History

of the

U.S. Food and Drug Administration

Interviewee:	**Deborah D. Ralston**
Interviewers:	**John Swann, Ph.D.** **Robert A. Tucker**
Date:	**October 21, 2008**
Place:	**Rockville, MD**

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBERS

GENERAL TOPIC OF INTERVIEW: History of the Food and Drug Administration

DATE: October 21, 2008 PLACE: Rockville, MD LENGTH: 90 Minutes

INTERVIEWEE:

NAME: Deborah D. Ralston
[redacted]

INTERVIEWER(S):

NAME: Suzanne W. Junod, Ph.D.
Robert A. Tucker
5600 Fishers Lane
Rockville, MD 20857

FDA SERVICE DATES: FROM: July 1972 TO: June 2008

INDEX

	44	ORAU (Office of Regulatory Action University) training
	48	Peer Review Committee functions
2-B	52	Presidential Award
	53	Concluding remarks re FDA career

INDEX

Tape	Page	Subject

Interview with Deborah Ralston

October 21, 2008

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. The interview is being done today with Deborah D. Ralston at the Parklawn Building in Rockville. The date is October 21, 2008. With Ms. Ralston are Dr. John Swann and Bob Tucker of the FDA History Office, who are conducting the interview.

Debbie, as we begin, if you could give us a brief oversight of your personal history, where you were born, educated, any work that you may have done prior to joining FDA, and then we can go into that career.

DR: Okay, thank you.

I was born in Auburn, New York, in 1950. I had a public school education and went to a private college in Pennsylvania, Lycoming College in Williamsport, where I graduated with a bachelor's degree in biology.

During the summers that I was in college, I was employed by Cornell University at their Agriculture Experiment Station in Geneva, and worked in their Food Science Laboratory. The area was enology, the study of wines. I did a lot of testing as to what particular components of the grape caused what particular smells, so that when you got a "good nose" from a glass of wine, what were the chemical components that caused it. This was an attempt to create new strains of grape. That was my first entry into food and

food science. It was a great job, but it was a laboratory job; it wasn't anything like what I wound up doing with FDA.

JS: What interested you in science? Anything in particular, or just something you latched onto even as a child?

DR: I had biology in 10th grade like everybody else, and had an absolutely spectacular biology teacher, a really, really great guy. I still remember him, and I remember on Friday we had what he referred to as "ice cream and cake," a test every single Friday. You geared up for that test like I'd never geared up for anything in my life. It was a very, very difficult class. He was a hard teacher. But I fell in love with biology in that class. And I never swayed. Even through all those lab classes when all my friends in college were out having a good time and I was in labs, it didn't faze me. I was very happy in that science.

RT: In the degree you earned, was that sort of a precursor to your interest in FDA?

DR: Well, FDA was interesting. It was kind of secondary in that, of course, when I graduated from college, my parents said to me, "You've got to find a job," so I took the Federal Civil Service Entrance Exam. And I was honest. I had roommates that took it and put down they were going to work in Hawaii. I put down that the primary places I would work would be New York and Washington, D.C., because I did the research, and found out that if you wanted to work for the federal government, those were the two

places that you could find the most opportunities. And that was when, following the Bon Vivant crisis, FDA was hiring.

The interesting part about that was, at the time they interviewed me, they didn't bother to tell me that they were hiring nationwide. So the folks out of New York District in Brooklyn -- because that's where New York District was at the time -- presented the whole job opportunity as being in New York City. No one told me that they were hiring in Buffalo, which was only two and a half hours from my home. They brought me on in New York City, only for me to find out that I could have gone to Buffalo or Boston. I could have gone anywhere, but I wound up in New York. As an only child, my mother really did not like that at all.

But I also look at it and think if I hadn't started there, I would never have had the career I had.

JS: It would have changed things substantially.

DR: It would.

If it had been another federal agency that had sought me out, I'm not sure I would have been as comfortable with it as I was. I had already worked a little in the food science area when I worked for Cornell, so knowing that it was food and drugs, I figured this was something I could probably do.

Going to New York was really quite the adventure, though. I was a small-town girl, and . . .

J

JS: Where is Auburn?

DR: Well, I was born in Auburn, but I grew up in Geneva, New York.

JS: Oh, Finger Lakes.

DR: Finger Lakes area. And so it's halfway between Rochester and Syracuse, 17,000 people, very small town. And Williamsport, where college was, was about 70,000 when I went to college there.

I had been to New York City a couple of times. I was an exchange student in high school, and that's where we went in and out of. But I had never been there for any period of time.

My parents and I took a dry-run down, and I lived at the Barbizon Hotel for Women. That's the only way my mother would agree to allow me to move to New York. So I lived there for about, oh, I guess six to eight weeks. It was horrid. The room was like a closet. It was in central Manhattan, and I took the train into Brooklyn.

JS: You came on as . . .

DR: A GS-5, under $6,000 a year.

JS: Well, regardless, it didn't go too far in New York, I guess.

DR: No, no. Project Hire, of course, brought in a whole bunch of new "kids," so I wound up rooming with two other investigators. We had an apartment down at the tip of Brooklyn, near the Verrazano Narrows Bridge, a two-bedroom.

I was in New York for five years.

JS: As part of Project Hire, you came in with a number of people who went on to long careers in FDA, particularly in the New York office, didn't you?

DR: Yes. I recently heard from Tom Hanson, who's a supervisory investigator on Long Island. An investigatory magazine had done a cover on him. At one point he carried the 007 badge for FDA. I actually found the article with him in a trench coat with his collar pulled up holding the badge in front. It was great!

RT: I think at one time Donald Healton had that badge.

DR: He may have.

But there are still numerous Project Hires.

Tom Gardine, who's the District Director in Philadelphia, and I started together.

JS: Look at Steve Niedelman, who was Deputy Associate Commissioner for Regulatory Affairs. Diana Kolaitis. Steve, Diana, and I started on the same day.

JS: Wow.

DR: We were in the same class and we were together forever. I went to Steve's wedding. I've known these people forever, a whole lifetime.

When I would talk to the new-hire classes, I talked a lot about the fact that ORA [Office of Regulatory Affairs] is a family. We truly are, we truly are family. We stay in touch.

JS: So your work in New York District, was it primarily with food, or did you also get into other aspects?

DR: I started in food. New York was, and probably still is, the home district to major corporate offices. So there was a Pfizer facility in Brooklyn at the time I was there, and there were several drug facilities out on Long Island and in Westchester County, but there were Resident Posts that served those areas. So those of us who were actually located in the district office in Brooklyn at the time spent a lot of time going back and forth into Manhattan to visit the corporate offices and do consumer-complaint reviews.

While I started in foods, they were not major manufacturers. They were, for the most part, smaller operations. I made a lot of noise about not getting sufficient training; thinking that I needed to broaden my horizons. I was sent to Basic Drug School, and wound up spending six weeks commuting back and forth between Westchester -- White

Plains, at the time, is where we were -- and conducting an in-depth inspection of Ciba-Geigy.

Probably the biggest thing I did in my career in New York that was different was blood-bank work. I was very involved in inspecting blood-bank facilities. Of course, at the time, Biologics was just being transitioned over from NIH to FDA and the Center was still resisting anybody but themselves doing their work. A team of folks came out from what's now known as CBER and trained me in plasmapheresis inspections. I was one of the first investigators to conduct them.

