

History

of the

U. S. Food and Drug Administration

Interviewee: Marie A. Urban

Interviewer: Robert A. Tucker

Date: September 30, 2004

Place: Rockville, MD



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INTRODUCTION

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

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



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

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PLACE: Rockville, MD

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INTERVIEWEE:

INTERVIEWER(S):

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5600 Fishers Lane
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FDA SERVICE DATES:

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Marie Urban

September 30, 2004

TAPE 1, SIDE A

This is another in the series of FDA oral history taped interviews. Today, September 30, 2004, the interview is with Marie Urban, Director, Office of Executive Secretariat, in the Office of Regulatory Affairs. The interview is taking place at the Parklawn Building in Rockville, Maryland, and is being conducted by Robert Tucker of the FDA History Office.

RT: Marie, as we begin these interviews, we like to have a brief sketch of your personal history, when you were born, educated, and any career experience you might have had that would be pertinent to this record prior to your joining the Food and Drug Administration. So, with that, I'll let you begin.

MU: Okay. I was born in Pittsburgh, Pennsylvania, on December 15, 1947. I was raised in Pittsburgh. For college, I went to Carlow College, which is in Pittsburgh, receiving a bachelor's degree in biology and a minor in chemistry, and then I went on to The Ohio State University in Columbus, Ohio, to earn a master of science degree in microbiology. From there, I went to the University of Pittsburgh Medical School for a year, and also worked at Montefiore Hospital in Pittsburgh.

I then came to FDA on September 5, 1972. I started as a microbiologist in what was then the Bureau of Biologics in the Division of Bacterial Products, and for five years I conducted research, tested vaccine formulas on *Bordetella pertussis* or whooping cough. I also conducted some inspections and reviewed IND submissions.

After I took food and drug law, I was fascinated how law and science fit, you know, how do you fit science into going to court, and I was fascinated by it, so I decided that my next move would be to go into compliance. In 1977, I went to what was then the Bureau of Veterinary Medicine, in their Division of Compliance, and worked there as a compliance officer. And then in 1979, I went to the Center for Drug Evaluation and Research, in the Division of Drug Labeling Compliance, as a compliance officer.

After a year there, I then went back to the Center for Veterinary Medicine because in the Center for Drugs you're very specialized. In the Center for Veterinary Medicine, you do the wide range of FDA-regulated products, and you have feed and drugs and medical devices, so it's a broader approach to food and drug law.

RT: Let me, if I may, regress just a moment.

As you first came to the Bureau of Biologics, what type of assignments were you given there?

MU: In the Bureau of Biologics?

RT: Yes, when you first began with the agency.

MU: I conducted research on *Bordetella pertussis*. I also tested vaccines before release, the DPT shots, and I would test it for pertussis to make sure it was potent and safe; and did a few inspections; and I also did a few IND reviews. But mostly it was research with *Bordetella pertussis* and vaccine testing.

RT: So that was in a laboratory?

MU: Right. It was Building 29 at NIH.

RT: When you got over to the Center for Veterinary, or the Bureau of Veterinary Medicine at that time, what were you involved with there work-wise?

MU: Well, I had a few cases. We did a lot of correspondence with industry for label reviews. I don't think at that point I was doing Freedom of Information requests. That came later. But I did a lot of correspondence and reviewed a few cases.

RT: Who was, if you recall, the director, first, of the Bureau of Biologics when you . . .

MU: Okay. Well, Hank Meyers was the director of the Center, and I specifically worked for Charles Mansclark.

RT: When you went over to the Bureau of Veterinary Medicine, who was the director?

MU: The Branch director was Phil Sheeler, and the Division director was Herb Freidlander.

RT: At the Center, the Bureau director was?

MU: The Bureau director at that time would have been Dr. Van Houweling.

RT: Donald Van Houweling?

MU: Yes. And if I remember correctly, Dr. [Lester] Crawford came right when I left. And when I came back in 1980, he left, and then I believe he returned in 1983, because I used to joke with him that that's a sign I ought to be leaving, since he came back.

RT: These names of management people helps to put the whole thing in perspective.

MU: Right. Let's see, in the Center for Drugs, I worked for Bob Heller, and the Division director was Rudy Apodaca, and I think -- who was the Center director? I think we had a changeover at that time, so I'm not sure who was the Center director. And then right when I left, Dan Michels became the associate director of their Office of Compliance.

RT: I might ask you, although this is regressing for a moment, what brought you to the Food and Drug Administration? Did you seek that placement, or was there a recruiting of your expertise?

MU: Right. I was a microbiologist at the University of Pittsburgh, and I went to the annual meeting of the American Society for Microbiology, and they had a job fair and saw that job, called, submitted my application. I was interviewed and offered the job.

RT: What grade level were you?

MU: Seven, GS-7.

RT: With a master's degree, I guess that was obviously a direct step into the 7.

MU: Right, right.

RT: Now, when you moved over to the Center for Veterinary Medicine, did that transfer result in a promotion, or was it a lateral move?

MU: Right, right. When I left Biologics, I was a GS-12, and I got my GS-13 when I went to the Center for Veterinary Medicine.

RT: I've interrupted our discussion, but perhaps you'll recall where you were going.

MU: Sure, sure.

I was a compliance officer in the Center for Veterinary Medicine, working for Homer Ransdell, and the Division director was Ed Ballitch. And I reviewed cases, primarily reviewed cases. I did some redacting for Freedom Of Information requests. But primarily I was a compliance officer and worked on the tissue-residue program, trying to revise it to make it more effective.

And then in 1984, I was asked to move over to the Hearings Branch. This was a newly formed branch to deal with administrative hearings, so we had -- well, DES was already over, but we were doing chloramphenicol, sulfas, and low-level antibiotics was my big one. I worked on low-level antibiotics a little bit back in '77-'78, and I worked on it again starting in '84, and did that for about two years. And then Homer Ransdell retired, and I applied for his position and I did get it, so I became the Branch director, Case Guidance Branch.

RT: Do you recall, in that period, were there any outstanding cases or issues that were dealt with by you or your staff?

MU: Oh, yes. We had the Algon action and Schuyler, and those were both about veterinary pharmacy compounding. And one of those cases has set up a precedent.

RT: What was the nature of those violations?

MU: They would make unapproved new drugs without application.

RT: I see.

MU: And they were really, even though they were compounding as a pharmacy, they were distributing the drugs nationally.

RT: How did that malpractice or violation come to the attention of the agency? Was that a matter of investigative findings or . . .

MU: The legitimate industry was complaining about it, and then we started investigating it.

