

**History**  
of the  
**U.S. Food and Drug Administration**

**Interviewee:** Margaret O'K. Glavin

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

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**Place:** Rockville, MD



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Interview with Margaret Glavin

October 1, 2008

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, October 1, 2008, we're interviewing Margaret O'K. Glavin, who recently retired as Associate Commissioner, Regulatory Affairs. John Swann and Robert Tucker are conducting the interview.

Maggie, if we could find out where you were born, your early educational history, and what led you to the Department of Agriculture, and later to FDA, then we could cover your FDA service.

MG: I was born in Elizabeth, New Jersey, and I went through grade school in Richmond, Virginia, and then went to high school in Summit, New Jersey, to Saint Bridget's in Richmond, Virginia, and to Oak Knoll in New Jersey.

JS: Oak Knoll, did you say?

MG: Yes. And then went to Trinity College here in Washington, where I majored in English.

I guess my interest in the government and in science, both came from my father. My father was a scientist. He was a research chemist, and he spent most of his life

working in private industry. But at the time that I was in college, he had joined the Environmental Protection Agency. So one piece of it was his lifelong interest in science, and the second piece was he really liked the move to the government service and encouraged me to do the same.

So when I was a senior at Trinity, Agriculture, the Department of Agriculture was interviewing people at local colleges because they were hiring. That was the days of the Great Society, and there was a lot of hiring going on. And so I was interviewed for a job in the Food and Nutrition Service, which was and still is the home of some of the big Great Society programs: food stamps, WIC, school lunch, school breakfast. So that was where I worked for the first probably 15, 17 years of my career.

RT: When did you get your degree from Trinity?

MG: I graduated in 1968.

JS: So you went right into the Department of Agriculture after graduation.

MG: Yes, I did. Well, pretty much. I went to Australia for the summer.

JS: That must have been fun.

MG: Yes. My sister was living there.

When I came back, my parents were quite anxious that I get a job, so they made it real clear that was the next step in my life.

JS: So you started out in the Food and Nutrition Service working on some of these programs that you mentioned. What sort of things were you doing? Sort of administrative work?

MG: Actually, I started out writing regulations. First I was working with the Child Nutrition Programs, not food stamps. That agency was divided into food stamps on one side and all the other programs on the other, and I was on the other. There had been new legislation passed before I came on board having to do with providing free meals to needy students as part of the school lunch programs. As a requirement to getting funding for the school lunch program and school breakfast program, schools had to provide free meals, and there needed to be regulations written. So there were a couple of us who had just been hired and were just told to write regulations, and we did. So that's what I did for the first couple of years there.

RT: So, had you obtained any kind of training on your own, or were you given in-house training for that kind of activity?

MG: A little bit. There were people in the General Counsel's office who were very helpful. But it was a little bit, you know, here it is, here's the law, read the law, and start working on how we're going to implement this.

JS: You obviously made an impression because you were in the Food and Nutrition Service for a number of years, but you became the Deputy Administrator for Special Nutrition Programs in the Food and Nutrition Service still. So, what led to that, and what were some of those responsibilities you had?

MG: Well, what led to it was really that this agency was growing by leaps and bounds. It wasn't called the Food and Nutrition Service when I joined. It was part of the Consumer Marketing Service. It had been very small. Those programs had been very small. They were growing by leaps and bounds, so if you sort of showed up for work and weren't a complete goof-off, there was a lot of opportunity. So, really, it was, if you were willing to work and weren't too stupid, there was a lot of opportunity. So I moved through supervision and management pretty quickly.

RT: When you first came in, what entry level did you start?

MG: I came in as a grade 7.

RT: Well, that was pretty good because a lot of folks started in FDA at a 5 and then went to the 7 after some experience on the job. That was a good start.

MG: There just was a lot of opportunity.

JS: The time you were in this position also coincided with a time in society and government, and especially in Washington, when, you know, government service is starting to be looked upon as something that may be more of a problem than a help. At least that's what a lot of people are being told from the White House on down. I'm just curious. What did it feel like? I mean, having played such an important role in programs like these in the Department of Agriculture, a lot of us don't have an appreciation, I guess, for what it must have felt like; I certainly don't, what it must have felt like being a dedicated civil servant at this time.

MG: Well, I think the programs that I was lucky enough to have really fallen into -- I can't say I really planned this -- were programs that do a lot of good on a very personal basis for a lot of people, and so it was sort of a feel-good kind of job in that sense.

Certainly, they grew very rapidly during President Johnson's administration, and even during Nixon's. They were still very supported. And being part of the work, there were a number of big television series on hunger in America -- I don't know if you remember this -- that went into places not very far from here, West Virginia, Kentucky, and into communities where children were stunted, where there was no food on the table, where people were feeding their children mud, and it was just . . . So, "Hunger in America" -- and there was a follow-on to it a number of years later -- was very much in the news. And Johnson was really committed to, despite getting, of all things, the Vietnamese War, really committed the Great Society programs.



RT: These programs, as you suggest, had public appeal, perhaps more than in the later period of regulatory affairs initiatives.

MG: Yes. I mean, certainly, there's always been political talk about how terrible regulation is, and we're squelching initiative. But this really wasn't a regulatory agency.

JS: These media programs you mentioned, were they just done by the press or by documentary filmmakers?

MG: There was a documentary on one of the major networks called "Hunger in America."

JS: Did they draw upon the expertise in your department for any of these, background or more?

MG: I would guess they did, but I don't know that.

JS: Was there a sense, not necessarily connected just to regulators, but a sense of, "I am from government, I want to help you, and this is a problem," as we were told? I think people who worked for the civil service at the time might have had a reaction to that sort of sentiment.

MG: Well, and certainly, with the antiwar sentiment, it was, that sort of increased.

I can remember I used to walk -- my office was in Rosslyn, and I used to walk across the Key Bridge to work. And I can remember walking with a black armband on my sleeve, and people screaming at me, just stopping the car and screaming at me. Get a grip! So it was an interesting time in Washington.

JS: Well, the next position, the next place you moved to within the department is where you spent the rest of your time in the Department of Agriculture, and that was in the Food Safety Inspection Service [FSIS].

MG: That's right.

JS: That was in 1984, where, of course, you served in a number of positions. But can you walk us through a little bit about the move there and how your responsibilities changed?

MG: I worked with that part of the department because a large piece, much larger in those days than it is now, of the nutrition programs was commodities, commodity donations, and that was handled by the part of the agency that FSIS was part of at that time, so I knew people there. That was how I got there.

When I came in, I was a special assistant to one of the deputy administrators. Then I became the head of the labeling, and the meat and poultry products, all labeling is prior approved. All meat and poultry labels are prior approved.

RT: The Senior Executive Service had been progressing along personnel-wise. When you went to this assignment you're speaking of now, what grade level had you achieved then?

