

History
of the
U.S. Food and Drug Administration

Interviewee: Cynthia C. Leggett

Interviewer: Robert A. Tucker
Ronald Ottes

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Place: Rockville, MD

Interview with Cynthia Leggett

December 22, 2003

TAPE 1, SIDE A

This is another in the series of taped interviews for the FDA Oral History Program. Today, December 22, 2003, we are interviewing Cynthia C. Leggett, Senior Public Affairs Specialist in the Office of Regulatory Affairs. The interview is taking place in the Parklawn Building in Rockville, Maryland. Interviewers are Robert Tucker and Ronald Totes.

RT: Cynthia, we usually like to begin the interview with a brief overview of your personal information, where you were born, educated, and any significant career experience you may have had prior to joining the Food and Drug Administration.

CL: Well, let's see. I was born in Jersey City, New Jersey, the daughter of a former WAVE and a marine who had met during World War II at Bethesda Naval Hospital after he was injured on Iwo Jima. She was his occupational therapist. He was from Augusta, Georgia, and that's where we moved and where I grew up.

I attended Augusta College, which is now Augusta State

University, and graduated in 1969 with a degree in sociology and psychology, and really prepared for nothing.

I had married young and had a child, and the marriage dissolved not long after my son was born, so I found myself having to get a job. I was able to get a job teaching in the state of Georgia at a time when the state had been ordered to desegregate, where they moved white teachers into black schools and black teachers into white schools, and that's what they called desegregation. Needless to say, lots of teachers resigned, so they were desperate for the likes of me, and I was desperate for a job.

I taught for a couple of years, and then moved to Florida, to Tallahassee, where my mother was on the faculty at Florida State University. I thought I was going to pursue teaching, but discovered I couldn't teach down there without further education.

So I was taking courses, had a child, a single parent, but I was able to get a job with the Florida Department of Agriculture and Consumer Services (FDACS), and that really was the launch of what became a career. That group, the Bureau of Food Grades and Standards, was in transition. They had moved from a good-old-boy system where who you knew was the job that you got, to a system where they were hiring and bringing in bosses and staff who actually were degreed and were experts in the fields of microbiology, entomology,

veterinary medicine and food inspection. I was hired by George Rose, the first DVM from outside the state of Florida. He had been brought on to improve their food inspection system. And, of course, I was the first college graduate they'd ever had in the office.

RT: What year was that?

CL: It was 1971. I was hired as a clerk typist, and that's literally what I did. I was filling out little forms by hand -- this is before computers -- on how many eggs were candled, how many pounds of ground beef were weighed, how many fat tests were run that these inspectors had done for the State of Florida. Florida had about 150 inspectors, which by FDA standards is a flush deal. I began to offer suggestions for streamlining and improving. I always did have a big mouth, and I discovered it in Florida. So I began to move up in the organization as positions came open.

And I ended up being secretary to George Rose and to his deputy, Jimmy Fortner. Pretty soon I began to put together seminars for the legislature on how we did our jobs, food inspection, how the equipment worked, how to do candling, what we were looking for, and that sort of thing. These were seminars for the legislature in order to justify our budget request.

Soon I found myself acting for both George and Jimmy when they were not in the office and telling the inspectors what to do, talking to them every day, giving instructions and training and that sort of thing, and I thought, you know, there's something wrong with this picture. I've never been on an inspection. How can I be telling these guys what to do and how to do it, and how can I instruct them if I have never actually been on an inspection? So we decided that I should go out and learn inspection work, and I became their first female retail food inspector.

And, of course, I realize now, it was a very EEO thing they did. They made way for this female.

They carved out a territory for me in and around Tallahassee so I didn't have to travel overnight, because I did have a child at home. And I began to do all kinds of inspections. I learned to work fires and floods, and a lot of the places I inspected were little tiny fish camps with six tins of Vienna sausages and five bags of weevily flour and that kind of thing. A lot of places were grocery stores on one side and restaurants on the other, and the restaurants were where they used the spoiled meats in beef stew and then served it to their neighbors and family for lunch and for dinner. It was an interesting experience, and it made me realize that I never wanted to do inspections for the rest of my life.

And then . . .

RT: If you found a place that was really bad, could you close them down, or did you just issue a violation notice?

CL: Well, the State of Florida had powers that, of course, FDA didn't have. We had stop-sale and stop-use that we could use, and I did do that.

I remember one store that was a grocery on one side and a restaurant on the other. The meat was green in the meat counter, and they were in the process of transferring it from the store to the kitchen of the restaurant for that day's food, the special of the day. I happened to waltz in in my white coat and hard hat, and I made them take the meat outside and pour Clorox over it. Then I put a stop-use on the meat freezer, the refrigerator, as well as the cutting equipment and some other things, and I pretty much closed them down. They were fit to be tied. They called Jimmy Fortner and raised holy hell with him about who was this woman coming in here, who did she think she was? And, of course, he got a big kick out of the whole thing and supported me completely. But I didn't give him that kind of trouble a lot, just generally I took care of the situation and I'd try to explain it and explain why this is a problem, and would you want to eat this, you know, da-da da-da da-da

kind of stuff.

Anyway. We had powers that FDA really didn't have, and I think it was sort of a different world, too. We didn't have computers -- it was all one-on-one. These were little places. I guess I was lucky. They had a little more respect for authority than perhaps we see today. I did have a badge, I did have a white coat, I had all the trappings, and it was just the fact that I was female that was so different.

Anyway, George Rose sent me one day to listen to a presentation on a new labeling law that was going into effect called, as we referred to it in those days, "nutritional" labeling. Little did I know that this was going to change my life. I went, and there were two Consumer Affairs Officers (CAOs) from FDA.

Now, I had worked with FDA a lot. I knew Maurice Kinslow and Dick Dawson and Les Pounds and all the other people who had been with FDA out of the Atlanta office. But I didn't really know FDA as an agency, didn't understand how it functioned, and I didn't know about all the other products that it regulated. My knowledge was minimal about the agency. I just knew people more than anything else.

