPH from North Carolina. The agency (the Pennsylvania Department of Environmental Resources) that I worked for valued advanced degrees, and you couldn't become a regional sanitarian, which is the equivalent of a Regional Food and Drug Director at FDA, without a graduate degree.

Well, I went through the summer, and we had a house by then, as young marrieds. Well, we had to rent the house. Well, I felt I couldn't go because I hadn't rented my house. On the day before we were supposed to leave, we rented the house. Don't tell me I wasn't supposed to go to graduate school. I believe in divine intervention.

We went down to Johnson City, Tennessee, we lived in married-student housing, and this relates to, John, when you asked me about my training in Pennsylvania. I had a bit of a character as an advisor. Dr. Iglar was my advisor, my professor down there, and I had a hard time coming up with a thesis subject. I wanted to be a teacher in undergrad school, a biology teacher, and I want to talk about the influence CASA (the Central Atlantic States Association of Food and Drug Officials) had on my career. But I got involved a little bit in that professional organization, and they had a training committee, and I was involved in this training thing.

So when I get down there, I said, "Well, maybe I could do something on training." My master's thesis is a comparison of three in-house training programs which basically were designed to take people with biological or physical science degrees and train them to be sanitarians. I took the program that I went to in Bucks County, and then there was another one, Penn State, and then there was a program at East Tennessee, where I was going in Johnson City, and I compared those three training programs.

In my paper, there was a diagram of how you build training. To this day, I use that diagram. So I'm one of the few people in a graduate program who has the opportunity to use every day what he learned in graduate school.

What I got from graduate school was so much more than book learning. What I got was confidence. I was a young man who didn't do very well in high school and undergrad school. In high school, I had a teacher. I didn't apply myself in high school, and that teacher, my plane geometry teacher, in high school said, "Gary, you will never amount to anything because you don't apply yourself." Well, that's a lousy thing to tell a young man.

Then I went to college at California State College of Pennsylvania. I had a professor who said, "Gary, you will never make anything of yourself because you don't apply yourself," and that was my plant anatomy professor.

Interesting enough, Mr. Tucker, you remember Heinz Wilms was my first boss, and he was your boss. I told Mr. Wilms that story that I just told about the high school teacher and college professor, and Heinz, to his credit -- we were on a road trip one day -- said, "Can I give you a piece of advice? You're a very successful man. You can stop proving to those two teachers that you're a success, because you are." What a nice thing, what a great story.

RT: Gary, what year was it that you spent that 12-year fellowship?

GEG: Twelve-month.

RT: Yes, twelve-month.

GEG: It was 1972 to 1973.

RT: Okay, thanks.

JPS: An impact that lived with you most of the rest of your career.

GEG: Careers, you know, here I am at my age, you know, 41 years of a career. Career is not paper and programs and number of students trained or whatever. Career is people.

You know, Heinz and I didn't necessarily get along that well sometimes. We'd bump heads or whatever. But Heinz was a good man, he was.

RT: I wouldn't take too much credit, but I remember you once talking to me, maybe when I was at a CASA meeting, about working for FDA in training, and I said, "Well, why don't you give it a shot?" and you did.

GEG: Well, yeah.

RT: And that's when you came into the Division of Federal-State Relations.

GEG: My career, what happened was, after I went to graduate school . . . In

undergraduate school, my grades were so bad. I had a 2.3 grade average. And I was afraid, when I went to grad school down there, I was afraid whether I could do it or not. I got one B the whole time that I was down there. It was the first semester. They were flunking people out, because what he (Dr. Morgan) wanted to do was get people in the program, and if you didn't work hard, they got rid of you. Well, I made it, and I ended up with like a 3.8 grade average. At my final oral exam over my paper that I wrote on comparison of the training programs, one of the questions that I was asked, "How do you go from a 2.3 to a 3.8?" and I gave this spiel.

I saw Dr. Morgan writing something and I asked, "Dr. Morgan, what did you just write down?" What he explained was, I had one chance. I had a wife and I had a son, and if I don't take advantage of it . . . And he wrote something down and I said, "What did you write down?"

He says, "Maturity," and it was.

So that big milestone of graduate school . . .

Then I came home, and here I am, I'm full of myself, this young buck. "Well, now I have a graduate degree," and I thought the agency would say, "Okay, he's gonna come back and change the world." Right? I came back, and nobody was offering any jobs to me. What is going on here?

I took a job in Harrisburg in the Bureau of Solid Waste, which was 30 miles away from where we were living in York, Pennsylvania, and it was a bad job, just to take a job and get a promotion. This tyrant, Mr. Sheffer, John Sheffer, was the guy who was my boss in York. I remember going to him, meeting him in a bar one night and saying,

“John, I made a mistake going into the Bureau of Solid Waste. Will you have me back as a sanitarian or whatever?”

He was a credible man and an honorable man, and he said, “Yes, I have one job here that I can’t fill. If you’ll come back and do that,” and I ended up being the sewage facilities consultant, helping plan community sewer systems. It was a terrible job; it was just a terrible job. But I had to prove my salt to this guy (Mr. Sheffer)

The job that I really wanted was the supervising sanitarian’s job, to supervise the inspectors of the restaurants and that kind of thing. So, eventually that came open, and I got it because I earned my stripes with Mr. Sheffer as the sewage facilities consultant.

My claim to fame while I was there was, I became very community oriented and got involved in the civil-defense program and during TMI (Three Mile Island). When TMI went off, I was in the bunker, in the county civil service or civil defense. Today people would teach a class on incident command, about how to run things during a crisis, and you run it like military. I saw it in person because there was somebody from the military came in, and he was in charge and he was running things and that kind of thing.

But my experience, I sent my wife and children home to her mother on that day during TMI, with an idea that we didn’t know what was going on. We thought that thing was going to explode. We didn’t know. Would it be something that, once it explodes, you couldn’t come back or whatever? And my wife picked up the children and filled the car and drove back to her mother’s house in western Pennsylvania.

My claim to fame, as the supervising sanitarian, was that, during TMI.

Then I get this chance to, this whole time -- and it's important that I recognize the importance of professional organizations, and there was a guy in Philadelphia, in FDA, a guy named Tom Price, and Tom Price was a gem. He's passed on now. But Tom Price really believed in a relationship between the feds and the states, and he promoted Central Atlantic States Association of Food and Drug Officials, and he was the cooperative programs director, and he worked his tail off of getting young people in the states involved in CASA. Because I had written this paper, my thesis, on this training thing and he found out about this, and he said, "Oh, you're a prime candidate to be in charge of our training program," I got involved in CASA and started leading some of their courses and just doing some things, rag-tagging kind of thing.

Well, at that point in time, a job came open in Harrisburg. It was the director of food protection. Again, here I am, full of myself, I had this master's degree. Well, come on, this is where I need to be. And, long story short, I applied for the job, I got it over some people that were a bit older and more experienced.

The interview was in front of the Secretary of the Department (what would be the equivalent of the Commissioner of FDA). I remember, in the interview, being called in -- there was three of us in the final interview -- individually, and then the three of us were pulled in, and this head of the department sat down and said, "I've selected Gary." And then he sent the other two people away. And he looked at me. I was 30 years old and I was this young kid again. He said, "You're too young and you're too inexperienced, but you can do this." He further said, "I expect big things of you." So if you think about the two professors who had no belief in me, and this guy who really didn't know me, but he said, "No, you can do this. Go to it."

He made me the Director of Food Protection, and through that job, I started to get some national contacts. I was going to national meetings, including AFDO (the Association of Food and Drug Officials), I was going to the CASA group, I became part of the chairs going through the committees and on the board of CASA. What CASA did was open my eyes to this world of federal-state relations. This business about being a fish in a pond and you're a big fish in a little pond, well, the pond started getting bigger from the CASA standpoint. I got in the chairs of CASA (Central Atlantic States Association). I don't know exactly what the sequence was. I think I was in the board, and I was the Director of Food Protection for five years.

At probably the third or fourth year into this, I became disgruntled with the job (Director of Food Protection) because my bosses -- I was in an environmental agency, and the hot thing was water pollution, air pollution, not food protection! If there were 100 programs in that agency, probably 98th was food protection, so I was always on the short end.

I remember going in trying to provide some leadership to my boss. My boss's name was Terry Kraemos. I went in to Terry and I wanted something, and his response was, he says, "I don't care what you do in that food program, but don't irritate anybody."

Well, how can you be a regulator and not irritate somebody, because when we regulate, often someone is upset. We don't irritate people on purpose, but we do enforce, and when you enforce, often you irritate. Not many people get a notice of violation and say, "Oh, thank you very much. Give me another one here." So I became very disgruntled.

Interesting, how I managed it and how I coped with this. Rather than throwing my energy into work, I became very involved in my church and I became Clerk of Session of the board of directors, at the Eastminster Presbyterian Church in York, Pennsylvania, our church, and I threw all my energy into church. I suspect work suffered a little bit because I hated going to work.

So out of this, out of the blue, Tom Price says, “Oh, there’s a job in FDA. You’ve got to pay attention to this.” And the gentleman in FDA in Cincinnati, the director of state training, was going to retire, and that gentleman’s name was Harry Haverland. And Harry Haverland was a captain in the Public Health Service. Everybody loved Harry Haverland. I’d never met Harry Haverland. The system at that time was all the states would send their requests for these courses, and I needed training for my staff out of Harrisburg around Pennsylvania, and I’d never get a course, and I get really upset with him.

So I boldly called Harry Haverland on the phone and I said, “You never give me a course.”

He said, “I can’t give you the course. You compete with all the other states.”

I asked, “Can you give me your materials?”

Harry Haverland sent me his Basics of Food Protection manual. And I asked, “Can I take your manual and put our logo on it?”

He says, “Yes, you can, as long as you keep the FDA logo on it.”

Harry Haverland to this day lives in the Division of Human Resource Development because we give the materials away all the time with the caveat, as long as

you still identify where those materials came from (the FDA). And I was doing that in the early '80s.

So here it is, I have this association with the State Training Branch. Mr. Tucker, you and I were probably going to CASA meetings, and you were out there recruiting, trying to find the right person, and thank you very much that you thought I was one of the right people that could do this job. I had a lot of people say, "Wow, this would be a great job for you." I was a young man, and I was into a retirement system of Pennsylvania. Can I leave? Should I leave? I did enough research that I found out that if I was tenured into the state system, I could actually retire after 15 years.

