History

of the

U.S. Food and Drug Administration

Interviewee: **Marleen M. Wekell, Ph.D.**

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

Date: **November 9, 2011**

Place: **Silver Spring, MD**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

TOPIC OF INTERVIEW: FDA Employment

LOCATION OF INTERVIEW: FDA White Oak Campus, Silver Spring, MD

DATE OF INTERVIEW: November 9, 2011

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Robert Tucker

INTERVIEWEE: Marleen M. Wekell, Ph.D.

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Interview with Marleen M. Wekell, Ph.D.

November 9, 2011

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, November 9, 2011, the interview is with Dr. Marleen M. Wekell, and the interview is being held in the White Oak headquarters of FDA. Dr. John Swann and Robert Tucker are participating for the History Office in the interview.

Dr. Wekell, as we begin, if you could give us just a brief overview of where you were born, where you were educated, and any employment you might have had prior to coming to FDA. And then, of course, we'd like to go in-depth to your career experiences. So, with that, we'll let you begin.

MW: Okay. Well, I was born in Spokane, Washington, in 1942, and then, after the war, moved to a small town outside of Seattle, Enumclaw, Washington, where I grew up and went to grade school and middle school and high school. And, actually, we lived in the mountains, so it was, my summers and all my time was, spent doing things people do on vacation: skiing and swimming and water skiing and hiking, climbing mountains with my father. In fact, he used to take me rock climbing, and I had my little pack, and he would just say, "Falling, you only fall once. Put your hands where I put mine, your feet where I put mine, and you'll be fine." It wasn't negotiable, but I learned a lot doing that. So I think I'm a pretty typical Washingtonian. Most of us have spent most of our time outside.

So, I went to undergraduate school at Seattle University. I think my parents thought I needed a little more mental discipline, and I got a very good education there, got my degree in

chemistry. And then I got married. I worked, had a child, and I'd always wanted to get my Ph.D. Then I did go back to grad school.

I started grad school in the biochem department (University of Washington) in about '65, and then the professor I was working under got transferred, and all of us were sort of put to the sword, so I went to another department, where I got my master's. So I was at the University of Washington from 1970 to '72, got my master's in kind of marine biochemistry. And got to teach at Friday Harbor, which is like the West Coast Woods Hole [Oceanographic Institution]. It was just a wonderful experience. And then got my Ph.D. and went on.

At the university, you had to get a master's and then get a Ph.D. You couldn't go all the way through. So then I was in the grad program from '73 to '75, and I worked on carbon cycling in lakes. So I actually got to backpack into one of the lakes in the Seattle watershed, which was a lot of fun -- hard work, though. I mean, you had to climb 600 feet straight up with a full pack with a lot of samples, got chased by a bear. Anyway, so I also studied chitin digestion [by bacteria], so my Ph.D. was really in environmental microbiology, biochemistry.

JS: Before you go on, I'm curious what interested you in science as a special pursuit. Did your parents have that background?

MW: Yes, yes, they did, yes, yes. I always was interested in science and always wanted to go into it, so my dad -- my parents got me a microscope when I was in, gee, first grade, so we'd go amoeba hunting and practically blew up the basement one time with my chemistry set. So they really did nurture me, and they were very intelligent people and I owe a lot to them. They were very good.

RT: Was your father in an area of science?

MW: He had been, but he had actually been in pre-med at Notre Dame, and then the Depression came along and he had to quit. And then the war came along and he was drafted. He was in the Normandy landing, and I never even knew that until we went to France and we stood on the beach [Normandy Beach] one day and he told me about it. I mean, he just never talked about the war.

And my mom was a schoolteacher, so she was very nurturing, taught me to read when I was two, only because I think she was bored because my father was at war, and she was working in a nursery school in Ellensburg, Washington, and I got to go to that. So I think I was just very lucky. I had excellent teachers in Enumclaw, in grade school and high school, took calculus my senior year, because I always wanted to be in science. I always was curious, coupled with just a love of nature, too.

JS: And it sounds like that combination of circumstances helped shape your interest, for example, in your Ph.D. work, right?

MW: Yes, yes, it did. I was one of the last few -- I got my Ph.D. in '75 -- that went all the way through grad school on scholarships, which was just lucky. I mean, I got a research assistantship for the Ph.D. And it was one that nobody really wanted, and it was the last one left in the department, to look at carbon cycling in lakes in Washington State. To me it sounded like a great opportunity, and so I took it. And after that, the assistantships started drying up. I had an EPA assistantship for the master's degree. So I was very proud of the fact that I was able to go to grad school on my own. I didn't have to take loans. I could sustain myself. I was married, too. My husband was in grad school at the same time.

RT: Now, the issue of carbon in lakes, what was the public health issue there?

MW: It wasn't too much public health, but it was more ecological. It was part of the Forest Biome, which was a huge national study at the time, and just looking at the whole ecosystem. So, carbon cycling in lakes, especially in the oligotrophic lakes up high in the mountains, was really important, because they don't have much nutrient anyway, and so it's all really tightly coupled. Then the eutrophic lakes like Lake Washington, Lake Sammamish, have too much nutrient. I got to study under Dr. Edmondson, the very famous limnologist who actually saved Lake Washington in Seattle.

RT: Does that presence of carbon affect fish?

MW: Well, yes, yes, yes. They're recycling the carbon. All the animals were involved. And it's really quite relevant to today's global warming. Of course, at the time, we knew that glaciers were receding. I mean, I grew up, my dad would take me up to the Nisqually glacier near Mount Rainier almost every year, and every year it was a little further back, so it was a real thing to us growing up in Washington State that the glaciers were receding. Yes, I always was interested in the environment.

JS: At this point, as you're finishing up your grad school, finishing up your Ph.D., I don't know if you had postdocs in mind.

MW: I did.

JS: You did.

MW: Yes. Well, I was starting to worry about finding a job, of course, and there was a bit of a recession in Seattle at the time, and I was very fortunate that a postdoc --as a staff fellow -- came up at the National Marine Fisheries Service, and it was just doing the kind of work I just loved to do. So I took it, and I was a research chemist there. So I always had the chemistry and the biochemistry and the microbiology.

And in that study, we looked at the, with salmonids -- there was a lot of concern in the Seattle area. At the time Don Malins, who was head of our lab and who's now in the National Academy of Sciences, had done some very pioneering work showing that a lot of the animal species in Puget Sound had carcinomas due to the pollutants. He really raised the awareness of people. So we looked at the effect of polycyclic aromatic hydrocarbons and PCBs on the mixed-function oxidase system in salmonids, and that's kind of an indicator organism. We looked at benzo(a)pyrene, how that's one of the precursors of the carcinogen. And so we were looking at the fish as kind of signaling systems for problems that may happen to the whole ecosystem and to people eventually. And we did find some synergism between the two, PCBs and benzo(a)pyrene.

What we did stumble on and I wasn't able to publish because it was contract work and we had to just stick to that, was that PCBs seemed to affect the fish's immune system, and that's since been verified. But we never published it, and I was just going crazy with what we were finding. That's the beauty of science, that you were truth seekers, and it's going to be found eventually, whether it's you or someone else. If it's there, it's there. And I always used to argue that in FDA, that we were prohibited from working on *E. coli 0157:H7* in the environment, because "what would we do if we find it?" And I said, "Well, if it's there, someone will find it. Better it's FDA showing how proactive we are," but there were some ostriches.

JS: Did you have a chance to present your results on PCBs?