RT: I see.

MU: We started doing a lot of tissue-residue actions then. We started doing a lot of undercover buys for veterinary prescription drugs.

RT: The tissue-residue problem, for those who may review this record, what was the focal point or the issues involved with tissue residues?

MU: Farmers will, or their veterinarians will prescribe drugs for animals, food animals. FDA works with USDA's Food Safety and Inspection Service (FSIS) to see when they deplete from the tissue so drugs will have a withdrawal time. And sometimes farmers don't want to wait that period of time for the drug to diffuse through the system. And so USDA Food Safety and Inspection Service tests the animals, either surveillance or for cause, and then they would notify us of a tissue, a violative tissue residue, and then we would go out and inspect. And I was fortunate enough to actually go out to Buffalo District and spend a week conducting tissue-residue inspections.

RT: With regard to those findings or reportings of violative residues, were those screenings at slaughterhouses?

MU: Right. It would be at the slaughterhouse, and USDA inspected at the slaughterhouse, and then they'd do certain sampling and testing, and then they'd notify us.

RT: So there was pretty good cooperation between the two departments.

MU: I think it was improving at that point. There hadn't been in the past, but we worked very hard, meeting with them routinely to develop a better working relationship. We started doing joint training out at Ft. Collins, Colorado, and trying to make sure that we

understood each other and what our roles were and try to complement each other. So we worked very hard to improve the relationship.

RT: Dr. Crawford, didn't he come over from USDA to FDA?

MU: No. Actually, he was in FDA, and then he left in 1985-86, and then he went over to Food Safety Inspection Service as deputy administrator, and then he became administrator.

RT: Okay.

MU: Then he went to the private sector and, of course, came to FDA as the deputy commissioner a few years later.

RT: Very good.

MU: I did a lot of work for Dr. Crawford. We had an issue with APHIS [Animal and Plant Health Inspection Service] in USDA on interferon. It was a bovine interferon product, and APHIS said it was a biologic and they should regulate it, and we said it was a drug and we should regulate it, and this went back and forth and back and forth, to very high levels, actually, up to the Department, and it was decided that FDA would regulate it as a drug. So we took the bovine interferon.

I also was chairman of CVM's Biotechnology Committee and represented CVM in the agency's Biotechnology Committee, and we also had an Interagency Biotechnology Committee with EPA, APHIS, FSIS, to coordinate what future products were going to be out there that we need to be thinking about to regulate.

RT: Which of those several agencies was the lead or the manager or chair of that effort? Was it just kind of a multi . . .

MU: It was multi, right, it was multi.

RT: It was not a single agency issue?.

MU: Right, because there were different issues. There were animals that were genetically altered, or you would have products from genetically altered animals, so depending on which way it went.

And I remember in 1984, we actually had a hearing. That was when Frank Young was the commissioner. We had a hearing on the Hill, and I represented CVM and went down there with Frank Young to testify. And he started out by telling the committee that he was the father of biotechnology and had been at a similar convention in 1964. But it was a very good hearing for FDA. We came across very good.

RT: What committee or what chairperson?

MU: For some reason, I think it was one of [John] Dingell's, so it would be in the House, I guess House Commerce. Yeah, Commerce.

And then a week later, I accompanied Dr. Crawford on a hearing on low-level antibiotics. We had received an imminent-hazard petition and had to respond to it, whether to declare it an imminent hazard. That means that we have to expedite a hearing to remove those products from the market. But we did not agree with the imminent-hazard petition.

RT: Those two hearings, I'm inferring, were not particularly adversarial to the agency or

...

MU: Right. In fact, the low-level-antibiotics hearing that Dr. Crawford testified in, Al Gore was in the House (this was before Gore moved to the Senate) at that time, and there was a government table and there was an industry table and an academia group. And they did the government first, and then they did industry. But that was pretty quick, the industry, because they said, you know, you have a vested interest here; we really don't care what you have to say. And then it went to the academia, and there was one professor from a college that got a lot of money to do research on low-level antibiotics, and he started, and Al Gore just said, "Do you get money from a regulated industry?" "Well, yes, I do." "Well, then, I don't think your testimony is particularly significant here, so you really don't have to testify."

RT: At least FDA didn't have that kind of a conflict of interest, did they?

MU: Right, right. Yeah, it was funny. It was my first exposure to Al Gore and how he just shot him down so quick.

RT: Is that right?

MU: Yeah, yeah, he really did.

RT: Interesting.

MU: Yeah.

I'm trying to think, when I was in the Center for Veterinary Medicine again, I told you undercover buys of veterinary prescription drugs, tissue residues. That was really the bulk of our work. We tried to focus on human safety issues. And also back then, a lot of the other centers were not doing a lot of enforcement, so I would visit districts and encourage them to really put their efforts in veterinary inspections, because while the other centers aren't entertaining that much enforcement, CVM *is* entertaining enforcement. And we did. We got a lot, we had a lot of good cases back then, and had a great working relationship with the field.

RT: Was that before the ACRA [Associate Commissioner for Regulatory Affairs] was set up by [Paul] Hile?

MU: Oh, by then, Paul Hile would have been . . . Let's see. Paul Hile left about, around '86, '87, and then John Taylor, Sr. came in.

RT: Right.

MU: And he was there for three years and then left, I guess, around 1989, yeah, maybe '89. And then Ron Chesemore became the ACRA.

RT: Well, I was just wondering. There was a time when, as you have intimated, the various centers or bureaus each were trying to get priority for their fieldwork, and I think there was some effort along the line to get people to work more as a team in the agency. I was trying to relate to that problem and when it might have been solved.

MU: Right. We had to be very careful because we had to work with the Center for Drugs, because you'd have veterinary drugs under GMP's and you also have human drugs under GMP's, and you don't want to be going two different ways, so we would have to talk quite a bit and have a lot of meetings, and there were a lot of disagreements.

RT: Yes. Now, were some, as you just suggested, preparations made to regulate drug use

in both the human treatment arsenal and in the veterinary animal field? Did you, for example, encounter problems of diversion of veterinary drugs to human use, or was that a minor thing?

MU: That was minor, yeah. You'd have occasionally, particularly out in the field, where one of the animal drugs are over-the-counter, and people would go in and buy them for their personal use.

RT: That's what I was thinking of.

MU: Right, right.

RT: It never became a very major issue?

MU: Right, right, because there were both held under the same GMP standard, so it's really not . . .

I remember one time I had my dog's tetracycline, and I started taking it before I saw the doctor, and the doctor said to me, "Well, how could you take that animal product?" and I said, "Listen, it was produced in the same place that produces the human stuff. Trust me." Yeah.