JS: By the way, we didn't talk about this, but when you came on board in '72, that was still not too many years after the first female inspector came to FDA. I mean, was it still kind of a rarity, or did you see a larger group of female CSOs by the time you came on board in '72?

DR: We had a bunch that came in with me. When I think back on those that came in -- I'm very bad with numbers -- I would say that probably half "survived," as in they lasted more than a few years before they decided that there were other things they'd rather do with their lives.

I would say that the mentality was still very much male. My first supervisor, who I loved dearly, and I had discussions about the fact that he wouldn't send me to a certain part of New York because I was a woman traveling alone. Of course, I looked at that as career-limiting. I expected to do everything that everybody else did. Ultimately he told me, "You look too much like my daughter. I would never send you to places like that."

RT: Well, he was probably thinking they were dangerous areas.

DR: But, still, my thought process was that I should go everywhere the men went. I pushed to do all those things because I didn't think I should be treated any differently.

But I think when I started there were four or five women investigators in New York, only two of whom came on as investigators. Two or three of them transferred, moved over from the laboratory into investigations, when Project Hire happened. There were a number of us who came in in Project Hire.

JS: Imogene Golinger started in New York, as I recall. I might be wrong.

DR: No. She wasn't around when I was there.

The most outspoken women in New York at the time I was there were our Consumer Affairs Officers [CAOs] because, back in those days, the field CAOs dealt actually with major media. If there was a public affairs office here at headquarters, it didn't play as large a role in that area as it has come to now, in today's environment.

JS: More decentralized at that time.

DR: Yes. The CAOs interviewed were personally interviewed by the seven o'clock news people. They were forces to be reckoned with."

There weren't that many women around.

I was head of the Federal Women's Program for a period of time. It was very small and poorly supported in those days.

JS: You mentioned earlier the Bon Vivant case. When you came in, I think we were on the tail end of that, but maybe in the follow-up of the investigation, prosecution, and so on. I wonder if you could say a little bit about that and the impact it had, from your standpoint, on the office, the agency, and sort of the way we deal with food regulation, because it certainly attracted a great deal of attention in the media, newspapers and so on. You mentioned, in fact, that you accompanied the son . . .

DR: The son of the man who died.

JS: The son of the man who died, to the trial.

DR: I was his driver.

JS: That must have been an interesting experience.

DR: It was, but certainly it was an unfortunate experience to start out with because of how we got to that particular situation. I was not permitted to speak to him about any component of the investigation or the trial. All of us who drove witnesses were given strict and very stern lectures from Alvin Gottlieb, who was infamous in those days about what we could and couldn't say. It was the first time I was in a federal court on behalf of

the agency, although I said nothing. We were instructed to sit separately, don't look at anybody who worked for FDA, look straight ahead. I was scared to death. I thought that judge was going to pick me out and kick me out of the courtroom.

It was a defining moment for me. I really wanted to be a Compliance Officer after that; to pull everything together to bring the bad guys to trial.

At the time of Bon Vivant, Brooklyn District was located in the nastiest bunch of warehouse buildings that could ever be in existence. One entire floor was filled with cans of Bon Vivant vichyssoise soup that we had collected. That situation caused the agency to focus on the safety of canned foods. Subsequently, there were all of the recalls of canned mushrooms throughout the Pennsylvania region, samples of which were added to the stash of vichyssoise. Cans exploded. Many of them were underprocessed. It was a horrible mess. All we did for months was recall-effectiveness follow-ups. It changed the way the Agency did business dramatically from a food perspective.

I worked unbelievable numbers of overtime hours. Some weeks I worked as many as 80 hours doing that kind of work.

If you looked at the group that came in in comparison to the folks that we get now as new hires, almost all were recent college graduates. Most of us didn't have families and were single, so when it came to working 80-hour weeks, nobody thought twice about it. We just did it. And it was expected. They had spent quite a bit of time explaining to us when we were hired that we were a 24/7 operation. If there was a national emergency involving products we regulated, we were expected to be there, and we were.

JS: You know, I think it's very possible that the general public probably doesn't appreciate or understand what the agency goes through, how the agency deals with emergencies, like a food emergency, drug, what have you. And hearing about experiences like this where you're pulling in a number of people who are working all hours night and day on a problem, that you can't go to a file cabinet and pull out a file and say, "Well, this is where your problem is, and this is how you solve it. With something like this, it's usually a national issue too.

RT: Well, actually, it brings to mind that Lou Dobbs -- I think he's on CNN -- was quite critical of FDA with the recent imported peppers problem. I was thinking, he certainly doesn't know of all the work that's going on, all the investigators and lab people. You know, his conclusion was that FDA is supposed to solve the problem right away and it's poor agency administration if you don't.

DR: Our own Commissioner doesn't understand what goes into it.

I've had recent discussions with folks who say that over the jalapeno and Serrano peppers' incident (I retired during this outbreak), he expected that the Agency had the ability to easily determine every single commodity containing these peppers; that there was some form of giant database in the sky where you could just punch a button and find this sort of specific information.

Unless you've lived one of these kinds of situations or worked for FDA for a number of years, you can't grasp how vast the realm of possibilities are for contamination

of foods, contamination of drugs, and what it takes to narrow down the cause. Each situation is different.

I worked for years with Ellen Morrison to publish an emergency response plan and trace-back documents. Each time we'd think we'd get to a final version, we'd have an outbreak that we'd have to investigate, and our friends at CFSAN (Center for Food Safety and Nutrition) would say, "Well, those don't work here." We'd say, "You're not following the book. We're trying to make this uniform and consistent across the Field. If you don't follow what we've agreed to as the plan, then you're not going to get it consistent from district A to district B to district C." And the response was, "Well, this isn't the same." Each outbreak brought forth something different, something new, and we were never able to get a playbook that was generic enough for folks to be able to follow. There was always some changes that had to be made.

And especially, too, when you're dealing with an agency like CDC (Centers for Disease Control and Prevention), which investigates all the foodborne illnesses. Their expectations of us are much more dramatic than our ability to accommodate them.

I agree there's a lot to be said for the fact that the world does not recognize how hard it is for us to expeditiously find the cause of an incident.

And, to be honest, this has been evolutionary. When I started in 1972, our job was not to find the cause. Our job was to tell the firm they had a problem; leave the list of inspectional observations and say, "Here's what I found." When they would say to you, "What do I do about this?" your response was, "I can't help you with that. I am not a consultant. I would recommend you seek out someone who has expertise in that area." We were the eyes and the ears, and we weren't there to help them.

RT: That's true. I worked for a number of years in a state food and drug program and that state worked closely with the district FDA people. I've been on joint inspections where there was an obvious problem -- and the plant manager really was sincerely interested in correcting it. He'd ask, "Do you know of anything we can do better?" And, anyway, it was a production operation of some sort where they weren't doing it well, and so on. So my FDA associate inspector said privately to me, "Don't tell them. We'll get a seizure." That was the mindset of some of the FDA field folks. In order to get ahead in the agency, the desire was to get a regulatory action, since you wouldn't get ahead by helping industry people avoid trouble.