Well, the bottom line was, this FDA job (Director of State Training) was announced. By then I was very involved in AFDO, and I was the chairperson of the Training Committee for AFDO. Mr. Wilms was calling me on the phone, and he was talking to me and, I guess, interviewing on the phone.

In June of 1985 -- I can't remember what city it was in, but it was June of 1985 -- I went to the AFDO meeting, and I needed to run my first committee meeting of the Training Committee of AFDO. I started to run the committee, and I wanted to know who that red-haired guy was at the end of the table. It was Heinz Wilms. Well, let me tell you what. To this day I feel my interview for the job (State Training Director) was that committee meeting, because he watched me run the meeting. I believe that, through that meeting, he got to know who I was, who I am.

There was a lady who was president of AFDO, Dr. Martha Roberts, and I became friends with her. I remember going to Dr. Roberts and saying, "I really want this job with FDA. Can you do anything?"

And she replied, “You’re a young man who is going to be on the rise.” I don’t know whether she ever said anything to Heinz or not, but it was like, there were a lot of people who seemed to want me to get this job.

So, in that summer of 1985, I get this call. I never thought about this, but I got this call, and I happened to be staying in Ocean City. And you know where I was staying? In the complex where we live full time now. We were in Ocean City, and somehow I got a message that I was supposed to call him. I talked to Heinz Wilms in a phone booth, and he offered the job to me.

I came to FDA in August. My first day on the job was on a Monday. That Monday afternoon, I went to the ORA Red Phone, which is this national call that we always have. I was such a naïve puppy. On that first day, Heinz Wilms gave me a ticket to Cincinnati and says, “Your job is to move your branch from Cincinnati to Rockville,” because there were three branches in the Division of Federal-State Relations, and the third branch was in Cincinnati, and they wanted to bring it to Rockville.

JPS: These branches were around the country? Is that it?

GEG: No. There were three branches. In Federal-State Relations, there are two branches . . .

TAPE 1, SIDE B

GEG: At that point in time, there were three branches in the Division of Federal-State

Relations. Mr. Wilms was the Director. There were two branches, one run by Mr. Tucker and one run by a guy named Captain Dick Moats. Those two branches were located here in Rockville. The third branch was the State Training Branch in Cincinnati, and that was in Cincinnati as a leftover from the old Public Health Service when they had the engineering lab there and they had this training facility, and Harry Haverland was out there forever and ever, and it was a deal, living in Cincinnati, being this national center, this training center.

Once I got there, I had no idea of the hornet's nest that I was put into. And the hornet's nest was, the State Training Branch staff, Mr. Haverland was going to retire. Well, this is the right time to move it into Rockville, but nobody on his staff wanted to move, so there were, well, the people were just plain nasty. They were upset. And I walked into Cincinnati very naively. I was told they didn't want to come. There was a secretary named Mary somebody-or-other.

A long story short, from August to September, my task was to move the facility or move the Branch into Rockville. And they (FDA) weren't really fair to me, as I look back to it, but we weren't allowed to stop providing service, so we had to continue to do all our training while we're in the middle of this upheaval. Well, I didn't know anything. I knew state bureaucracy, but I didn't know federal bureaucracy. I mean, I didn't know acronyms, I didn't know, you know, it's just . . . I mean, this is a task.

As I look back on my career, that was one fine moment, for me to be able to pull that off. One of the best things I did was I hired . . . While they were hiring me, they were posting job announcements for trainers.

The first trainer I ever hired was a guy named Steve James. Steve James was a guy that I knew from Baltimore through CASA, and he was a retail food specialist in the region there locally. Once I got Steve, he helped make this happen.

So we moved the Branch into Rockville. There was the guy who was the milk trainer who finally, the guy's name was Ron Smith. Ron Smith didn't want to come. He was in the Commissioned Corps, and if I would have known about the Commissioned Corps what I know today, he would have been working in Rockville, no questions asked, but I didn't know the system that at the time.

Anyway, he stayed there. The District Director, Mr. James Simmons, pawned off one of his worst employees on me, and he dumped a nasty young man on me, and I had to deal with that personnel.

JPS: This was the District Director in Cincinnati?

GEG: Oh, yes, yes. He was slick. He saw me coming, and he dumped a real, I hate to call an employee a loser, but this guy was a problem.

JPS: I wonder if you could just say a little bit about the responsibilities of this Branch and the scope for those who aren't familiar with the Branch.

GEG: The State Training Branch had a very focused Branch, and it was a Branch that simply put training courses on around the country in food protection, milk safety, some rad health, but basically milk and food, and they were the cooperative programs, the milk,

the food, and the shellfish areas. The objective was to help the state programs to, you know, the people, like I was in Harrisburg where we had a restaurant inspection program that help them to better do their job.

As I look back at this, there was frustration. Okay, I had five people. Let's say I gave each of my trainers 10 courses, so that's 50 courses a year. If there were 40 people in these courses, I was training, at most, 2,000 people a year. Well, that's a drop in the bucket, a drop in the lake, really. That was one of the things which I realized early on. The mission was very noble, but what we were doing was just so minuscule compared to the need. Because I remember up in Harrisburg, I needed this training now! I just hired all these people. Come on. Come up and help me train. "Oh, no, you're not on the list." They had a lending library of videotapes and manuals and things. You couldn't even get those because here I was in Harrisburg wanting to borrow some videotape, and it was loaned to somebody in Colorado. So it was a good program with good intentions, but as far as delivery, it didn't do much.

But I have to say, what I learned from that is you take what I knew when I was in Harrisburg and what I was learning from CASA and what I was learning from AFDO, and as I look back, I used that opportunity for the State Training Branch to get to know the state people. I got on a plane, I went to a lot of courses, and I wanted to see what was going on.

The little bit that I remember, the lot of bit that I remember from my graduate studies, I looked at the training that we were doing and it wasn't very good. Mr. Wilms would ask me, "Well, how successful is your program?" and I would say, "Oh, we trained 20 people," 40 people, whatever it is. "We train 2,000 people a year." We

weren't measuring training. What we really were saying is we had 2,000 people sitting in a chair attending, but the sense of accomplishment, the sense of learning was never there. So the programs were not all that good. They were very good-intentioned, and I'm not trying to minimize what Harry Haverland and all his folks did, but the training was not good.

Courses were all over the country. There was a bit of a good-old-boy network. The people who some of the other people knew or some of the instructors knew, golly gee, kept on going back to those same states. Some of that good-old-boy stuff was going on.

RT: That was a problem. I'm aware of that, because we had a public health officer on my staff, and he really was making a bid to go as an instructor to one of Mr. Haverland's food training courses in Hawaii. It was clear to me that he was primarily motivated by a desire to go to Hawaii rather than really contribute to the course. So that was certainly true.

GEG: So, I think probably the most important need for my career at that point was what I learned about FDA.

I keep on repeating myself -- I was a young, naïve young man with a family commuting a long distance from Pennsylvania down to Rockville and back, spending three and a half, four hours a day in a car, and I chose to do that simply because I didn't want to move my children, who happened to be doing well in school and sports and going

to church, and all the good things that they are to this day, and I was doing the commute to protect or to support my family.

What I learned -- and here's the story about FDA at the time. I went to Boston to observe a course and get involved with some of the people in New England. I remember walking into whoever the District Director in Boston was at the time, and these people who were in this District office were walking around, they were worshipping this guy. I don't remember the name of the District Director. You know, he was just a guy with a suit on, just like me. And they're buzzing around like little goslings around a goose.

So I was introduced. "Oh, we'll get you into the Director's office and introduce."

"Okay, fine, take me in."

So I shake hands, and this guy says to me, "Who are you?" and I tell him. And he says, "Well, where'd you come from?"

And I said, "I came from the state." And I remember exactly what he said.

He says, "That's too bad."

I asked, "Why would you say that?" I was offended, and I was full of myself at that time.

When he said, "Well, that's too bad."

And I directly asked, "Why is that?"

"Well," he said, "we all know how those state people are on the take and they aren't very good," and whatever.

What I found out later on was they just had an experience with the Massachusetts Department of Health where they'd found some people on the take. Well, it was fresh in his mind, and maybe he was involved in this investigation or whatever. But I didn't know anything about that. And I knew, I thought I was pretty good. I had training, I had experience, I had a master's degree. I was just trying to do the right thing. And he's telling me that's too bad.

I remember what I told him. I told him something to the effect, "Sir, where are your investigators located?" and he pointed out to his Investigations Branch. "And I'm going to say something to you." I said, "You know, you're exactly right. There are some real bums in the state programs. But if you go out and you look at your staff, you have some bums too. And guess what? You have stars on your staff. And if you go into the state programs, there are some real stars there too." And I turned and walked out.

Now, I had no idea that, oh, my goodness, I was supposed to kiss his tassels on his shoes or whatever. I had no idea how revered or whatever this word is that we worshiped these District Directors. But this guy had zero tolerance for state people, which brings me into something else.

I came from the state. I found out there were 50 or 60 people that wanted this job that I applied for and got. There were a lot of people who wanted it, people that I found out later on were very smart, very qualified people, and they picked me. As I look back, I'm still honored by the fact that Mr. Wilms picked me.

When I got here, though, what I didn't realize was, FDA was full of themselves. And I have an expression that I continue to use to this day, those "blueblood" FDAers, because FDA was so convinced at that time that they were the gold standard of regulatory

agencies, and if you didn't start in FDA, kicking flour sacks and doing all this stuff that FDAers do when they start their careers, you weren't it. You, as I say, you weren't blueblood, you didn't get the secret handshake -- and this is a little sarcasm on my part because for seven years, I wanted to be accepted into the club of FDA, and I felt for a very, very, very long time that I was never accepted.

I believe it did take me at least five years or so to prove myself with the FDA. Someplace along the line, I must have, because at that point in time our Director -- I guess he was the ACRA, somebody can help me here -- but there was a gentleman named Ron Chesemore, and Ron Chesemore saw what was going on in ORA. There was the State Training Branch that I was the head of, and there was another group called the Education and Training Branch whose job it was was to teach the investigators and analysts. Ron Chesemore's observation was, training is training, and there's a duplication. So why shouldn't training be under one Division? I don't know all the politics behind that or the decision-making behind that, but it was decided that we would merge the two training functions within the ORA. That was probably about 1992. That's when this new division was envisioned to be created.

There was a lot of jealousy, and at that point in time there was a lot of, between the gentleman who also happened to be in the Commissioned Corps, a captain in the Corps, and myself, we both thought that we should be selected for this job. Mr. Chesemore had the Director of the Office of Resource Management at that time, was a guy named Jerry Henderson. Jerry Henderson was a bit of a character, a lovely man. He's gone now. He was the one who had to make this decision. After a lot of jockeying

or whatever, I was lucky enough to be selected to be the Director of the Division of Human Resource Development.