One other thing, when I was working with APHIS on biologics, drug biologics, I had the opportunity to go out and do one of their inspections, and we went to Fort Dodge,

afternoon and he said, "Guess what? We found cyanide in grapes in our Philadelphia laboratory."

So, for four of my five weeks down there, that's all I did, was Chilean fruit. I went down to Tampa, to the docks down there, was interviewed by the papers and so forth. We would go down to Canaveral. We had planes coming in Miami, and you'd just see pallet after pallet of grapes that were destroyed. But we started by inspecting it ourselves, and then we got workers in and we audited them. But that went on for four solid weeks, where it kept changing which fruits from Chile could start coming in because we had been convinced they wouldn't be contaminated with cyanide.

RT: That episode cost some lives of FDA personnel, too, didn't it?

MU: Yes, it did; yes, it did. We went down to Chile to do inspections down there, and the plane crashed. I believe we lost two people.

RT: That was unfortunate.

Well, Dr. Young, who was commissioner then, as I recall, really wanted to go to the nth degree to assure safety. I guess we didn't have a great number of lots that were found, but there was a very genuine effort to assure consumer safety.

MU: Right. It went to the courts, and the courts ruled in agreement with Frank Young. If in fact you have SOP's, then you must follow your SOP's, and if you don't, you must

justify in writing why you didn't. But Frank Young didn't have any procedure to follow in a situation like that, and he erred on the side of safety, and so they said what he did was totally appropriate.

RT: That's right.

Marie, you, of course, came into the agency later in the course of women being in the agency's professional staff. Initially, some of the women who came in, at least in investigational operations, had to prove themselves to some of the skeptics that they were as competent as the men.

MU: Absolutely. I mean, I had a situation, when I was in the Center for Veterinary Medicine, where two female investigators were conducting feed-mill inspections, and the company kept complaining about them. And these were both outstanding investigators. And so I remember I wrote a memo to Ron Chesemore telling him that from CVM's perspective, these two women are outstanding investigators, and these men in the feed mills better start getting used to it.

RT: I just wondered, because we've interviewed some of the lady investigator pioneers, and they reported having had various reactions to them personally. It's been well established now, of course, that women are very competent in this work and there are now many in leadership positions, even as you have been, so that's progress.

MU: Even it can be advantageous.

I did a tissue-residue inspection with Mark Prusak in Buffalo, and we went to -- this guy was a hauler. He took the animals to the slaughterhouses, and he was a pretty rough character. And, anyhow, while Mark went off and prepared the 483, I talked to him, and he just spilled his guts. He was just . . . And what was funny was I was just there on a week's detail, and the trucker looks at Mark Prusak when we were leaving, and he said, "You must be a pretty good investigator to get the pretty little secretary to go with you." And Mark was just, "No, no, no, no!" And I must have laughed five miles down the road.

And my last day there, we went to a slaughterhouse, and I prepared myself all the night before, "Please don't get sick." And so we were on the kill floor for about an hour, and Mark Prusak looked at me. He says, "Can we leave the kill floor?" I said, "Hey, you're the boss."

RT: That certainly would be somewhat of a challenge. Slaughterhouses are not the most pleasant places.

MU: No, they're not; no, they're not.

RT: We used to have a veterinarian, when I worked for the State of Indiana before coming to FDA, and he was kind of a rough guy. I went one place with him, and the kill-floor workers kept throwing animal viscera parts at him to try and get under his skin, but

he didn't let it bother him.

MU: Right. You have to be tough when you go into places like that.

I know when we went to an auction yard, it was pretty rough. And they had just brought in a bull that killed its owner. Mark said, "I think we'd better get going here. That guy looks rough." And he was really -- they were having trouble controlling him.

RT: Sure.

MU: So I had a lot of good fun back then, I really did. I still have fun, a lot of good memories. Yeah.

And then in 1989, the Office of Regulatory Affairs decided to have an Executive Development Program, and I applied, and I was accepted. There were seven of us that were in ORA's Executive Development Program. And with that, I had the opportunity to do details at different offices all throughout ORA, even outside of ORA. I did a lot of fieldwork. I went to laboratories for a while. I shadowed the regional director, Burton Love. I became Detroit District director for a month on detail. So I had really wonderful opportunities throughout the agency.

And in November 1990, Ron Chesemore named me as the director, Division of Compliance Management and Operations in the Office of Enforcement.

RT: Were you a member of one of the early Executive Development groups?

MU: This was just one that ORA did on its own because they couldn't get the agency to do it.

RT: I see.

MU: The agency wasn't interested. So Ron decided that he would do it on his own.

RT: So you were in the first cadre of those folks?

MU: Right. And Jerry Henderson managed the program.

RT: Well, that was usually a wonderful opportunity for advancing in the agency. One of the caveats was, though, you had to, as I understand, plan your place after it. You weren't necessarily guaranteed a plush job.

MU: Right. And I remember going to talk to Ron before I applied, because by this time Richard and I were dating, and we were hoping to get married, and I couldn't really have Ron give me a district job, and so I was a little concerned. Not that he promised me anything; he didn't. I had to take my chances. But he did keep me here and give me a division job. And Richard and I got married. Let's see. I got that job in November of 1990, and we got married December 1st.

RT: Well, I know that in subsequent moves that involved Richard, you were able to work at the same location. That, I think, is progress from the earlier times in this agency, when personal considerations weren't given great credence and you had to go where you were told whether you liked it or not, or perhaps never maybe be promoted thereafter.

MU: Right.

RT: We've moved ahead in that regard, too.

MU: Right. It's interesting you say that, because I went up today to say goodbye to John Taylor, the current associate commissioner, and we started talking about that. He said, "You know, you can't move people around anymore, and you have to understand it's not one person working, it's couples that are working." So you're going to see more and more, I think, of moving couples and taking couples on rather than an individual.

RT: That certainly makes for a higher morale in the agency, I think, when personal needs or personal preferences are at least considered.

MU: Right. And you'll see that a lot, where couples move to a district and get two different positions.

RT: Yes.

MU: Okay. Anyhow, so that was what we called DCMO [Division of Compliance Management and Operations]. Debbie Ralston was my deputy. Howard Schloss was my senior compliance officer. Lana Orgram was one of my compliance officers. I hired Fred Richmond out of New York, stole him, brought him down. And this was in the heyday of the Dr. [David] Kessler days, when we did lots of actions, lots of regulatory actions. Two years in a row, we had 188 seizures go through each year. We did prosecutions. OCI [Office of Criminal Investigations] didn't really get started until 1992, so we still had prosecutions while OCI was being set up. And then, of course, Terry Vermillion came in and headed up OCI, and so prosecutions then started being handled by them. But we continued with injunctions and seizures, and a lot of good cases because that was mindset back then, was to build cases, and that was back when -- I remember the American Red Cross.