MG: Well, I was in Food and Nutritional Service, I was an SES, and I resigned from the SES in the Reagan administration at the request of the administration, and so I was again a 15.

RT: Right. And how many years was that again, 15 or 20, since you came in?

MG: I came in in '68. And when did I go to FSIS?

JS: Eighty-four.

MG: Okay.

RT: So you moved right along.

MG: Yes.

RT: That's great.

JS: So you had to resign your position in the service, the Senior Executive Service.

MG: Yes.

JS: Okay.

MG: Those things do happen.

JS: Yes, they do.

MG: Christmas Eve.

JS: Oh.

MG: That was really nice.

JS: Oh, yes, good timing.

MG: Yes, yes. Anyway . . .

JS: You mentioned before, when you were talking about how labeling, how poultry and meat products had to be preapproved.

MG: Still does.

JS: Still does.

MG: Yes.

JS: How is that done? Is it something that's negotiated?

MG: Well, with the industry, you know, there's a lot of consultation back and forth. There are regulations, as there are here, on what can go on the label and what can't and what has to be on the label and what can't be on the label, and so there's a lot of consultation on that. The industry submits a label for a product, and it is reviewed.

Now, in practice what happens is -- I don't know if this is still true or not, but in those days there were legal expeditors; there was a whole industry of legal expeditors. This is how the government works.

JS: These are people in the government?

MG: No, no. These are people who, for a fee, hand-carry your label applications

through the system. Otherwise, it just sort of fell into a black hole. It was a whole industry, a whole cottage industry in Washington. Yes.

JS: Well, it sounds kind of like the FOI (Freedom of Information) cottage industry and how they work with people who maybe want to file an FOI request.

MG: Yes, very much, very, very much the same. And so they were people who (1) really understood the rules; (2) understood how to get things through, and they did.

I don't know what change occurred, but there was a change after I left there that caused that industry to sort of go away.

JS: So, what drove this kind of a change?

MG: I mean, you could not market your product without an approved label, an officially approved label, and so if you had a can of Campbell's chicken noodle soup and there was a standard for, I don't know how much chicken had to be in it, etc., etc., and you wanted to say "chicken noodle soup with more chicken" or "chicken noodle soup with all white meat chicken," I mean, it was like a whole new thing to get it through. You would have to say what is white meat, does it include the thigh, does it include the wing, what is "more." How much more does it have to be to claim it on the label, there's more? So, yes.

And, I mean, you know, it sounds sometimes as if CFSAN thinks wouldn't it be nice if we had a prior-approved label for this, but it's really crazy because each one

becomes a precedent, and so you sort of say, okay, for more chicken, you have to have at least -- make up a number -- 8 percent more chicken than the standard was. So when somebody comes in with more beef, do you remember that and say it applies to beef also? Or does somebody else look at it and say, well, it's got to be at least 9 percent, and then you've got these things that go and, you know, they get more and more different over time, and it makes no sense.

RT: I wonder if your agency had a PC or precedent correspondence file. This agency at one time, before the days of computers, had a little office down in the Commissioner's area in F.O.B. 8 that had lots of precedent letters, and whenever somebody had an issue like you're speaking of, they would consult that repository to keep uniform interpretation.

MG: Yes, there was something similar to that, but, still, differences creep in. I mean, this was thousands and thousands of labels to get approved every year.

JS: For the sake of those that are listening to this who maybe don't know, what's essentially the difference between the way things are done there and the way things are done with food products that come before FDA?

MG: Well, the label is put on the product. There are certain rules and standards, food standards, etc., but lots of products don't fall within those criteria. And so in FDA, if somebody wants to say "more carrots" in vegetable soup or whatever, or say "carrots are a good source of vitamin A," they would just do it. And if FDA didn't like it, if FDA

didn't have a written policy on it, FDA would have to go after the company and say, "Take that off, and here's why. You can't market that or we'll seize it."

JS: So it's an after-the-fact arrangement as opposed to the way things were with poultry and meat product labeling.

MG: Yes.

RT: This agency, FDA, of course, got into food standards. Did USDA develop standards for formula products?

MG: Yes.

RT: I would think so. Otherwise we would not be consistent across agencies.

MG: Yes. What is ground beef and what is lean ground beef, and the standards define each product. But it certainly doesn't cover every conceivable product which may be marketed.

RT: Well, in our agency, for example, peanut butter, there was a big case about the peanut content in peanut butter, such as not having enough peanuts in the formula. A major food company was taken to task for that. What you've been describing, I wonder if it's also somewhat of a requirement for various products.



MG: Somewhat, yes.

I'm trying to remember why Kessler seized the orange juice.

JS: It was heat-processed, but it was labeled as fresh.

MG: That was it, yes, yes, and that was what FDA did. And it was very effective. He was great at that. He had the cameras on while he did it. So, yes.

JS: That's right.

MG: But, I mean, generally, seizing a product to get it off the market is not something anybody really wants to do. You can pick a good example.

RT: Was the seizure process in Agriculture somewhat akin to that in FDA?

MG: Yes.

But the other big difference is that no product, no USDA product can be marketed unless it's been inspected, and the inspector's job is to determine that the product is not adulterated. So it's really, the laws are in some ways really wildly different. I mean, there's a lot of similarities, but the inspector in a meat plant or chicken plant makes a determination that the carcass is not adulterated, and therefore can be marketed. Until he makes that determination, it is illegal to bring it to commerce.

JS: Well, since you brought that up, I guess, I wonder how the inspector would make that determination.

MG: Well, there are all kinds of standards and rules and what is acceptable and what isn't, and it's basically done on the carcass level, on the animal being used for human food. Well, in fact, now, one part of being not adulterated is it's produced -- and this is by regulation -- that it's produced under a HACCP [hazard analysis critical control point] system. Mike Taylor and Tom Billy cooked this one up, aided by Bob Buchanan, that since an inspector had to determine the product was not adulterated, that they put in regulations. They were regulations that said if was not produced under a HACCP (Hazard Analysis of Critical Control Points) program, you can't determine it's not adulterated. It's a leap, but it stuck.

JS: This implementation of the HACCP system under FSIS, this followed what FDA's implementation of systems, of a similar system too, or did this proceed . . .

MG: It proceeded.

JS: Okay.

MG: At that time, FDA was working on HACCP for seafood products.

JS: Okay.

MG: And, then, juice was later. Was it, am I right? Seafood was first, and then juice.

JS: I'm not sure, honestly.

RT: We had probably some of those same concerns.

JS: We're still working within the period of about '84 to '94, right, before your next position within FSIS? Right?

MG: Well, what's the next position?

JS: I'm sorry. The next position is your appointment as Associate Administrator for FSIS in 1994.