And I knew that we had contracts with them. The contracts started about that time, and I remember they were a mixed blessing as far as the State of Florida was

concerned. Florida liked getting the money to do the inspections. They didn't like FDA telling them what and how to do it. That's not rocket science.

We were also required by those contracts to begin the process of going on computer. I was made the liaison between the office staff and the computer people.

So I was doing inspections, I was working with the early computer folks, I was doing training of new investigators and new inspectors, putting together seminars and doing training of the legislature. I had hodgepodge of duties, with my finger in almost all the pies at that point.

I was tempted to learn about this nutrition labeling law, so I went, and there were two Consumer Affairs Officers there, Carol Young, who was located in the Tampa office, and a new person they had just hired, Ana Rivera. Carol was transitioning from FDA over to the Consumer Products Safety Commission (CPSC), which had just been created, and she was about to move to the Atlanta office. She was training Ana on things FDA. Ana had come to work from the VA. She was a dietician.

They did their presentation on nutrition labeling, and the light went on. For the first time in my life, I could see what I wanted to do when I grew up. I could see that I could do this job. This was everything I'd ever done. It was teaching, it was regulatory, it was explaining law, it

was everything.

I had been complaining about the fact that I was essentially number three in the office, but because I was female, I received less money than the new, fresh, uneducated, untrained male inspectors that we were hiring. They were men, they got more money, and George and Jimmy had done everything they could for me. The policy in Florida, though, was women just didn't make the same salary as men, even for the same work. I thought, this is what Joan Baez and all those other folks are talking about when they sing those songs. There's something wrong with this picture. Maurice and Dick had told me that at FDA, men and women got paid the same for the same job. I thought that was the most earthshaking thing I had ever heard of. I could not imagine, and I thought, this is where I want to go, and I want to be a CAO (Consumer Affairs Officer).

So I wrote to Ana and to Carol and asked them about their jobs and what did I have to do to apply for this kind of a job. Of course, I got back very stiff, formal, bureaucratic responses that were only somewhat helpful. I don't even remember what time of year that was, but I guess I must have talked to Maurice Kinslow about a position. He said, "Well, you know, I hear they're hiring in Houston. They're looking for a CAO in Houston. That's another district, but you might -- Tony Whitehead is the DD

(District Director) you might want to see about writing and applying there."

And so I got a copy of a SF-171, and of course, as I said, no computers, no self-correcting typewriters, nothing like that. I went to see my family for Christmas, and spent the entire two weeks I was there struggling with a portable Olivetti typewriter, trying to fill out the SF-171. That SF-171 still exists in my personnel file. It's the sloppiest, messiest-looking piece of work you ever saw. But I guess there were lots of them at that time.

Also, I showed up at the FDA office in Atlanta the day after Christmas. I didn't call ahead; it didn't occur to me that people might not be there. I just showed up, and from the regional office downstairs I was taken upstairs to the district office and introduced to Wilhelmenia Lombardi, who was the Regional Consumer Affairs Officer for the Southeast Region, or for Region 4, I guess it was in those days. She was wonderful.

We must have talked for a couple of hours. She took me all over the office and she said, "And if you're hired, this will be your office," da-da da-da da-da.

Now, I was applying for Houston. I didn't hear anything, didn't hear anything, didn't hear anything. And then I heard that the Houston position was out, so I should file for Orlando. There was going to be a position filled

in Orlando. So I applied for that. I never heard anything, never heard anything. And then I heard through the grapevine that they had hired someone in Orlando. I was really angry that they hadn't had the decency to respond to me and to let me know. So I wrote this rather nasty letter, very uptight, angry letter that I was disappointed in their "customer service," (today's words). I got a nice note back from Willa saying that she understood my pique, and that these things take time, and that there would be other positions opening up.

Along about April of that year, 1974, I got a call from Dick Dawson saying, "I'm calling to offer you a job," and I said, "Doing what?" He said, "What do you think?" I said, "I don't want to do food inspection. I hate it. I can't stand it. It's a filthy job." He said, "No. I'm calling to offer you a job as a Consumer Affairs Officer," and I said, "Well, I'll take it. When?"

They told me they could bring me on as a GS-9, which, oh my gosh, when I looked at the salary for that, I was just blown away. Well, then, of course, it turned out they couldn't bring me on as a GS-9; they had to bring me on as a GS-7. But even that was pretty good. It was half again what I was making for the State of Florida, and at that time a GS-7 made \$9,200 a year. I thought it was the most money anybody could possibly make. It was just incredible to me.

But they also told me I'd have to go and take the FSEE (Federal Service Entrance Exam) exam and that I could go to the Post Office on any Saturday and take it. Now, to take a federal exam, I think you have to make an appointment years in advance; you have to get the blessing of the Pope. It's just a very difficult process, if they even require it now. But in those days, you just walked into the post office conference room, with a roomful of people, they handed you an exam and you took it. It was the most ridiculous exam, and the fact that I passed it is pretty much a miracle because it was totally clerical: what's an in-box, what's an out-box, basic addition and subtraction.

My problem was that I'd been fooling everybody that I was actually a secretary or a clerical type and that I knew what I was doing. They put up with me. I had to learn to type in order to do the job for the State of Florida. I didn't know what an in-box was and an out-box. We didn't call them that. So I didn't know a lot of the clerical stuff.

I made, I think, an 87 or a 90 on the exam. Maurice Kinslow was thrilled. He said, "I've never had anybody do that well on that exam," and I said, "You're joking." I said, "It was a ridiculous exam, easy questions, and then things that don't matter to anybody." And he said, "Well, I know, but it's a process."

Anyway, so Dick called, and I packed up my son and my household furniture and I moved into my parents' basement in Atlanta. Being a CAO was a traveling job, and so my folks were able to take care of Timm when I had to go out of town.

And that's how it all got started.

And, of course, then I married, met and married an investigator, and . . .

RT: Moved out of the basement.

CL: Moved out of the basement and into Don Leggett's house.

RO: Did you have any formal training in the consumer affairs program, or was it mostly on the job?