DR: Well, I think there were two schools of thought. There was that school of thought, certainly, that we were a regulatory agency, the only regulatory agency in the Department, and getting regulatory actions was something you want to do.

But even if a formal regulatory action was not possible, the environment I grew up in -- and it may have been unique to New York because New York was a district unto itself in those days -- we're not there to help you. We are here to regulate your products, and it is up to you to find someone who will get you "off the bad list and onto the good list" by helping you correct your problems.

There were people who were in there for the "ticky marks," you know, getting the legal actions. We then "warped" into the age of voluntary compliance wshere the goal was to get voluntary compliance versus a regulatory action. Tracking voluntary compliance to show what you've achieved was then an issue.

The pendulum has swung in a number of different directions, and I'm not sure what era I would say we're in now. It's certainly not one of regulatory actions, but I'm also not sure it's voluntary compliance either.

JS: We're at crossroads right now. A very different enforcement philosophy.

DR: Yes.

RT: Well, in my younger days with FDA, we had a Case News report -- I think it was a sort of pink sheet -- that went around. You would see certain litigations or cases carried on and on and on and on. It wasn't really an efficient compliance strategy in some cases, and I think the agency recognized that little voluntary compliance education efforts might move industry compliance along better.

DR: I think there's a balance; there's a need for both, and when we're at our best is when we recognize the need for that balance. We really slap those people who deserve to be slapped, and those people who are making an effort, we give them a chance.

I can't say that I always felt that way. When I was a Compliance Officer in Boston, my boss used to tell me I was too heavy-handed.

JS: I want to actually go to that, because you have an interesting anecdote in your retirement announcement about that.

But just as an entree, you moved on to Boston in 1977, where you spent about a year or a little bit over a year as a Compliance Officer. What kind of led to that when you moved to Boston? You were based as a CSO (Consumer Safety Officer).

DR: There was a nationwide hiring initiative, a nationwide football draft, we called it, that happened in '77, I guess, five years after I joined FDA. Of course, they hired all these new investigators then. As we all grew up in the agency, there was a need to have more people to supervise and to do compliance work. So they held this football-draft thing for compliance officers and supervisors throughout the United States.

I don't remember all of the rules, but you submitted one application and then you picked the locations where you wanted your application to go to. You had to be serious about going to these places because whichever place offered you a job first was the place you were going. So I knew at that point, I didn't want to stay an investigator all my life.

Being an investigator in New York was different than being an investigator elsewhere. It takes two and a half hours to drive to get to an inspection that's 45 minutes as the crow flies. It's just a very, very hard place to be an investigator unless you went to one of the Resident Posts. I really didn't like investigations' work that much. I much preferred writing.

My boss at the time told me I really was a much better writer than I would be a supervisor, so I should be a Compliance Officer. I took him at his word, applied in the nationwide draft and got the phone call from Boston about half an hour before the phone call came in from New York.

We were all at Advanced Drug School in Houston when this was happening, and it was quite hysterical to watch us all be called out of lectures, taking these phone calls to pick us up. And I was there with some guys from Boston, Peter Smith, who ultimately came to headquarters; and someone else who encouraged me to go to Boston. I had become friends with them, and when the call came in, they said, "You really should take it." So I did. Half an hour later, New York called, and I said, "I'm sorry, I pledged my heart to Boston." That's how I wound up in Boston.

RT: That gave you different field experience, too, didn't it, than New York?

DR: It did. In some respects I'm sorry I didn't stay there longer.

Boston had an extremely active Compliance Branch, and I think I may have written numbers down in my retirement notice. I was handed four prosecutions that were in court. I wrote a revocation of probation recommendation which no one has even heard of today. I did a misdemeanor prosecution with seizures across the United States. This was in a one-year period of time. They didn't do injunctions in Boston at that time. I don't remember what the reason behind that was, but virtually everything was a prosecution. I also recommended a felony prosecution for the species substitution in fish.

I had the opportunity to, just before I retired, do a congressional briefing with Don Kraemer on seafood fraud. I mentioned that prosecution to him and he thought that was the last seafood-species substitution case we ever took as an agency.

JS: In 1977-78?

DR: Yes.

JS: Oh my.

DR: Those economic adulteration cases, in the overall scheme of things, were not necessarily sexy to a United States Attorney who had to weigh how he spent his time. I mean, if you look at that as a felony from the standpoint of let's get corporate America, show how this guy made so much more money, we had to do unbelievable amounts of research to be able to show how much scrod sold per pound versus turbot selling per pound . . .

TAPE 1, SIDE B

DR: The stuff that we had to do to bring that kind of case was very different. It was not your typical FDA filth case.

JS: One of the cases you mentioned was -- I mean, several of these were fascinating -- one that particularly stood out was a case you were involved in in New Hampshire. This was a case involving funny honey.

DR: Funny honey.

JS: Can you tell us a little something about funny honey? I gather this was an importer from Mozambique.

DR: Yes. It came out of Africa. We knew it wasn't real honey, but we had no mechanism by which to analyze it in the FDA laboratory. I can't remember exactly how we found out it wasn't real. I guess it was the price. The price that it was being offered for was far too low for what it should have been if it was the real thing. I did some research, talking to some folks in the laboratory, learned that there was a test that could be done, the carbon-ratio isotope test, and found a laboratory in Cambridge that would do it for us. I carried the samples over to the laboratory and I sat on the bench next to the analyst as he analyzed it so that the chain of custody would be assured. It was a geological survey laboratory. The test validated our belief and was the basis for the seizure.

I tell people who say we can't use outside laboratories in regulatory actions and cases that, "I did it. Don't tell me we can't do it. I did it."

JS: Why couldn't we? What's the argument?

DR: The argument is, I guess, it's a not-invented-here, that you have to have the presumption of regularity, and so it has to be our laboratories. Outside laboratories are always a question as to whether or not they are credible.

What I did, of course, was spend a day personally doing this. You'd have to set up a whole procedure to make that a regular process.

It worked. The case went to court and I went to New Hampshire where the U.S. attorney, wearing hiking boots, jeans, and suspenders, appeared in front of the judge.

The product was seized. It was in 55-gallon drums frozen into a field in New Hampshire. They couldn't get it out. It sat there till the spring thaw, under seizure.

JS: Well, it was, obviously, an unusual case, and the judge obviously was quite convinced by the evidence done by the outside lab and the whole case that the agency put together.

I noticed in our quarterly activities report on this case -- I'm just going to quote very briefly a couple of sentences from this story. This says that, "In an unprecedented move, the judge refused to allow the claimant to ship the product back to the country of origin, as allowed under Section 304(B) of the FD&C Act. The judge felt that since the importer had had trouble with African honey in the past, he should have been suspicious of the product in question and performed tests to confirm its identity."

So this was quite an interesting case, and a path-breaking case in some ways.

DR: It was a lot of fun. You know, and in those days, when you're young, people tell you you can't do things, you don't listen to them, so I didn't.

RT: I thought it was notable that you apparently were once given an award for losing a case. Do you want to say something about that?

DR: Oh, that was Herbalife. Yes.

JS: That was in your next position.

DR: Yes. That was here at headquarters.

JS: When you moved into headquarters.

And I have a special interest in Herbalife. We have actually a fascinating video that was done, a documentary that was done about the Herbalife company.