MG: This is after that.

JS: Okay.

MG: It actually was the Clinton administration. Right?

JS: I think you're right.

I sort of wanted to go into another area of exploration in your FSIS work. This is a fascinating story.

But as Associate Administrator and Chief Operating Officer, one of the things you became involved in was in the design and implementation of an organizational change within FSIS, transitioning that agency, leading it from an inspection agency to a public-health-focused food agency.

MG: Right.

JS: Now, that, I'm guessing, would have an impact later on, after, I mean, from FDA's standpoint, when you come to the ORA. But here, can you elaborate a little bit on how this was done, what you did in this context for FSIS?

MG: This was going back to Mike Taylor coming to the agency. His charge was to improve the safety of meat and poultry, and to use the enormous resources that FSIS has. You know, how you use them is determined by law. But to try and focus them more on public health, not just on a marketing tool. So the mark of inspection in one sense can be seen as a marketing tool. You have a mark of inspection, so you have a good product, you have a safe product. And so this was an attempt to say, yes, but you're not going to get that unless there's really reason to believe it's safe.

JS: Do you mind? I just wanted to, because there might be some context here that might be helpful. Were there any events or any sort of public health issues that prompted this growth in awareness at this point in time, any recalls of products?

MG: It was mostly 0157H7 in ground beef, that there were a number of outbreaks of people dying, usually small children because they're the most vulnerable, just from eating hamburger.

You know, I don't know which is the cart and which is the horse. FDA and FSIS put a lot of money, invested a lot of money in CDC (Communicable Disease Center) to set up better surveillance of foodborne illness, and them to set up Foodnet, so the more you look for it, the more you find. And so there's a little bit of what was driving what, but there were a number of high-profile outbreaks.

Remember Jack in the Box? You know, a very respected fast-food place. People very comfortable taking their kids to them. It wasn't a hole-in-the-wall dive.

JS: And, of course, these would prompt the kind of congressional investigations and media attention that would, I guess, kind of focus the need on doing something about this.

MG: Right. So that was sort of the charge, and so Mike Taylor and Tom Billy and others were really focused on what is, and, you know, from the beginning were looking for something like HACCP as the approach to take and worked out ways to do that within the legislative authorities.

But we also had a work force that was . . . You can't run a plant without a federal inspector in it. So, you know, there's sort of variations on this. In a slaughter plant, if there's not an inspector in the plant, you can't operate.

RT: In that context, were there any user fees involved?

MG: Generally not. The inspection is paid for by tax dollars, with some exceptions. If you are doing unplanned overtime, the plant pays for that, pays the inspector for that. But if you have planned 24-hour shifts, the government pays for it. So, generally, it is paid for by tax dollars, to this day. There are other exceptions, like export certificates can be charged.

JS: But you were saying slaughterhouses had to have an inspector in place or they couldn't . . .

MG: They couldn't operate.

JS: They couldn't operate.

MG: For processing plants, they are not inspected as much, there's not somebody there all the time. They're supposed to be visited every day or every several days or whatever.

RT: Yet it's in the processing plants where some of the problems have occurred.

MG: Yes.

RT: Ground beef ones, anyway.

MG: Well, yes, they can be processing plants. Those would be staffed all the time just because it's high risk.

RT: So, how many, how large was the cadre of inspectors at many plants?

MG: Well, the agency was about 10,000 at that point. Most of those were food inspectors.

RT: Were a lot of those veterinarians, or was that a requirement?

MG: The sort of top of the hierarchy were veterinarians, and there had to be a veterinarian in slaughter plants. Absolute processing plants would not have a veterinarian in them. So there were veterinarians and there were food inspectors.

RT: But the non-veterinarian inspector was in some way credentialed for that responsibility?

MG: Not as rigorously as FDA has. In fact, it was while I was still there that FSIS moved to the -- what's our Consumer Safety Officer, CSO, food inspection series?

TAPE 1, SIDE B

MG: FSIS adopted FDA's Consumer Safety Officer series. But many of the inspectors before that had maybe a high school education. I can't remember what the series was, but you needed some sort of an agriculture background. It grew up out of the Department of Agriculture, so it was fairly uncredentialed.

Now, the veterinarians were a different thing altogether, obviously. They had to be veterinarians, have those degrees, and many of the inspectors had food safety or consumer product safety education and experience, but by no means all of them. And I know that's still true today.

RT: Did the Department have some formal training for those persons that weren't previously experienced?

MG: Yes, yes. There was both classroom and on-the-job training. When I first went to FSIS, there were, I think, at least three training universities.

JS: I guess in this transition from FSIS to with a more public-health-focused food agency, really implementing the HACCP standards was a foundation of that.



MG: Yes.

JS: Again, there's change, there's organizational change within FSIS itself that is concomitant with that transition.

MG: Right.

JS: That's something, as COO, that you're very closely involved in. Can you say a little bit about what happened there?

MG: Right. It was looking to make better use of the resources that were there -- obviously, resources don't grow very easily -- and so to streamline some of the structure and to put more of a focus on science by . . . There was the inauguration of a technical center -- I don't remember what it was called for now, but a technical center that was in Omaha; it's in the middle of the country -- that was staffed by -- and this was a new idea -- staffed by people who had expertise in various areas of meat, both the slaughtering process and the processing process and the marketing, so that could serve as a resource for the inspector out in the field. There was much more emphasis put on training to make sure that the inspectors understood HACCP. It just seems so rational, but it's not intuitive; you still have to figure it out and what it meant to inspect in that kind of a situation.

There was a -- I'm trying to remember; I think . . . We put more focus on the district offices and closed the regional offices -- eventually closed all the regional offices.

JS: How many were there?

MG: Maybe five.

JS: And district offices? How many . . .

MG: I think there were somewhere between 20 and 25.

JS: Were laboratory facilities associated with each of those?

MG: Not with each one, no. Actually, FSIS has three labs, three lab locations; they did at that time and still does have three.

RT: Located geographically?

MG: There's one on the West Coast, one in St. Louis, and one in Atlanta, so, yes, they are.

That predates my knowledge; there had been more labs, but they were down to three. These changes were made, and then remained three.

JS: Budget is always a struggle, but when you talk about diminished resources, I mean, we're talking about the need to . . . If you can't get more money out of Congress, you have to deal with what you have. Is that part of what we're talking about?

MG: Well, yes. If a meat plant can't operate because you don't have enough money to hire an inspector, then you don't need to go to Congress for the money, the meat plant goes to Congress for the money (laughs). It's actually kind of a nice little deal. And so starting with, probably with Reagan, I'm sure there was a proposal to get user fees, and the meat industry beat that back every year. They said it was a tax, a meat tax or some such thing. And they've succeeded so far. But, yes.