MW: Our boss did. Yes, it was published. But I was a staff fellow, and the philosophy in that particular lab was that only the lab director presented your work. And I learned a real good lesson there for my future -- I always filed everything away as I progressed -- if you're going to become a lab director and lead people, you have to let people benefit from their own

efforts, and if you take the credit or don't let them shine a bit in their own excellence, they'll shut down. And that happened.

JS: And this is a philosophy that you say you took with you as you became a director of a lab?

MW: Yes. Never do that. Well, what not to do.

JS: The difference between maybe an academic environment and a public one.

MW: So I tried to learn. Our lab director was a good guy, and I still have contact with him. He's eighty-something now, just had open-heart surgery, Don Malins. But his philosophy at the time was really very harmful, and there were some geniuses in the lab. I mean, one guy made an amino acid analyzer out of a Bomarc missile guidance system. He was so creative. He kind of shut down. He wasn't able to present his own work.

JS: Almost like the old Germanic research institutes.

MW: Yes, he was. He was very like that. I always tried to look at people who were my bosses, what did I like about what they did, what were the good things they did, what were the bad things they did, and I could try to emulate the good things and throw out the bad things. Only the people that I've led can tell you if I was successful. I hope I was.

JS: Well, this is one of the reasons why we like to talk about background before we get to FDA, because there are things that come up that do affect people in very substantial ways.

MW: I mean, you're always learning. I still am. But when I was coming up, in '76, I was kind of coming up to the end of the staff fellow positions, and so I was invited to apply for a faculty position at the University of Washington -- again, which I really wasn't looking for it, but it was really hard to find jobs in the Seattle area at the time.

JS: And you really wanted to stay in that area.

MW: I wanted to stay in the area, and I think the most painful thing in the year 2000 was having to leave that area, but I had no choice. But it made me stronger.

But anyway, so I applied for that position at the University of Washington. It was in the Nutrition Department. And, again, I always try to think of things as opportunities. I didn't have a background in nutrition, but then I thought, well, gee, I have a good background in biochemistry, and nutrition is really just applied biochemistry. So I boned up on the things I had to and I got the position. And I remember the seminar I gave there as part of the interview process. I gave a talk on fish, "Fish are not rats," and how difficult it is to work with fish as an experimental animal compared to rodents.

So I was at the University of Washington Nutrition Department as Assistant Professor from '77. And at that time, the National Marine Fisheries Service asked me to stay, that they had renewed my position, but it was too late. I didn't know. But I was happy at National Marine Fisheries Service. I really enjoyed the position. But I'd already taken this other position at the UW, and I tried to be upfront with them.

So I went to the University of Washington, and I think the whole time I was there, I must have taught 15 different classes. Wow. But I taught food chemistry and food microbiology, and I put together a course on naturally occurring toxins in foods and food additives, and I was on the graduate and undergraduate faculty. And I got some med students for some of those courses. They were really outstanding students.

And I had a couple of grad students that. It was probably the hardest job I ever had because, with most jobs, if you're not ready the next day for your work, you can probably do okay. But in teaching, if you're not ready, you've got those little eyes staring right at you and

you're immediately confronted with failure if you don't do a good job. I think I put in 10 hours for each one-hour lecture. And I taught a lot of different classes, a lot of lab classes.

JS: Was this a situation where the junior faculty member was assigned the bulk of the teaching?

MW: Yes. Oh, gosh, yes. I taught two classes a quarter. But the lab classes were the hardest because I put together our own lab manual. I remember one of the courses I taught, the students were talking about nitrites and how dangerous they were, so I thought, okay, I'll show you. So we did an experiment where they chewed celery. I saw this in one of my journals. The indigenous bacteria in your mouth will transform nitrate to nitrite. And so we measured salivary nitrite levels after the celery, and they went right up. They said, "You know, we're not experimental animals."

JS: Yes, they are.

MW: You probably couldn't get away with that now with human subjects. But I enjoyed the teaching. I got really good reviews. We had a five-point scale, and I'd get like 4.8. I wasn't that successful in getting grants. I think I just couldn't shortchange the teaching, which you would have to do. I mean, some people can really do it. I admire people who can succeed and be good teachers and get research grants, and I don't think I was one of them that could do both.

I think it was a great tragedy, as we watched in the '60s, when the universities started relying on federal funding from the grants to start running the universities. And so the emphasis on good teaching went by the wayside replaced by ability to get grants. And the research is important. It's good to have people teaching young people who are really in the research and know what's going on. But the teaching also isn't valued. That's what I've seen. But I loved

the teaching. My mom was a schoolteacher, my uncle was a principal, and always thought I'd never be a teacher.

But then, in 1981, the state went through a further reversal. I wasn't tenured yet, and our department was eliminated, the Department of Nutrition along with four or five others.

JS: The Department of Nutrition was eliminated?

MW: Yes, yes, it was.

JS: Oh, my.

MW: Yes. And that broke my heart. And I had a year to find another job because I wasn't tenured. The tenured faculty was absorbed into the Department of Environmental Health, and some to the med school. But that happened to a lot of nutrition departments or food science departments in those days. And so, I was heartbroken. I think the way they did it was the hardest, and I haven't really talked much about this: instead of just saying you're not tenured, you'll have to find a job in a year, they did not do this. They forced me to go through tenure prematurely and then denied it, which was very heartbreaking and emotionally absolutely devastating. And they let me think that I was not acceptable, and then they eliminated the department a few months after, so I went through just incredible pain. And I got quite depressed.

I remember one day walking across the Montlake Bridge, and I was kind of at the bottom, thinking life really wasn't -- I wasn't suicidal by any means -- but I was just thinking life just isn't much fun. And at the other side of the bridge was a quadriplegic in a wheelchair, probably a Vietnam War veteran. And we met at the center, and he just looked at me and said, "Good morning," and it was a beautiful morning like this. And that's what turned me around. I thought, oh, my gosh, Marleen, you're feeling so sorry for yourself. You're healthy, you've got legs. Snap out of it. So I started hunting for another job. That's when I went to FDA.

JS: Right. You were interested in a job just for employment, but was there something about public health or was it FDA's mission that attracted you?

MW: Yes, there was. In fact, my major professor at the University of Washington had been an advisor, Science Advisor, for the FDA lab in Seattle, and so he'd always talked about it.

JS: What's his name?

MW: Dr. Matches, Jack Matches. He just died last year, wonderful man, absolutely wonderful. And so I was familiar with FDA. The funny thing is, when I'd gotten my bachelor's degree in chemistry in 1964, I applied at FDA. It was one of the places where I applied. And they asked me if I'd be willing to move anywhere in the United States, and I said, "No, I want to stay here," and I didn't get the job. But I applied a lot of places.

When I got my bachelor's degree, I actually worked at Seattle U for a year, running a research project, and then I went to the med school and worked in the labs there, working on leukocytic pyrogen and the mechanism of fever before I went to grad school. So I always worked, because I was so interested, I liked the science, I wanted to do that, and it was more than just wanting to have money. I felt it was professional. But I could see the writing on the wall that I had to get an advanced degree if I wanted to go anywhere and not just be a technician.

So, yes, I always was interested in public health. I think I've always been interested in trying to make a difference. I think the FDA mission is a profound one, and that's what I loved about it, working in the field in Seattle. I mean, everybody really, even older people, truly believed in protecting public health. And you hear so much bad said about government workers, but I've seen them working 24/7, missing their kids' soccer games or banquets because there was a bot [botulinum] scare and running a bioassay on mice for bot toxin. You can't pay people for missing their kids' soccer banquet because they had to work.

JS: That doesn't make as good a sound bite, I suppose, as the other side.

MW: No, but there are some really dedicated people in FDA, and I truly enjoyed working at FDA.