DR: Really?

JS: So we definitely want to ask about that.

But before we go on, this case that you mentioned in which you wrote and arranged approval for a revocation of probation, this involved a bakery that had some problems. Now, you mentioned that you thought the attorney actually didn't want you there because of an arrangement with the fellow.

I guess what I was interested in in this case, not just the case itself, but also your personal enforcement philosophy. I mean, you bring everything to bear that you've learned and experienced in the agency at this time. But you have a pretty solid idea of how the law should deal with those who violate the FD&C Act.

DR: In those days I certainly was much more hard-nosed than I grew to be as time went on. But this particular individual had been prosecuted previously and been placed on probation. We were following up on the previous prosecution continuing to inspect his facility, and he had not learned his lesson. I thought, and still think, if I were faced with that scenario again, I would come out of it the same way. You have certain obligations to the public when you provide things to them -- in this case it was bread. To provide a clean product, and this bakery was "a pit." It was horrible. I was furious with the Assistant U.S. Attorney for settling the case. I didn't think a weekend in the Charles Street jail was that big a deal. Maybe the guy would "get religion" and recognize that he had an obligation to the public.

We don't take filth cases hardly ever anymore, and that's all this was: filth. Can someone say that would have harmed them? No. But certainly if you were to go out there to the public and say, "Do you realize what you've been eating, you know, all those little brown spots in your bread are insects, not that it's overbaked."

JS: They're not sesame seeds.

DR: I don't feel you should be allowed to violate the law. I do believe that there are certain circumstances that warrant warnings, and you ought to be offered the opportunity to correct your ways. But when you've been offered an opportunity and you don't, I think the agency needs to go after them with guns blaring. I just do; I always have. I feel very strongly about that.

JS: There are situations where, depending on the commodity, depending what we're talking about, tolerances are set up, but that's not what we're talking about here, is it?

DR: No, no, no. I was not in Boston at the beginning of that series of inspections and trials, and didn't go back to look at the specifics of what led us to that point. But if a court felt strongly enough to convict an individual the first time through and place them on probation, then we as an agency should feel strongly enough about proceeding against him when he doesn't correct his ways, and the court ought to feel strongly enough about backing up their initial decision, which was why I was annoyed at the assistant.

I still remember him very vividly. Now that I'm older, if I were to find him, I'd give him a piece of my mind. Those days, I just sputtered. I just stood in the hallway and sputtered at him, I was so furious.

Although years later, when I read that document that I wrote, I said it just wasn't up to my expectations of my writing, so maybe that was part of it. I don't know.

JS: Well, your stay in Boston was somewhat short-lived, and the opportunity to move to headquarters came up in 1978, where you moved to the Field Compliance Branch. Just briefly, how did that work out?

DR: There was a 30-day detail that was offered.

To be honest, the workload in Boston was just about killing me. We had so much work that there was no way that you could ever finish it, especially since I was not only

doing regulatory work, but was also the only Compliance Officer doing imports. Imports was supposed to be a half-a-day job each day, with the rest of the day being spent doing the other work. I had no life, and while I loved the work, I had to find a place where I could actually have a life.

So when this detail came up, I went off for 30 days, and at the end of the 30 days I was offered a job. They said, "If you want to transfer down here, we'd love to have you." And now that I think about it, I never even applied. It was a lateral. They wouldn't give me my GS-13 in Boston because I was leaving.

So I transferred to Field Compliance Branch, which was, in those days, like the Division of Field Science and Field Investigations is now. It was a group that was put in place to help the compliance branches. Legal actions didn't come through them at the time. They were there to assist.

I wrote a lot of appeals. When a Center turned down a case, I would review it from the standpoint of whether or not it was a valid decision, and if not, I would write an appeal. During those days, I worked for Al Gottlieb and the appeals that I wrote had to go through him, a former manager in the Chief Counsel's Office. There were several that I did seven, eight, nine drafts of. At one point in time, the secretary actually had little hash marks on the wall for the number of drafts that I had done for him. There were probably two of them that I won; where I got a Center to actually listen to ORA.

I also wrote all of the inspection warrants that the agency did at that particular point in time. There was a period where I guess we'd do two or three a month, kind of asserting our authority to inspect. Many of them were done in an attempt to formalize the use of photography as an inspectional tool. I'd worked very closely with Bob Spiller in

the Chief Counsel's office, and John Fleder, head of the civil side of the Office of Consumer Litigation at the Department of Justice. Writing a brief because we thought Shedds Margarine in Baltimore was going to challenge our use of photography. John and Bob Spiller went to court with the brief in their pocket and sat for the day, waiting for them to challenge us. We were never challenged.

JS: We haven't been challenged since the time of the 1906 Act, when we were using photography as part of our investigations of establishments. Or have we been challenged?

DR: Not that I'm aware of, not specifically on photography.

Our theory, at least back in the days when I was doing inspection warrants, was, it had to be a common-sense use of photography. If you couldn't document it in another way, if you really had to have the photograph, then we'd "go to the mat" for it. But if it was photography for photography's sake, we would encourage investigators not to push the limit on it because there was some concern that we might lose.

But, no, to the best of my knowledge we were never challenged.

JS: And do you know what happened to this brief that was prepared but never utilized?

DR: I'm hoping that Bob Spiller's got it somewhere. We laughed about it, because if

you had ever been in Bob Spiller's office, the paper was up to the ceiling and it would be tough to find.

Bob's now teaching the Food and Drug Law course, which I was extremely pleased to see. Much of the law he's teaching is law he was involved in making, as one of our best Chief Counsel attorneys.

JS: Is Russ Munves no longer teaching?

DR: No. He hasn't been teaching in two or three years, even longer than that probably.

But, yes, I would hope Bob has that brief.

JS: I do too, because I think that would be fascinating, a fascinating document, and people would be interested in seeing that if it's releasable.

And, Bob, you were asking about the . . .

RT: Yes. I think in that period of time, you once got an award for losing a case, and you said it related to Herbalife.

DR: Yes.

RT: Which was a dietary supplement.

DR: Yes.

RT: What were the circumstances of that award for losing the case?

DR: Herbalife, of course, was making all sorts of unfounded claims for its dietary supplements, which, of course, in those days weren't really known as dietary supplements. They were drugs because drug claims were being made for products that were really no more than vitamins. In some cases they weren't even those, which was of particular concern with their children's products. We were living in an environment at a time where people were thinking that if one is good, two are better. These were products that were, for all intents and purposes, uncontrolled drugs. We worked very, very hard to bring this case, reviewing hours and hours and hours of videos that were made by the president of the firm.

JS: Mark Price?

DR: No, that wasn't his name. Shoot, I've lost it. Mark Hughes. Anyhow, he married a Miss Sweden.

I sat in the CDRH (Center for Devices and Radiological Health) offices for hours just taking down the claims that were made, including the testimonials, because we were going to be making a pitch that the testimonials constitute labeling.

We had actually planned to execute five mass seizures at five of their largest distribution facilities in the United States, simultaneously. I worked very closely on this one with Debbie Grelle, who was a Compliance Officer out of Cincinnati at the time.

JS: Who was the Chief Counsel at this time, by the way?

DR: Tom Scarlett was Chief Counsel, if that helps.

JS: Okay.