And so what really gets squeezed is the labs, the processing plants because you can kind of fudge on those, and the overwhelming number of resources are in the slaughter plants, and maybe that's where they belong, maybe it isn't, because they can't operate without inspection during plant operation.

RT: What kind of surveillance, other than at the plant, did the Department have for marketing or sales, anyway, livestock sales of animals that were diseased or . . .

MG: Well, I don't know about the sale thereof, but you can't slaughter an animal unless it has passed inspection while alive. Maybe this is what you're asking.

Certainly the sale of dairy animals is something that FSIS and FDA work very closely together on, because if FSIS finds animals coming to slaughter that are

overmedicated, they go back to FDA because I think FDA -- I know this is right and I'm going to say it wrong -- FDA has a responsibility for prohibiting the slaughter of an animal that has not gone through appropriate withdrawal of drugs. So that's really an interesting connect. It's actually a program that is fairly successful, that FSIS comes to FDA, FDA goes back to the sales volume and starts dealing with it, and will, if there's a pattern from a farm or from the sales volume, FDA will really focus on it. If it's the random thing, they'll do a basic follow-up, but give them short resources. But they've really been very active in trying to get the bad actors out of the system, the ones who consistently sell animals that shouldn't be sold.

RT: So that was the liaison, then, between FDA and USDA. Was that activated through the FSI Service, the Food Safety and Inspection Service?

MG: Well, I think it was a real partnership. I mean, I think the rub was one that hit FSIS, because they ended up with animals going to slaughter that had illegal levels of residues, and so that was where it comes to a head. So I think the initial push was coming from FSIS, but it's obviously a concern to both agencies that shouldn't be. That is a public health concern and needs to be taken care of. I think it's an area where the two agencies work really well together, and over a period of years figured out ways to clean up the system by working together and not having it be a situation where we would say, "Well, we can't do anything." They really work together. I think it's been a success story. I mean, it still happens, but . . .

RT: Well, it probably has because even in Congress we've had members suggest the idea of consolidating the two agencies to avoid problems of that nature.

MG: My prediction is, not in my lifetime.

JS: Well, a lot of people share that view.

MG: It might be a great idea, but . . .

JS: Well, who would have thought that Homeland Security would be what it is.

MG: Yes.

JS: Much more involved consolidations have happened in the federal government.

Before moving on to your position as Acting Administrator, I just wanted to ask what you had believed was important in terms of the reorganization of FSIS and what sort of actually happened. Did that sort of fulfill the needs were to and what the FSIS felt the needs to accomplish that transition?

And also, I don't know what kind of metrics one uses here, but how do you measure the success of that reorganization in terms of what FSIS is accomplishing?

MG: Boy, that's a tough one.

Some of the successes of the reorganization were the tech center, which both the field force and the industry really liked. They felt that on both sides they could get an answer. Whether you agreed with the answer at the end of the day or not, getting an answer, you know, in a regulated industry, and with on both sides was the regulators and the regulated, is really important, and getting it in a timely manner.

I think the labs are also an enormous success. As part of the HACCP scheme and regulations, there's an enormous amount of testing that goes on in the meat product plants by the government. Three labs were beefed up as a result of the reorganization, as part of the reorganization, and they do hundreds of thousands of analyses. Now, they're doing a limited number of screens on, in FDA terms, a very limited range of products, and so it's not like you're giving 50,000 different products coming in the door for 200,000 different issues. But they have really, the resources were put there and there was a new Office of Science put up to really drive this. That was one of the changes, and I think that's been very successful.

JS: That was a change within headquarters organization?

MG: Yes. So I think those are the two big ones they really worked out in terms of making sense of some very high-cost resources. Labs are -- I'm not sure how to say this. But they are very expensive to run, maintain, and staff. So making them as efficient as possible was really important. Technical support is not too dissimilar. It isn't quite as expensive as labs but the staffing needs really competent people with really good skill sets, good communicators.

RT: I think the next step on the resume was your role as a visiting scholar. Was that still . . .

JS: I just wanted to say, who did you succeed as Administrator?

MG: Tom Billy.

JS: Thomas Billy.

MG: Tom left, and I was acting for . . .

JS: Two years, it looks like, 2001 to 2002.

MG: Yes.

JS: Okay. So you succeeded him. Your responsibilities obviously expand, and you are obviously implementing, as Acting Administrator, a lot of the changes that you had engineered before you came there.

Any interactions with Department, with Congress? Anything that stands out in your mind as Acting Administrator during this tenure? Obviously, this also came on the heels, I gather, around the time of 9/11.

MG: The election.

JS: Yes.

MG: The election and 9/11, yes.

Gosh, being Acting in a high-profile position for a length of time like that is really dysfunctional, both for the individual doing it and for the organization. You have responsibilities and you don't have authority, and it's not good for either the organization or for the person.

JS: No. Okay.

MG: And I think the government tends to do it a lot.

JS: Oh, here in FDA, we know that. We know that well.

MG: Yes, and it's not good. My successor, my prediction is, won't be replaced until there's a new administration, a new administrator, commissioner.

JS: Well, the head of our agency during, what, the past . . .

MG: The past eight years, yes. It's not that the person isn't talented and committed,



and not that people are actively undermining. It's just, there's not the authority. I mean, there's so many at the level of Commissioner, at the level of ACRA (Associate Commissioner for Regulatory Affairs), at those jobs, you're making tough decisions all the time, and if you don't have the firm authority . . .

JS: Well, it is a confirmed position. Is the FSIS a politically confirmed position?

MG: No.

JS: Well, certainly the Commissioner of Food and Drugs is, and you certainly speak with a different voice to Congress when you go before Congress with that confirmation in your pocket.

MG: Absolutely, absolutely.

RT: One of the probably long-term effects of frequent managerial changes, administrative changes, one administrator may have certain plans, and they're not there long enough to see all of them achieved, or if they're not good plans, they escape the responsibility for having implemented them.

MG: Yes. Well, I guess in the last eight years, there's a lot of change in Commissioners here, but generally I think people tend to stay in those jobs.

RT: Yes. Well, in the earlier history of our agency, the Commissioner was sort of a career achievement position, and now, of course, that practice is not followed. It's become an administration choice, whatever administration it is, putting their own person there.

MG: Right, right, yes. It's a political appointment.

RT: I was going to ask you, when you did serve as a visiting scholar, you did the research on food safety issues and the food safety system. You mentioned in your resume that you published an article in *SAIS Review* on food safety.

MG: It was the Johns Hopkins School of SAIS.

JS: What does that acronym stand for?

MG: School of Advanced International Studies, maybe. It's SAIS.

JS: We can find it. We'll find out.

MG: It's a Johns Hopkins graduate program in international studies.

JS: Talk about a different kind of life, I mean, as a reflective scholar now, after . . .