JS: When did you start?

MW: It was in '82.

JS: Eighty-two. What was your position?

MW: Well, my position was in one of the recently established research centers in different field laboratories; ours was the Seafood Products Research Center (SPRC), and so I led that. And I came in, I was supposed to be a GS-14, but I came in as a GS-13. And at that time, I mean, I really wasn't as aware of GS levels. I was an 11, I think, as a staff fellow. I mean, that was kind of foreign territory to me. But our mission was really to develop methods for looking at seafood, whether they were of good quality or safe to eat, so we did work on microbial pathogens, on marine toxins. That's one of my greatest loves. And we did publish many papers, and I gave lots of talks; we all gave talks.

That was my first group, aside from being at the university and nurturing grad students. I also had some technicians when I was at the National Marine Fisheries Service, so I had some experience with supervision. But FDA was my first real experience managing and developing a laboratory, so those poor people had to suffer under my learning curve, and they're still friends to this day.

JS: This was a new lab, and it's part of the whole system that was established, and it was a long time in coming, this national system of field labs, because certainly some of the headquarters entities weren't completely enthused about this.

MW: No.

JS: Did you hear about that?

MW: Well, when I got on board. I didn't know until then. So, yes, not only did I have to deal with the Center for Food Safety, who felt that only they could do research, and nobody in the field knew anything. I also had to deal with the laboratory there in Seattle where the lab director felt he should have been in charge of the research center. And he had a bachelor's degree. He was a wonderful lab director, John Wiskerchen. John Wiskerchen was the lab director for Seattle, and he was actually excellent. And I think I can still count him as a friend. We exchange Christmas cards. But I think there was a natural antagonism that he felt that . . . And we had researchers, and they weren't doing regulatory work, so there was some antagonism that's a natural result of having a different group with another group where their missions are a little bit different. And research is a lot different than doing just regulatory work, doing samples.

JS: Organizationally, where was your laboratory within the Seattle District?

MW: I was equal to the Lab Director, so I reported to the District Director, Ken Hansen, who hired me. He was a wonderful man. He lives in Colorado Springs, and I send him Christmas cards -- we talk every Christmas. And then Jim Swanson was our Regional Director. And at that time there were 10 regions, and Seattle, of course, had a Regional Director and a District Director. They were both wonderful fellows. They hired me into FDA, and I held them, and still do, in high regard.

JS: How big was your lab, I mean, how many people were there?

MW: Not a lot. I think when I started, we had maybe six, five or six. It was small, not a critical mass, and that was a problem right away. And the lab, the regulatory lab, I think they might have had 30 or 40. They were both small. But I quickly saw that I would have to try to

integrate as well as we could with the regulatory lab, work with them. And we would take on unusual samples that were, you know, we tried to build a good rapport with them.

I also worked closely with the National Marine Fisheries Service because I had my contacts there, and then in Oregon there was, in Astoria, there was a similar research group, so we developed ties with all the other seafood research groups to try to collaborate as much as we could. There also was, at that time, an FDA research group in Rhode Island. We worked with them. And then FDA's Dauphin Island group, we tried to work with them, the seafood group, and they're still there, on the Gulf Coast.

And I quickly, I was sent to CFSAN [the Center for Food Safety and Applied Nutrition], and they fed me to Dr. Read, who at the time was head of microbiology at CFSAN, marvelous fellow. But he was really gruff and kind of a bully, and I didn't know that. That's why I said they fed me to him. But I did okay.

JS: What was the purpose of your assignment to CFSAN?

MW: Oh, I went there because we all felt that we would have to work with the Center for Food Safety and Applied Nutrition if we were going to survive, and show them that it would be worth their while for them to support us. And so I know Dr. Read -- I really did like him. He died. But he was quite a character. And we got into a bit of an argument -- not an argument, but anyway, I held my own, and I guess by that, I earned support from him for the rest of my life. And it was on marine toxins, and that was something I knew a lot about.

But as a consequence, actually, Dr. Read -- this was in '83 -- he said, "You know, we don't know anything about the *Vibros* on the West Coast. "How would you guys like" -- and we had a mobile laboratory -- "How would you guys like to look for *Vibrio* on the West Coast of the United States, and I'll give you $20,000?" I said, "Yes!"

So in ’83, we took our mobile lab. We did a lot of shellfish work. We did a lot of environmental work with the shellfish program, because I knew that we were going to have to work with a lot of these other programs if we were going to survive. We just wouldn’t survive if we didn’t. And so a lot of our publications were on shellfish. So we took the mobile lab and we went down to the border of Mexico, and I went too because I thought, well, I’d like to get away from my desk, so I worked in the lab and out in the boat. We had a boat, getting samples. We worked all the way from the border of Mexico to the border of Canada, and we looked for *Vibrios*. We also looked for *Aeromonads* and some other pathogens in the environment, and we published two papers.

JS: Where were you looking for these?

MW: We were looking in estuaries, in shellfish-growing areas, and we were looking primarily for the pathogenic *Vibrios*, *Vibrio cholerae*, *parahaemolyticus*, and then we threw in *Vibrio vulnificus* because at that time, in ’83, it was becoming a bit of a problem, and we found it. So the publication that resulted is kind of a landmark paper. It was a survey, and a lot of people say, “Oh, surveys aren’t research, and it’s not that hard.” Well, it was hard because we were all kind of environmental microbiologists, chemists, and we learned that what might work in San Diego for enrichment media for the *Vibrios* and *Aeromonads* might not work at the border of Canada. You have different competing flora, and we had to kind of work our recovery media. So we learned a lot.

In grad school, we had this ground into us through environmental microbiology, like food safety begins with the environment. You’ve got to start there. You can’t just look at the finished food. And so I carried that with me in FDA, too, and so we did that. And so I think Dr. Read was pleased with us, and so I was just thrilled to do something like that.

JS: A couple of things. One is, you published based on this?

MW: Oh, yes. Everything we did, we published. We had a long publication list. In the peer-reviewed literature, we published that in *Applied Environmental Microbiology*, which is an ASM [American Society of Microbiology] journal which has a fairly high rejection rate.

JS: Having a publication in hand, you know, we have a pretty good idea of how that works if you're in the academic world and what that means to your progression as you go along. What about in the government world, if you have a publication under your belt, for members of your staff, for example, does that figure into their advancement?

MW: It did. All research scientists in FDA, USDA, are under peer review, and to maintain grade and to get promoted, you have to go through scientific peer review, and that's still the case, and so one of the criteria in peer review is publications. Unfortunately, that reward system I don't think is serving FDA very well now, and I was on the Science and Technology Committee for the Commissioner when I left, and I kept saying, a number of us did, that you've got to have a reward system for your scientists that reward them for what FDA wants out of them, and if you don't want them to publish, which most good scientists try to do.

TAPE 1, SIDE B

MW: That question about publication . . . because in ORA [Office of Regulatory Affairs], it got kind of used against us. They were very kind of blue-collar, some of the people in ORA, and there was some resentment: You guys with Ph.D.'s don't know everything.

JS: When you say ORA, do you mean ORA headquarters?

MW: No. [The field offices of the] Office of Regulatory Affairs. Our laboratory in Seattle was an ORA laboratory. And so a lot of the people in the field . . . And there are good people there, but there was a bit of an antagonism between, say, Ph.D.'s and bachelor's degree people doing regulatory work, and I think a misunderstanding, you know, that all you guys want to do is publish papers, you're not giving us what we want. And so I think there was, not having come from grad school and academia, I think there wasn't a good understanding that we were kind of on a different track and being rewarded for different things than they were being rewarded for.