I talked about this jealousy between these two branches, and the other group thought the only training that counted was FDA, and this arrogance that I talked about that existed in the agency -- that state people were basically second-class citizens.

RT: That is true. I worked for 11 years in state government and came into FDA in 1962, and I've seen that metamorphosis over the years. It was slow in coming; it really was slow in coming.

GEG: To the credit -- and I want to make sure that I get this on the record today -- that's not the case today. If I were to say the things that I see that have changed in 25 years of working for FDA, one of the things is the difference with how we approach state people, and I'm going to talk later on about some of our new-hire training, but right now, very actively will we recruit from the state ranks, and those folks are marvelous. I do some training with the new-hires and I tell them how this has changed, that in fact you are valued and you are appreciated.

RT: I think some of the elements contributing to a better respect of state people has come about through the interagency agreements, which were pioneered primarily by Philadelphia under Dick Davis and Tom Price.

And also through the state contract program, where we contract with states to do work that's beyond our resources to accomplish on a timely basis. That's helped, I think.

GEG: When this division was formed, it was intended to have some economies. Audiovisuals, you don't need two audiovisual people, you have one, and that person provides that service to both training groups.

I realized that there was a divide. I remember, after some time period, a short time period, we were in separate offices, but somebody got this bright idea that we should be in the same space, and they moved us down to Crabbs Branch Way. We finally got out there as one unit, and I still saw this jealousy and this divide. I remember going around to all my trainers and asking them what it would take for them to buy into this new division of ours. I remember going to this one trainer, and I gave her my pitch about trying to work together, and I said, "Okay, I'm your boss. How can I serve your needs as your boss?"

She looked at me with all sincerity and said, "You know, I never wanted you as my boss, and I still don't want you as my boss."

My response at that time was, "I can appreciate that because this is a change. I just hope that I can do enough and earn enough that in fact you'll change your mind." To that lady's credit, I don't think she ever did like the change, but on the day she retired, she came in and she said, "You're a good guy." So we did make some headway there.

But what happened through that -- and I'm trying to think about some chronology here -- is the merging was very significant. From the states' perspective, though, they were so worried that by us moving, they were going to lose their clout, and to this day the gentleman who works for me fights, I want to make his group the food

group, and he wants to be the State Training Branch because the states still want that label to hang their identity on as far as where they get their training.

JPS: I think that about covers it.

RT: Well, I think we're getting to the point of a break, if you'd like.

[recording paused]

GEG: All right. Well, one of the things is that, once we moved these two units together, this -- and I keep on talking about this arrogance, okay, naïve me, I see in my mind a state guy and an FDA lady, guys, ladies, whoever, in the same class. We have a food class; why don't we just have one food class, not a state food class and an FDA food class. There was at that time, and there's still a vein of some of this continuing today, this idea that the state people were dumber, not as prepared, couldn't do what the FDAers could do.

JPS: Could I just ask a question? But don't the two entities have different responsibilities under the different laws, under federal laws and state laws?

GEG: They do but they don't. In today's environment, I'm involved in a project right now, Integrated Food Safety System. The food safety system of this country today is based on the states doing most of the inspections, and FDA and USDA and CDC providing leadership with standards and that kind of thing. If I ever came to the role of

being ultimately responsible to design it, that's exactly how I would design it. I'd have the FDA providing the standards and the training and the leadership, and I'd even, if I had a whole bunch of money, I'd give it to the states and let them do it, because, quite frankly, the states can do it better than us.

RT: Further, Gary, the states can maintain a more frequent interval of inspections. Some inspections by FDA may lapse a long, long time.

GEG: And I'll even add to that. When I was with the state, I had a red embargo tag and I had a red tag, and I could walk in and, the best example I remember is seeing some untagged clams, and they were from a questionable source. I put a red tag on it, and it was in a storage area of a restaurant. I told the guy, "See that? If those clams are moved, I'm coming after you. I'll put you in jail." But the states have more power and less bureaucracy, less developing a federal case. I could pull off stuff when I was the county supervisor and when I was the state director. I could get things done a lot quicker than the FDAers. Today, FDA uses that state flexibility, that capability a lot easier.

RT: For many years they've done that. There have been instances, I recall one about gumball machines where FDA wanted to take a regulatory action and got many states to go around and embargo these little dispensers, but then lost the case. This really embarrassed the state people because it wasn't their action in the first place. So there's a two-way street here, and the convenience of the embargo has sometimes been about the only real working contact, historically, the FDA district people had with the state people.

GEG: I'm going to start talking about how we changed from this training system. As I talk about that, I want to talk about what we were training, that is, how to inspect, how to take and build enforcement actions, and how to analyze products. Those were the three target areas which I had for both the state people and the FDAers. My vision and my charge from Mr. Chesemore was to weave these two separate functions into one function. The name did it, as I said, and the staff did it, but I have an expression that, if you want to prove yourself, you can talk all you want, but you've got to behave it. It's what you do and how you behave and how you act, not those idle words.

I don't know when it came about, but I want to mention GPRA (Government Performance and Results Act) -- and I forget how GPRA talked about performance; it talked about results as opposed to actions. So I learned about outputs and outcomes, and when I related outputs and outcomes, outputs was, as I put on a training course; outcome was, as a result of the training course, when people could do something or were able to better do their job as an investigator, as an inspector. I believe that was one of the significant learning events that I had which was not good enough for me to report 2,000 people in a training course, but, instead, I now report 2,000 people know how to do an inspection of a juice plant, a drug manufacturing facility, and so on, and that was very, very significant.

RT: The Congress approached that issue and recognized it by their enactment of the Federal Technology Act.

GEG: Right.

RT: Which really was an act encouraging agreements between government agencies and private companies to stimulate cooperative research and development. I think, from that initiative, perhaps this was a basis of your being able to develop the CRADA (Cooperative Research and Development Agreement).

GEG: Right, which is a connection, and which is part of this.

Then there's something else that is significant. I don't know when, but someplace along the line, in one of these training journals that I read, people started talking about a corporate university. I wanted to be the best, and I'm one of these people who understands today I'm not the best, but I still strive to be the best, and I wanted to be the best and I never thought we were the best at this (training).

Okay, what's a corporate university? I convinced some bosses to send me to Phoenix, Arizona, and it had to be in the summer because I remember you could fry an egg on the sidewalk. It was a terrible time. This was no junket to Phoenix, trust me. But we went to Motorola University, and these people were beating their chest about how marvelous Motorola U. was, and I was one of the few government agencies in attendance, and they said, "Yes, governments could have a corporate university."

The twist, the significance, in my mind, of what a corporate university is simply this, is that training and development prior to this time, in our economy, was looked at not a moneymaking proposition but a cost. A guy at Motorola said, "Look, what you

have to do is go back and make training part of the strategic plan, so that, in order for your agency or your corporation to get to someplace, you have to sell your training function and you need “me,” you need the training function in order to be successful to reach that strategic-plan goal.” That made one heck of a difference. And I believe that trip to Phoenix was the beginning of this vision that I had of having ORAU, Office of Regulatory Affairs University, and it came from that two- or three-day seminar.

So I came back. There was something else that happened. I read an article about branding, and somebody told me, in this article, about the importance of a product, a company, an agency picking an icon, a brand, and making sure that the brand stood for something. The best example I have is Heinz 57. Heinz 57 stands for something. When you see a Heinz 57 ketchup, you don’t expect runny, you know, run-of-the-mill ketchup. It’s going to be flavorful and it’s consistent, and you know Heinz 57 ketchup when you smell it and taste it because that’s what Heinz 57 means.

Well, to this day we have an ORAU logo, and I said that when you put that logo on, this is good training. And I have to tell my staff to this day, “Don’t put the logo on that which couldn’t stand up to a Heinz 57 test.” That was significant.

So, what happened, and someplace along the line with Mr. Chesemore and the follow-up actors, I convinced this leadership that training should be important and that when there was a senior staff meeting, “training” should be invited and not, you know, if they’re going to have a fat-cat meeting in Kansas City, that I should go, because when they were deciding where, the issues of the agency, where they are and what needs to be done, don’t tell me after the fact, at the eleventh hour, “Oh, we need training.” I should

know at 2:30 in the system here of what I have to anticipate and what I should have to plan for. So, again, this connection with the strategic plan.

There were other things going on, and I can't put this in a timeline. There was a lot of crazy organizational things going on at that time, change.

I went to a class on change. How do you manage change, and how do you get people to anticipate and embrace change? That was a significant thing for me to learn.

This agency got, I'm going to use the word, "sucked" into a concept of self-directed work teams, was one of the worst things we ever got involved in. We had one of our senior managers in ORA who walked into one of our staff meetings one day, and say, "I have this vision that I'm going to walk into a region or district office, and the whole office is going to look like busy bees." I still remember busy bees. He became a follower of this concept of self-directed work teams, which minimized the responsibility and the worth of first-line supervisors. This is 15 years ago, at least. I believe that we're still suffering from that.

JPS: I'm not sure I know what a self-directed team means.

GEG: A self-directed work teams is, rather than a boss, a first-line supervisor, sitting there and directing and dealing out work and then reviewing work, that there was no boss, but that there was a team of investigators, and they directed themselves efficiently in a way of who's going to inspect this firm and who's going to inspect that firm. And it was terrible.

JPS Do we know where this direction came from?

GEG: Oh, it was a movement across our country.

JPS: Okay.

GEG: This was this idea that supervisors, rather than top-down, that employees know better than the supervisor does.

JPS: Well, I know there was . . .

TAPE 2, SIDE A

RT: Okay, I think we're all set again.

JPS: I was just observing that, I think at the time this directive came down, it was sweeping across the country, I think, I don't know if there was a connection here or not, but it maybe was also a time when we were reducing or actually expanding the number of people that supervisors had responsibility for. I don't know if there was a connection there or not. But anyway, please go ahead.

GEG: Well, interesting from a budget standpoint, these were not good budget years. I have to say, until probably the last five years of my career, I never had enough money to carry out the training function.