CL: Yes. In fact, I was very fortunate. I and two other new Region 4 PAS's (Public Affairs Specialists) or CAOs were hired, Barbara Banks in Nashville and Kathy Jones in Orlando. Maurice was really very far-thinking in many things that he did, and he already had three consumer affairs officers in the Atlanta office. He had Willa Lombardi as the regional CAO for Region 4; he had Minnie Lablang Golden; and Millie Coleman. They had already been on board the last year or two, so they were experienced, and they all worked together in putting together a three-month

formal training program that the new three underwent. There was classroom training; there was OJT (on-the-job training); they did actual filming of us doing interviews and actual radio interviews; and then did critiques. We had to do presentations to the inspectional staff. This was a training program that no other Consumer Affairs Officer had ever, ever, ever had, and it was special. Frankly, I think it put us way over the top as far as knowledge and understanding of the agency.

Now, I still got DESI (Drug Efficacy Study Implementation) and the OTC (Over The Counter) review all mixed up. I still had a hard time telling the difference between a prescription drug and an OTC product, and I didn't understand why one was one and one was the other. I had a hard time understanding how vaccines were reviewed and cleared as opposed to drugs, that these were such totally different processes. And I didn't understand how and why a *Federal Register* announcement could just languish for years and years and years and years, some kind of a proposal or a notice or a regulation. It all seemed so cut-and-dried. Let's just finalize the sucker and get this show on the road. It didn't happen like that. But I did have a good understanding of the law and what it said, and, of course, we had experienced public affairs specialists to work with, too, and a lot of people did not have that luxury.

We also had the world's best secretary, who could have done our job any day, Merrie Milner. She was as knowledgeable and as capable as any Consumer Affairs Officer.

RO: Did you get any exposure to the program at headquarters, or was it all regional training?

CL: Yes. CAOs had an annual training conference always held in this HQ area, so we always got to see and to meet headquarters people. My first conference, Maurice arranged for the three new ones, Barb and Kathy and me, to spend three extra days visiting all of the different centers up here in headquarters. We stayed over and went down to CFSAN (Center for Food Safety and Nutrition) and we got to meet people down there, and they explained to us what it was all about. We went to the Bureau of Biologics, then to Drugs, and to the new CDRH (Center for Devices and Radiological Health).

I remember, in CBER (Center for Biologic Evaluation and Research), meeting Russ Abbott. He talked to us about how they used horseshoe crabs to do certain kinds of analysis or to gather something that was of use with humans. I remember seeing the tanks of horseshoe crabs. Then later, he gave us each a set of photographs, which I still have, taken with

the electron microscope -- this was new technology in those days -- of ragweed pollen and *staphylococci* -- just very interesting.

We went down to CFSAN and participated in a tasting panel on some new products that were under FDA label review. They were meat imitators made from soy -- Morningstar Breakfast Farms, sausage and bacon, products that have become a way of life for us now, but new technology at the time.

I remember this was the first thing we did that morning. We were young and had probably stayed up half the night carousing, and hadn't eaten breakfast. So by the time we got down to the Bureau of Foods and had this taste panel, we could have eaten sawdust and it would have been wonderful. Of course, we gave rave reviews to this stuff.

When I got home, I said to my husband, "I've just found the most wonderful imitation bacon and sausage." I went out and bought it and brought it home, and we ate it. And we looked at each other and said, "Oh, my gosh, this is the worst!"

Anyway, Maurice and George White, my District Directors, were wonderful about training opportunities and exposure to headquarters.

RO: As a public affairs officer, you worked with

counterparts in state governments.

CL: Yes. We had four states in our district. We had North and South Carolina, Georgia, and Alabama. And I eventually ended up being assigned to the state of Alabama, so I got to know -- in fact, George Wallace was governor at the time -- I got to know Mr. Wallace and I got to know Annie Laurie Gunther, who was his commissioner of consumer affairs. Her position was unusual among the states. He also was rather far-thinking in many ways. Annie Laurie Gunther. She was an institution, a political woman, knowledgeable about the systems, and had lived in Alabama her whole life. She was a real political animal.

TAPE 1, SIDE B

It was unusual for a state to have a consumer affairs office, and I think Alabama was probably ahead of its time.

And so I did a lot of work with her, and, of course, with other state and county government people, nutrition and WIC programs.

RO: Did you like that job?

CL: I loved it. It was the best job in all of FDA. It's a job that carries its own warm fuzzies with it. You may not get them from your co-workers within the agency, but you

sure do get them from the outside world.

It's also one of the most creative in those days, especially. It's creative today for another reason.

In those days, we had one major outreach campaign that came from headquarters every year. We spent a good deal of our time implementing that campaign, and at the time, it was the nutrition labeling campaign. So we had wonderful tools that headquarters provided us, videos, a film with Dick Van Dyke, "Read the label, set a better table," as well as all kinds of accompanying things, brochures and public service announcements and all kinds of things to use with the media. That was our big campaign.

In addition, we did our own thing on the drug review process aimed at medical professionals, health care people, and explaining to the public how to be responsible consumers, how to participate in their own health care, how to be responsible patients, and that kind of thing. Plus we did a host of other programs. Many times, we had to create our own materials for our local campaigns. The Headquarters was just not quite in the business of producing materials as it is now.

RO: Who was the headquarters liaison at that time?

CL: Well, you'll like this.

For a long time, I thought the man who was in charge of all of us was named Ed Rowe, and they were always talking about Ed Rowe this and Ed Rowe that, and I thought it was Ed, E-d R-o-w-e, Ed Rowe. And, of course, EDRO (Executive Director of Regional Operations) was Paul Hile, and then Don Healton. But for a long time, I thought the name of this person was Ed Rowe.

There would be changes in organizational names, and I didn't understand that. I remember when we went from ACC, Associate Commissioner for Compliance, to EDRO. Was that it? Was that the sequence? He was called the ACC, Associate Commissioner for Compliance, and then became the EDRO, Executive Director for Regional Operations.