JS: And did your staff, in the research center, did they have sort of a different background than those in the lab?

MW: Yes, yes. Most of them had Ph.D.'s. And although I've seen some outstanding scientists with bachelor's and master's degrees, I mean, you don't need a Ph.D. to be labeled brilliant. But what grad school gives you is the discipline that you may not get elsewhere. But I have seen people in the reg lab without Ph.D.'s who were every bit as good researchers as a Ph.D. So I think you have to be real careful. And I think I tried to look for that myself when I became a lab director, not to be, wear blinders. And some of the best researchers I work with actually had master's degrees or had some exposure to grad school, and a couple just with bachelor's.

But we were on a different track, and it had conflict built into it, and I think ORA didn't, the management of ORA was mostly from the investigation side, and they weren't scientists, so they're, even in ORA, they're always . . . At the time, there was a bit of, not conflict, but a bit of a gnashing together between laboratories and the investigators. A lot of investigators thought, oh, you can get all the proof you need for a case from investigational evidence alone. You don't

need a laboratory to confirm it's *Listeria*. We don't need you. You cost too much anyway, and you're a pain in the ass, because we would always ask questions.

I'm not trying to belittle them. I think they're all good people, the investigators. They do things that are just amazing, and they have to sometimes confront business owners with adverse findings, and I don't think I could be as good an investigator as some of these people were, and they were very good. I think all in all, though, when push came to shove, we did work together as a happy family, I think, during the Excedrin crisis. I mean, we were all working 24/7 together very well. But I think when you're not as busy, people can get into mischief, and little conflicts can arise. So I was always trying to defuse things like that so they wouldn't happen.

But I think, like today, the scientists, they're still under peer review, and a lot of the work now requires cooperation. Very few research studies now can be done by one person with one background. You might need a geneticist, you might need a biochemist, you might need a statistician, and so you have to cooperate more; where on peer review, if they look at, first off, the publications as whether you're going to go from a 13 to a 14, or 14 to a 15, and you're in a collaborative environment, you've got conflict built in there, and it happens.

And I saw it happening in our own group because we did a lot of work together, so I solved it one time by, because one of our people going through peer review was claiming work of one of our other scientists (and also going through peer review) as his. So I said, "Okay, you two, before you submit your peer-review documents, exchange them, and I want you to sign off on each other's peer-review documents," and they both got changed. And I said, "There's enough room here for everybody. You claim what you did, you claim what you did." So that worked.

JS: You developed, apparently, some patents for some of the work that you were doing.

MW: We did. We were doing three.

JS: And I wonder if you could say a little bit about that. And also, tell us about what it was like getting a patent as a researcher at FDA, and to what extent there was any precedent to this that you were aware of.

MW: I think other people in FDA had gotten patents. We weren't the only ones.

The reason we did it -- and that was our acronym, SPRC, Seafood Products Research Center – we were accused of just trying to make money. Well, we never got a cent out of it. The reason we did it is that we had stumbled onto something, a cell assay that was a really nifty method of detecting marine toxins, because you were looking at the actual toxic event. Like with the tetrodotoxin and saxitoxin, they block the sodium channel, and you were actually observing that blockage and you could measure it. You could quantify as well. And then for ciguatera toxin, it's also, it's acting on a different site on the sodium channel, but it opens it up. They both are potent neurotoxins. They kill people. And so we were able to take advantage of that with our neuroblastoma cell assay.

Well, there were other people kind of on our trail in academia, and we patented it more to keep the information in the public sector. We thought it would protect FDA. We knew we wouldn't make any money, and that wasn't our goal. And I remember Ron Manger, who was the lead author on the paper, who's now at the Fred Hutchinson Cancer Research Center in Seattle and is still a dear friend, was the lead on that work, and Jim Hungerford, who's still involved in this work, and I just talked to him last night, and we're still good friends. And we all kind of got together. I mean, I had some ideas too, because I said, "Well, you know, if it works on the

sodium channel blocking toxins, our assay ought to work on the opening ones," so we tried it, and it did work. I mean, we all, you know . . .

RT: Having a patent makes the agency then sort of the sole proprietor or user of that technique, is that correct?

MW: Well, not altogether. Some people, other people have done it. We did it more to protect. And we went through the FDA's Office of Contracts, and I forget the name of the person. She was just wonderful to work with. I mean, it cost the agency money to proceed with developing a patent, and they paid for it, with all the patent lawyers and everything. Yes, we got three of them.

JS: The patent was dedicated to the public, right?

MW: Yes, yes.

JS: So there's no profit involved.

MW: No, none. That wasn't our goal.

JS: Of course.

MW: And at the time, I was the AOAC [Association of Official Analytical Chemists] General Referee for Marine Toxins and Seafood Quality, too, and there were other people who were trying to patent things. Personally, I'm not comfortable with patenting things like that. I'm not comfortable with patenting gene sequences or anything like that. I think that really gets in the way of science, especially applications for drugs and things, and I'm not in favor of it. And so it was an interesting experience, but it was really Ron Manger and Jim Hungerford who did the majority of the work. And there were five of us on the patent. I mean, some of the ideas were mine, too, but most of them, and the one who really made it work was Ron Manger.

Having been a Director, I always try to be careful not to take credit for their work and try to get them the resources they need, get out of their way, help them as much as I could. But I would kind of, I got this from Abraham Lincoln's book, but I do it anyway, and that is, you take the slings and arrows and protect them from them as far as the politics, so I would try to do that, and I've always tried to do that. But the patent experience was really interesting. That was fun work, the marine toxins work, and we published it in one of the more difficult journals to publish in. And it was based, I mean, you're all standing on other people's shoulders in science. It was based on some work that had been done in Canada, and we cited that. Very few things are ever done in science *de novo*, and you're standing on the shoulders of your predecessors, and you try to be really careful to give them the credit.

JS: You mentioned previously how well the folks in the Seattle District Office worked together. You mentioned the Excedrin crisis, and I wondered if you could say a little bit more.

MW: That was an experience! Prior to the tampering incident, Mr. Ken Hansen, the Seattle District Director, asked me if I would be the Acting Lab Director. That was early in '86, because John Wiskerchen, the Lab Director, was involved in the in planning and eventually working with GSA and others on the building of a new facility in Botheil, WA (north of Seattle). We were being kicked out of our laboratory downtown on First and Madison, across from the new Federal Building, by GSA. I visited it in 2010, and the Forest Service now occupies some of the space where our labs used to be; they allowed me to wander around where our old labs had been. Our new building was to be a design-build, and John did an extraordinary job. I mean, we eventually had a very fine new laboratory as a result of his work. But he couldn't do that and be Lab Director. So I think Ken had enough faith by then in me -- in '86 -- I'd been there since '82

-- to both direct the research center and the lab. And Ken was a great one in moving people around. One time he had the Compliance Director, Ray Mlecko, and the Investigations Director, Jim Davis, change places because they were not always in agreement. So he made them change places.

JS: Shrewd.

MW: It was very shrewd. And he also knew there were some undercurrents of other problems, so I think he did this to help the situation. Ken was a wonderful man. I really like and respected him. And so I accepted in ’86, and I learned a lot. And in June of ’86 the Excedrin tampering occurred, and I would like to say that’s the first time a person who tampered was caught, tried, and put in jail in the United States.

JS: What were the circumstances?

MW: Okay. There was a death, Sue Snow in Auburn, Washington, from Excedrin, and it was purchased in Auburn. And at that time Excedrin was in a capsule.

JS: Was this . . .