It's an interesting process that I used to go through as far as submitting a budget for my training function. I would go and do a needs survey to the districts and to the states and say, "What training do you need?" I would get a number of courses that we needed to put on, and that was algebraically X. X is how much training needs to be done. I would say, in order to do that, I need how many millions of dollars to get this done. Then I would submit and say, "If you give me X minus 10 percent, this is how many courses, basically that many fewer, and at X minus 20 percent, X minus 30 percent, X minus 40 percent. I literally kept those with the idea that if anybody ever complained about why we weren't doing more training, I was telling the agency how much training we need, but you didn't give me enough money. In those days, obviously, and I'm not double-guessing the leadership or whatever, in those days, we only had so much money. So, what did you spend your money on? You spent it on inspections, enforcement action, and analysis. This is not the training administration, this is the Food and Drug Administration who takes enforcement action.

Again, remember my comment about how training has to become a part of the strategic plan. For too many years, training was thought of as a luxury, and I believe this has changed or turned around. In my tenure, that's one of the things that changed, is that now, when there's an issue -- right now we're talking about tobacco and we're talking about changing of the food safety system, changing the drug safety system -- whatever it is, when they start dreaming up the solutions, the trainers are pulled in.

Now, I want to go back to something else. This was, I used the word change. Change was a sexy word at that point, government and there were change exercises or whatever. I hooked onto an idea of organization development, where training . . . I said this earlier. Training is not the important thing. Learning. Learning is changed behavior.

On the back of my business card, which I don't have today, I came up with a language. It's not about how many people go through the training, it's what that training does to improve the performance on the people who take the training and how their careers happen to lay out in order to protect the public health. That's when training becomes successful.

So, how do you do that? Well, you do it through training, but one of the other ways you do it is organization development, group thinking, group decision-making, that kind of thing. So I got really involved in change, and there were people, when we had a thing, ORA 2000, whatever it was, twentieth century, we had all these dreamy kind of things. All at once, I was being identified as somebody who should be at the table, training *and* change.

So what was going on out in the field was, well, we were self-directing work change and we were doing this, and somebody needed to write a newsletter for the field and share what happened in New England out to Dallas or whatever. I ended up being the editor of the Change Sheet. Once every week or every two weeks or whatever -- and this is early into computers, I was not very good at computers at the time. I couldn't cut-and-paste a computer at that point, and it was difficult. But this was, again, an element in

this growth of the appreciation of training that happened, and it was related to this Change Sheet on how we were doing.

RT: Maybe before you got to the university stage, you did, as I recall, develop a video training satellite type of training.

GEG: Let me talk about this idea. While all this was going on, here we are talking corporate universities and change or whatever, I went to a training program on distance learning. I had no idea what distance learning is. But it was downtown in D.C., and the demonstration was how people were using technology to teach high school kids how to drive. What I saw on the screen was this, somebody, the windshield of a car and how we were teaching this kid to turn on their right-turn signal to take the exit ramp or whatever. When I saw this, I leaned back in the chair and I said, "Oh, we could teach investigators how to do that." I decided on that day, we were going to get in the distance-learning business. I had no idea how that was going to happen.

Again, let's go back. I'm going to get in the distance-learning business, and I don't have enough money to fly to Kansas City or Denver or wherever to put on a course. How can I do this? Here's the story about how we ended up with the Web-based courses at ORAU.

There was a company in New Jersey who went to Diana Kolaitis, who was the District Director in Philadelphia at the time, and this company -- EduNeering -- a Web-based training company in Princeton, New Jersey, went to Diana and said, "We'd like to help the Food and Drug Administration in the distance-learning business."

And Diana said, “Well, I’m District Director. The guy you need to talk to is the training guy in Rockville.”

So this gentleman and his vice president came, made an appointment with me, and they sat down and told me what they did, and couldn’t we do something together? Well, I didn’t have any money. It sounded like a great idea. As the Director, you know how many vendors come through the door? They’re all promoting something to sell. This was just somebody else selling.

I need to back up a little bit with this.

Mr. Henderson, who was my Director, I told him that we needed to get into the distance-learning business, and he said, “Yes, we need to get into the distance-learning business, but you have one problem. You have no money to do it.” He invited me to a briefing at one time where we talked about CRADAs, Cooperative Research and Development Agreements, which were a result of the Federal Technology Transfer Act, I think. Basically a CRADA is where the government brings what they know and puts it on a table, and a private industry puts what they know on the table, and they build a work product, and government gets to use it at no cost, and private industry gets to use it, maybe sell it, certainly make a dollar out there.

Well, the first time I heard about a CRADA, I literally backed away from the table. That sounded about as illegal and unethical as I could ever believe, and it made me nervous. This idea of CRADAs and distance learning we had tried two or three times to get some training companies involved in a CRADA and they wouldn’t buy it.

Now I’m going to circle back to Eduneering coming from Philadelphia into my office in Rockville, and I said, “Yes, I’m really interested in distance learning, but I don’t

have any money.” I said, “But, you know, we have this thing called a CRADA,” and I explained what I thought of a CRADA. These people wrote down what I was saying. The guy’s name was Bob Delmontagne. And he said, “Let me do some research.”

This guy went away for a year. A year later, my secretary comes up to me and says, “There’s some guy here from New Jersey. What’s on your calendar?” I asked, “Who’s that?” “Bob somebody-or-other.” I literally forgot who this guy was.

He came back, made the appointment, sat down, and says, “We’re ready.”

And I said, “Ready for what?”

He said, “We want to sign up this CRADA thing, and we’re going to build distance learning for you and FDA.”

“What are you talking about?”

He says, “You don’t remember me?” And I literally didn’t remember this guy.

So he sits down and starts pitching this thing about how he and his company are ready to build distance learning, asynchronous Web-based training for states and FDA. The bottom line is, all we have to do is provide the content, and he’s going to “Web-ize” these courses, post them on the Web, and all the FDAers and all the state people can take this training for nothing.

Well, what a deal! Why wouldn’t you like this? Well, he got my attention.

So I circled around. Understand, FDA’s orientation to all of us is to be very leery of industry, and all at once I’m supposed to get in partnership? I’m supposed to get in a deal with this guy?

Long story short, we signed the CRADA. This is a personal story where there were people in this agency who didn’t know about CRADAs, and, of course, the

company wanted to use it as a marketing tool, so they put some press release out that I didn't know about.

One of the old Commissioners who I happened to know called me at 4:30 one day on the phone and said, "Gary, what have you done? What you've done with that company is so illegal," and he chewed me out.

I was on my way home. I had to drive home to Pennsylvania. I came back, and I didn't sleep a wink that night, because what if I had done something illegal? How could I do something illegal? I had sent it through all these attorneys in the agency, and the Commissioner at the time had signed off or whatever. But the word out was it was so strange and so unusual that the old guys, the old good-old-boys, couldn't understand why a young buck like I was ready to do something like this.

RT: What was the year that first CRADA was signed?

GEG: I suspect that that was 1998; that was the beginning.

It took us a year. What we did was build a prototype, and the prototype was a tour of the FDA, and that's what we posted on the Internet site, the FDA, and it was a great little tour, very rudimentary, very early on. That was supposed to be our marketing tool.

Now, also interesting -- personal story -- now, you understand, corporate university. In FDA, there's DHRD (Division of Human Resource Development) and ORAU (Office of Regulatory Affairs University), and then there's staff college directors, and we had this loose organization. I'm sitting there saying, "This doesn't make any

sense for us to be building this Web-based training for just ORA. Why not be for the whole agency?” And, naïve me, I put this presentation together, and the Commissioner at the time was Dr. Jane Henney. I think Dennis Baker was the ACRA at the time, and Dennis gets me on the agenda of the agency’s executive leadership, and I have this Powerpoint presentation -- early Powerpoint, too, it was a very crude kind of thing -- and I make this presentation. I remember the Center Directors being there, and they roasted me like nobody could have ever been roasted, because, again, it (the CRADA) was so uncomfortable. They basically said, “How dare you think that ORAU should be the training unit in this organization. I” -- one of the center directors -- “have my own, and you’re not going to take that away from us.” So, again, there was turf here.

After I got roasted in that meeting, and Dennis Baker’s wisdom, he said to me, “Gary, not a very pleasant experience, was that?”

I answered, “No, it wasn’t.”

He said, “Here’s a little wisdom for you. You go back and you build ORAU because that’s what you’re responsible for, and don’t worry about FDAU.” To this day, I think that was a mistake. We should have provided the distance learning to the whole agency, not just ORA.

Today, our agency should have, there are things that should be in our agency that should be agency-wide, and to this day we have five Centers and ORAU, and the Commissioner’s Office doesn’t even have a training function to this day. We compete in a certain way, but it’s in common things like administrative training, leadership training, supervision. Supervision is supervision; leadership is leadership. Right? Why is ORAU, why am I building leadership training, and the lady over at CDER doing the same thing,

and the lady over at CBER. We are tripping over each other, inefficient. But you know why we can't do that? Because of turf. That's all it is.

So, try to get my thoughts here about the CRADA.

Okay, so we have the CRADA. We start building courses, and my staff -- I talked about the lady who didn't want me as her boss. Well, when she heard that I was talking about distance learning, she thought I was phasing her out, and she happened to be a little bit older lady. She was so threatened by my announcement that we were going to be doing distance learning that, in fact, she retired.

Now, I want to stop because I have forgotten once something very significant here.

Web-based training was not the first effort that we had in distance learning. The first effort we did was satellite training. I heard this idea that we could train thousands of people simultaneously, and I hooked up with a guy out at the studio, at the CDRH studio, Dr. Bob McCleary. I don't know who befriended who, but we sort of fed off of each other.

At that time, the big need from the states was HACCP (Hazard Analysis and Critical Control Points) training in the retail area. There was a gentleman on my staff named Chuck Higgins, and Chuck Higgins was one of my absolute best trainers. I got this idea that we should do satellite training.

So I hooked up Higgins with the people out of the studio, and I said, "Let's build a HACCP thing," and this was exciting. There was a buzz. Man, I was fired up and I was wound up about this.

Higgins went out and started seeing what the assignment guy gave him. I remember him coming back and saying, “I don’t want to do this.”

“Why don’t you want to do this? This is an exciting assignment.”

He said, “No, I want to go back to training people.”

I said, “No, you’re going to train a lot of people using this technology.”

Well, Chuck Higgins was very, very good. In fact, he was a bit of an actor kind of person, and he was an entertainer, and he fed off the crowd. So when he went out and talked to 50 people, he saw somebody excited, and he fed off of that excitement. Right? Now he’s talking to a little red light on a camera, and I had to say, “Look at the red light and, in your mind, see the excitement that’s in Podunk, Pennsylvania, or Peoria, Illinois, or wherever.”