DR: We were all set; we were all set to take these seizures. I don't remember the specifics of how it all transpired, but the bottom line was that we were told -- and Tom was involved in this -- that the cases were legally sufficient but politically unattractive. And at some point later on, I think it came out that there had been significant monetary donations to the party in power.

JS: From the company.

DR: From the company. I believe that there were some adverse actions that occurred to some people who worked in the agency. I think one individual was fired, and I believe that this was instrumental in Mr. Scarlett's departure from the agency.

JS: The Herbalife case.

DR: Yes.

RT: That's interesting.

JS: I mentioned there was a documentary, which we have in the collection, a video at the FDA History Office that was done I think by CNN or TBS, one of Ted Turner's stations. I don't know that it was ever aired. But it's a fascinating documentary . . .

DR: I'd love to see it.

JS: I'll be happy to show it. But it's quite incredible in that you see footage of some of the seminars, if that's what you want to call them, that the President and his chief of research gave. Often they're told how to handle it when the customers, say, ask about how one of these products work. And they repeat, they give a mantra of how you, how the salesperson for Herbalife is supposed to respond. You respond by saying, "Well, I don't know about that, but when I take it, this product makes me feel better and has all these sorts of effects."

DR: Exactly.

JS: It's a fascinating video -- I'm sure it was not shown, maybe for political reasons too, but also possibly for liability issues. But when I noticed in this summary that you were involved in the Herbalife case, this is the first thing I thought of.

DR: It became my case. I was very wedded to it. My boss at the time was Chuck Everline, and he was the one who put me in for the award. What they were doing was so wrong. And I really did believe that there was a significant possibility that adverse public health consequences could occur, and may have, for all we knew. There may have been some that were ultimately documented that we didn't know about. I think he put me in for that award purely for my mental health, because I was so torn up by the fact that we had worked so hard, and it was legally viable. It would have brought them to their knees. I mean, we hadn't done five simultaneous mass seizures that I was aware of at that time.

JS: Ever.

DR: Well, we may have since then, but not then.

JS: But a very unusual enforcement strategy, right?

DR: Yes, it was. It was certainly not something I dreamed up independently. You know, I was working very closely with the attorneys, and there's no way that the attorneys would have let something of this magnitude go forward if it were not legally sufficient. I mean, they're just not, these guys are people who were looking for future careers, potentially, outside the agency as well. it. So, it was just very, very sad.

So, yes, I think my husband was the one who coined the phrase, "the first person to get an award for losing a case." The award does not mention Herbalife; it's written very generically.

JS: A case that deserves further study by perhaps those outside of the agency.

DR: It might.

RT: I understand that you then got into tissue and mammography activities.

DR: Yes.

RT: You worked for Jerry Vince, Director of Regional Operations. He was described as a colorful person in one of the write-ups. In what way?

DR: Well, everybody had a nickname. I'm trying to think what yours was? I'm sure you had, yeah, you had a nickname.

JS: What was yours?

DR: He would just go, "Ms. Ralston." He would just call me Ms. Ralston. But Steve Niedelman was Mr. Needleperson. Mr. Cheesemore. Mr. Chesemore. I'm sure more will come. But everybody had a nickname. He just had an interesting way of dealing

with people. He didn't mince words, he always cut right to the chase. You knew exactly where you stood with Jerry.

I would go to "one-on-ones" with Jerry and Ron Chesemore. I, of course, knew Jerry very well and knew when Jerry was being honest and when Jerry was bluffing. Ron did not. Finally at one of the last meetings that we had, Jerry and Ron were chatting about something, and Ron asked Jerry a question that required a definitive, factual answer, and Jerry gave it to him. Ron looked at me and said, "He's lying through his teeth." And I looked back at Ron and said, "Yes, he's been doing this to you for the last five years." The man could bluff, oh, could he bluff!

Once I got close enough to Jerry to be able to challenge him, I would. In private I'd say, "You don't know what you're talking about. What are you saying?" He goes, "They don't know I don't know what I'm talking about."

He was an extremely intelligent man. Even if he didn't know specifically the issues, you could pretty much guarantee he was on target.

I worked for him for several years as his deputy, one of the best bosses I ever had. He really was.

I would suggest that he and Chuck Everline probably formed my management style as I grew up in the organization. Chuck gave me the ability to do whatever I wanted to do and taught me how to be a good Compliance Officer. Jerry did much the same, only Jerry's input was managerial. He taught me by sharing responsibilities.

Ron Chesemore was the one who decided to make me the tissue and mammography queen, literally within a month or two after I got the job as deputy. Ron might deny this, and but he certainly felt having a woman involved in mammography

didn't hurt the organization. I worked very closely with Dr. Florence Ho at the CDRH, really the mother of the mammography program at FDA, a spectacular individual. One of the best programs the agency has ever, ever, ever done was the follow-up to the Mammography Quality Standards Act. Back in your days Bob when you were in DFSR (Division of Federal-State Relations), I mean, we never had a better-run program, with Gary Beard and Bob Dickinson. It was spectacular.

RT: With regard to the state contracts.

DR: State contracts, and the ability to manage this kind of an activity, a fee-for-service activity that we got the fees for, which was very unusual, of course, in those days. That was '92-'93.

I went to see the doctor recently to have a mammogram. It's digital now, and the technician who was there teaches mammography. I mentioned that I was involved when this whole thing started, and she actually thanked me. It was very, very sweet. She said she was involved before MQSA (Mammography Quality Standards Act), and it was a circus. She said, "I used to do the old ones, when they were x-rays," and it was just horrible.

Tissue was very interesting too, because it was an entirely different thing than regulating blood.

I got to be on the ground floor of a lot of really neat things. I was very fortunate.

JS: There were a couple of things that I wanted to see if you could flesh out a little bit during your time as deputy, Deputy Director in ORO (Office of Regional Operations).

One is your involvement with the Foreign Inspection Working Group. How did that come about? What did they do? I mean, especially today, with all the issues with foreign inspection, what was your involvement with that?

DR: Well, Dr. Friedman was our Acting Commissioner at that time. The agency was taking a lot of heat on the conduct of foreign inspections and inconsistency between foreign and domestic and so forth. How do we get better intelligence from foreign countries where we're doing inspection? How do we leverage, the famous L word, how do we leverage all of the information that's out there so that we don't have to do every single foreign inspection at every single facility that brings products into the United States? How do we make sure we're inspecting the right firms abroad?

It started out to be a general evaluation of the agency's foreign inspection process, so we dealt with each Center independently, dealt with the Office of International Programs from a standpoint of agreements that we had with foreign governments, with the attorneys for what we could and could not do in a foreign setting, etc. Sometime during its life, it wound up transitioning to be almost exclusively a drug initiative. That's how we ultimately wound up with a tiered approach to foreign inspections in the drug arena. CDER (Center for Drug Evaluation and Research) categorizes the importance or the significance of particular kinds of drug manufacturers based upon the drug in question, difficult manufacturing, single source, that sort of stuff, and they would

prioritize them. We would try to get all the tier-ones done one year, and then try to broaden out, doing tier-twos and tier-threes. The evaluation was to be an overall review of what we do in the foreign inspection arena, with suggestions as to how it could be improved. We actually still have four or five copies of the document floating around. They're with Kara Lynch, who put all the pieces together and was the primary author of the document.