MW: Not the Tylenol incident.

JS: Right. But the Tylenol, the second Tylenol tampering case, was that not also ’86? I’m wondering, was this on your minds?

MW: I can’t remember.

JS: Okay.

MW: I can’t remember, and I didn’t get involved in that. And I’d been away. I went on one week vacation a trip to Victoria, actually, and I came back to this. And so we were analyzing massive numbers of bottles of Excedrin. This was really before desk top computers were common, like they are now. We weren’t allowed to have desktop computers. We were still

using those horrible DEC things. We quickly learned that the people in the lab had to be on a schedule because they would just work to death, 24/7. There were just so many bottles of capsules coming in. And I remember well how we sat around the District Director's conference room and many places opening them up. We could see we this was inefficient.

JS: By hand inspection and by emptying out the contents?

MW: Yes, yes, yes. And the Sue Snow bottle, a copy of the x-ray I brought to you, I insisted on x-raying it before we gave it to the FBI. I mean, we'd have to give the evidence to the FBI, and then they'd fly it to their lab in Washington when we found cyanide. We didn't have an x-ray machine. The Coast Guard had one in the basement of our building, so we took the bottle downstairs to the Coast Guard and they took an x-ray for us. We took two x-rays. I kept one, and the other went in the official records, so that's a copy. I never did pay them back for the x-ray film. And so we x-rayed it for cyanide is quite radiopaque and shows up on x-ray film.

MW: Anyway, here it is. Here's the x-ray of the Sue Snow bottle containing cyanide.

JS: So this is an x-ray?

MW: That's the x-ray, which I'm going to give to you. I'm going to give you the original copy.

JS: Wow! That's quite . . .

MW: But you can see, and you can also see the silicate that was in there as a desiccant.

JS: This would be really a very effective way at screening mass numbers of capsules, wouldn't it?

MW: We didn't have the money at the time, but we rented two fluoroscopes because this would be more efficient. And so then we started passing samples through the fluoroscopes

instead of emptying the capsules. And I can't credit myself for coming up with the x-ray thing. There were many others in the lab and the District who knew about the radiopacity of cyanide. And so that was the basis for the fluoroscopy. And there's another funny thing about that. It's a long story, and I could get into it.

I have a very good nose. I am genetically able to smell cyanide. A lot of people can't. And it turned out, some of the people from the medical examiner's office who conducted the first autopsy on the index case that initially went undetected couldn't smell cyanide. They were genetically incapable of it. And so they attributed the death to emphysema, which they told us can look similar to a death from cyanide. It looked to them like a case of early emphysema, and the man had been a smoker.

So I will now back up, before the Sue Snow death and before this happened. Stella Nickell lived in Auburn, Washington, outside of Seattle. She'd taken out a fairly large insurance contract on her husband. And I can't remember how much it paid, but I think it might have been $200,000 or $700,000 in case of accidental death, so she poisoned him and he died. But it wasn't attributed to cyanide but to emphysema. She got away with murder, but she didn't get the money. So then I think, if I recall correctly, what she did then was tamper with Excedrin. Sue Snow died, and she said, "Whoa, my husband had died, and he had taken Excedrin from the same lot number." Usually the spouse of a deceased in a murder case is one of the first suspects, according to the police. So she now became a suspect, where she had not been one initially.

And it turned out, and I saw this. In some of the capsules, there were little blue specks with the cyanide. It looked different, too. It was hydroscopic and it looked different than the Excedrin would look in the capsule, so I never would have taken it. And I could smell it even before they opened up the bottle. And each capsule had enough cyanide to kill somebody. I

don't think FDA ever got the credit we should have gotten for it. FBI got lots of credit. We worked very hard although I don't think FDA gets credit for the role played. I put people on schedules.

Back to the tampering analyses. The recordkeeping became the most important thing to report back to headquarters, how many samples we'd analyzed every day, what we found, and so we had this. We captured all the data, so we'd tell them each day. And we did find another capsule in a bottle our investigators took from the stores. (They collected all the Excedrin bottles.) This never made the news. This is the bottom of those two capsules, which I'll give you. And we did find an Anacin out there, and this was a bottle taken from one of the stores. It never hit the news, but we did find one.

Anytime there's a tampering, there are copycats, and so I don't know if that was -- I just don't remember if the bottle we found had cyanide added by Stella Nickell or if it was someone else for it was a different brand. But we had a lot of copycat cases in Seattle after this. We had people calling up saying, "I put cyanide in the milk at such and such a store." I mean, we were just going crazy. So we started doing little studies of how long can you detect cyanide in milk after it has been added, and we started doing little things to make sure we could detect cyanide in a variety of matrices if it was there. So I think the regulatory lab . . . and in this emergency, our research group was in there. We stopped our research when we were in there, too, and did a great job. Everybody worked together so well. I just can't say enough good things about all the Seattle District people.

JS: We have that tradition in the agency. When there is an emergency, everyone pulls together, as many people as are needed.

MW: Yes. I mean, and it didn't matter. You had managers opening capsules before we got the fluoroscopes. Everyone pitched in.

JS: By the way, I just wanted to ask, in looking at this x-ray, it seems that not all of the capsules are highlighted here under the x-ray. Does that mean that only the ones that are shown were the ones that were tampered with?

MW: Exactly, yes. That's the normal appearance of Excedrin

JS: So the tamperer would obviously not tamper every capsule.

MW: No.

JS: But just a few.

MW: Just a few, yes. It's a good observation. These are the records of all the different x-ray films and how I had given them to FBI. You can have that. Here's one of the positive controls we did. This is a positive control of cyanide at different levels. I think it's 100, 50, 20 grams.

JS: Are you saying, in one of the bottles, that you have different levels of cyanide?

MW: Yes. This was 100 percent, this was 50 percent, and this, or maybe this was 50. Anyway, you can see.

JS: You're still catching it.

MW: Still catching it, because we wanted to make sure. And we always ran positive controls with the fluoroscope every so often just to make sure that we weren't missing anything. I mean, our investigators got all the Excedrin bottles off the shelf in the Seattle area, and they just did an amazing job. I mean, they were working night and day, we were all working night and day. I was working night and day, and it got so I'd get home at like four or five in the

morning, and I'd take people home on my way home that lived near me. And my dog would bark at me because I was coming so late!

JS: But it's striking difference, using this approach as opposed to that which was used during the Tylenol crisis, which was hand-inspecting every capsule. And while somebody could do maybe a lot of those . . .

MW: But I think I was lucky in Seattle. There were a lot of clever people there. We always tried to find ways that were still effective. I mean, you don't want to have a false negative, and so we did run positive controls. These are the two x-ray films of the index cases that you have here that we ran. I've been keeping these all these years, and I just, I told . . . And the originals, FDA has somewhere.

JS: You mentioned that the tamperer was caught.

MW: Yes, Stella Nickell, but the FBI actually took over after FDA found cyanide. And I have to say the FBI agents we worked with were just phenomenal. They were just fun to work with, and we had a very good working relationship. Their office was across the street. And this was before the days of OCI [FDA's Office of Criminal Investigations], when we used to get to talk to FBI ourselves, and investigators used to do all the cases before OCI took the cream of the crop. But you're seeing some of my biases here, because OCI is very good. I think they are excellent.

I think FBI has a much better promotional capability than FDA does, so they did have a TV program about the tampering on national television -- a mention of FDA. I saw all the agents that I'd worked with. And they did a good job. They found Stella Nickell mainly through those blue flecks, because she had an aquarium, and there is a potassium cyanide preparation available through aquarium stores to kill algae, as an algaecide, and that's how they caught her. They also,

in the Auburn, Washington, library, found her fingerprints on a book of poisons, on the cyanide page. I mean, they did a good job, they really did.