I remember in, I think it was 1988, John Taylor Sr. put the Red Cross under a voluntary agreement, and they never really could get their act together. So in 1992 -- it was December 23rd, and the reason I remember it is we started around three o'clock in the afternoon with a meeting with ORA, the Center for Biologics Evaluation and Research, Dr. Kessler, and Dr. Jane Henney [Deputy Director of Operations] . . .

TAPE 1, SIDE B

RT: I had to turn the tape, and you were speaking about . . .

MU: Right. It was December 23rd, and we had a meeting with Dr. Kessler and [Dr.] Jane Henney, Center for Biologics, and ORA, to discuss what to do about the American Red Cross. And this meeting went on until nine o'clock that night.

RT: At that juncture, what was your position then?

MU: I was director, Division of Compliance Management and Operations, in the Office of Enforcement. And so pretty much, particularly ORA, felt that the agreement had not worked, and the next step would be to enjoin the American Red Cross, which is what happened. And they were under a consent decree, and they are still under a consent decree in 2004. They've never gotten out from under it.

We did also a lot of inspection warrants back then, where somebody would refuse giving us information that we have a right to.

We had one really kind of nasty situation. It was in Utah. I don't remember the name of the company. But we had an informant come in and tell us that he was dealing in unapproved new drugs, and we corroborated it. And the District sent in a search warrant. Now, a search warrant is criminal because there were criminal acts going on there. An inspection warrant is an administrative warrant to obtain information that we have a right to in the law. So this was clearly a criminal search warrant.

But we had one guy go bad up in the state of Washington, and so Dr. Henney and

Dr. Kessler wanted to know every time we did a warrant now. So we had a search warrant, presented it to them, and they made the decision to convert it to an inspection warrant. I'm convinced we should have kept it as a search warrant because immediately Orrin Hatch got involved, so it was not a pretty situation.

RT: He usually did when anything of importance occurred in his state.

MU: Utah, right. And that was really the beginning of the dietary supplement problems, and then DSHEA [Dietary Supplement Health and Education Act] passing. This is when these companies would claim that their products were dietary supplements, but they were not; they were drugs. But they wrapped themselves into the whole thing.

Remember, Mel Gibson would say, "You're arresting my vitamin C"? And so the public really was taught by the media, you know, or the media convinced them that we were taking away their vitamins. And so I was told by somebody who worked for Senator [Robert] Dole on the Senate that they got more letters about dietary supplements than anything else in their history. And as a result, of course, DSHEA passed in, I believe, 1994.

RT: And the sort of great deluge of letters was confined, then, to Mr. Hatch.

MU: Orrin Hatch. He haunchoed it, he haunchoed it **[note to editor: I can find no listing in the dictionary for "hauncho" or "haunchoed."]**

RT: But those letters were also coming to other members of Congress?

MU: Absolutely, yes, because the person that I got this from worked for Senator Dole.

RT: A minute ago you mentioned a consent decree, and, again, for those who may review this oral history and may not be familiar with what that is, can you briefly explain the term?

MU: Sure. One of FDA's authorities is to go to the courts and enjoin a firm from future acts. In other words, we have a history that they have been violating, and we want to stop that behavior. And we file an injunction, usually a preliminary injunction. If there was a major public health issue, we could do a temporary restraining order. And then they can contest it or they can sign a consent decree. If they contest it, we go through trial. And then, if we win -- and hopefully we usually do -- we get a consent decree, and that's a court order that they must do something.

For example, if it was a GMP case, they must shut down until they have fixed their operation, and then they may have to have a consultant come in and verify that everything's okay. So they're under a court order, and if they violate it, it can either be a criminal violation or a civil violation. And there are different scenarios of why you would do one criminal and one civil.

I remember we had a case against a woman who, it was veterinary drugs, and she

violated the consent decree, and we did a criminal contempt. And she (Sissy McGill) just started the business, running the business from jail.

RT: Is that right?

MU: We never could get control of Sissy McGill.

RT: Now, of course, for example, the Red Cross, which continues to be under the consent decree, so periodically the agency's investigators are checking?

MU: Absolutely. It's being run primarily out of Baltimore District because the American Red Cross headquarters is in Washington, D.C. But there's guidance to all of the districts on inspecting American Red Cross facilities, not only under our authority, but also under the authority of the consent decree.

RT: Would the district court in Washington be the judicial oversight point?

MU: Right, right.

And, of course, for seizures, we go directly to the U.S. attorney, the Department of Justice Headquarters. With injunctions, we must go through the Department of Justice Office of Consumer Litigation. And we had very good working relationships with those people down there. In fact, the director, Gene Thiroff, called me the other day just to

wish me well in my retirement.

RT: Well, I think that's helpful to have a little explanation.

MU: Okay.

Then in 1995, Ron Chesemore came to me and he said, "Marie, would you take over ORA 21?" and I said, "What is ORA 21?" "Getting us ready for the 21st century, whatever that means."

And I went home that night and I talked to Richard about it. He said, "Listen, you like to be in control of your future. If I were you, I'd take it." So I did, and I wasn't sure what it was going to turn into. I had no idea. I knew we had to make changes, and I started meeting with other federal agencies, and we developed the Compliance Achievement Reporting System, which was a brainchild based on the Government Performance and Results Act, and that database is still in use today, coined CARS.

And basically, the thought was that, when I was in the Office of Enforcement, investigators would go out, say, to do a check to see if the goods were still there, they would do an availability check, because we don't want to bother a U.S. Attorney unless the goods are there to seize. And, of course, the investigator would go out to do the inventory, and the firm would call their food and drug lawyer, who would say, "It looks to me like FDA's going to seize the stuff." And the firm would say, "Well, then, I guess I'll just destroy it." The investigator would go back, tell the compliance officer it was destroyed. The compliance officer would say, "Damn you! You've ruined my seizure

now.” That did not make sense to me. If in fact we can get violative goods voluntarily destroyed, it saves this agency a lot of money. And we evaluate our investigators on how many seizures and injunctions, and that’s the wrong focus. That’s not focusing on the mission of FDA, and that is effective and efficient consumer protection. And if an investigator can get correction right there when they’re out to do an inspection, that’s the best consumer protection you can get.