In hindsight, Kara and I laughed at how we wound up working on this project. It was one of the bizarre Fridays after Thanksgiving when we both worked, and I got like three or four assignments, one of which was chairing this foreign inspection working group for Dr. Friedman.

I think in some respects, it portrayed the distinctly different charges that each Center had with how they did and why they wanted foreign inspections to be done.

There was no entity around, although Dr. Friedman probably could have been that lightning rod had he been permanent, to put his foot down, bang the table, and say, "We're all going to do it this way," because we could. You know, there could be a lot more uniformity between the Centers and how we go about doing foreign inspections.

So it was a document that was very interesting to a number of folks. GAO did a study on it. I was dragged down to the Hill for failing to produce documents, with Alan Slobodan screeching at me regarding my failure to provide GAO with certain supporting documents in the time period that they wanted them.

But in the endgame, it fell on deaf ears.

TAPE 2, SIDE A

DR: We laughed because much of it is as timely today as it was then. You know, much of it is consistent with the problems we have today -- agreements with certain countries where we give everything and they give nothing back; educational efforts we've done with certain countries that have not panned out. Much of it is still the same. I think the recognition that we can only govern that which we have control over, so what happens in a foreign country is more difficult to control.

JS: How do you suppose, if you don't mind my asking about the future here, how do you suppose the change to establishing foreign inspection posts might help the situation? I am curious. The issues that you said are . . . Well, why don't you pick it up where we left off with what happened with the Foreign Inspection Working Group, because you said that . . .

DR: Nothing really did happen with it. We were supposed to continue to have meetings after the report was finished, in order to act on some of the recommendations that came out of the group. The focus changed to something other than foreign inspections, since all components of the Agency really didn't have the same interest in it, thus it was one-sided. I mean, certainly Dr. Friedman wanted it. Certainly I was excited to be involved in it because I was hoping to have more uniformity and consistency between the Centers because it would make it much easier for us (ORA) as the inspectional arm of the Agency to accommodate their needs if we didn't have to do A for the Center for Drugs and B for the Center for Biologics. You know, if we could

capitalize on those things that were consistent between them, we'd do a better job for them, perhaps in a more timely fashion.

I'm not convinced that the way the agency is going now with stationing people abroad is going to work. I don't think it will. I think it's going to cost us far too much money to do it over time. I think it's a, to use one of my father's phrases, it's a flash in the pan. It is this particular Commissioner's initiative. I would be very, very surprised to see that it would continue beyond the initial ones that they have started. When I left, there was a whole laundry list of countries that they intended to start these foreign offices in.

I remember dealing with this kind of question during the years that I was in ORO. You know, the initial price estimate was $350,000 per year per person to station somebody abroad, and that was in addition to their salary. It was just their care and feeding. I think the newest estimate was $500,000 per year per person to station people abroad.

Then the other issue that I don't believe has changed is that basically once you are on an embassy staff, you work for the ambassador. So you could be a drug investigator, and they could have a food issue they want you to deal with.

JS: And the embassy could dictate a work plan.

DR: Yes. That was my understanding, and I don't think it's changed.

I think perhaps it's been minimized and what they've attempted to do is work through all the agencies, Department of State and all the agencies they need to work

through to get this process to be more FDA oriented than just having one or two people somewhere. But when push comes to shove, I wouldn't be surprised at all if our folks were used for other purposes.

I think I've come a long way in being able to see other people's sides of things, but I'm not convinced this is the answer to the problem. Anyway, to quote Mr. Michael Rogers, what question is this the answer to, and if the "question" is doing lots of additional foreign inspections, I don't see it. I don't see it as the answer to that "question."

I think it'll be very interesting to watch the foreign inspections in the future.

JS: Well, it certainly is a problem, the issues that we have with imports. It's a huge problem.

DR: I heard from somebody that they actually have us doing over a thousand drug inspections this year, which we've never done. Someone wrote me a note and said they don't know who was around that agreed to that. It wasn't me.

JS: We have all these people now that we're bringing on.

DR: It takes a lot of money to send people abroad, though.

JS: Yes.

DR: We've got to have the money.

JS: At this time, during your tenure as Deputy Director, you also became involved with Team Biologics, and it would be, I think, interesting to hear more about what Team Biologics is, how it came about. Obviously we're talking about a formalized agreement, I suppose, between ORA and the Center for Biologics, right, or . . .

DR: Yes, more or less.

The Center for Biologics was undergoing unbelievable congressional scrutiny. They were living on the Hill. There was nothing that they could do that was right. Jerry Vince was the one who really started this, working very closely with Mark Elengold and folks at the Center. As time went on, Jerry "morphed" his way out it. I think he was anticipating retirement and that someone else would have to take it over. I became more and more involved in it.

There was, being very blunt, a lack of confidence on the part of the Office of the Commissioner in the Center's ability to appropriately inspect these facilities. 20/20 hindsight might cause me to say that they (Biologics) were too close to the facilities, that there wasn't enough actual regulatory scrutiny, that they needed to be dealing with biologics firms like ORA dealt with the rest of the regulated industry that we inspected. So the Office of the Commissioner made the decision that ORA was going to take over those inspections.

RT: Was the Biologics group more voluntary minded?

DR: Yes, much more voluntary.

JS: I'll just very briefly say there's a long tradition dating from the 1902 Act, which was still in force, let's face it, of this being something worked out between scientists. That was sort of the mindset throughout its history in NIH. I believe when we were working on the centennial of that Act, we found that the first regulatory case -- Peter Hutt I think confirmed this too -- was brought under the 1902 Act in 1964 against the Calise blood bank.

DR: Wow.

JS: So, that says maybe a little something about that.

Now, we're also talking about 20-30 years after that, and more than 10 years, 20 years after Biologics came to FDA. You mentioned there was some dissatisfaction with the way inspections had been going.

DR: Yes.

JS: Were there some specific cases or problems that you can recall that prompted that sense?

DR: No, I can't recall them. I suspect that those that were closer to it at the time probably could.

This wasn't blood or plasma inspections. Those had already moved over into ORA. These were the biological pharmaceuticals, the ones that were quasi-drugs, quasi-biologics, that to a certain degree lent themselves better to an ORA kind of an inspection. There was significant training that the ORA folks had to have in the actual science that they got from Biologics.

In numerous presentations that I gave to the industry as the team was forming and storming, the biopharmaceutical industry was very unhappy to hear that ORA was going to be inspecting them. At some of these meetings you would meet industry folks that had dual responsibilities. They had, within their corporate structure, traditional drug manufacturing but they also had biopharmaceutical manufacturing. The biopharm side of the house was being inspected by CBER and the drug facilities were being inspected by ORA. They were two entirely different inspections. I actually spoke to groups where the biopharm folks were saying , "You can't do this to us. This is unfair" (applying drug inspectional standards to biopharm products). I mean, this is exactly what they would say. You'd have the people on the drug side saying, "Sit down and shut up. It's your turn. You've gotten a pass for these kinds of inspections." So I think it was part of the reason for the congressional pressure; the standards the biopharm firms were being held to were perhaps not the same standards that similarly situated firms were being held to. So it was a very, very difficult challenge.