And I got to go to the trial; we all did. And it was a federal trial, of course. And there she was, sitting there with her two sisters knitting. It was like the French inquisition, you know, knitting at the scaffold. And with her was her latest boyfriend, and we all thought, "Oh, my God, he'd have to be crazy to be a boyfriend of this woman." It was sad, because she was very clever, and had she used her intelligence for good . . . She was a screener at Seattle-Tacoma Airport, like TSA today. Kind of grossly overweight. But they caught her; she's in jail.

And I can't remember, I don't know if there was any other death besides Sue Snow. I mean, that was the sad thing -- an innocent person died, so she [Stella Nickell] could try to get the insurance money.

But it was an absolutely fascinating case. I was really proud to be part of it and proud to work with the people I worked with. They were just superb. And we were very lucky. We were able to get two fluoroscopes. And, you know, we didn't have the money, but I just did it. I figured we'd find it. It was worth it. And you just have to take risks sometimes and catch hell if you're going to. I felt this was justifiable. I mean, there are human lives we're trying to save.

JS: You're not suggesting that someone, that you were rapped on the knuckles for this?

MW: A little bit.

JS: Even though what you did helped immensely.

MW: Eventually everything got cleared up. But initially I got criticized, I don't think by people here in Seattle, but in headquarters, who didn't know what we were dealing with. When they finally learned what we were dealing with, then I think they realized that that wasn't

a valid criticism. But initially -- and you had to be ready for that, and I kept that with me all my career in FDA, too. I might tweak people, and I was a bit of a risk-taker, sometimes too much of one. But you can't be timid if there are lives at risk out there. But we all felt that way. It wasn't just me. And I wasn't a lone wolf, because that would make my accomplishments much more meaningful if I had been the only one, but I wasn't. I was in a group. People in the Northwest are a little different anyway. It's a different culture.

JS: Well, there are just a couple other things that I wanted to ask about, which you mentioned in your summary, and that was a couple other crises that you, in particular, were associated with. One was the glass . . .

MW: In baby food.

JS: In baby food, and also the *Listeria*.

MW: Yes, and those were big ones during that year. In fact, I remember Ken Hansen said, "Boy, you really got the baptism of fire, didn't you?" Yeah, but I learned a lot.

Yes, there was glass in baby food. It was actually Gerber. And so all the field labs were having to analyze baby food for glass, and you'd put it through sieves and it was labor-intensive, and we worked all night sometimes. I mean, baby food is really high up there as a priority.

RT: Was that sort of a singular finding?

MW: No, no. It was all over the country. It was some kind of manufacturing defect. I can't remember enough about it. I don't know if we ever found any. We also used, if you found the glass, you used a refractive index to show whether it was glass from the bottle, that bottle, or from some other source, so we had pretty good tools.

A funny story associated with it, though, was that the whole field had done a great job with it, and it was under control, and the problem got solved. But the Commissioner had been

given faulty information and went public saying we'd done so many thousands of jars of baby food, and we hadn't done quite that many, and so the whole field had to work all night to do that many to make the Commissioner right. And so those of us in the lab said, okay, and we talked to inspection branch. We said, "Okay, get the easiest stuff to sieve . . . this is not public health." And so we had them pick up the easiest stuff to analyze for glass in the Gerber products, because by then we knew which ones. So we were done at eight o'clock with our assignment because we figure this is a political thing, this isn't public health. We'll do what we were assigned to do, but we'll use our heads.

JS: So you managed to come up to the . . . to QS to the number required, right?

MW: Yes, yes. I'm probably going to get in trouble for saying these things.

But *Listeria monocytogenes* in food, that was a fascinating case, because we had done some work with that in our laboratory. And it was really the beginning of an awareness of *Listeria monocytogenes* as a pathogen in humans. There had been a few cases, but the history of this organism was that it was considered a veterinarian's disease and a disease of animals. It causes spontaneous abortion in cattle and it's well known to veterinarians. But it really wasn't, at that time, as well understood as a human pathogen as it is today, and it's a particularly nasty one. It has one of the highest case fatality rates and hospitalization rates even today. It could take up to two weeks or longer before symptoms occur, especially in pregnant women, from eating contaminated food, and so it becomes very difficult to link it to the food. I have always felt that it's, as sad as it is when there's a miscarriage, it's too bad we don't culture them for *Listeria*, because I suspect a lot of miscarriages may be related to that because it can get through the placenta to the baby. And it's a pathogen that can go systemic. It's very nasty, and in the neonates, can kill them with meningitis. It's just horrible.

JS: At this time it was highly unusual to find this in the food supply.

MW: Well, this was about the time of the Jalisco cheese case in Los Angeles, and that woke us up. And I remember how furious we were because, according to "hearsay," CDC really didn't inform FDA -- this would be the Los Angeles District -- until they had every "i" dotted and "t" crossed, and we could have been in that plant earlier and shut them down, because they were a very dirty plant when FDA finally got into it, the Jalisco cheese plant.

JS: You're talking in the L.A. area.

MW: In the L.A. area. And so I think it pointed out to us that we need to work more closely with CDC, that they need to tell us earlier so we can get this stuff off the market. I mean, I can't remember how many deaths, but it was high, and some were neonatal deaths.

JS: I remember talking to a microbiologist, Richard Ruby about this.

MW: Oh, yes. He would know more about it than I . . .

JS: We're talking about the Jalisco incident.

MW: Yes. He did an outstanding job on it.

JS: Right. But that was obviously a separate incident than the one you were facing.

MW: It was, but it was in that context, and so it was being found in soft cheeses, especially imported ones. And so we found it in our laboratory, and I remember we worked pretty closely with CFSAN, and I would be on the phone with them together with Ray Mlecko from Compliance, because I think it's really important, and I carried that with me when I went to CFSAN. You really do need to work closely together with people. But then I remember asking one day, "Gosh, if . . .

TAPE 2, SIDE A

RT: We'll resume again now.

MW: Okay. On *Listeria monocytogenes* in the soft cheeses. Well, I think the agency did a pretty good job of getting, you know, people from CFSAN were sent over to France and dealt with the soft-cheese industry, and I think they did a pretty good job of handling that. I remember, though, one time sitting there thinking, "Gosh, could it be in seafood?" and so we looked and found it.

JS: *Listeria*?

MW: *Listeria monocytogenes* in seafood. And some people weren't too happy we found it. In fact, the people in the lab wanted to publish it, and the agency wasn't going to let us do it, or let them do it. And so I argued. I said, "Well, wait a minute. If it's there, someone else is going to find it. We need to get the credit for it and do something about it." And it turns out that *Listeria moncytogenes* has been a real problem in seafood plants, and especially cold smoked salmon, because that's consumed without any further cooking. We did some work with it, found the levels are very low, and this is a pathogen that grows very well at refrigeration temperature. It's cold tolerant. And so what we did -- and by this time Ken Hansen had retired and we had a new District Director, Roger Lowell, who was just really wonderful to work with. We clashed from time to time, but actually, in retrospect, I think I might have been wrong. He taught me a lot. It was painful, but I think he was right, as much as I hate admitting it -- I've never told him that. But he was a good boss. Anyway, he felt that the first important thing is public health and getting these firms into compliance, because we were finding it everywhere in fish plants or crab processing plants, everywhere.