Long story short, our first effort on satellite training, we trained 5,000 people simultaneously on HACCP. I forget what the title of the course was. Great idea, great technology, but a problem. If you were on the road or you were in a dentist’s chair or whatever when the class was going on, you missed the event. So then we taped it. Videotape does not equal training, so that didn’t work. We had call-ins and faxes-in to questions or whatever, but once you videotaped it, it was static, and it ended up being bad training. But it was a start, it was a success, it was an excitement, it was the precursor, it was the pre-event to where we are today with the Web-based training.

Now I’m going to circle back to the CRADA.

We started building basic food courses, introductory courses. That was, we started in ’98, it probably took us a year to do the tour of the FDA. We started to build basic new-hire courses. 9/11 came along.

9/11 was significant. The impact it had on training here was, as a result of 9/11, everybody downtown, the President, the Secretary of HHS, was so interested in getting people on the street, inspectors. I remember that the Secretary apparently made an announcement that, in fact, FDA was getting 700 new investigators. My boss at the time, the Director of ORM (Office of Resource Management) was Malcolm Frazier came to me and said, "Okay, you have an assignment."

I said, "Okay."

He says, "You're in charge of training investigators."

I said, "I know that."

He says, "You get 700 new investigators to train."

Typically, to train an investigator to do basic work, it would take at least 12 months, typically 18, maybe 24, by the time you get the classroom and the OJT and that kind of thing.

But I remember Malcolm saying, "Okay, you're getting 700."

The Secretary was Tommy Thompson, the guy from Wisconsin. Secretary Thompson said that we're going to have these people on the street right away, and Malcolm on that day said, "Your problem is you've got to find a way to get these people on the street in two months."

My jaw dropped, and I said, "I can't get people trained in two months when it takes two years. What kind of training is that going to be?"

Malcolm and I negotiated back and forth, and what I thought then was, by doing some distance learning, that I could, using Web-based training, get to a point where people or investigators could do very basic work, and I mean the basic of all basics, a

very crude inspection kind of thing, maybe at the border, opening some cartons and looking for some very gross violations kind of thing, and actually do it in six months. So that was the challenge; that was the charge.

I remember going to EduNeering. I was giving a speech to some people from the pharmaceutical industry in northern New Jersey, and we had the President of EduNeering in the room, and I said how 9/11 had impacted us and with these 700 new people. I looked across the room and I saw this gentleman, and I said, "I'm going to ask something. That's my partner over there from EduNeering. I need his help in order to build an interactive course for our new-hires so that we can get these people on the street in six months." The commitment between that company and FDA was made in front of 200 people during a speech that I was giving.

After the speech, he came over and says, "Whatever you need." It was patriotic at the time. He said, "Whatever you need, we'll help you."

So, what we built was . . .

JPS: But the CRADA was in place at the time.

GEG: The CRADA was in place, but it wasn't being optimized. We were being diligent in building it, but, by 9/11, we basically had to turn the heat up and make things really, really happen.

We had a meeting in Florida, and we brought a bunch of FDA people together in Florida and basically we had to reengineer the new-hire training program. We brought Directors of Investigation Branch, and investigators and members of my training staff.

We brought just people from all over the country to reengineer, restructure the new-hire training.

In my graphic mind, I said, “We need a curriculum guide.”

I’ve got to interject another thing that I learned at this point in time.

I learned a phrase, “blended learning,” at this time. Blended learning is simply taking whatever kind of training that you have, the right kind of training, and whatever the task is, using the right instructional system tools in order to deliver what you need to deliver, knowledge and skill. So blended learning could be Web-based training, it could be discussions, it could be exercises, it could be OJT, it could be classroom. But if you blend all those together, depending on the task, you end up using the right tool.

I was hot on the idea of blended learning. We completed the meeting in Florida, and I remember there was a regional directors’ meeting in Baltimore, and after the Florida meeting was over, I had to immediately go up to Baltimore and tell the RFDDs what we had decided to do in Florida.

What we decided was to build a blended-learning process, and I described it -- based on a Bingo card. Well, my idea of a Bingo card is a card of squares, and each square is an assignment, a part of the curriculum. I believe that the square became the elements of what you had to do in order to be trained. And in the center of the Bingo card is free space.

Well, in the center, instead of free space, was the audit, and we haven’t talked about the significance of certification yet, but I need to get to that. But certification basically is take the training and then, performance-based, you have to pass a test of performance and can demonstrate that in fact you’ve learned “it.” So here we’re going to

teach you to be a new-hire, and then, at the end of that, we're going to send you out with an auditor, and that auditor is going to say whether you "got it," whether you can do an inspection.

So we built a blended-learning curriculum, which I very crudely described as the new-hire Bingo card, and that became the origin of what continues today to be the new-hire training curriculum for ORA. It's blended learning, it has I don't know how many elements, and the elements are the Web-based course, and the best way I can describe this is, one of the things an investigator has to know is how to collect a sample, for efficient sampling. Well, we have a 45-minute module on how to collect a sample. At the end of that, there's a little test, drag some things around, answer some questions. Do you really know, at the end of that, how to collect a sample? Probably not.

So, what's next? Well, we built four or five questions that the student then goes to their boss, and the boss asks a question, "Well, John, what kind of equipment would you need to collect a sample? What information do you fill out?" You talk about the sample collection form. You talk about that you need a "whirl" pack with a sterile spoon, all this kind of stuff. After these discussions, do you know how to collect a sample? Probably not.

Then we have an exercise. As your supervisor, I say to you, John, the new investigator, "Meet me in the storage room, and you go to the equipment closet and get whatever equipment that you need." So you go over to the equipment closet and get the "whirl" pack, you get the spoon, whatever. In the storage room, I have a bag of beans. And I say, "Collect a sample," and you get the "whirl" pack, you collect it, you fill out the form. Do you know how to collect a sample? Well, you're getting there.

The next thing that we do is we send you out on a road trip with some senior investigator. While you're out there, the senior investigator says, "John, go out and collect a sample." You get your spoon out, get the whirl pack, and you collect a sample. Well, you've probably been taught four or five times already how to collect a sample. This is important, so we're reinforcing.

After that part of the curriculum, the Bingo card, is a three-week new-hire course that we have. Half an hour of that course is set aside for collection of an official sample. Again, it's reinforced.

Then, after that, then we send you out on this audit. During that audit, you will collect a sample. So probably there's five or six different reinforcements on how to collect a sample. That's the blended-learning model that we have.

JPS: You mentioned bringing in DIBs and others, and I guess that leads me to ask, where does the content come from for these courses? I know this is a pretty basic question, and it may be self-evident, but it's, we're covering, FDA has so much responsibility here, and you obviously, and your group, has responsibility for training these people. So we're talking of pretty complex stuff here. Where does the content come from?

GEG: Where does it come from? When I said that we merged our two branches in 1992, there was a process in place which continues to this day and maybe needs to be updated, but we called it a course advisory group process led by my trainers. I have some people on my staff with master's degrees in adult learning and that kind of thing. I have

other people who are past investigators, past state inspectors, analysts, and if they do not have a degree in adult education, I send them to a series of short courses to learn how to train. But my staff knows, hopefully knows training, how to set objectives, how to build courses, exercises, that kind of thing.

What they do is -- and let's pick a topic, food security. If we have to put a course on food security, we will go to the Center and say, "Give us your expert on food security. We will know, then, people from the districts, from the headquarters people, and basically bring the experts around a table to build the course.

My staff are not experts on food security, how to inspect facilities, how to inspect a drug, but my staff, with an understanding of the broad, general, the food and drug law, and the function that we have to do, brings these people together. Over the years, I have encouraged my staff to use a very simple formula during these CAG (course advisory group) meetings, and I related to my . . .

TAPE 2, SIDE B

GEG: My eighth grade English teacher still makes an impression on me that, when I wrote that article as an eighth-grader, it was who, what, where, why, and how. But I don't think she taught me in the right sequence because when someone says to me, "Hey, we need a training course on such-and-such" -- food security, basic drug, whatever it is -- the program person, everybody seems to think they are an expert in training, and they already have it in their mind how that training is supposed to happen. They want to immediately start saying, "Oh, this is how we're going to do it. We need a two-week

course or a one-week course,” or whatever, and they start talking how. What we do is start with the why. Why do we need this? Maybe there’s a new law. Maybe we find people getting sick on this. Maybe we learned by on-site evaluations for the performance of our staff doesn’t know this or that. If you define why, it’s very telling and it focuses you on why the course is needed.

Then you ask the what. Okay, at the end of this course, what do these people need to know or be able to do? Then you can start talking about who: who are these people, how many of them? If there’s 2,000, having courses of 20 people doesn’t make sense. If there’s 2,000, you’re probably talking a distance-learning event.

If it has to be done, the when, you know, there’s a crisis, there’s people falling in the streets, we have a mandate, a legal mandate that it has to be done by July 1st, maybe we have to do distance learning. So that’s when the when comes in.

The where, are we going to do it in the District offices, are we going to take the training out there, are we going to bring them into ORAU, or where it might be on the Internet.

Finally, we get down to the how, and finally you get down to the how of building the curriculum, with the what’s, who’s going to teach this thing. But it’s a very simple outline.

I talked about blended learning. Now I want to talk about something also significant, is certification.

In my time as a state person, I was involved with the retail food program, and the retail food program had a standardization process where the FDAer would come out to Harrisburg and he would standardize two or three people that worked for me, and then

those two or three people would then go into the counties and standardize the inspectors, that kind of thing. That made a lot of sense to me.

Well, sometime right after I was the Division Director, in '92, '93, '94, someplace there, Mr. Chesemore, the ACRA, was getting -- my language -- chewed up by the congressmen over medical device programs, about inconsistent device inspections. Apparently an FDA inspection in Philadelphia wasn't the same as an FDA inspection in Denver, whatever it is.

Mr. Chesemore was asked by Congress, "How do you train your people, and how do you know that they in fact know what they need to know?" So the RFDD at the time was a guy named Dick Davis in Philadelphia, who was the head of the ORA Human Resource Committee. Dick Davis and I were assigned to come up with a scheme of what Ron Chesemore is going to go back to Congress with regarding how do we train and whatever. We came up with this idea of taking that standardization mentality from the retail food program, and applying it to the other FDA programs.

Interesting, the guy that I talked about early on, Steve James, who, for a lot of reasons -- hopefully his reasons and my reasons -- stuck around, I needed one of my best people, and he was the best person on my staff to help me. With his food background, I said, "Help me build a certification program for device investigators."