I remember when this change was announced to all of us, and my eyes got this big, and I went to our chief of compliance, who was Charlie Blough, B-l-o-u-g-h, and I said, "Charlie, wow. What does this mean? What difference is this going to make in our lives?" He reared back in his seat, "Oh, Cynthia. Well, let me tell you how it's going to change. You know, names change, people change, but the work, it never changes." And I remember thinking, "Oh, he's such a depressed character. Cynical about all of this." And, of course, I found myself saying that to a lot of people. "Don't take it personally. Things will still be the same tomorrow."

RO: Was Alexander Grant in the Consumer Program then?

CL: You know, Alex was just beginning to come into his own at the time. I came up to headquarters in 1978, and Alex was just beginning to be something more than one of the workers in the Office of the Associate Commissioner for Consumer and Professional Programs assigned to the consumer area. Bill Whitehorn was in charge of professional programs. I can't remember the name of the person who was above the two of them. Alex was not really a high-up muckety-muck, just somebody who showed up periodically from headquarters and wanted to be escorted around. And it wasn't until after I came to headquarters that he was in his position.

RO: When did you come into headquarters?

CL: 1978.

RT: So for about four years, you were out beating the bush.

CL: Yes.

RO: And presumably you received an advance in grade when

you joined headquarters?

CL: Eventually. I had been hired as a GS-7. I think I had already gotten my 11 out in the field, and I came to headquarters as an 11. The only job that I could find was working for what was then the Office of Consumer Inquiries, which eventually ended up under Alex, but at the time that I was there, it was part of the Commissioner's Office and independent, and it was run by Ruth Beeler White. She was the director. Frankly -- I have to be quite honest, that was just to get me in the door up here. It was not the kind of job that I wanted to do.

RT: Why did you leave the field?

CL: The reason I left the field was because of my husband. He wanted to come to headquarters. He was considered the black sheep down there amongst all those people, and he had found it difficult to get the kinds of dishy assignments that he'd always received. He'd do an inspection. He would establish the basis for a case by identifying all the violations and collecting the samples and all that kind of stuff, and then they would take the case away from him and give it to somebody with less experience. And he found himself doing mundane kinds of work. So he wanted to leave

Atlanta, and as my mother said to me, "When you married him, you made a commitment, and it's for better or for worse," although I hated leaving Atlanta.

So we came to headquarters, and I've always said he dragged me kicking and screaming up here.

RO: Where did he go in headquarters?

CL: He came into CDER (Center for Drug Evaluation and Research), in Compliance, and he worked for Al Lavender and Rudy Apodoca. And, you know, I'm sorry, I can't think of the name of that group. It changed names several times, drug labeling compliance or something. And he was a health fraud expert in the days when we were doing something about health fraud. He became an expert on steroids and the use of steroids by the muscle industry, gyms and that sort of thing, counterfeit drugs, early counterfeit drugs.

RO: With Consumer Inquiries, then, you were the ones that fielded the inquiries that came in from the public?

CL: We answered all those letters that came in from the public, and that's one office that has pretty much disappeared. It's a sad thing because we really need a group to do that kind of thing, both Internet and written as

well as telephone inquiries.

RT: Those inquiries now are directed to people in the field rather than headquarters.

CL: Well, a lot of them go to the people in the field, but the ones that come to headquarters, I do not know what happens to them. I know the system that I had established with the public affairs liaison. That's a group that you probably need to look at, too. They are the headquarters representatives in each of the Centers and Offices who support public affairs specialists in the field. They're the technical experts that we deal with, and that's a group that I created when I came up here, because although PAS's had contacts within the centers, they were not a formalized group, and they needed to be pulled in. So one of the early things that I did in this job was to bring them together for facilitated meetings so we could talk about our similarities, our differences, and how we could, as a group, do a better job of providing information to the field offices.

RT: When did the CAO job or consumer affairs job change to the public affairs specialist?

CL: You know, I don't know. It was sometime when I was downtown working for CFSAN, and the person who could tell you that is Ada Nelson.

RT: Where is Ada now?

CL: Well, Ada is about to retire, and she's someone you ought to talk to because she really does have the history on the PAS's.

RT: Is she in Headquarters?

CL: In fact, she's in today. I don't know that she has the time to meet with you, but I certainly could talk to her. In fact, do you want to call her? We could call her.

Anyway, I could ask her to stop in and see you today if you're interested, maybe not to do an interview, but maybe to schedule something, because she could do it by telephone.

RO: Well, you know, we resisted changing the name to Public Affairs Specialist in the '80s.

CL: Oh, really?

RO: Because we were afraid if you changed it to the Public

Affairs, the department would want to take the public affairs specialists in the Regional HHS offices.

CL: And that's exactly what's happening, and now they're talking about changing them back to CAO.

Well, and public affairs specialists, the PAS's, CAOs, whatever you want to call them, felt that having the PAS title broadened their scope, that being called a consumer affairs officer limited them to consumers, and many of them were not dealing just with consumers. They were dealing with industry, they were dealing with state and local officials, they were dealing with medical schools and high-level stuff, not just answering consumer questions. But that was the case before anyway.

RO: That CAO job title was unique to the FDA.

CL: CAO, yes.

Anyway, we came to headquarters. I worked for Consumer Inquiries, and then that group was moved under Ellen Williams, who was the Associate Commissioner for Policy Coordination. She was the one female on Don Kennedy's staff, and she offered me a position as a policy analyst and wanted to move me out of Consumer Inquiries and give me a promotion. I went as a GS-12 to the Policy Coordination

Staff, assigned to the Bureau of Foods downtown, dealing with food issues. Sandy Miller was the Center Director. I guess Dick Ronk was his deputy at the time.

That was the worst experience of my life. It was two years of hell. I was in over my head. I didn't understand what was going on. I managed to offend everybody, Tony Celeste, everybody who came along, crossed my path or whose path I crossed. I was one stupid person. And it was not intentional on my part. I didn't know what I was doing. I didn't understand strategy documents. Poor Paul Hile got so frustrated with me, it's a wonder he can even speak to me today. And we'd go to meetings, and Janet Showalter was the person, from Exec Sec, who was assigned to me, and she was the executive assistant taking notes at meetings and keeping up with all the documents that had to appear, miraculously, at every meeting. But we just had the worst system.