And so what we did, we put a road show together, Roger did, and we would all give talks. Roger would say, "Okay, if we find this organism in your plant, here's what I'm going to have to do as District Director, and I don't want to put you out of business." And then he would have me give a talk on the growth characteristics and how to control it and that kind of thing. And then we had Mel Eklund from National Marine Fisheries Service with us, who also gave talks. And, actually, Mel worked with the plants more than we could to try to get them into compliance. And then we worked with the industry and in the state, so we all tried to work together to get these plants in compliance, to teach them what they had to do, and we got them in compliance. But it was only by working together. And that was Roger's way of dealing with things. The number one goal is to have them in compliance. Okay, instead of clubbing them over the head, we won't have any plants left in the Northwest, because he came from the investigation side, but he had a master's in botany, I believe, and he was very well grounded in science and investigations and public health. And so I think we did some really good work. We worked together with state health departments in Washington, Oregon, California, so the whole West Coast was working together.

We did the same thing with domoic acid that I didn't mention. That was found in, it's a neurotoxin found in molluscan shellfish on the whole West Coast in '93, I think, for the first time. We went on the road and we talked about it, how you detect it, what it does. But I think that became a really good model.

JS: How does *Listeria* find its way into the food chain?

MW: It's an environmental organism. You can find it in the environment.

JS: So from the standpoint of seafood, that makes sense, but what about the raw milk?

MW: That, too, for cows.

JS: Same?

MW: Yes, yes. It's also very salt-tolerant. We kept the stuff going for over a year in saturated saline. I mean, we were just dumbfounded. It wasn't happy; I mean, it was kind of crinkled, but still alive. So we did a lot of work with *Listeria* to try to define how it could survive, where it could survive, so we would know where to look for it and maybe give us some ideas how to control it. So we had a lot of papers published on *Listeria monocytogenes*.

The domoic acid was a, that was first found in 1987 in shellfish in Prince Edward Island, Canada. And so the Canadians -- and we knew them from meetings and things; we knew all the Canadians who'd worked on domoic acid, or often called amnesic shellfish poisoning. And they had just done a heroic job in determining what it was, developing methods to detect it, and even putting together a regulatory guideline for Canada on domoic acid. So we pulled them in. We thought, well, we don't need to rediscover the wheel, and so we invited them, our friends from Canada.

Peter Barton Hutt once said at a meeting that we had never, FDA had never used a regulatory limit set by another country, and that's not right. I jumped up, but he didn't see me. We adopted the Canadian level, which was a reasonable level for shellfish for the United States. And so we leveraged their knowledge and gave them credit, and they willingly helped us with our problem. And so now there's monitoring for it on the West Coast, and it is still a problem from time to time. It causes short-term memory loss. It's a glutamate agonist. It's a permanent short-term memory loss, too. It's a terrible toxin. It also was found (at specific sites in shellfish) by the National Marine Fisheries Service researchers. It was located mostly in razor clams in the digger, which is something relished by children. My mom used to fix it for us when we were little kids. I mean, that was something -- it's just a wonderful, succulent part of the razor clam.

JS: Any heat process would take care of it?

MW: It's heat-stable. So, I mean, there were a lot of things.

We also, before I left Seattle, developed the *Regulatory Fish Encyclopedia*, which is still on the website of CFSAN. ORA didn't have a website or capability, so we didn't care. We went to CFSAN. And we worked together with Fred Frye, who's still at CFSAN, because he's a great chemist with CFSAN, and a computer guru. In fact, he used to come every year and work with us, and he'd stay at my house. So he was our other SPRCan, so he and Brad Tenge, in our group, and Ngo-Lan Dang had put that on the website. And the whole purpose of the fish encyclopedia was safety and economic fraud, because if you ask the seafood industry what's their biggest problem, they'll say economic fraud. You see it all the time. You know, snapper fillet, it says snapper, well, it's rockfish, and how are people going to know? And so, at that time -- this was before DNA work got done in the '90s -- we were using isoelectric focusing for muscle proteins to speciate. So we had those on the website together with photographs of the appearance of the fillet of the fish, the market fillet, and then photograph of the fish in the round.

And then we went to the California Academy of Sciences and worked with Warren Savary, at that time was at FDA in San Francisco. He's now at Nogales, Arizona. He stays at our house when in town, we see him a lot. He's at the Resident Post in Nogales. But he's a wonderful taxonomist, because I said, "You know, we can have the best chemistry in the world to speciate, but if we don't found it on good, solid taxonomy . . . And I've taken fish taxonomy, so I knew how to key out a fish. It's not that easy. And you go to the dorsal spines and all kinds of . . . So we had it pretty well grounded for economic fraud, and we had almost a hundred species up there on the web, and we'd add new ones as CFSAN asked us to. But it was a true collaborative effort.

JS: But your laboratory was behind it.

MF: We started it, yes.

JS: They had the creation of this encyclopedia.

MF: Absolutely. And that would be, the credit goes to Brad Tenge, who's now still in Seattle, but he's in the computer center now. What happened was -- and we got, I think, about $70,000 from CFSAN to do it, they did help us, because we had to pay for a lot of different things to get it on the Web. And then ORA paid maybe $20,000. Of course, they paid our salaries. But at that point, in about '99, '98, there was a regime change on the West Coast. I don't know if anyone has ever talked about it.

JS: Tell us.

MW: Well, it's not pretty. But there was a new Regional Director put in who did not support things like the fish encyclopedia or our research group.

JS: This was the Regional Director?

MW: The Regional Director of the Pacific Region.

JS: Right, okay. Obviously, by this time, Seattle is part of it.

MW: Yes, Seattle is part of the regional system. And so, basically, our research group was on the chopping block. A lot of people were. It didn't mesh with the philosophy of the new Regional Director, and I got demoted. By this time I was a 15, which I earned through peer review. I rose up to 14 and 15 through the research peer-review process. I had to now report to the lab director. Oh, and John Wiskerchen was made to apply for his own job as Lab Director. His wife, Jacky, had cancer, spinal cancer, a very rare form, for the last 10 years, and you'd never know it, and he was taking care of her and being a good Lab Director. And Seattle is one

of the best places to treat this, so he couldn't leave. They made him apply for his own job, and the Regional Director gave it to someone else.

JS: He had to apply for the position he was already in?

MW: Yes, yes. The Regional Director, they made that lab, then, one of the mega laboratories, and so, where before it was a district lab and the Lab Director and I both reported to the District Director, well, this was now made into a regional laboratory like they have in New York, where the Lab Director reports to the Regional Director. And so they argued that he (John) would have to apply for this job, and he didn't get it.

RT: Was this gentleman . . .

MW: John Wiskerchen.

RT: Yes. I assume this may be Richard Baldwin. Is that right?

MW: Yes. And so Baldwin put in one of his cronies, who's still there, and I really don't want to get into that.

JS: You mean in the lab?

MW: As the Lab Director? And so John didn't get the job. He retired.

John was really magnificent about it. We gave him the most loving . . . We used to have this thing in Seattle. When people left or retired, we had a party for them, huge parties, and we put on a skit. And we'd even rehearse these skits, like when our Regional Director left, we had a skit for him, like a play. When Ken Hansen retired, we put on a play for him. When Ray Mlecko went to Chicago as District Director, we put on a skit for him. And we'd usually kind of, not a roast, but we would make fun of them. So we put on a skit for John, and it was like "What's My Line." It was just a riot. I came in. I remember I was dressed as, they had to pick who was the real Lab Director, so I was dressed as this hunter. I killed things because John liked

to go hunting. I had a gun; it was a cap gun. And our Public Affairs Officer, Sue Hutchcroft, came in dressed as a duck, and so I was going to shoot the duck. She had on a duck suit and everything, and I was going to be John and, oh boy, I like to kill things. And little did Sue Hutchcroft know that I'd put real caps in the gun, so I shot her, and this big bang killed her. This was before 9/11. (I think she finally forgave me!)