That happened in the mid-'90s, and we have built a certification program for investigators. We started out with medical devices, we now have a certification program in drugs, we have a Level 1 investigation, which is the Bingo card that I talked about before. Level 1 is the basic investigation, and then Level 2 is a specialization into drugs, devices, foods, that kind of thing.

Because of the lack of a buy-in from the field staff, we have made this a voluntary program, so we made a certification program, and we made it available. Basically, certification is a curriculum of required courses, “X” number of inspections using practical application of those courses, and then an audit, and we had that program in place. So far it’s a voluntary program.

Why I bought in to voluntary was, I never thought that I could force it down the throats of the District Directors and the DIBs because, as I told the story about the gentleman in Boston. These District Directors are very autonomous. “Don’t you dare, in headquarters, tell me what’s going on in Philadelphia. I know what’s going on in Philadelphia. I know what’s going on in Dallas and Denver.” To the new young buck in headquarters, “Don’t you dare come out and tell me what my staff needs to be able to do,” and that’s what I was running up against.

So I said, “Well, let’s make it voluntary, and let’s make it so much of our culture, a part of our culture, that they’ll never be able to get rid of it,” and that’s exactly what happened, because now, here we are in this global environment, this world of ours right now, in this process of revitalizing ORA and our agency. We’re in this era of ISO, international standards, and I’m big into standards.

Because of some of these revitalization things we’re talking about, we are in the process of taking our voluntary program of certification and we are getting it accredited by the American National Standards Institute, which is based on ISO-1702. So, in fact, we are getting our certification program accredited.

The significance of that is, I believe in the not-too-distant future, it will be a requirement for every investigator to be certified in one of these specialties because, in fact, certification has become a part of the fabric of how we operate.

JPS: This is fascinating because . . . A couple of questions.

One is, do you know where the ACRA came down or the ACRA's have come down on the issue of certification, if they would prefer to see it required, or are they satisfied with it so far being voluntary?

Number two is, what's the difference between a certified investigator a non-certified investigator? Is one on a more expedient promotion track, or is there a practical difference between them?

GEG: The first thing is, the ACRA's have always been supportive of certification. But we had union issues. What are you going to do if we made it mandatory, and what are you going to do if Charlie over here has been doing it all these years, and he doesn't pass? What if you've been doing it, Charlie, wrong for 15 years, which is my fear. So the issue about what are you going to do with the existing people continues to this day. But in today's environment, and especially with the oversight of Congress -- and I'll whisper this -- saying, you have some people who, yes, I want to be the best, and you have some investigator who says, "Okay, I'll take any training." And what happens is, if you're in a certification program, have your hat in the ring, you start getting training that other people don't. So that's one of the things that, what's in it for me, you get training.

There are some people who fail the audits. That gets around the office, that gets around the country, saying, "Oh, Charlie over there failed. Oh, man, I thought he was better than that," kind of thing. There are some self-esteem kinds of things here. Unfortunately, right now, we have some people, we have some old goats in the districts who are saying, "Nah, you don't need that," or whatever.

But, to change this right now, we have a Level 3 certification in drugs, and we have a lot of support from the Center for Drugs right now. We're going to connect grade to Level 3. In order to get your GS-13, you've got to be Level 3. All at once, money talks, and that's where we're going to be headed with this.

The other thing is, with this ANSI (American National Standards Institute) thing -- and I talked about coming in 1985 and being the gold standard, yes, we're the gold standard. Let's go to Beijing today, or let's go to India or let's go to Brussels and say you're from the FDA. I suspect somebody would say, "Yes, so what?" I suspect if you go to Beijing today and you say, "I'm going to make an inspection," well, what makes you qualified to make an inspection in Beijing of a food plant, a drug plant, or whatever? It's such a global environment now that this agency cannot afford not to subject itself to third-party standards and offices. That's exactly what we're doing right now. We have a good program.

We just went through an ANSI audit recently over our new-hire training program, and we learned so much. This month, we're going to be accredited by ANSI, so that says we have a good program.

Now, in order to get that, we had to change some of our qualities, processes, and that kind of thing. But that international standard is part of the present, but it is also really part of the future.

I talked about ANSI accreditation someplace in this arena, this timeline. I'm big into standards. I found out about the International Association of Continuing Education and Training. I had a good deputy at the time, a lady named Leona O'Reilly

[continuation of interview]

RT: We're continuing the interview with Mr. German today, January 28th, and we're now in the FDA History Office.

All right, Gary, let's go on from where we were. I think you were discussing standards and the importance thereof when we last convened.

JPS: Which was two days ago. And here we are, on January 28th, resuming the oral history.

GEG: Okay. I can't exactly remember where the flow was, but the significance of ANSI and the significance of the IACET is that the days are gone by that FDA can sit here and self-proclaim themselves to be the best. We have to subject ourselves to outside standards and, therefore, meet those standards. Whether it's ANSI and IACET and the other -- ANSI standards are based on the ISO (International Standards Organization) standards, and that's an international standard; 17024 has to do with the training and

certification of individuals. My whole point is, is that I believe that's the future, and certainly ISO, throughout the agency, from a standpoint of training, we have to subject our training to those kind of standards, which now is going to allow me to jump into the future as to what I see as the future based on the standard.

I talked about how I started in 1985. I can't remember whether I actually said this or not, but I want to show, from a resource standpoint, how things have changed.

When I was asked to move the state training branch of Cincinnati, there was myself, five trainers, and a secretary. Today, I have a Division of Human Resource Development, and I have 60 or 70 people on my staff, which is a combination of managers, trainers, instructional designers, graphics people, records people, support staff. I actually have an organization chart that projects all the way up to 100 people. That's all a function of budgets, so let's talk about budget.

My first budget, in 1986, to put on 40 or 50 state training courses with those five people was \$100,000. My budget in 2009-2010 approaches, might exceed, \$16 million. That's a big change. We have records of how many, it's not hundreds of people, it's thousands of people.

I think I mentioned the fact that this CRADA that we have with the EduNeering company, we have hundreds of courses available to state and local people. We now can expand that CRADA to not only FDA, but to CDC and USDA, and the folks up at EduNeering in Princeton have agreed to that.

I asked them, at a closing-up meeting as I'm getting ready to retire here, how much do you think FDA gained from that CRADA? Again, to repeat, the CRADA is, we put the content on the table, they take the content and they Web-ize it, and then they in

fact share a learning management system with us where it houses and launches these training courses. The vice president of the organization said, "Let me get back to you." She suggested, since we've had that CRADA, we've gotten \$11 million of training for nothing. Wow!

JPS: It's ironic. You're talking about pulling in these other agencies, CDC and others. What about the other components of FDA that do training? Is it still . . .

GEG: No. Those other people are still of the opinion it's all about turf in this agency, in training.

RT: I wanted to ask you, Gary, about the universe of the training. I guess it started primarily with food and microbiology and perhaps public health per se. With regard to devices and drugs, the other entities, are those currently embodied in the training?

GEG: Well, the training, for state training, obviously, our relationship with the states is primarily foods, and California and Texas and maybe Colorado, where I have some very minimal device programs and drug programs. But the majority of what we do with the states is foods.

But when you look at the training function of DHRD, of ORAU, it's hire-to-
retire, so the orientation, anything that even hints at technical training, new-hire training, basic investigative techniques, the basic analyst training, and then the more journeyman-level courses, the device schools, the drug schools, the biologics schools, all the way up

to this higher level I talked earlier about, the Level 3 certification, and because the agency at one time had agency-wide leadership and supervision training, and they dropped that several years ago. Well, ORA is forced to have their own leadership training now, and that's too bad, because leadership is leadership, supervision is supervision. If I were to make a recommendation, somebody in this agency needs to build and offer that kind of training across the agency.

One training that we do not get into is ethics training and EEO kinds of training. That's the one thing we don't do. But anything technical, yes, we do.

Now, let me jump into the standards, and I go back to these ANSI standards or whatever. One of the issues, and the issue about budget, right now, because an interest in the White House and the Congress, and because of some of the outbreaks recently, there is much movement afoot to revise, change, retool the food-safety system in our country. There's an initiative, Integrated Food Safety System Initiative, within our agency right now, comprised of work groups and task forces. We had a 50-state meeting last year or two years ago where we had a training group that was trying to look at how the training system in the Integrated Food Safety System would work. There's an idea that there should be an academy similar -- and I compare it very similar to what's down at Quantico at the FBI Academy, where they teach the FBI agents, but then they bring all the county and state policemen in there to certain kind of academies, and there's a vision of that.

The future, as I believe it, is that FDA cannot look at themselves as the only provider of training; that, in fact, I believe that the states want us to set standards. I believe that they want us to help assure that there's a system to develop and then deliver

training, and possibly some certification, and then allow the states to do the inspections because they have the workforce out there versus how many investigators that we have.

So there is a movement afoot that in fact we will build a training system whereby FDA -- possibly, it would be great if CDC and USDA were at our elbows working together -- get some state and local people, build the standard, do a job-task analysis of saying, okay, what does an investigator, what does an inspector need to know, be able to do, in order to make a good inspection, develop learning objectives, develop a curriculum for what would it take to train the ideal investigator, inspector. Then come up with a system, maybe centers of excellence, grants, money going out to universities, maybe some agencies, maybe some associations, whereby FDA was not actually doing the training, but setting the standards, providing the curriculum, other people actually building the training and delivering the training, and ORA, FDA, auditing that training to make sure that it meets these standards.

Then, after that, and separate -- and there has to be a separation between training and certification -- after they're trained, then somebody, through some sort of a certification board or whatever, would actually make sure that the training has been done properly, maybe some experiences, and then administer a test. In the old days, we used to have registered sanitarians, that kind of thing. Well, this is very similar. Maybe the test is not a multiple-choice test. Maybe the test is a computer-driven game kind of thing, or like the airlines do, simulations, that kind of thing. If I were to talk about my vision of what the future should look like, it's that nationwide training system followed up by a certification system. In fact, I would say 30,000 people out there who are involved in inspections and regulation actually having a certification.

JPS: You're talking about training state, state officials, obviously, not FDA investigators and inspectors, using this approach.

GEG: Yes, I am. I am talking about FDAers and state and local people sitting elbow-to-elbow in the same training.

JPS: But having someone else train FDA inspectors besides FDA people?