MG: Oh, yes. It was like night and day, and it was a really good time. I still stayed Acting; it finally dawned on me, I wasn't going to be Administrator. I'm a little slow learner. And this was good. It was good to stay involved intellectually in the food safety issues, but in a completely different way.

I had to learn all kinds of things. I had to learn how to answer my own phone, how to do Powerpoint slides by myself, how to . . . I had to go out and buy *Word for Dummies*. There you go, you're on your own. I'm doing a little bit of the same thing now. There's no help desk to call when my computer won't do what I think it should do. So that was kind of fun.

JS: What led you to focus on the issue of food safety as a global concern?

MG: This was because SAIS was looking for a paper on that subject, which trickled over to me. They actually were down the street from my office. And so it was . . .

RT: So you really moved from the position of Acting Administrator for FSIS to scholarly or intellectually driven research . . .

MG: Yes. And this was a think tank, in one of the areas that -- they're largely in the area of economics -- but one of the areas they had an interest.

RT: You developed grant proposals.

MG: Right.

RT: Those were grants for research?

MG: Yes, yes. I mean, that's what think tanks do. You ultimately have to bring your own money in.

RT: Sure.

JS: How did you do with that, with the grants?

MG: I sort of started to get the hang of it. I had gotten a couple of grants for the organization. I was still a government employee, but, yes, I got a couple. I think I had a little beginner's luck. I learned how people do it all the time. Always looking for the next grant while you're working on the one you just got money for.

JS: Well, how did this -- if you don't mind us moving forward here, how did this position as Assistant Commissioner for Counterterrorism Policy at FDA come about, which you started in 2003?

MG: Bill Hubbard.

JS: Bill Hubbard.

MG: Yes. Bill Hubbard could talk you into anything, and he talked me into this. He had the responsibility for filling that job and, because it came under . . .

JS: Was it policy?

MG: Yes. And he had advertised it, and they had a panel, and he didn't like the panel very much. There was a particular person on the panel who lived outside of Washington, someplace in the Midwest, who really wanted the job, and Bill really felt it could not be done long distance, that it required somebody to be here.

JS: Well, this person wasn't planning on moving here to do the job, was going to operate from where he lived.

MG: Right. And the person had an in at the Secretary's office, so Bill was panicked. Anyway, he came and talked to me, and he convinced me to take it, he and Jeff Schurr. So that's how I got there.

JS: Okay.

MG: He really could sell me anything, even now. He's just amazing. So that's how I got here.

JS: Okay, okay.

Well, tell us about your responsibilities and staff oversight and which priorities emerged.

MG: Well, there wasn't a staff when I came to the job, only one clerical person. Bill sort of portrayed the job as building a staff and setting up an office that could pay attention to counterterrorism policy and interact with Homeland Security and Agriculture and all the various players in that world, and the White House was really hot, you know, it was really cool to be in counterterrorism prevention. It's not one of my favorite jobs.

So that was the task, to describe a mission, you know, come up with the mission of this office, and establish the boundaries within which it will work, and hire a staff to get that done. It was never clear how much money there was.

JS: But this must have brought you into touch with most of the segments of the FDA, though, particularly ORA and the Centers.

MG: Yes. Certainly, CFSAN -- I worked a lot with LeAnne Jackson and Bob Brackett on their pieces of it, and then, in the medical areas, developed medical countermeasures. Diane Murphy was very active at that point.

JS: CBER, too, I would think.

MG: Ed Neisen was also with CDER. So, and even CDRH because there's a fight that's still going on -- test kits, screening tests. CDC still doesn't believe that they need to do this. You need to come to FDA for this. That fight started when I was there, so, because they were doing all these, you know, the CDC comes up with all these tests between these other labs, and they never get them approved because they say these are not our labs. Well, then, with anthrax, they started being used all over again, and FDA -- the medical product centers -- were getting adamant that this, you know, if you have a test that's testing the mail and it turns up anthrax, CDC would say, "That's not a medical device." Well, but then hundreds of people are going to get treated with Cipro, a course of Cipro, as a result of that test coming back positive. That has real health consequences. So, anyway . . .

JS: Especially for people with reactions. They might have a reaction to Cipro.

MG: Right, yes.

So, anyway.

JS: Imports become an issue too, don't they?

MG: Oh, yes.

JS: So you must have had interactions . . .

MG: You know, it was really more -- at that point it was really more intentional contamination. Well, of course, on the food side, the whole prior-notice center came out of 9/11, the idea that the things were coming in. But that's still, even to this day, only foods; the primary center was foods, not devices or others.

RT: A number of years ago -- this has been some time ago -- there was a scare of anthrax, and it was in bone meal, and FDA got involved . . .

MG: In bone meal?

RT: . . . down to the farm level in checking those things. But anthrax in general, is that a more prevalent threat in counterterrorism?

MG: Well, it was at the time because, remember, we had the anthrax attacks. That was really the hot issue.

RT: Right.

MG: And I guess it's real easy to cook up, so you don't have to be world-class scientists to . . .



JS: But the challenge is modifying the anthrax itself, the powder. There's some . . .

MG: Yes, there's some trick to it, but I gather it's . . .

JS: Actually, making it . . .

MG: It was, because we'd had the attack down in Florida and in the Congress, and so it was an emergency alert. I mean, you know, people really, we were all really scared in those days anyway. Now we don't think about it so much, because 9/11 had happened then.

JS: We were on edge.

MG: Yes.

JS: We were definitely on edge.

Unless you wanted to explore some more of this, I kind of wanted to take us now, finally, into ORA. And I guess there was this transition.

John Taylor was the ACRA, and it was April -- actually, I found the announcement from the Acting Commissioner -- April 29, 2005. He announced that John Taylor, III would be stepping down and you would be succeeding him. John Taylor's departure was, for those of us in ORA, we don't know where that came from. But I don't

know if there's any insight into that which you have before we start getting into your tenure. I actually have some things I want to start out with. Your baptism under, not under fire, but under the fire of public health. As far as becoming the ACRA, I mean, how did this come about?

MG: I had worked for Les Crawford before in Agriculture. He had been the Administrator of this office at one point, so he knew me. He called me one day and said, "This is in confidence. John Taylor's leaving." He said, "If he does, I'm trying to talk him out of it, but if he leaves, I want you to take that job." So that was how it happened.

I think, my conjecture is, he did not want that hole, you know, to be there at all. He knew I had run a field organization before, and we had worked together before, so he had some comfort level -- but I wasn't going to grow a second head or do something. So I think that's where it came from. He really saw what a hole had been left by John's leaving.

JS: Well, he might have been sensitive to that himself, as he was Acting Commissioner at the time that this announcement was made. And, you know, for those who remember, he went through a lot of very tough congressional hearings during his tenure as Acting Commissioner.