RT: Sure, and the most economical.

MU: Right. And so that’s when, in 1996, we put in place the Compliance Achievement Reporting System. I remember Doug Tolen calling me and telling me he was so pleased with CARS data. He said he had a seafood firm with decomposed seafood, and he said, “You know, in the old days, I would have sent in a seizure.” Three months later he’d get back to me and we’d seize it. I called the company and explained the situation. They destroyed everything, recalled what was out there, destroyed that. He said, “I got far more consumer protection than had the District gone the old way of recommending a seizure.”

RT: In the earlier times, you’re right, the criteria for really success, as an investigator anyway, and probably as a manager, was the number of regulatory actions in the courts. And the case news reports that used to circulate, some cases would go on and on for a long time because of delays and so on.

MU: Right, right.

RT: This certainly is a step forward.

MU: And when I was in the Office of Enforcement, Jerry Bressler was the Compliance Branch director in Chicago, and Ed Atkins was the Compliance Branch director in Orlando, and both of them were my high producers of seizures. And so when Ed would send one in, I would call Jerry Bressler and say, "Jerry, I just got another one from Ed Atkins. It looks like he's going to beat you." The next week, I would get a seizure in from Chicago and I call Ed Atkins, and "Guess what? Jerry Bressler just sent a seizure in," and Ed would get me a seizure. That's a good way to get your numbers up.

RT: Sure.

MU: Competition.

RT: I remember Jerry Bressler when he was a plebe inspector going out with Charles Curry from Chicago when he was being trained in tomato industry inspection and then worked in the State of Indiana. We had a pretty close liaison with FDA. Recently, I interviewed Jerry for the FDA Oral History Program, since he retired. It was evident that he had matured into a pretty good compliance director.

MU: Yes, he did; yes, he did. And when he was there and I was in enforcement, Burton Love said, "You make sure you keep Marie informed of things. Don't you pull anything." So he would call me constantly.

And I remember one time I answered the phone, and he hooked me up with the U.S. marshal who was out in a bakery seizing product, and Jerry's saying, "Marie, they want to know if they can put that in the refrigerator." And I said, "Jerry, it's under the order of the court. They're not my goods. They're the courts'. The marshal is acting on behalf of the courts. He can do whatever he wants. He doesn't have to get my permission."

RT: Well, he evidently wanted to do the right thing.

MU: He was told to keep me informed, so he did.

Anyway, then, going back to ORA 21, which started in 1995, we started doing a lot of good in changing things. We changed, I think, the culture. Ron Chesemore sent a number of memos about how we needed to change the culture and we needed to think outcomes and really focus on the mission of the agency.

And I remember one day I got a call from Bruce Smith, who was with the National Performance Review, which was Vice President Al Gore's reinvention-of-government initiative. And the guy said, "I understand you're doing a lot of good things with CARS and other great things that you're doing. We want you to come down and

meet with us.”

So Gary Dykstra was the deputy ACRA, and he and I went to meet Bruce. There were several other people who used to come in on detail with me all the time when I was in that office. Almost every month I would have somebody from the field on detail. And we went down to their office on 17th Street, and they sat on one side of the table and we sat on the other, and it just was like a wonderful experience and exchange back and forth of all the great things that FDA was doing. And they said, “You know, you need to meet with EPA and you need to meet with OSHA [Occupational Safety & Health Administration],” and I did.

I met with OSHA: “What do we do from now on?” And what we did is we formed an Interagency Regulatory Reinvention Forum, and we’ve changed it now to the Interagency Regulatory Forum. But it still goes on today. And not only do regulatory agencies attend it, but other agencies, because it’s the only big communication in Washington, D.C., for federal government to find out what other federal agencies are doing and what OMB’s [Office of Management and Budget] expectations are. And so that meeting goes on every other month still today.

And then we started getting the Hammer Awards. The Hammer Awards were given by the vice president for good reinventions, and we were way out there. I got one for CARS, but we started really getting ORA a lot of Hammer Awards, and a lot of people would say, “So what?” but the important thing was people are being told they’re doing a good job. And some of our Hammer Award presentations were elegant and some were not.

And there was one that wasn't tremendously elegant, but it touched my heart, it really did. This was Lynn Isaacs in our Orlando District, and she had partnered with the elderly community, and she taught them food safety. And they in turn went out and taught others food safety. So she was able to reach millions of people by leveraging through these elderly people, and they loved doing it.

And the fellow -- and I don't remember his name, but he worked for the vice president in his Reinvention Office, and he and I went down to do the presentations, and, of course, I introduce him that he works for the vice president. Well, I guess they think his office is next door or something because this is incredible. So they get their Hammer Awards, and I've just never seen a bunch of people so excited. And when we finished the presentation, I said to him, "Well, we have to get him to an airport in half an hour, so if any of you ladies would like to have your picture taken with him," whatever.

The next day I talked to the head of NPR [National Performance Review], Bob Stone, and he said, "You know, Marie, he came back and said he's never had so many women kiss him in his life." To see the happiness of those people. I thought, they'll continue to partner with FDA and they'll continue to do outreach for us.

RT: That's good.

MU: Yeah. That was a very touching one for me.

But we had many. We had the medical-device industry.

I remember Georgia Layloff had gotten four Hammers. She said she was going to

do earrings and a necklace or something. And Elaine Messa was very good at getting a lot of Hammers. Doug Tolen was very good at it. So it was spreading around.

Fred Fricke got a Hammer Award for his international partnership. And Tony Blair was coming in and we decided that we would try to have the ceremony while Tony Blair was in. And as it turned out, Fred Fricke and his international partners went down to the White House and had a breakfast with Vice President Gore and Tony Blair, where they received their Hammer Award. Pretty exciting, you know, pretty exciting.

So, yeah. We had a lot of good awards out there, and we were very proud of them.

The other thing that came along then was customer service. The president had set an Executive Order for agencies to do customer service, and regulatory agencies thought, "That does not apply to us because we don't have customers." Then in 1995, the president issued another Executive Order and said, "You regulatory agencies better start getting it too."

Now, I know everybody had angst over it, and I used to say, "I don't care what you call the industry. We just have to survey them. Don't call them a customer. Call them a compelled customer. Call them something, but we have to survey them, and that's what the Executive Order says." And we did.

I went to each Center director and each associate commissioner and gathered money so that we could have a contract to survey, and we decided that as an agency. I formed an agency group, and we decided to survey regulated industry, states, consumers, and health care providers, and it was kind of interesting. A lot of the attributes since

we're regulators, but are we professional? Do we treat them professionally? Things like that go a long way. It's not that the industry is a customer. It's just that we have to conduct ourselves in a professional way.