GEG: Yes. What I see them training is, I see academic people. The University of California at Davis has great training. Louisiana State has good training. The University of Minnesota has great training. Having those academic places train on the science and technology of the regulated industry that we regulate, and then still having FDA or the states teach the law and the regulations and the enforcement process. It's this, it's not one place fits all, but, okay, the University of California at Davis is going to teach the epidemiology; the University; Purdue University is going to teach the low-acid canned food; Cornell is going to teach this; and maybe Cornell, Minnesota, and California all teach the same course, and it's a matter of being regional geography kind of thing, but they're all teaching from the same standard. In that LACF course, we have to teach these principles and this concept and this and that, and it's a standardized course around the country.

RT: How do you see that being funded? By the agency, or by other sources?

GEG: I believe it ought to come out of the federal budget, and that's a real statement in light of the deficit, that kind of thing.

JPS: The states certainly couldn't pay for it.

GEG: Well, the state -- and the states can't even travel to the, you know, the guys in Nebraska can't even go across the river to Des Moines kind of thing, let alone across the country. And that's one of the issues.

Now, the other side of this is, immediately we start thinking about training as having 40 people in a room. In today's technology, training is a Webcast, training is training on a Blackberry or on an iPod. Training is an asynchronous Web module where the guy, you know, his wife goes to bed and he says, "Well, I think I'll take some training," and he clicks on and he takes a course in food safety on ORAU. That's exactly what we're doing right now. That's exactly how ORAU works right now. A guy has an account with ORAU and, instead of watching "Saturday Night Live" at 11:30, he can take a course on food microbiology. It's just-in-time training.

The other thing that distance learning allows you is that there's two trainings that need to be done. There's one training, which is the basic knowledge and skills in the building blocks, a bar, a high-jump bar at four feet that says, "This is the minimum that everybody should be able to jump." But as soon as that man or woman jumps that bar, there's new information out, there's a new outbreak, there's a new nuance of the

regulation, or whatever, and we have to build into this the opportunity for updates, and that's, again, a place where the distance learning really gets into it.

JPS: There's some interplay here, too, between this kind of training, the occupational training, but also there's education here that you haven't talked too much about that the investigator brings into the job, whether it's at FDA or at the state level. I wonder if there are changes that you might imagine that can take place at that core educational level at universities, whether it's UC-Davis or the University of Minnesota or places like that, where they can better equip people who want to go into a career as an investigator either at FDA or with the Pennsylvania Department of Health, or what have you, that can have a role here as well.

GEG: You know, as I respond to that, I'm going to be critical of our agency.

In 1969, when I was hired by the Pennsylvania Department of Health, and then further employed by the Pennsylvania Department of Environmental Resources, those agencies valued graduate degrees, advanced degrees. Today -- and in Pennsylvania in 1969, you had to have a bachelor's degree either in biological or physical sciences. You had to have a degree. Today, what's the requirement for an investigator for FDA? Thirty hours of science -- not a degree, not a bachelor's degree, let alone benefiting, rewarding someone with a master's degree or whatever advanced degree.

In the recent hiring surge that we've had, I and others have been pitching the fact that we ought to be going to universities seeking people with advanced degrees. An example -- and we've actually done this already in a small case -- where we've gone to

North Carolina State University, and they have a marvelous pharmaceutical engineering program. That person -- and John Thorsky is the District Director in Kansas City. He went with me on some other work, and he hired a lady with an advanced degree, and he has brought that person from North Carolina State to Kansas City, and rather than starting that person as a GS-5, starting that person maybe as a GS-9 or even a GS-11, providing, because she has knowledge that, I don't know, it might take five years for us to teach some of what she walks through the door with. So there are some people in the agency right now that are seeing that 30 hours of science doesn't cut it as far as I'm concerned, and I -- if there were something that I could change today, I would change that right now.

As I look back at my college degree, for a lot of years, what did I learn in college? What I learned in college was how to think and how to make decisions and how to, basically a decision tree, to get here and say, okay, you're either going to go A or B, and if you go A, then you're either going to go X or Y. Well, that's what investigators do. I learned scientific method as a biology major in my master's program.

When I look at the new hires that we have -- and I believe that it's a function of the economic situation now -- we're hiring marvelously prepared, intelligent, brilliant young people, but some of them aren't so young. Some of them are on their second or third career step. But we're hiring veterinarians, we're actually hiring doctors, we're hiring nurses, we're hiring people with all this marvelous experience. Think about if you have a nurse who has gone through her nursing training and has been on a nursing wing and has used the medical devices. Then send that woman, send that man out to make a medical-device inspection. All at once they have a whole new world of, how is this device used, what might go wrong, or whatever, and it's an insight that's just terrific.

The other thing that I say relating to this is that, for years and years, people have said to me, an investigator is an investigator. If you can inspect foods, you can inspect devices or drugs or whatever. Yes, I buy that to a certain point. Okay? We'll teach him investigative skills.

But, again, go back to my nurse's example. She knows what that heart valve is going to do or that electronic whatever thingy is over there. She can go and make that inspection of that plant with an insight that a guy with a bachelor's degree in biology or a guy with a marine biology background -- the marine biology guy ought to be over here on the Eastern Shore inspecting the blue-crab picker; the lady with an engineering degree ought to be inspecting people with, you know, who are doing electronics or diagnostics, that kind of thing. The example I used from North Carolina State, a degree in pharmaceutical engineering . . .

TAPE 3, SIDE A

GEG: I'm talking about the individual from North Carolina State. And it's . . .

One of the other things right now in ORA, that they have these congressional mandates. The Congress has said, "We're going to give this money to FDA, but, in return, we want so many inspections of things." So the Acting ACRA is up there looking at me and says, "You can't take seven years to get these people up to speed, and you can't take five . . ." He's pushing me, rightfully so, to get these people functioning, out in the districts and functioning. One of the ways that I believe that we can make that happen is with specialization. Then, again, you get a guy with a degree from Penn State

in food technology, why aren't we saying, "Hey, you're going to be a food guy, and we're going to put you in that food track and we're going to send you to LACF school and acidified food school, or whatever these things are"?

Where I would really like to go -- and it's interesting how my world in training has changed in that some of my district directors have said, "Well, this guy has all these degrees. Why does he have to go to all those classes?" And it's a fair question. "Just give him a test." Well, making a test is not easy to assess whether he knows enough not to have to go to a certain class that we put on.

So, one of the things I just absolutely fell into, I have hired a psychometrician for my staff, a person whose understanding, whose expertise -- and the guy has a Ph.D. from Maryland over here -- on assessment and testing. He is now teaching our staff how, that we could do all these certifications, what's a test that will hold up legally, so that if somebody fails that test, "Oh, it wasn't a fair test." Now, he's teaching us how to do this legally.

One of the other things he's helping us do is with this idea to challenge out of the course kind of thing. Okay, someday we might have that. Right now we don't. But, again, the Deputy ACRA up there, he'd like to see us go into that too, accelerate into the training, which now is going to allow me to jump into something that's happened here.

In the last three years, four years, I've been fortunate enough to be involved in some processes within, initiatives within ORA where we are actually looking at ourselves, and are we prepared for the future.

We had an ACRA whose name is Maggie Glavin. Maggie Glavin declared to ORA that, with the budget things, whatever we have going here, FDA can't continue to

do all the things that everybody wants us to do, so really what we need to do is start looking and see if there's a hundred things, and if we only have so much money, which of those hundred are we not going to do. Well, we're not going to do these 25 things. We'll just go down and tell Congress. She had a transformation leadership group to start studying that. For a bunch of reasons that came up, that TLT initiative was stopped.

But the need to look at where we're going didn't go away. So, what she did was she formed a revitalization of the ORA program where in fact we looked at inspections and we looked at imports and we looked at compliance and we looked at administrative things. One of the things that we had, a staff development group. I shared the leadership of that group with Mr. Thorsky from Kansas City. We looked at the training function, how it could be better.

As part of that, it came out that maybe what we should do is take a look at how effective our training is.

And we talked about a hire-to-retain white paper, and we have a hire-to-retain white paper that talked about, in general terms, how we should change hiring, recruiting, training, just in general terms, and I would suggest that you folks get a copy of it. If you call Bobbie Giganti over on my staff and you tell her that you want a copy of the hire-to-retain white paper. It would give you some fine insight as to where we might go in the future, everything to retention, how do we keep people around, that kind of thing.

(See Attachment A).

Okay, so we have hire-to-retain, and then we have this process of a consultant who came in, went out in the field, came to headquarters, and actually looked at how good and effective is our training program. He gave a series of recommendations. We

presented these to our Regional Directors, to the ACRA. There's like 32 or 39 recommendations.

What he found is absolutely significant to me. If I could boil it down to two very succinct things, the one thing he talked about was the significance of first-line supervisory training, and I think I talked earlier about what I thought a disaster, was those self-directed work teams. Well, I think this is actually relating back where, when you talk to our first-line supervisors and our people in the field, where we do an abysmal job of training and preparing people to be supervisors, and there's a clash, there's a conflict. I believe that a first-line supervisor's most important job is to develop his or her staff so that they can do the real work that they have to do. When you ask our first-line supervisors what their job is, he comes out and says, "We have to get those numbers for those congressional mandates," and they see that as two different answers. I see that they're the same answer. If you're going to have to do a hundred inspections, the only way you can a hundred inspections is to take the staff that you have. If you have three journeymen, get them inspecting. You have three brand-new ones, get them up to speed so you have six people trying to get the hundred done as opposed to the three. The one aspect or one recommendation that the consultant had was to improve first-line supervisory training.

The second thing is significant, and it relates to our division and to the name of our division, the Division of Human Resource Development. It is not the Division of Training. For 17 years, we've had a Division of Human Resource Development, and I criticize myself, as the Division Director, for that time period, being too focused on training and not recognizing the significance of *development*. Over the years, I tried to

get in the development business, but people in the field just said, I remember a District Director saying, “Hey, I run such-and-such a district. I’ll decide if that guy is trained. I don’t need you to come into my district and tell me.”

What the District Director was describing was I am in the training business and I put courses on, new-hire courses, device courses, blood courses, food courses. That’s only half of human resource development, training. The other half is, after you train, the question is, then, can that person take what they learned and then apply it in the workplace, and that’s the development part of it. The consultant has basically said, “You guys do a really good job of training. What you don’t do a very good job at is development.” I relate this to, some people say, “Oh, in the old days, we used to sit around and tell people to read manuals,” or whatever. Real training occurred when there was an expert out there, and the new investigator would have to go out with that expert and follow them around for, literally, a year or two, and then tell them the nuances of how to make a good inspection. What was happening there was, was development, and they were really good at development.