MG: Yes.

JS: So perhaps that was part of it.

Well, I wanted to mention, I actually went through some records to find out some of the things that were going on.

So you began in late April, almost May of 2005. It was an interesting summer that you had to face here as the ACRA -- not that you didn't face emergencies and crises before in your career at FSIS, but maybe not with the variety that you faced here in the agency. In June we had cyclospora outbreaks in Florida related to fresh basil; we had a recall of Guidant implantable defibrillators and cardiac resynchronization therapy defibrillators; we had also in June, a positive BSE test in the beef system. There was, later in the month, a nationwide recall of Vail Products canopy bed systems due to the possibility of entrapment and suffocation. In July, there was a nationwide health alert related to potential salmonella contamination of the Orchid Island orange juice. Purdue Pharma . . .

#### TAPE 2, SIDE A

JS: Okay. Well, to follow on where I left off, in July, Purdue Pharma had to withdraw Palladone, which is hydromorphone hydrochloride, from the market due to unacceptably high risk of dose-dumping in the presence of alcohol. Later that month, smoked salmon was recalled, several brands, due to the risk of listeria. U.S. residents later in July were told that those who may have imported Lipitor from so-called pharmacies might be in big trouble from suspect supplies. Oh, and in August, we had Hurricane Katrina. So, this was an interesting baptism for you in a sense, not that this was the first time you had faced crises. Obviously, you faced many crises in your

positions in Agriculture and in FDA in counterterrorism. But how do you deal with just this onslaught of one emergency after another, one crisis after another, as the head of the part of the agency that has hands-on dealings with these kinds of events?

MG: As you are demonstrating, this is, that was not an unusual period. Katrina obviously was unusual. But the FDA has such a broad mandate over so many products and so many things that there's always an emergency going on. I mean, that would be a typical summer.

I think that the answer to your question is that the ORA is really adept at responding. The people of ORA are down to their bones, down to their toenails, just really committed to protecting public health and doing whatever it takes to do that. And so they always rise to the occasion. There's a lot of work going on now in ORA on trying to officially recognize that is a huge part of what we do, that it's not what we do on the side, but emergency response and crisis response is what we need to build up so that the same staff people don't always get called on and burn out. But because it's, you know, each time we have one of these things, I'm like, well, we got through that one. So we always, at least in my tenure, seemed to see it as something unusual. And I think in the last year or two, the Deb Ralstons and the Mike Chappells and the Steve Solomons really began to push for, no, this isn't a crisis, this is our life. This is what we do. And it's really important to think about it that way, it's not something that we're going to get through this one and then we'll go back to normal, because that, as, you know, your list, your litany there shows, that is what's normal. There's always something like that going on.

I think that it's a huge challenge, and it's one of, you know, I can't imagine how Mike [Chappell] is going to survive this over the next few years because it really is figuring out how we staff what had, if it wasn't always, certainly has become a constant crisis mode for these things. I think that's the major challenge of the position.

JS: Do you think that others in the agency, people on the Hill, the administration, the general public, appreciate that?

MG: I think others in the agency do have that recognition.

The chief-of-staff's office role in trying to help manage a crisis by pulling together the press people, the legislative people, the field people, and whatever Centers are involved, and sort of serve as the overall coordinator.

JS: Are you talking about the ORA Chief of Staff or the . . .

MG: No.

JS: OC, the Office of the Commissioner Chief of Staff.

MG: Office of the Commissioner's Chief of Staff, yes, has tried to and has experimented with a number of different ways of doing this, but actively tried to serve as the convener of a hub for all of that work which has to go on when there's a crisis. So I think that's been recognized as a vital function of the agency.

FDA is, organizationally, a very strange place. They have these product centers that are kind of quasi-independent, and then we have the Office of the Commissioner. I mean, all organizations are crazy, but I never did figure out the FDA one.

RT: I think that's one reason that an earlier ACRA predecessor, Paul Hile, recognized that each Bureau or Center, as they are now called, was leaning on the field staff with their own interests without considering other organizational unit impacts. The role of the ACRA really was established to try to better manage and administer the field force, and let everybody compete properly for their little pet project.

MG: So, yes, I think that's a huge challenge. With better information on outbreaks, going back to, you know, CDC has done a really good job in this area, so that's made our job harder. I think it has improved public health, so I'm not criticizing; that absolutely is not a criticism. But their success has a huge impact on FDA, and on USDA, as well as just the knowledge that we have now, that when people get sick, we find out about it. We recognize outbreaks really quickly, and we see things like the heparin and the melamine in pets, that is noticed very quickly, it gets into the press very quickly, gets in the public eye. Americans -- and I'm really glad of this -- really believe that our government ought to be taking care of us, and we shouldn't be getting sick because some jerk put melamine in a product to make more money or because whatever, messed up the heparin to make more money. But part of it is that we know about it.

RT: During one of the recent incidents -- I think it was peppers from Mexico -- one of

the national newsmen was very critical of the agency, which indicated to me he didn't really understand all what's involved here. He felt FDA should have solved this long ago, and asked what kind of an ineffective agency we've got here. It was obvious he had no concept at all of all the FDA people working overtime and giving up holidays and so on, that a lot of private people won't do.

MG: You know, they all think it's like CSI ("Crime Scene Investigation") -- if we were just a little smarter, we would find it faster, and I think you're right. There's no concept of the legwork that goes into doing these investigations. Maybe that's a signal that FDA needs to think about putting more responsibility on the industry, on records. I don't know what the answer is, but look for what are the solutions, because shoe leather is slow, and when there are people getting sick, nobody likes slow.

JS: Well, that's true.

You had many responsibilities as ACRA. One of the things that we focused our attention on was how to make use of the resources that we had available. This was at a time before, I mean, in the last couple years, we've been pretty blessed by increased budgets, but it hasn't always been like that. We've had to, obviously, rely on diminishing resources. These kinds of problems are, as you said, not crises but everyday events in the life of ORA. In dealing with these, we, of course, have a structure, an organizational structure that goes back decades, goes back to the very origins of the agency in some ways, having laboratories connected to district offices throughout the country.

So one of the things you did was to focus attention on that through something that was called ORA transformation. I wonder if you could talk about that, how it sort of came about and how you proposed not only looking at what we needed to do, but how we would go about studying this and figuring out a way to make best use of our resources, if that indeed was the driving force.