CBER (Center for Biologics Evaluation and Research) did not want to give up the responsibility. Mark Elengold -- it would never have happened without him. He came out of ORA, understood the ORA mentality, and was a Deputy Center Director at CBER at the time. He told them the handwriting's on the wall and you need to work together.

Over years, we developed a spectacular relationship. CBER product specialists would go out on inspections with ORA investigators, lending the scientific expertise that they had from application review, from knowledge of the industry, to the investigators' technical expertise and what one would expect in a Good Manufacturing Practice operation. A very symbiotic relationship was worked out, but it took years to get us there. It continues. During the transformation leadership team and revitalization efforts, when David Horowitz would have his meetings with the Centers to try and figure out how ORA could serve them better, we told him, "You will get nothing but a love fest when you meet with Biologics." He didn't believe us. They sat down with ORA and had no suggestions whatsoever. They love working with us and we love working with them. We really didn't seem to have anything at issue. But it took years to get us together.

The team -- I think we've got 12 investigators on the team now. They're all GS-13's. We had two GS-14's; they both retired. Their inventory is about 165 firms across the United States and internationally. The team travels all over to make those inspections.

Biotherapeutics ultimately became a CDER responsibility and the team isn't doing them anymore. They still do allergenic extracts and *in vitro* diagnostics of biological origin. That's it.

JS: This might be a good opportunity, just for people who don't know how things work in the way that ORA works with or doesn't work with other Centers. When we inspect commodities, how do we interact with the Centers, whether it's CDER, CFSAN, CVM (Center for Veterinary Medicine), and so on? Do they inspect establishments? Does ORA? How does ORA work with the Centers when it comes to that?

DR: Well, for the most part we continue to be the inspectional arm of the agency, and the Centers will more often than not work with us to develop the priorities that they want inspected in a given fiscal year. Many times they have information that we would not have that would dictate the kinds of inspections that should be done.

The Centers, over time, have come to ORA identifying certain areas they want to do their own inspections in. Probably the only one that has not done this is the Center for Veterinary Medicine. There are still folks at the Centers -- and there may be a few people in Veterinary Medicine, that make inspections. In most instances, they are former ORAers who've gone to a Center, and the Center has seen a need to keep up their inspectional experience so that they have a real-life CSO they can go talk to when they want to find out how it really works in the inspectional environment.

There have been times in our history where there were Centers who have felt that they would prefer to do all of their own inspections. We have fought that and have won so far. We always offer them the opportunity to make international inspections.

But, as Bob alluded to before, having one oversight arm over the inspections and the compliance activities that we take adds to the consistency of how the agency does business.

It's rare that a Center will ask us to do inspections and we say no. We do occasionally say no; we say that they're not warranted. Typically, if it's a specialized assignment and not something that would be considered normal and routine work, we want to know why we're doing it. Tell us why you feel that this should take priority of what we typically have to do. In the Office of Regional Operations, once those specialized assignments come to us, we evaluate them for whether or not they need to be done and negotiate with the Center as to whether this is somebody's wild goose chase or whether it's really crucial that we spend our scarce inspectional resources on this versus something else. We try and work as a team.

I think over the years the field committees have done a much better job getting in on the ground floor when the Centers make decisions at the beginning of the fiscal year as to what our workload should be, making sure that it's "the best bang for the buck" and that they're really prepared to move on the evidence we collect.

RT: During your tenure as Director, you also got into, I believe, new-hire training and its development, instruction. Was that something that you went around over the country and gave regional presentations to, or was it more formalized?

DR: That was the formalized three-week course that Gary German's office sponsors for all the new hires.

Before ORAU was built, we used to travel around the country conducting it regionally in those days.

I was tasked with doing the ORA headquarters portion. Sometimes it was an hour and a half, sometimes it was an hour, sometimes it was 45 minutes -- but kind of the ORA overview and hot topics. It ultimately morphed into a presentation, which to this day is probably the most favorite thing I've done with the agency: "Here's where you are in the organization, how you fit." Then I would follow it up with, "and these are the things that are happening in the organization now and to the agency now that you will have a role to play in"

It became quite the commercial for ORA. I felt so strongly about what a wonderful career I had had with the organization and the tremendously good work that we did. I always felt that we never really . . . that no one ever really talked about that. You know, just the opportunities you get within ORA, and the Centers too (but I can't speak to them as I can to ORA), to go on details to try out new jobs. You know, the way your career can evolve from being a fledgling investigator to being an office director. The teaching cadre sums up the number of years of experience they have on the cadre, and we always have been 150 and 200 years of experience on the cadre that teaches the course, and that we're a family. I talked about the "family" fact when John Taylor, Jr. was the ACRA, that his father was the Center Director for CFSAN and the ACRA; that Michael Rogers' father was the District Director in Kansas City; and we'd go through a whole discussion about the fact that this is a good place to work and you do good things to help the public. It gave me an opportunity to tell them some of the interesting things that they would be involved in as well as where they fit in the organization. I spent a lot

of time talking about what my office did and the fact that we were there for them whenever they needed us.

Toward the end of my career, I had a number of students come up and say that I was just about the only person who actually went out of their way to say, if you need help, we're here.

RT: Was that sort of a corollary of the Peer Review Committee that you chaired?

DR: No. It was two entirely different things.

Peer Review used to be chaired by the Director of the Office of Enforcement. A decision was made that because a person who was the Director of the Office of Enforcement wasn't a CSO (John Taylor), that the Chair ought to go to somebody who was a CSO. That's how I wound up with being a chair of the CSO Peer Review Committee. It was another thing I truly loved; I really enjoyed it.

RT: What was the charge or the work of the Peer Review Committee? That name suggests, I guess, comparing various strata of management. Is that it?

DR: The Committee dealt with the promotion of working-level CSOs for the most part. It was an agency-wide committee. There was a representative from each one of the Centers and two from ORA on the committee. There's a headquarters ORA vote and a Field vote, because we had two distinctly different kinds of CSOs. The Committee was how a working-level CSO could get a GS-14 or a GS-15.

From a headquarters perspective, you know, most everybody who's a CSO ultimately grades out to be a 13. You used to be able to do desk audits to get your GS-14. Peer review was another mechanism by which to get people their GS-14's and GS-15's.

JS: Is this also a way to identify those who had become national experts in product commodities, or was that a completely different procedure?

DR: You could become a national-expert investigator at a GS-13 level, and that was just a job, that was just an announcement. But if those people wanted to be elevated to a GS-14 or a GS-15, they had to come before the Peer Review Committee.

I would get frustrated because I would see people within the Centers getting GS-14's and 15's and not see corresponding promotions within the Field. I tried to become an advocate for the national-expert investigators, some of our Compliance Officers and the work that they had done. We ultimately did have some GS-14 Compliance Officers out there.

We now have two national-expert GS-15 investigators, Mary Carden in the biologics arena, and Deborah DeVleiger in the food arena. They are international experts, and they are GS-15's.

There were Center people who were getting promotions into 14 and 15 positions that didn't have nearly the expertise that I was seeing in the Field, so I would nudge field folks to apply.

JS: Did their supervisory or nonsupervisory status have anything to do with that grading? No?