As we lost all these experienced people in retirement and we became so focused on getting numbers, well, you didn’t have the time for development. We thought we were making these people prepared to do their jobs. Really what we did, we gave them the training, but no one was there and then connect this with the supervisor who wasn’t, who didn’t see quality necessarily as the most important thing, but getting the inspections done. I believe that there’s a misfire or a disconnect right now, that in fact we have to have a better system that says, after they’re trained, are they getting the right assignments, are they getting mentored, are they being sent out with experienced people

to get this is how it really is done, or, you know, when you learn such-and-such in this class, what that means during a drug inspection is this or that.

What we're doing right now in the Division is building a development initiative where we've actually built, we're in the process, we just selected a Branch Director, we've selected staff. I've hired a young lady who used to be the human resource development person for the Montgomery County Schools. She now works for me. She understands how to build individual development plans (IDP). We've required individual development plans for the district people, that every person in ORA has to have an IDP done. What that means is, these are the courses that you have to take in order to be successful, but also, this is the kind of work, this is the kind of OJT (on-the-job training). Once you put that all together, hopefully, then you will be prepared to do that work.

Then I even connect it even further. Well, after you've taken the courses and after you've had those experiences, why don't you just take the assessment related to certification and we'll certify you in drugs and devices. So it all now comes together.

So my criticism is, based on what the consultant opened my eyes to, is, we're pretty good at training. What we need to do is get the districts and the first-line supervisors and the DIBs to understand the value, the importance that they see their role of being developers of their staff. DHRD in Rockville, can only do part of it. That does not mean that our division doesn't have a responsibility. I believe that we have to build the framework in order for those people to go through their details and their OJTs, that kind of thing. But who actually does it are the people in the field.

JPS: Anything else?

GEG: Do you have other questions, Mr. Tucker?

RT: I think you've covered it rather well, Gary.

Let's see. In the course of things, was the unit, or you as the director, recognized by any awards? Did that come along?

GEG: I personally have been recognized. Probably the biggest award I had was the Harvey W. Wiley award from AFDO, and they were very kind to me to recognize the importance of training. AFDO believes in training, and they saw what I was trying to do over the years, so I believe that's probably the most significant award that I've received.

RT: What year did you receive the Wiley Award, Gary?

GEG: I don't recall, probably in 2002. It was in Portland, Oregon. That's what I remember.

JPS: This is the highest award that AFDO confers, by the way.

RT: Well, I guess one further question might be, obviously, you had support from higher-level management through your FDA career. Have there been any Commissioners or any directors of units who have been especially helpful, or on the contrary, maybe unhelpful?

GEG: Here's how I'm going to respond to that, and this is a good trigger to acknowledge something.

When I first got here, when I came from Cincinnati and moved the state training branch, there used to be a surplus furniture store someplace in this building. I remember going once a week to see if anybody brought in navy grey desks and that kind of thing. When we worked in the Parklawn Building, having nice facilities was not the thing. Right after we were made a division, probably '92, '93, we were running out of space in Parklawn. So, one of the units that the folks in ORA senior leadership felt could be independent and not have to be in the building was ours, so they moved us out to Crabbs Branch Way. This is the first time where the training unit actually had their facilities. When I talked about the state training branch and the education and training unit, one group would be at the end of a hallway and the other group would . . . So we were never together. So we never got that chance to be together. But when they moved us to Crabbs Branch, we were all in one facility, and that helped solidify one unit of training, so that was significant.

Then -- and you're looking for a name -- I would say every ACRA, from Ron Chesemore on, I'd give Ron Chesemore the credit, seeing the importance of having one training unit and melding it together. I give Mr. Chesemore a lot of credit for that.

There were others -- I already mentioned Maggie Glavin. Maggie was terrific in the fact that she saw division of FDA facility, ORA, needing to change, and she saw training as part of that change, so that was good.

But the guy who helped us and who made sure that we actually have a training facility was Dennis Baker, and Dennis Baker was a colleague of mine. I met Dennis Baker a long time ago at an AFTO meeting, and I was still in Pennsylvania, so this was in the early '80s, and he still worked for the Texas Department of Health. We probably ran into each other at the bar. We went outside the next day and went for a walk, and we realized how close what went on in Pennsylvania was close to Texas. Eventually, I got a chance to come to the FDA, and eventually Dennis Baker ended up being an ACRA.

It was Dennis who knew what I did, what we were trying to do with the Training Branch, and who found the initiative to form or to make sure that the building at 11919 Rockville Pike, ORAU, exists, and today, that's where DHRD, ORAU is located. I believe the credit for that should go to Dennis Baker. He said, "We need a training academy," so in that facility today, we have three floors, and it's growing today. They're moving over there today, moving into more spaces.

We have four marvelous training rooms, state-of-the-art. I have people coming in from industry, I have people coming from other agencies who said, "Wow, this is really good." Thank goodness, in the wisdom of the agency, as we move over to the facilities at White Oak, there is nothing like that at White Oak. I have said to my bosses - - Jim Strachan is my boss now -- and I said, "Please help me keep the training facility here," and at this point it looks like DHRD is not going to have to move to White Oak, and we will be able to continue to use those facilities.

That was a long answer to say, who are the supporters. Dennis Baker. John Taylor was a marvelous ACRA. He was just a delightful man, and his background was an attorney, he's an attorney, and he knows the importance of training and getting out to

the field and developing people, and he was always very, very supportive.

RT: You're talking about John . . .

GEG: The young John.

RT: Thanks. His father, John Taylor, Sr., was an earlier ACRA.

GEG: But John Sr., I didn't have that contact. That was early in my career, when I was a state training branch guy. He was always supportive of us, too.

It's also interesting that, when you start talking to these leaders -- and I had this opportunity to get some notes from these folks as I'm getting ready to retire, and the comment, they're almost making, saying they're sorry for some things that happened to me and my career, because the comment was, "We always kept on barking at you to do more training, more training. We hired more people, hired more people. Then the next thing was out of their mouth, 'We're cutting your budget, we're cutting your budget, we're cutting your budget.'"

Somebody very recently gave me a little note of thanks and appreciation for my career and said, "That wasn't fair." Well, I never, I just never thought of it. I talked about how you do what you do, and we had people to train, and we trained as many people as you could, then that's what we did.

RT: I guess one point we haven't covered is that the current CRADA has a time limit. Is it five years?

GEG: It's been expanded. We just signed that, and we extended that, and I think it's for another four or five years. But that CRADA was pretty limited at the beginning, and EduNeering, the company, you know, they were being careful and so were we, but the courses were only going to be available to FDA and state and local people. Well, I've run into things where we were doing joint training or joint initiatives, and could we give it to the people from CDC, and could we give it to the people at USDA, and I kept on saying, could we expand it, could we expand it.

I haven't talked about this yet, and there's this chance for me to say, when I first came here in 1985, all I worried about was training people in this country, and I believed that was the case. We were pretty much a domestic agency. But now, with the Internet and everything, we're a global organization. So now we have offices in China and we have offices in India, and we have colleagues -- there's a guy named Michael Krazchuk, who's in the office in Beijing, and he's over there working with the Chinese officials. He's been on some of my course cadres and teaching our classes. He writes me a note from China and says, "Oh, we have to talk." Well, what he wants, and all at once, not only are we a national of training FDAers, but we're training state people. There are people that want our work unit to train the world.

What we have, those CRADA courses that we're talking about, we got some money in one of these congressional mandate divvies out of the budget where in fact

we're translating these courses into five different languages. But, when you translate things, it's not only just the language, but you have to start worrying about the culture. If you show a certain refrigerator that's in Pennsylvania, they might not use that kind of refrigerator in China, so you might have to change the pictures you pick. So, slowly, and here we are talking about the future. I believe that our organization is going to have to recognize that just training people from New York and Wisconsin is not enough, because if . . . and here we are, we're trying to talk about accepting products from all these other worlds, what standards do they meet, maybe what we have to do is set a training standard, a certification standard, and tell the Chinese and the folks from India, okay, this is the standard, and then maybe we go internationally and audit them.

The other thing is this idea of a third party audit, where we, as an agency, can't inspect but could we certify in some manner Joe's inspection firm that could inspect shrimp plants in Thailand, and we actually have some people being involved in that a kind of thing. Because my staff has this experience in auditing, all at once folks are calling us and saying, "Hey, can you let me have so-and-so on your staff for a while because we want to build an audit for these third-party inspections?" and that's something we're nibbling around.

JPS: So at this point, we don't have any MOUs or anything with authorities representing the food and drug directorates in India and China, but that could be down the line.

GEG: Oh sure, absolutely. As we are more international and we have these

international offices, you know, I laugh, and I say it with a big smile on my face: mother, apple pie, and training. I mean, what's not to like about training? I mean, you show up, if you show up as a trainer and you do a good job, you walk out of town with a white hat. I mean, everybody loves training. And that's one of the things I liked about being a trainer. I've been a regulator, I've been an enforcer in my career. I don't like it, because when I used to make inspections, I used to have a boss who used to get on my case, and he says, "It's not your job to go into that restaurant that I was inspecting and tell them how good a job they're doing." He used to tell me it was my job to tell them how bad they were doing. But my educational background and my personality type is such, I wanted to go in and, "Wow, this place is a lot cleaner since . . ." and I wanted to go and nurture the guy.

I believe that, here we are talking about regulatory training. At one time, our agency spent time on industry training. I have this mental look at a bell curve, and I believe that maybe 5, 10 percent of the industry is out of compliance all the time; 5 or 10 percent in compliance all the time; and then the rest of the curve, the big chunk of the curve, is in compliance and out of compliance off and on. I think we treat everybody like they're out of compliance. Why don't we let the good guys be good guys? Why don't we take a hammer or 2x4 and go after the guys that are out of compliance because we know they're out of compliance. We'll inspect them and enforce, file cases against them, whatever. That big group of people, why don't we help them be in compliance? Why don't we teach them how to? Because I believe the industry, I don't believe the industry is bad or bad people or whatever. I believe they want to be in compliance, build,

develop, construct, and manufacture good products. So, as an educator and as I go about things, even as we do with the industry, I think we could do more with education.

JPS: That sounds like a good place to leave it, I think.

RT: That certainly would be a further progression of the agency thinking. In my view, a marked change.

We appreciate very much your participating in the oral history program, and we'll make sure that we have a draft transcript for you to review before final copy is made.

GEG: I want to say that I'm honored to think that the History Office thinks that training is important. That's pretty cool. I actually think that that's quite a, yes, that's pretty good. Thank you very much.

JPS: Our pleasure.

END OF INTERVIEW