MG: Absolutely. When I walked in the door, Jim Strachan started telling me about the budget, because it was the beginning of May, and the budget was just moving through, and last year's budget was about over. And so he spent a lot of time showing me what resources we had and where they were going, what was happening. As you will remember -- you just referred to this -- we were in a period where we were shrinking by attrition. We were losing virtually almost all of the resources we had brought on, all the people we had brought on, bodies we had brought on board, the same people necessarily. The FTEs that we had brought on after 9/11 were just about gone. We were not sending people to training. We had travel money in some places, we had to sort of move people around, hope for the best. And so it was a way of getting through some bad times, but it looked like the bad times were going to continue. But that was just, it was becoming, we were sort of cannibalizing ourselves by not having enough money. We just won't hire and we'll lose people, we have X percent attrition rate. If we're lucky, that attrition rate will keep up and maybe get a little more so we can lose some more people and pay the rent. That was where we were. So it was not a good time. That was the origin of saying we really need to take a look at ourselves and what are the essential things we need to do and how are we going to do them.



RT: I think over a span of time, the field administration office that we're in had made an effort. Historically, people in the field really got promotions by moving all around the country, getting different kinds of industrial exposure and experience, many against their family's wishes, a hardship for their family and so on. And I think in more recent times, there's been a more realistic approach to that and giving transfer opportunities to those that were seeking to improve themselves rather than just mandating that everybody play musical chairs for a while. I think that's helped the morale of the field over the years.

MG: Well, I think it's also that the workforce has changed, and most people now live in families where there are two careers. And people aren't as willing to transfer because it's much harder to do so, and (2) they don't want to do it. So, yeah.

RT: So that realism, that kind of management I think is an example of good management philosophy and has led to the agency trying to best utilize the resources they have and not lose them. Everyone that's lost is more than just a loss of that individual. It's retraining and time lost.

MG: Right. But this was a situation when we had to lose because we couldn't afford, we wouldn't make payroll otherwise, I mean, as the cost of each individual goes up every year with pay raises and in-grades and etc., and we had the fixed cost of rent and GSA cars and etc., etc., etc. So it's not wanting to lose people, but we had to compromise.

JS: What about other parts of the agency? Were Centers or Offices sort of in the same boat? I mean, obviously, some Centers are, have user fees that they can draw upon.

MG: Right.

JS: ORA was not one of those. Right?

MG: Right.

JS: Now, CFSAN was . . .

MG: They were also shrinking. They shrank enormously over the same period for the same reasons again. They couldn't make payroll or buyouts, and we were offering buyouts. You know, it was enough that, from a rational point of view, we said we need fewer people to do our job. It was that we can't pay all these people. And so CFSAN was doing the same thing.

JS: So, how did you envision our dealing with this in a longer-term sense?

MG: By bringing people from throughout ORA together to think through what is our core mission, what are the things we have to do, how are we going to, what are things that we could do less of, what are things we could stop doing, what are the consequences,

and how do we figure out how we're going to operate within the dollars we have to spend and do our job the best we, you know, give whatever . . . There's never as much money; we're never going to have unlimited resources. But given what seemed to be very, the continuance of very tight resources, what are we going to do to perform the best job possible with those resources in protecting public health? Understanding, as you all do, that it's not just the total resources, but that we get resources tied to certain programs. We get resources tied to foods, we get resources tied to pharmaceuticals, etc.

JS: So that offers even more restrictions.

MG: Right.

JS: As if just overall dwindling resources was not enough, we have restrictions on where we can put them.

MG: At the same time, a growing recognition of the challenge of imports, that imports were fast getting out of control, if not already out of control.

JS: So this analysis begins sometime after you begin as ACRA. Is that right?

MG: Yes.

JS: And how did that . . .

MG: I think we pulled people together for the first time in the fall. I think that's when it got started.

JS: Fall of '05?

MG: That would be fall of '05, yes. And it was people in management, so it was non-bargaining members, employees, and we tried to, within that group, have a pretty good cross-section of people at different levels in different parts of the organization to just think through, you know, what are the issues, what is our core mission, what are the things that when, you know, what are we going to spend our last dollar on, sort of doing one of those exercises.

In fact, we did -- one of the exercises we did in trying to think this through was a zero-based budgeting exercise, you know, which was hateful, but they sort of concentrate the mind and make you think about and, well, gee, if I really only have one dollar, where is it going to go; where is the last dollar going to go.

And so, I mean, we had a consultant who led us through a variety of exercises on how to, because nobody wants to think about we're going to be smaller than we are. And when you start there, almost everybody goes into mental freeze. There was a series of exercises on, okay, what really is most important to us, what is most essential to our mission, what is our mission, you know, sort of updating the mission statement, which didn't change it substantively, but put it in slightly more contemporary terminology. So we went through that process.

JS: And what was the outcome of it?

MG: Well, the outcome was recommendations on areas we needed to put more resources into, and how we were going to come up with money to do that. And that included closing a number of labs; and consolidating a few of the districts. The districts' consolidation was driven largely by the fact that some districts had gotten so small because they had shrunk so much that the management structure didn't make sense anymore. It wasn't that we thought the districts needed to be smaller, but they were, and so did you need that much management or could you consolidate some of the districts.

And the labs, just a recognition on, one, how expensive they are, and, two, that investing in a smaller number of labs will give you more capacity and flexibility.

JS: Now, we had certainly consolidated laboratories before in ORA. We tried in the late 1980s without much success. We did in the early 1990s. We consolidated districts before. That's not new. But what was different about it this time?

MG: I think the labs were definitely the flash point. I think the lab people were not sufficiently involved in the planning. I think that closing the Detroit lab was the biggest mistake I ever made. Once those people who opposed the proposals got a voice in this matter, it collapsed. Politically, it's very hard to close federal offices.

JS: A provision was made, if I remember right, that the people were given the opportunity to relocate. Is that right?

MG: That's right.

JS: Of course, that's, you know, a different -- and a tough -- choice.

MG: Yes. If, you know, while I was a federal employee, I was told, "Your job is now in Montana," I couldn't have gone. So I understand the personal price of closing offices, consolidating offices, closing labs. But I still think ORA would be much better off without all those labs.

JS: In addition to these proposals for the field organization, you did incorporate changes within headquarters.

MG: Right.

JS: Can you just say something about how that changed?

MG: Gosh, I'm trying to remember now.

JS: We had inspectors that you . . .

MG: Right. And there's certainly a decision that the current ORO (Office of Regional Operations) has too much on its plate. I mean, that organization bears the brunt of the enormous amount of the work in ORA, and it needed some help. I think choosing to go to a science inspectorate . . .

JS: You have a compliance, I'm sorry, a science inspectorate and also, science directorate, an inspection compliance directorate, so those . . .

MG: Yes.

JS: Those were new creations within the ACRA, in the ACRA's office?

MG: Yes, and it was in large part to ease the ORO overburdening that had been developing for years. They had all science, all imports, all inspections, everything except enforcement. You can subdivide within that organization, but the people in the group, which included a lot of ORO people, felt that it needed a more substantial, a more fundamental giving up of those things and recognizing that when things are separate, there are issues too.