RT: As far as the public is concerned, I assume that part of this ORA 21 activity involved getting soundings from consumers as well about the agency.

MU: Absolutely. We did a lot of outreach then, a lot of outreach with both the industry . . . We did a lot of industry training back then, too. But a lot of outreach.

I think that that's when the public affairs specialist, recognizing they are frontline, they are our risk communicators out there. There's an agency risk-communication group now that has been formed under FDA's Strategic Action Plan. I am the ORA representative, and I said, "You know, we have forty-five people out there in America and that is their role, to do risk communication. And so as we are to develop training on risk communication, let's make sure that the public affairs specialists are part of this.

RT: Sure.

MU: And so I think that program became heightened at that point as an important program.

RT: Good.

MU: And now everybody has customers. That's the term everybody uses: partners, customers, whatever. So it's just the changing culture.

RT: Well, that's, I think, very good.

MU: Yeah. And then, well, Richard became the regional director out in the Pacific Region, and, of course, I had a staff here in the Parklawn Building.

RT: When did that occur?

MU: Nineteen ninety-eight. Richard went out in March. I had to sell the home and all that stuff, but basically Ron agreed, and Kathy Vengazo, in personnel, believed my program was national in scope and therefore it could be done from any location.

RT: When you got out to the regional office, what was your position?

MU: I stayed as director of ORA 21. I was just managing my staff from Oakland, California.

RT: Good, that's great.

MU: Yeah. The only downside to it from my perspective was, when you're on a conference call, you don't have the benefit of body language, so you do miss some of the communication.

But I flew back a lot, obviously, came back here for various issues.

RT: You were out there how long?

MU: Two years.

RT: Then Richard came back to headquarters?

MU: Right, right.

RT: When you came back, you continued in the same capacity?

MU: Right. Well, not quite. Let's put it this way: it evolved. By then, Ron Chesemore had left, and Dennis Baker was the associate commissioner. And so we came back, and since it was already into the next century, we decided ORA 21 was not a good name anymore. So we changed it to Performance Results Staff to help ORA go to outcome measures rather than numbers. And so we worked with various offices, particularly FDA's Office of Planning.

And then, John Marzilli was the deputy ACRA, and he asked me if I would begin

Iowa. I was to inspect Fort Dodge Laboratories. And one side was biologics and the other side was FDA-regulated products. And while FDA tries to control the manufacturing, USDA's approach is end-product testing. And so when they went to do the inspection and the manager found out that I was with FDA, he said, "Please, you have to understand. This is my biologics side. They don't have the same standards as I have on my human or my animal-drug side," because we just have a different approach to regulating.

RT: Okay.

You have an outline, so I'm going to let you move to the next point.

MU: Sure, okay.

Well, in 1989, I decided I had done a couple trips to the field, like one- or two-week details, doing GMP inspections or tissue-residue inspections, and I really wanted to get more experience. And so it was 1989, and I think it's like April, and Ron Chesemore was the Director, Office of Regional Operations, and it was a Friday that I called him. And I said, "Ron, what can I expect to face when I go down to Orlando District as Director of Investigations?" And he said, "You're going to face hell." He said, "We just got a call about Chilean fruit and the cyanide in the Chilean fruit." So I flew down to Orlando.

Richard Baldwin and I were by then dating.

And I got down there Sunday morning, and he called me about four in the

an executive secretariat type of office, because correspondence was getting lost, nobody knew who had it, we were not timely about anything because there was no system to manage correspondence. So we started that, and, in particular, we got correspondence from the FDA's Exec Sec Office, and a lot of congressionals.

RT: There was still a separate Executive Secretariat for the commissioner.

MU: Right. He has his, and now ORA would have their own Executive Secretariat.

Which is aligned with what the Centers have done. They all have their own offices, too. And so we set up a database, CORRTRACK, to manage them, and that started in, I guess in 2000, and it still exists today. And a lot of congressional activities.

RT: In regard to congressional activities, did you work in liaison with the Office of Legislative Services or Affairs?

MU: Right. I worked a lot with the Office of Legislation, a lot.

RT: When there's a hearing, do you have a role in developing testimony, or is that still carried by the Legislative Office?

MU: We help with testimony. We help with briefings. I mean, I think the one that, the biggest one I've done for John Taylor was the Miami situation. This was after a few

staffers visited Miami, and the Import Office down there wasn't following procedures. And they had become very antagonistic with the Customs agent, and so the Customs agent told the staffers some of the problems with FDA, and they started sending in letters with questions. As it developed, John asked me to look into it and find out what was going on. There were quite a few situations where our Miami import people, instead of complying with the law and notifying the consignee that we were detaining it, they decided to consider Customs the consignee. And so they sent one letter of detention to Customs. And there was one particular shipment that the staffers were aware of, that was 1,233 packages of Viagra coming into this country. And it got into a big issue because they were released and Congress found out about it, and then we had a hearing. John has been at a lot of hearings on imports. Imported drugs are probably *the* hottest political thing. It's the next dietary supplement for the agency.

One hearing that John testified, one senator was killing him for allowing the drugs in, and the other was yelling at him for not letting them in, so you can't win. It's very political. And we testified and testified that we cannot assure the quality of drugs coming in from foreign sources.

RT: This seizure or detention you mentioned a moment ago was Viagra. What was the problem with that drug?

MU: It was an unapproved new drug coming in from Belize.

RT: I see.

MU: And it wasn't counterfeit in the true sense of counterfeit, but it certainly pretended to be Pfizer's Viagra.

RT: I see.

MU: And, of course, now imported products are a huge problem.

RT: We've had international terrorism, and now we have the Office of Homeland Security. This situation has impacted on the Food and Drug Administration and their work and their priorities, too, has it not?

MU: Absolutely. The bioterrorism legislation of 2002 has given us a lot more authority. Prior notice. They have to notify us ahead of time what's coming in so that we have an opportunity to determine whether this could be a product likely to be involved with a terrorist attack. And so we've now got a Prior Notice Center down in Virginia, where this is all managed. So before we go through our normal way of doing imports, it has to get cleared at the Prior Notice Center. Then we treat it like we normally would imports from before.

RT: Has the agency received an increase in budget or funding for these activities, or has

it had to be absorbed?

MU: We got 655 new FTEs for the field for investigations, mostly investigations, but some laboratory and I believe a few to OCI. And then I think we hired another 200 that year just from attrition. So we had about 800 new people that year.