Don Kennedy was absolutely impossible when it came to clerical stuff. He had started various programs. One was called Operation Shakespeare, and we had someone on our staff, Larry Bachorik, who was in charge of that. It was intended to make people write better. It got to the point where any piece of correspondence that had Don Kennedy's name on it went through so many channels and so many reviews and so many rewrites that sometimes there would be two pages of those little one-liner things that told you who did what,

rough draft, review, clear, da-da da-da, initials, da-da da-da, two pages of this for a letter that was this long. It was tedious; it was stupid. I didn't understand the politics. It was just a horrendous, horrendous time. I was useless most of the time. In fact, I was functioning on probably two or three hours of sleep each week, I just worried so about everything. It was ghastly. I didn't know where to go, and Ellen would say inane things like, "Well, you're the policy analyst for food. Throw your weight around. You tell them what to do."

RT: Let me ask you this. Did each one of the bureaus or centers have a policy analyst?

CL: Yes. Sarah Butler was the policy analyst for drugs, Rick somebody or other was for CDRH, I was for food. Who else did we have? CVM? Probably Dan Brand was CVM, but he was really our boss. CVM was kind of a minor center. Does that take care of them? CBER? Maybe Sarah was doing CBER and drugs at the same time. There was a policy analyst for each center.

And supposedly, we knew everything that was going on within the centers, we helped them put together strategy documents, we pushed them. They had their weekly meeting with Don Kennedy. He insisted on a one-hour meeting every

week with each center director, "one-on-one" -- but not one-on-one. Usually, it was a cast of thousands. And it didn't matter whether they had anything to talk about. He insisted.

I remember having to go down to see Sandy Miller and say to him, "I'm sorry. It's too bad that you don't have anything further to report on these issues from last week, but you'll have to still meet with Dr. Kennedy." And quote, "Goddamn it, Cynthia," da-da da-da da-da, and went on and on and on. I was in tears; I was in tears all that time. It was a mess; it was horrible.

And then . . .

RT: Ellen Williams didn't stay very long.

CL: Oh, no, and she was a total embarrassment. She set women back in FDA 100 years. The day she showed up late, pregnant and waddled across the stage at the FDLI meeting, I thought I would die. I was so embarrassed for her and for the agency. She was a travesty. And I just remember, after Don Kennedy left, sitting in the commissioner's conference room for those godawful weekly staff meetings, Sherwin Gardener was acting, and he looked around the table and he said, "Well, I see that bitch Ellen is not here. Good. If she never darkens my doorway again, it'll be too soon." I

was shocked; I was shocked.

And after that, I wouldn't have missed one of his meetings for the life of me. He turned me around as far as my attitude. I can survive this. And this is a loser group. I don't want to be a part of this group anymore.

So I was offered a job at CFSAN in industry education, working for John Tisler and Taylor Quinn.

RO: John Tisler?

CL: T-i-s-l-e-r. He just retired after 43 years with FDA. We were part of the Division of Consumer and Industry Programs, working for Ed Steele. We were the consumer part. I don't know the industry part. Then that was all part of the Office of Compliance, with Taylor at the helm, Taylor Quinn. And that was a lifesaver for me. It put me back on track professionally, and personally. It put me back into the education realm rather than waving a stick over the heads of experts who were smarter than I was kind of thing, which was the way it had been working for Kennedy, Ellen Williams. And that's when I realized that you stick with what you know. You may have to learn some new language and a new way of doing things, but if you have a talent and you have an ability, why try to do something that's totally foreign?

RO: What year was it, then, that you got back into the mainstream of FDA?

CL: Nineteen eighty, 1980. And that was a wonderful experience because I traveled the whole United States doing industry education. I got to know a lot of people in the other field offices. I was always going out. And, of course, this was an era when Taylor Quinn really hated the whole idea of industry education. He was like Don Healton. The best education is in the courtroom.

I don't know, but someplace there was this kind of little mandate that had come down, and he had to kind of cope with this. So we were always having to justify what we did with him, but we always managed to get it done.

When the bottom dropped out and funding began to dry up for the kinds of things that we were doing, that's when John and I went out with hat in hand to trade associations and began to ask for their support and cooperation in doing industry education programs. We realized that we had a message to give, but they would lend a credibility with their membership. And so we worked with the trade associations -- we had started a program with the Independent Cosmetic Manufacturers and Distributors, ICMAD, that still exists today. In fact, their next workshop is in

February in Santa Monica, doing education for their membership on cosmetic labeling.

RO: Independent Cosmetics?

CL: Independent Cosmetics Manufacturers and Distributors, Inc. It's ICMAD, Inc. They're out of Chicago. We did incredible workshops, and they became very popular. ICMAD is now a bigger organization, has more members than CTFA (Cosmetics, Toiletries and Fragrances Association), which is the more well-known trade association.

As a result of these workshops, they also published the Cosmetic Labeling Guide, which is something that no one else has, was Heinz Eiermann's word on cosmetic labeling, and, you know, he was the expert. He wrote the cosmetic label regulations in many ways.

We also developed a program on warehouse sanitation that still exists with the National Pest Control Association, and a number of other programs. So this was early "leveraging." They funded the workshop, they invited their people. We provided speakers and materials at no cost to them.

Then I was asked if I'd be interested in being detailed to the new Seafood Task Force, which was being established in 1990. There were about five of us who were detailed to

the Seafood Task Force. We were led by Bob Wetherell, who was on detail from the Office of . . . Oh, no. He had been reassigned during one of those upheavals in headquarters.

RT: Up to the Northeast Technical Services Unit.

CL: To the north, right. And he was brought back and was just absolutely wonderful.

Bob was one of those early top managers that I always think fondly of, because in those good old days, it didn't matter how lowly you were in the field. These people would come from headquarters, and they knew your name. I mean, Gerry Meyer and Dick Crout and all those office center directors, they knew who we were, and you could walk through the hall and see these people, and they would greet you and you could have a conversation. And now, shoot. I don't know half the people who are wandering the halls.