JS: Okay. I mean, there was a point at which you had announced to all of ORA in August of 2007 that we were going to suspend the work on the current plan to transform ORA and were going to go in a different direction now in looking at the organization.

Would you say a little about that new direction and the suspension of the ORA transformation? You've already touched on that.

MG: Yes. Well, it was essentially driven by the Hill. I mean, the Hill just was not going to sit still for what was on the table, and so, you know, at some point you stop hitting yourselves over the head with a frying pan and say okay, lost that one.

The decision to take a different approach was to look at some of the weaknesses of the earlier approach and recognizing that one of them was excluding our bargaining-unit employees, just lots and lots and lots of people who just were excluded the first time, and so that was really important; and in trying to figure out how to approach this afresh and say, listen, we still have some problems we have to deal with. Some things aren't going to get better on their own; we can't just walk away from it. We said we're not going to go this way, for all kinds of reasons, but basically we can't, and so how do we figure out a way forward?

A contractor who's been used around the agency before was sent to me as somebody who might be helpful, and he, after a conversation in which a number of us sat around and said, "Here's what's going on, here's what's happening, here's what the issues are," suggested somebody hold a future search. And I actually had participated in a future search when we did the SIAS organization, and, I mean, let's just say really powerful tool. And since I had done [unclear], when he said it, it was like a light bulb went off. Bingo! That's [unclear]. He's very risky.

Did you take part in it?



JS: No.

MG: Yes. It's very risky because it can go bad, but it really is a methodology for, I mean, the basic premise of it is that people with very different points of view and very different stakes can agree on common ground. Now, in large part, that's fine, narrowing and narrowing and narrowing what you're doing till you can get to something that, yes, everybody can agree on, at least sit still for. But, anyway, that was the approach we used.

We also made a conscious decision to put a very short time frame on this because it otherwise drags out. You have more opportunities to unravel.

JS: Well, I would think if you're trying to find common ground with a large -- and we're talking about a large group of people and all of the . . .

MG: We did it in three days.

JS: I would think that could really be drawn out.

MG: Yes. But a time, I mean, that's the methodology, has this three-day time frame. So it was driven by a report by the Commissioner, and we used that as a way to say, this can't drag out, because time only unravels stuff. We were trying to make some important changes. Time is not really on your side. I think in retrospect that it was another mistake in the earlier effort that led to a poor result. It gives everybody a chance to figure out

how they're being hurt. You know, change is hard. It's going to hurt every one of us, because none of us likes change. I mean, it's fine for me to say you're going to change, but I'm not. But then we figure out, oh, maybe if I think about it long enough. So, anyway.

I think, whatever else, that the process and the effort allowed a lot of healing to go on that needed to happen.

JS: You know, if you look back -- and we did spend some time talking about this . . .

#### TAPE 2, SIDE B

JS: We spoke about your experiences with looking at the organization and the efficiency of an organization with respect to where you wanted it to go in terms of public health and so on with FSIS. As you look back at that, well, you mentioned the future search and how you did that with FSIS. Was the reorganization at FSIS done in a faster way compared to what happened with ORA?

MG: Well, I think it was less revolutionary than the initial proposal for ORA. I think that FSIS had a very weak union at that time and only covered a particular part of the workforce. And there was not a lot of officer closure involved.

JS: There were some laboratory reductions, though, in the FSIS, were there not? Maybe I misheard you.

MG: No. We only had three labs.

JS: Oh.

MG: So we didn't close any labs. In fact, we invested in those labs.

JS: Okay. Well, obviously, very different experiences, but then, as you said, what you were proposing to do or what the group was proposing to do with ORA was of quite a different magnitude.

MG: There was a lot more pain.

I also think the union, an organized union, that can organize opposition in a way that individual employees can't, so I think that was where they came from. [unclear] unions are bad, but they can do what they do, what they're there for.

RT: Is the federal employees' union a factor here in these kinds of circumstances? Is there enough membership, do you think, in ORA to let that be a moving influence on anything?

MG: Well, I don't know how much active membership there is, but, I mean, all of our, we have a lot of bargaining-unit employees. When they're threatened, they're a whole lot more supportive of the union than when they're not. No, I think it does. I mean, it

enables people to come together around something in a way that could happen without a union but would take a lot longer, would be more diffuse. That's all.

RT: Yes. Well, I think there were a lot of people -- I was one of them when I was full time -- who really didn't look to that kind of an approach to manage what would be my way of doing things. In other words, more of the professional outlook [unclear].

MG: Yes.

JS: You know, we've talked a lot about issues, and taking a serious look at ORA and what ORA should be, what it should look like, how it's going to carry out its mission is crucial. But there were many other elements to your tenure as ACRA.

Again, we started this out with just the everyday kinds of things that one has to deal with, and they certainly continued with very high-profile issues, the *E. coli* outbreak with spinach in 2006; the Peter Pan peanut butter issue, that brand, how that brand is going to recover. The pet food you mentioned.

We've had a major hiring initiative now that started during your tenure.

But I guess I'm also interested in hearing about how what kind of a relationship you had with the Commissioner, for example, when you were here, and if you found that to be a productive and supportive one.

MG: The Commissioners in my term were Mark (McClellan) and Lester (Crawford), and the others were acting.

JS: Two of those were Acting anyway. But Lester Crawford and maybe Von Eschenbach were acting at one time before being appointed Commissioner.

MG: My experience was they were very approachable, and they all had the 8:30, briefly 8:40, meeting every day, and used it in different ways. But that was, from where I sat, a very useful way to stay in touch. But all three of them were very open to, if you needed time, then you got it. And to my knowledge, nobody has ever abused that.

I think the tougher times, as we discussed, were the acting times.

RT: We had a Commissioner, whom I won't identify, a number of years back who used a timer, just an oven timer. He said, "How long is this going to take?"

MG: I did not have that experience.

Also, you know, they all had different configurations, but they had some top people you needed to go through and all those things in place.

RT: I think, at one time, employees might have wondered about the proliferation of associate commissioners and so on, as how that might dilute the communication within the agency.

MG: That was deputies. There are almost no associates at the moment.

JS: Who knows what will happen after January.

MG: Yes.

RT: Apparently it's working out all right.

JS: Well, we've covered the things that I thought you wanted to cover, and I . . .

MG: This was fun. You told me I would say that.

JS: We're glad to hear that. But thank you so much for sitting down with us and sharing your experiences here and in your earlier career, too. It gives us yet another set of insights into FDA history. So, thank you.

MG: Thank you.

RT: We've noted that you were honored with two Presidential rank awards, and that's something that not too many people have in their careers. Those were during your USDA years, weren't they?

MG: Yes.

RT: Well, thank you again for participating.

MG: Thank you. I enjoyed meeting with you.

END OF INTERVIEW