RT: Who in the agency is the lead or the liaison with the Office of Homeland Security? Does that come to John Taylor as . . .

MU: I think primarily it's coordinated by Ellen Morrison. Which is one of the reasons she's no longer in the Office of Regulatory Affairs. Because of crisis management, it was lifted up to the commissioner's office. So she's the one that works with the Department of Homeland Security in coordinating various activities or exercises or tabletop exercises that have been conducted.

RT: Well, does that bring us pretty much up to . . .

MU: Yes, to where I am today.

RT: Where you are now?

MU: Where I am today. Right, right.

RT: You certainly have had a varied and, I'm sure, a challenging career, and you'll be missed, I'm sure, when you retire. Do you have a sense of the continuation of your duties?

MU: Absolutely, absolutely.

The Office of Legislation is upset that I'm leaving, but Fran Noyes is there, and she won't be up to speed right in the beginning, but she'll get there.

RT: Now, that's Fran . . .

MU: Noyes, and she was Dennis Baker's secretary and then came down with me as a management analyst.

RT: Well, this has brought us to where I suppose we could close; however, Marie, before we finally close the interview, I'd like to cover in a little more detail the work you're doing in ORA's Executive Secretariat. We earlier touched on it, but I don't think we really got into much detail about it.

MU: Okay. Well, it's a hodgepodge of assignments. It's sort of anything John Taylor wants me to do. In addition to managing his correspondence, both his correspondence, the commissioner's correspondence, and correspondence from the Office of Legislation,

managing it. The Office of Legislation, it's either going to be from a for a constituent or generally from a committee because they want to have a hearing or they're investigating. Right now I've got one with the American Red Cross down in Atlanta, with Senator [Charles] Grassley. We've had a lot of import problems too. About 90 percent of stuff I get from constituents up on the Hill are import issues. So I know more than I ever wanted to know about imports.

RT: Do you or your staff do reporting or transcription of conferences and meetings that ORA has?

MU: Well, one thing we have done is, this is something John Marzilli asked me to do, actually, when I was out in California when I was just coming back. The Department has a courtesy contract, and this is a contract for scientific international activities, and ORA was not getting any money from it. And John asked me if I could help, and Carol Montalvo from Field Science was on it, but nobody was responding to her when she'd ask, and nobody paid attention to it.

So I got into the field and got a bunch of proposals for international activities. In particular, Fred Fricke had a number of international scientists he wanted to bring in. I've had \$15,000 for a GLP [Good Laboratory Practices], international GLP meeting; EU activities; health fraud activities; bringing scientists here, or speakers, and then part of that money can go for translations.

RT: Translation of documents from other nations?

MU: Right, right, yeah. Like a speech or something, and you're translating it. We've gotten quite a bit of money. We've probably gotten about \$70,000 each year.

RT: You had on your staff persons who are linguists or translators?

MU: Well, no. They pay for this. International Affairs pays for all that. They have it done. I don't know who they have. They have it. It comes out of the courtesy contract.

RT: So it isn't a function of the staff *per se*.

MU: Right, right.

I mean, in addition to just the correspondence, I've also been assigned to both, well, to CDER, Devices, and CFSAN's risk-based fieldwork planning. So I helped with the '05 work plan for Drugs and Medical Devices to set up a risk-based approach to performing our inspectional program.

TAPE 2, SIDE A

RT: Continuing now about the Executive Secretariat, Marie.

MU: Okay.

One of the things John assigned me was the GMP initiative for the 21st century. There are a number of subcommittees, and one of them was to develop a risk-based work plan for the field for '05. So this year I worked with the Center for Drugs and some experts on risk management to develop an '05 work plan that is risk based. And it's a quantitative risk-based approach, so it's far more sophisticated than what we've done in the past.

I also was the area representative to Devices risk-based work planning. They took a little different approach, but certain device classes will have priority inspections because of recalls or adverse events associated with them.

And CFSAN. I was on their risk-based -- it wasn't work planning; it was just a process, to put in place a process of strategic problem-solving and risk-based approaches.

RT: And, Marie, in the Executive Secretariat, how large a staff do you have besides yourself?

MU: Actually, we're very small anymore. Betsy Adams left last December. I have Fran Noyes and the secretary, Isabel. That's it.

RT: So it's a very small group.

MU: Very small group, yes.

RT: And staff.

MU: Right.

Also, John assigned to me Good Guidance Practices. It used to be managed in the Office of Enforcement. Now I have that. And that's just tracking Good Guidance Practices that are final and then those that are under development. And then they have to publish in the *Federal Register* annually on ones under development, which I think probably is this summer.

Well, risk communication. There's an agency Risk Communication group, and John assigned me to that. It really gets into our Public Affairs Program because they really are risk communicators.

Because of my understanding of the Government Performance and Results Act, which measures outcomes, I'm put on a lot of agency committees to help the agency get to outcomes. So I've been working with the Office of Planning on ORA's business practices: what do we do well, what don't we do well, what do we need to do and what don't we need to do?

Let's see.

Oh, for the financial people -- and this started a few years ago -- Jeff Weber, who's the financial manager. We were in some meetings, and he, I can't remember exactly, but I decided I'd do little one-page state write-ups. And when the commissioner would visit appropriators, he'd have that. And what it would say is what industries in that state, what food, how much food, what percent, medical device, drugs, so it would break

down in the different FDA-regulated industries; and then all state contracts and partnerships; and then highlights of things that are unique to that state. Gives them FDA's presence in that state, and this is the industry that we're regulating within your state, and we've worked very well with your state agencies and here are some contracts and partnerships. So it started as just a one-page for each state, and it was really to help with those appropriators. But it got to be very popular, so now I do all fifty states annually every February, and get them out to the public affairs specialists so they have it when they do congressional visits.

RT: The data that you develop then goes to the district or to the regional or the district.

MU: Uh-huh, right.

RT: And to the program provider.

MU: They all get a CD-ROM with all states on it. I help the Office of Public Affairs with their ORA fact sheets. These are their, again, one-pagers about what ORA's activities are. For example, one they just sent me talks about how many people we have and what is the industry we regulate, and I sent it back to him and I said, "Don't send me this until the end of October because we won't have our numbers in until the end of October."

RT: And that data is then used in what way?

MU: It's put up on the Internet. With fact sheets on any hot issues, like BSE [Bovine Spongiform Encephalopathy]. Anything that's highly visible, they try to do a fact sheet and put it up on the Internet.

RT: That's accessible by any interested parties.

MU: Right, right, right. Let's see.

Well, I mentioned to you, there's a lot of congressional investigations, and I'm always wrapped up in the middle of a congressional investigation.