Anyway, Bob was brought in to head us up, and it was Mary Snyder, Judy Lee, George Hoskins and I. I can't think of who else. I think there was a fifth person, but I can't think of who it was. We shared a little office; we had three desks and three computers, and whoever got in first in the morning got a desk. And we were charged with trying to establish a HACCP (Hazard Analysis and Critical Control Point) system for seafood inspections through a pilot with

NOAA, the National Oceanic and Atmospheric Administration.

Then there was some kind of little upheaval within CFSAN management, and suddenly Bob was out and Ed Steele was brought in. We all sort of sweated a little bit because we'd worked with Ed before, and couldn't remember whether we'd burned some bridges with him or not. He could be difficult. Oh, my gosh, what was the last thing I said to this man? However, we were finally given regular offices in the conference room on the first floor of CFSAN, and they brought in others, and the office began to expand.

Doug Archer was made Acting Director of the Seafood Task Force, Office of Seafood, whatever. And then they brought in Tom Billy from NOAA to be our director. We were formalized and moved to luxurious offices over on Vermont Avenue.

RT: Did you have any liaison with the National Marine Fisheries before Tom Billy joined FDA?

CL: Oh, yes, we did, because we were working on this pilot HACCP program with them. So, yes, oh yes, very much so. In fact, we knew Tom and all of his staff.

RT: That unit was more prone to deal on a cooperative basis rather than a regulatory one. Is that correct?

CL: Right. They were paid for their inspectional activities. They were paid by the industry to do inspections. This was totally foreign to FDA. And, of course, we thought they were less than us in many ways. They did not require college education, they did not require science or anything of their investigators.

RT: Now, when Tom Billy came over, did he come over in a managerial role?

CL: He was appointed director of the Office of Seafood.

RT: Did he seem to have any trouble with changing from an industry-supportive to a regulatory scene?

CL: You know, he had the same problems that a lot of these people do who come from another level of government, and that is that things can be very complicated in the FDA. We have so many clearance points and systems, and we have so many rules and regulations that we have to abide by to make sure we're not skimming a dime off the system or out of the budget or whatever.

TAPE 2, SIDE A

CL: Well, I have to say I loved working for Tom because

Tom's feeling was -- in fact, I remember his little speech to us the first day on the job. He arrived and had a little meeting with all of us, and he said, "I want . . ." He said, "We have an opportunity here to do great things, and I want you to reach and to stretch and to think of new ways and new ideas, and I want you to present those new ways and new ideas; I want you to do things differently because it's a better way to do whatever, and I don't want you to be afraid to do that." But he said, "Just remember, I always want you to stretch and to reach for something better."

I was so impressed with that, you know. Stodgy old FDA. You know, we do it this way because we've always been doing it this way, and yet I recognize that legally, we're in a different ballpark than NOAA or the National Marine Fisheries Service, although we're moving in that direction now with PDUFA (Prescription Drug User Fees Act) and MDUFA (Medical Devices User Fees Act) and getting paid to do the work that we're supposed to be doing under mandate. But I just was impressed with his views -- he was kind of a breath of fresh air. And so we did. We came up with new ways of doing things.

We also had money up the kazoo, and I remember calling Jerry Vince and asking for some kind of field support in doing something, and I didn't know Jerry Vince. I found him to be kind of unpleasant and irascible in most meetings and

all that, but I also thought he had kind of a clever little twist with the way he thought and with a lot of the things that he said. He loved words, and he would turn them around, and I always got a kick out of that. But at the same time, he just -- he could be most unpleasant. And I remember calling and talking to him, and I was a little anxious about what he might say to me. And so before he even had a chance to respond, I said, "And of course, Mr. Vince, we're going to pay the bill." Well, as long as you pay the bill, he'll do anything.

So that was really kind of nice, and it was just a whole new way of functioning, to be in an organization where money was no object, ideas were welcome, and, in fact, I think, to the detriment to the Office of Seafood and probably to the agency, we were busy tweaking the rest of the world and making them go a little crazy with our savoir faire and our flamboyance and all that sort of thing.

Anyway, it was just a wonderful time. It was a totally different world for me from what I had come from because things had gotten kind of stodgy in CFSAN and those other offices, and our resources were such that we could hardly do the job we were supposed to do. Although I loved working for John Taylor, Sr.

But I was working for John Tisler. John Tisler, in those days, was waiting patiently for death or retirement,

whichever came first, and it drove me crazy because I need to be busy. I like to have activity. So I began to develop a way of -- I would send Sandy Miller some little article I had seen in the newspaper or something and say, "This is kind of interesting. Have you ever thought about this way of doing something about a CFSAN violation or a problem that CFSAN is having to deal with?" And he called me up there and he'd say, "You know, this is a really good idea. What if we did a workshop on emerging microbiological hazards, campylobacter? There are some new things coming out that are becoming problems. What would you think about doing -- do you think you could do such a workshop?" And I said, "Sure, I can put something together." And I'd say, "But that's _____. You have to go through my boss first. I can't just walk down there and say, 'Sandy Miller wants me to do such-and-such.' I can't work it that way. You've got to go through the channels." So he said, "I know, I know. Fine. I'll call the guy."

RT: I was going to ask you, based on your experience with the task force, what was the end product?

CL: Well, we did come up with the HAZZP (Hazard Analysis Critical Control Point) program for seafood. The pilot program with NOAA kind of went by the wayside. We didn't

have enough industry groups or companies willing to participate to make it a real go. But eventually HASZZP became a fact of life for the seafood industry. Don't know how it's going. I really haven't heard anything about it. But it did finally come to be.

At, at the same time, I think that the Office of Seafood found and does find themselves much more involved in the whole international piece, thanks to E.U. (European Union) agreements, NAFTA and other agreements. So HACCP is maybe the foundation, and it's being applied to all these different groups around the world.