DR: Yes and no. Initially, we didn't review anybody who was a supervisor because their grades typically were theirs based on the fact that they were supervisors. Then we started running into folks who actually had some really heavy-duty scientific expertise, that not only did they supervise, but they were the expert in nanotechnology for a given Center, for example. So while maybe they could only be a GS-14 as a Branch Director, they might be eligible to be a GS-15 based upon the fact that they were the expert in nanotechnology. In some circumstances you were looking at people who were managers, but you didn't look at them from that perspective. It was all based upon their educational and work expertise.

JS: This has been disbanded now.

DR: Yes.

JS: So, how is this . . .

DR: I think they're going more through desk audits now.

The last I heard -- and I'm not sure it actually went through -- Richard Barnes of the Division of Federal-State Re;atopms had a person on his staff that he was trying the new process out for, and I heard that the 14 had gone through.

There were a couple of Administrative Officers at two of the Centers who thought that because ORA chaired the committee, it was an ORA thing, and why were they playing. Point in fact, probably three quarters of the folks in peer review were Center people. Only about a quarter of them were field people. So it was a service that ORA, that I was and my predecessors were actually providing to the agency, although we (ORA) got very little benefit out of it. And they didn't realize that they were screwing their own people by trying to get it killed, and they did.

I felt it was good because it leveled the playing field.

JS: We mentioned just briefly earlier the Prior Notice Center, which came about while you were Director of the Office. It came about on December 12, 2003. I wonder if you could talk to us a little bit about why it came about. I know that there are some issues of disclosure, but why it came about and what it does.

DR: Well, the "Bioterrorism Act of 2002" was passed containing a number of authorities that the Agency had for over a number of years as it pertained to foods that we didn't have: mandatory recall authority, marking for refused goods, additional information to be made available to the agency before products are brought in. And what it turned out to be, in this particular Act, was kind of a compilation of things that we sought plus things that the Congress thought we needed, written by folks who didn't

know how we did business and didn't consult with us before they wrote it. So what we got was something that was extremely difficult to do anything to implement, a direct response to 9/11 and an attempt to assure that products brought into the United States -- that we had better control over what they are and what potential terrorist threats they might possess, even though so much of it still can't be determined before it reaches the United States. This was Congress' best effort at coming up with a law that would allow us to better control those kinds of problems.

What came with this was an unbelievably unreasonable time frame by which we had to have regulations promulgated, and if we didn't, there were drop-dead dates, as in, "you'll do this regardless."

It's funny, when you live something at the beginning and then you see it at the end, you have a tendency to forget how horrible it was at the beginning. And Leslye Fraser -- she's at the Center for Foods and is in charge of the regulation, writing operations at CFSAN -- she was charged with writing this regulation under the Act and was given 18 months to do it.

When she spoke up at my retirement party, she said, "This has never been done in the agency before. Have we ever done anything of this magnitude in this kind of fashion?" I remember the sleepless nights before having to drag myself around with Leslye to all the congressional committees to brief them on prior notice. But the actual heartburn of the whole thing is something that is gone now. I don't remember it other than the sleepless nights that I spent doing it.

Leslye is truly the subject-matter expert on the bioterrorism regulations. She could speak much more articulately and fluently on it than I could.

I had several spectacular people to work with on it. Joe McCallion . I could not have done it without Joe. As far as actually setting up the 24/7 operation, that was Dominic Veneziano in its entirety. He did all the work.

The Prior Notice Center is the agency's first 24/7 operation. It runs 24 hours a day with FDA people, ORA people there, answering the phone. When the phone rings, it's always answered by a human being, and it's answered 24 hours a day, seven days a week. It provides for advance information on every food commodity that enters the United States before the official entry is filed. It's unheard of.

It provides, perhaps, a false sense of security in that it's not like we're analyzing everything before it comes into the United States. It's a paper information system. It's not collecting a sample for analysis. It's designed for potential terrorist threats and/or foods that could be intentionally contaminated or identified as harmful. We have, in recent years, extrapolated it to things like adulterated products coming from Mexico, you know, contaminated foods coming from Mexico. We take a stronger view and look more conscientiously at the Prior Notice status of those things.

I couldn't be prouder of an organization or an operation than I am of those folks.

The work that they did for Hurricane Katrina -- I don't think people will ever, ever know what those folks did to keep harmful products from entering the United States after Katrina. Customs opened the border. Products were not being declared; they were just crossing the border. And if it weren't for people in the Prior Notice Center and folks there working more than 20 hours a day at various State Department locations, I don't want to know what kind of disaster would have occurred.

TAPE 2, SIDE B

JS: That's helpful, putting the Prior Notice Center in perspective like that. And obviously it generates just a mountain of data that I can't imagine sorting through that, but we do.

DR: One of the very good things that Dominic Venezians did, as the Director of the Prior Notice Center, was to establish a tremendous archival recordkeeping ability. They track everything that they do, e.g., every phone call that comes in, plus every single thing that they do there, so that they have a history for comparison purposes for additional products that enter.

JS: I wonder how long they keep that.

DR: I don't think they'd ever thrown anything out.

JS: We like to hear that.

DR: I mean, at some point in time it probably would be good for you to talk to Dominic about it, and Laura Draski, too, now that she's in charge of that group.

RT: Now, Debbie, I think this past year, you received the Presidential Meritorious

Rank Award, and that's a real accolade to your dedication through a varied and long career with the agency. Was that primarily for recognition of your accomplishments?

DR: Yes.

RT: That's great.

DR: My understanding was that John Taylor had recommended me, and then, through a series of coincidences or changes in management, Diana Kolaitis ultimately finished the process. It was in large measure due to Prior Notice, I think. I've always felt guilty about it because I certainly did not do that independently. If I hadn't had Joe and Dominic, there's no way. Plus Dominic put together a spectacular staff of folks to handle it. I constantly tell people that the award is not mine. I wish that I could give it to everybody.

JS: True, although it is obviously a recognition of leadership and insight and foresight, so I, you know . . .

DR: Perhaps being in the wrong spot at the wrong time. I remember when I got the assignment to do Prior Notice, John Taylor originally had it. I said, "What can I do to help you?" I said, "You want me to take Prior Notice, I'll take Prior Notice." And then I realized, what did you just do?

RT: Does that pretty well cover what we'd like to today?

JS: Well, it covers what we had hoped to cover. Now, if we've left out things that you think need to be here, I hope you'll let us know.

DR: I think that the biggest thing gets, for me, to the fact that I was very fortunate to be able to hire really good people. When I left, David Horowitz had asked how did I come across all of these great people? I can't say it's a gift because I also hired a couple of people that I wouldn't hire again. If I have a legacy to leave the agency, it's the fact that I think I did have a bit of an insight into who were good people to bring on board. I think the team that I left in ORO was a spectacular team, and the organization worked as well as it did because of those people. My husband had a friend who was in senior management somewhere who basically said he did nothing but hire good people and let them do their jobs. For years I tried to emulate that, you know, just give them what they need to do their job, and turn them loose and let them do it. So the recognitions I've gotten over my career really belong to them as much as they belong to me.

But it was a great 36 years. I couldn't have asked for a better time.

RT: Great. Well, we very much appreciate your taking time to share that with others through this oral history interview. Thank you, Debbie.

DR: Thank you for the opportunity.

END OF INTERVIEW