RT: I asked earlier about the commissioner's Executive Secretariat being a separate staff. Do you parallel with them or track with them, or are these coordinated in any way?

MU: Oh, absolutely. I mean, we work very closely. Anything having to do with ORA, they'll bring to me, and then I'll coordinate ORA's response. And a lot of it is for the secretary's signature or the commissioner's signature, or some things they'll delegate down to ORA and I'll do it for John Taylor's signature. Some of these pieces of correspondence I'll sign myself. But, yeah, we work with Exec Sec on correspondence that comes into the Department and to the commissioner. Although I would say the bulk of it seems to be the Office of Legislation.

RT: Now, when you first came into close proximity or association with the commissioner, was that Dr. Young?

MU: Right. We had Frank Young. We had low-level antibiotics going on, and we had an Imminent Hazard Petition, and I put on a huge public meeting at the NIH Mazur Auditorium, very medical, and Frank Young. We went from eight in the morning till eight at night, and it was very well received by the press. That was really my first big interaction with the commissioner.

RT: In your position, you have worked with each successive commissioner since Dr. Young.

MU: Right.

RT: Do you have any impressions that you care to share about any of the commissioners or the top-level managers. I'm not soliciting criticism, but just wondering if you had any reaction, from where you were, to their *modus operandi* as head of the agency. Each have had, of course, different priorities.

MU: And different agendas.

RT: Right.

MU: Yeah. I mean, Dr. Kessler came in around, I guess 1990 was when he came, and enforcement was his big thing, and he pushed very hard for enforcement. And while he was criticized for some of the things he did, he really got the bang for the buck, and a perfect example was the orange juice seizure. Oh, wow, he's seizing it, wasting our resources just because it said "fresh." In fact, we got more compliance by other food commodities from that one action than we could have ever gotten otherwise. It was incredible. Everybody else was looking at their label and getting it fixed. So we got a lot of compliance out of that one action.

And, of course, he went after the breast implants, which was a big one of his initiative.

So, yeah, he was really the enforcement person.

Then when, I guess, Dr. [Mark] McClellan came . . . No, Dr. Henney was here too. I forgot about Dr. Henney. Isn't that terrible?

RT: Understandable.

MU: Yeah. Dr. Henney. I did a lot of stuff for her on the American Customer Satisfaction Index. This was started by the vice president's staff. Prior to that, only the private sector participated in this index. And various federal agencies were going to get involved.

And so I met with Dr. Henney, and she decided that she wanted us to interview or have the survey under contract of principal food shoppers, and they would have a line like the USDA does this, the FDA does this, and then whichever direction the consumer went, they'd either survey them about USDA or about FDA. And that came out actually very good. We got a 66, if I remember correctly, index, which, for a regulatory agency, is very, very good. Regulatory agencies are not loved by the world.

RT: You said 66. What does that mean?

MU: Out of 100. It's not a percent; it's an index that the University of Michigan has developed. And we got a little bit better than USDA FSIS. We scored a little higher there. But we were one of the higher of the regulatory agencies. The service agencies obviously, you know, I forget what agency, but it's one that gives out money, so obviously, here's your money and, by the way, what do you think of my service. For us, it's different, and it was tough to educate the vice president's staff that regulatory agencies are different. And HHS. HHS wanted to publish all of the scores. I think there were three of us that participated. ACF was one of them, the Administration on Children and Families, and one other one participated. Well, they had better scores than us because they're service. And so I fought to not publish all three scores together because how would the public understand that? They'd look at that and say, "Well, look, FDA got the lowest and HHS," and that's not the way it should be interpreted.

Several years in a row I worked on that with Dr. Henney. And I know that the

vice president sent her some letters about me and the stuff I was doing.

See, I got to know her fairly well, fairly well.

And then Dr. McClellan came in. I really like Dr. McClellan. I think he's an absolutely brilliant, brilliant man.

RT: In the time that Dr. McClellan was here, of course, he's moved on up into the Department in a more responsible job, but were there any accomplishments or any issues during that period that should be mentioned?

MU: Yeah. I think the most impressive. We were getting him ready for a hearing on ephedra, and we were concerned about the reaction toward Dr. McClellan in a hearing on ephedra, the dietary supplement. We were afraid he was going to get badly beat up because we'd known of ephedra since the early '90s and still haven't done anything. And, in fact, it was a love feast. It was an absolute love feast. He just said, "You know, I've been commissioner for seven months. Look at all I've done in my seven months I've been here. We're getting there, folks. I'm trying to do the best I can."

"Oh, yes, you are, and we'll support you a hundred percent."

It was an incredible hearing. It was a love feast. It was just incredible. I was utterly impressed with him and the way he handled himself in it. For a young guy, he's pretty darn sharp.

RT: Let's see. Currently, FDA's stewardship is in the hands of . . .

MU: Dr. [Lester] Crawford, who I have worked with many, many times when he was in the Center for Veterinary Medicine. And, in fact, I just ran into him this morning because he congratulated me on my retirement. Yeah. He knows the agency. He's been around. He was in CVM. He's always been involved with regulated industry somehow, so he's very knowledgeable of FDA programs. So when he came as deputy and then acting commissioner before Dr. McClellan came in, I know I had a few meetings with him, and one was the Customer Satisfaction Index because we wanted to continue it, and so he gave me the money necessary to continue that contract.

This past year we stopped it because it just, the budget's so tight, even \$30,000 is tight to find.

RT: Yes.

MU: Let's see. What else?

RT: Well, if we had stopped before, we would have missed inclusion of what you've just been speaking about. This information has made more complete the record on what you and your unit are doing for the agency.

MU: Right. Like I said, a lot of it is the Office of Legislation. It's just incredible. That takes up most of my time. There's just a lot of congressional oversight. And the

importers, I think, in their SOP's, it says, "If you don't get your way with FDA, contact your congressman," and they do. And invariably I get these calls about an entry, and nine times out of ten it's not FDA's issue. The broker didn't provide the right records; they didn't code the product properly; it's been released but the importer didn't know because the broker didn't communicate. It's amazing. Most of the time it's not our issue, or it's already been released. "What are you complaining about? We already released it." Because by the time the constituent goes to his congressman and his congressman forwards it to Office of Legislation (OL) and OL gets it down here, we've already released the lot.

RT: Well, thank you for giving us a little further insight into the Secretariat function.

MU: Okay, great.

RT: And regarding the Office of Regulatory Affairs.

MU: Great.

RT: Thank you very much, Marie.

MU: Okay. Thank you.