RT: Comparatively, now, has the stature of the NMFS (National Marine Fisheries Service) vis-à-vis FDA changed?

CL: Well, it has changed. You know, NMFS converted all of their inspectors over to the CSO 696 series. That was something they did to upgrade, but I think also to begin the task of requiring a certain amount of education for their people. I think they're doing as well as they ever did because now they're helping their industries comply with FDA requirements. They're doing a task that we don't necessarily have the resources to do.

I know at one point they were talking about moving NMFS in under FDA, and it became one of those old things where

NMF was dying to become a part of the FDA and FDA didn't want them. It was one of those political stupidities where FDA was going to get the responsibility but not the FTEs. Maybe that was it. We couldn't take on the task without the people. Why give us the task if you're not going to give us the people to do the job? And so I think that little issue finally disappeared.

RO: Who took that over after Tom Billy left?

CL: Phil Spiller. He's the director now and has been for quite some time. And I left after he came on board. I came out here to ORA (Office of Regulatory Affairs). When Tom left, my job kind of evaporated. I had been Tom's speechwriter, I did a lot of traveling and I gave a lot of speeches. I did a lot of audiovisual stuff for him and for other people in the office. I was doing a lot of communications kind of work. And when Tom left, Phil didn't feel the need for all of that, so I was kind of at loose ends.

RT: So you came back in ORA what year?

CL: Ninety-four on detail in Claudette Guillford's position as acting director of the Consumer Affairs staff. What were

they called? I can't think of it.

RO: It was still Consumer Affairs Officer.

CL: Yes, working for Jerry Vince and for Debbie. And I loved it. I was detailed for six weeks, and then we did so well together, all of us, we decided to renew the detail. At that time, the job was the culmination of everything that I had ever done with FDA. It was consumer affairs; it was industry education because you can hardly separate out the different groups; it was all the admin stuff; it was everything, and it was wonderful to be back in the ORA fold, and I got along really well with Debbie and with Jerry. We were like peas in a pod in many ways. I just loved being in what I considered to be the center of the universe, because that's what ORA is to me, being involved in everything that the agency is dealing with.

RT: You mentioned Debbie. You mean Deborah Ralston?

CL: Ralston. She was Jerry's deputy at the time.

And, of course, I came back, ran into so many people I had met over the years in my various capacities and all over the country who were either back here in headquarters or were now in managerial positions out in the field, so it was

really great.

Of course, it was difficult being moved into DFSR (Division of Federal-State Relations), and that occurred after I had been on detail. That happened over the Christmas holidays. Anyway, I had gone back to my regular job and then came back, and they still had not filled the director's position at DFSR, so we had a number of actors. We had Ed Duta and Tom Schwarz, Pat Wilson. I don't remember; a number of people, but all people that I knew and had worked with in other lives, so it was quite nice to come back even though we had been moved to this 12th floor. I was still participating in the same way with Jerry and Debbie, attending the stand-up meetings and that sort of thing, but I was just physically in a different location.

It was still kind of nice, and because I had prior working relationships with each of these people as actors, they treated me quite nicely, and so the true feelings that the men in DFSR had about us did not show until Richard Barnes came on board.

RO: How was that program in the field? At one time, we had three and four CAOs in each district.

CL: CAOs, yes.

RO: Then we had to scale back.

CL: Right. We have 43, but, of course, now six are retiring. I don't know what will happen. And in Florida, every single CAO OR PAS there is retiring. So Florida is decimated, and so is Cincinnati. I don't know what will happen.

But 43 is still higher. Well, it'll be 39 now, so we will be at the work-plan FTE levels, which are 39. It used to be 55. That was the highest it ever was. But we don't have the numbers that we used to. And we have them spread around more. We have more PAS's working out of resident posts than we used to in the old days. Atlanta has two public affairs specialists, one in the city of Atlanta and one in Raleigh. Brunswick, Ohio, and Cincinnati each have one PAS. Both of them are retiring. I don't know what they'll do.

RT: What are your responsibilities now, being a senior Public Affairs Specialist?

CL: Mine? Well, I'm coordinator of the field public affairs specialists. I'm their person at headquarters. I represent them, I am their champion, I promote them to the rest of the agency. I work with all of the centers and the

offices of the commissioner in assuring that the PAS's receive timely information. I work with the centers and offices in trying to develop new materials and in new programs that the PAS's can use, tools that they need. I try to be the go-between.

I also work with the centers and offices in channeling what they would like to have done to the PAS's. CDER has developed a program on generic drugs and they would like for the PAS's to adopt it as a major national campaign, so I've been working with CDER in getting that sold to the public affairs specialists.

Now, in the old days, we used to have the PAS Advisory Committee, which was just like a regular field advisory committee, headed up by an RFDD (Regional Food and Drug Director) with one or two DD's (district directors) plus public affairs specialists as members. Then Richard Barnes decided -- and I guess he had Debbie's blessing -- that we should go the route of the retail food specialist, which is a council to head them up -- I'm not real sure about the retail side of it; that's something that I've not been involved in -- and that this group, this committee, be made up entirely of PAS's, and they make all of the decisions for the public affairs specialists.

Well, that's all fine and dandy, but you still to have to have somebody in headquarters to pave the way, to attend

the meetings that are called here, where the PAS's names may be invoked to coordinate their function in headquarters.

And so the PAS Advisory Committee was disbanded, and the PAS Executive Council was created. The council has an election every year, two new members are elected and two members drop off. They have biweekly conference calls, and they pretty much make decisions for the public affairs specialists across the board.

RO: Is the council made up of FDA or . . .

CL: FDA public affairs specialists.

Now, Tom Gardine, who is the district director in Philadelphia, has just been appointed by Debbie as a manager advisor. I am a part of the council but separate. The council can have meetings without me, but generally they can choose to have meetings with me because they've discovered that I do have some knowledge about what goes on, and I have certain contacts. It's not just knowledge, it's educated knowledge, been there, done that, and so it's been a difficult five years in the council, kind of finding their place and discovering that the promises Richard Barnes made to them about being totally autonomous . . . I mean, do we know anybody who's totally autonomous in the Food and Drug Administration, or in government? All those promises that

he'd made were not necessarily so, and that if they didn't do right, Debbie would slap them down, and so it's happened a number of times. They finally understand that they don't, they can't make all their decisions without clearing them with the higher-ups, and that's part of what I do.

It's, you know, names change, jobs change. I mean people change, names change, but the job never changes.

RT: You've spoken of a few commissioners who had interests of various sorts in the program. Do you recall any commissioners who you would identify as being very supportive of public affairs work?

CL: Well, Dr. Mark McClellan seems to be very interested in outreach. Unfortunately, he doesn't realize what a valuable tool he's got because he's only seeing it from his narrow little place up there on the 14th floor. And although I think I have a good relationship with Peter Pitts, Senior Commissioner for External Relations, they still don't realize what a powerful force the PAS's can be. They think they're doing outreach by issuing us a talk paper or a press release on the FDA's position and support of the department's fight against obesity, but that's all they do. They're not providing the public affairs specialists with massive quantities of materials to spread the word across

the nation. They're just issuing this one-shot deal of a talk paper.

Now, if they expanded that or if they expanded the message on personal importation to include public service announcements and brochures and all kinds of things that the PAS's could paper the country with, they'd have a real outreach campaign. But as it is, they're not, and so, therefore, it isn't.

Plus, the public is real doubtful of this FDA message about personal importation. They see it as FDA protecting the industry, sure enough.

So Dr. McClellan has an appreciation for the concept of outreach and consumer education, but I don't think he has a full appreciation for the magnitude of the tool that he's got out there in the field and how it could be put to good use.

With respect to other commissioners, I really don't know because I -- it wasn't until I came to this position in ORO (Office of Regional Operations) that I really found myself interacting with people at that high level. Even when I was working for Don Kennedy, it was just a different ballgame. And the relationship between the commissioner's office and ORA, or EDRO at the time, was not what I'd call good. They worked against each other. I don't feel that as much now, maybe because I'm part of it. I don't know.

People also used to get confused between Alex Grant and the Office of Consumer Affairs and the ORA Consumer Affairs Program. They didn't understand the difference.

I know that when I was in Atlanta as a consumer affairs officer, Dr. Mac Schmidt came to town, and I had been sent to South Carolina to do a cable television show, one of these call-ins with health professionals, doctors and nurses, and I'd been sent up to do this program because it covered the state of South Carolina. It was two hours of interview and call-in time, and it was a coup to get that. Although South Carolina was not my territory, George White wanted me to go. He said, "Now, I want you to come back first thing in the morning." The show was at night. He wanted me to come back first thing in the morning because Mac's going to be here. I said okay.

So I flew back into town the next morning and got to the office just as Dr. Schmidt was arriving, and George introduced me as the neophyte consumer affairs officer. And Mac said, "Oh, you're new too." He had just come on board. "So, what do you think of this place? How are you seeing it?" And I was just blown away that he would even be interested. And so I told him that I just thought it was wonderful. I thought it was the best place I'd ever been, and I loved the people, and they were so smart, and that FDA was top of the heap as far as I was concerned. And he said,

"Yeah, I kind of feel the same way, too." And he said, "Well, listen, I just want to wish you good luck," and put his arm around me. And all of the Atlanta managers came up to me afterwards and said, "Do you know him?"

RO: Has somebody been identified to take over your position? I realize they can't replace you.

CL: I'm sure they'll find somebody.

RO: But have they announced it.

CL: Richard says he plans to fill my position and one other of the PAS sites in the office, because he's losing all of us. He does have Pat Alexander, who worked for Alex Grant.

But there are three of us who are leaving. Each of us does something totally different. And so somebody is going to have to be brought on board to fill in for some of us. It will not be the same.

I would like to see him bring somebody in from the field if possible. There are a couple of new young ones out there who in my opinion are the future and who would be wonderful here. And they've been in the field long enough to have learned the job, so they would be good. They are also computer literate, much more so than I am. They would

know how to deal with the new technology of communication.
So somebody like that would be very good.

RT: Do they still have a few men out there?

CL: Oh, yes. We've got men. In fact, the men are among the best public affairs specialists. They are educated, they are devoted, and they are technologically in tune, which I can't say for all of the women. It's a man thing, I think. We have Alan Bennett in Seattle; we have Joe Raulinaitis in Boston; we have Frank Goodwin, except he is retiring, in Orlando; we have Steve Davis in Milwaukee; Gil Meza in Phoenix; Devin Koontz in Denver -- we call him divine.

RT: Who is that?

CL: Devin Koontz, K-o-o-n-t-z. I can send you a list of the public affairs specialists, a current list, if you'd like.

RT: Yes, thank you.

CL: I'll be happy to do that. Are you on the e-mail list?

RT: Yes.

CL: Okay. Oh, Don Aird, Don Aird.

RT: I was wondering if he was still with FDA.

CL: Yes, Don Aird is in St. Louis now.

RT: He was the only one who was with us 15 years ago.

CL: You know, you really ought to do an oral history with him. You really should, because we call him Mr. Wonderful. He is wonderful, and he has memories that just can't be compared with anybody else's. And, well, in fact, all of the guys. They just would have a different slant on things. They'd be the ones to talk to, the male point of view.

RO: Well, is there anything else you want to add?

CL: I've talked your ears off.

It's a wonderful experience to be a public affairs specialist. My feeling, and one of the last things I said in the stuff that I sent out to the PAS's was, in my opinion, every single person in the agency should have a detail as a public affairs specialist so they can find out

what's really going on out there and see FDA as actually affecting the world and learning what the real world is all about. I just think it's a wonderful job. And, of course, this job up here is not the same as being out there.

RO: No.

CL: But it has its own share of warm fuzzies.

RO: Cynthia, we appreciate very much your giving us this interview.

CL: Thank you. I've enjoyed it.

RT: Thank you for participating in the oral history of the agency.

CL: I love doing this kind of thing. It's kind of fun.

END OF INTERVIEW