Anyway, it was a loving party for John. And, actually, he's gone on to consult, and he says probably it was the best thing he ever did. And I remember he asked Ron Chesemore at the time, who was the ACRA, you know, "Why did this happen?" And Ron said, "Well, you never applied for District Director jobs." And John said, "My wife was dying of cancer. I couldn't leave Seattle." "Oh, I forgot."

But things do tend to work out for the best. And I've seen John from time to time. In fact, he married, after his wife died, maybe five years later, he married one of our researchers from SPRC, and they're very happy. I'm just happy for them.

JS: Well, when this regime change came, they dissolved the research center?

MW: In essence, that's really what happened. ORA won't say that, but it is what happened. And I was made to report to the Lab Director, the new Lab Director, who I did not respect at all, and I knew I just had to get out. They were really setting us up for failure, and, as an example of their maliciousness, I can tell you that one of our researchers, Walter Hill, who's a Ph.D. in genetics and just brilliant, had had a cardiac arrest and almost died, and he'd had a heart attack in '83. He'd had to have a defibrillator implanted. I mean, he lived, he was so lucky. A couple months later, they put him through peer review, and they tried to take away his 15. And because it appeared they had loaded the peer review panel. At that time it appeared to us in the field that it was easy to maybe tweak the peer-review system. If you got all your buddies on the

panel, you could give your people promotions or deny it to deserving people, and that did seem to happen for a while in ORA. I hate to say that.

JS: When you say peer review, these are peers within the agency, not peers in the outside world?

MW: No, no. Many were not peers. And so they forced Walter to go through peer review right after his near-death experience, and he did. He put all his stuff together. And it appeared that they were trying to actually take away his 15. They didn't do it. But I knew I was going to be next, and so I knew I didn't have a choice. So I started looking for another position. I couldn't find anything in Seattle, and so, long story short, I did get the job in New York as the Lab Director -- not that I . . . I just felt I didn't have a choice. So I left in 2000, January, actually December of '99, the place where I'd known all my life, you know, skiing, hiking, and mountain climbing, and my family was all there, and so it was the hardest thing in the world for me to do. And I remember flying into New York over Central Park and just thinking, what have I done? I was so scared, country mouse. But I loved New York. I had a great time. I was treated well.

JS: This was the regional laboratory in . . .

MW: Jamaica, Queens.

Actually, what doesn't kill you, as Nietzsche said, makes you stronger. I learned a lot. I mean, I even got a divorce. I left everything. And we're still friends, my former husband and I. We just divided everything. The only thing we really argued about was our REI number, you know, Recreational Equipment, because we had a real low one because it got started in Seattle, and we both wanted it, and he got it.

JS: He got the REI number.

MW: And the Hasselblad. But we're still friends. We talk all the time.

But it took a lot of courage, just every ounce of courage I had. And so, but I really enjoyed it in New York. Diana Kolaitis, our Regional Director, was a joy to work for, and . . .

JS: You reported directly to the Regional Director, the regional lab directors?

MW: I did, and I was still a 15, so I took a real hit. I mean, it costs so much to live in New York, and I was getting divorced. It was really hard to start all over, but I enjoyed it there, I really did. They were great people to work with.

RT: Who did you succeed? Was it Boone?

MW: Yes, yes, George Boone. And also, at the time they had moved, so I didn't have to work in the Brooklyn lab. They moved from Brooklyn to Jamaica, Queens, to this new building that George had actually been instrumental in getting. It had a lot of problems. I mean, we had to retrofit a lot of things. I mean, that's true for a lot of new laboratories. So I spent a lot of my time, Al King and I -- he was head of Drug Chemistry-- Al and I did a lot of work trying to get that lab up and running.

JS: You were, of course, fortunate not to have to spend any time in Brooklyn.

MW: Yes, I was. Although Jamaica, Queens was dangerous. I moved to Long Beach and Al King and I rode the Long Island Railroad every day together, sat in the same seat. Everybody knew each other. And we'd have to walk from the Jamaica, Queens train station to the lab, which was a little dangerous. I mean, we'd walk by the methadone clinic and see the guys out there, the same ones every day, and sometimes you'd see drug deals going on and you'd just pretend like you didn't see it so you wouldn't be shot as a witness. And we had to walk through this urine-soaked tunnel. And there was someone shot there one night at 5:30 accidentally in a little argument with some people. Actually, you got to know the street people

because you'd see the same ones every day, and pretty soon you kind of got to be friends, and pretty soon you're telling them good morning.

And it wasn't at all what I thought it would be. You had access to so many people there, like I got to meet the guy who ran JFK or La Guardia and Newark Airports. We met. Diana would drag me along, and Jerry Woyshner, District Director, to the World Trade Center. We met at least once a year, if not three or four times a year, with the Port Authority in their efforts to, with the Coast Guard and with the Customs, in efforts to try to coordinate the federal effort for imports with the Port Authority. And of course, they're trying to have New York as a big business, and that worked really well. In fact, the wonderful fellow from the Port Authority who ran those meetings was killed on 9/11. And so I have a magnetic card for the World Trade Center with my picture and the magnetic strip to the World Trade Center, to go there. And I remember one time Diana dragged us up to Windows of the World, and we all walked around and looked out, and the view was just phenomenal.

And we got to know the Customs people, and in fact they were -- and this is relevant -- they were remodeling their lab, and we had two floors of empty labs. And I remember telling Tom Guarino, their lab director, "Well, why don't you guys move in with us, and then you can get your lab remodeled. It'll be easier." Well, he remembered that. On 9/11, their building went down, World Trade Center 6. I mean, it was destroyed. In fact, they had to keep one guy from running in to save his mass spec library. I mean, they lost everything. They lost 30 years of mass spec libraries. Sure, office computers are backed up, but mass spec computers are not backed up off-site, and that's still true for FDA too. So they lost everything. He was in my office the next day, and that's the only time I've ever seen paperwork and everything set aside. They had phones, they had desks, they had everything within a few days, no red tape. So we

were actually very proud that we were able to help somebody, and so we took in the Customs lab in New York. We were all very proud of that because it was such a horrible day.

I was in Chicago, and I couldn't get back till that Saturday. But the NY FDA people watched the second plane hit from the building roof, and they watched the buildings go down. And so when I got back . . . And we all knew people who had been killed. I mean, it affected the whole city. And I've never seen a city change, and it was really true. There was a different attitude in New York City after that. People were kinder to each other. You weren't a hyphenated American anymore, you weren't black or white, you were American. And I went down there and saw it right afterwards, and it was so painful. That odor I'll never forget, of jet fuel and death and concrete dust. It was terrible.

And I also was on the task force the state government put together for bioterrorism. New York was very proactive. They didn't wait for the feds. After 9/11, they did things. We all worked together, and it was just a profound experience. We had a lot of things happen there that we were all a little jumpy about, and so we all decided whatever lab is nearest, we'll take it. Whether it's USDA's or FDA's, we'll do it and ask questions later. And that set the stage for the nitrite, that there were about five people in the hospital near death with methemoglobinemia, and they thought it was bioterrorism.

JS: When was this?

MW: And this was -- and I brought the Weekly Morbidity and Mortality Report [WMMR] of it. This was 2002, and the container was this, from Egypt. We had several people in our lab from Egypt who read all this. They could read Arabic. It was a very multicultural laboratory -- every language spoken.

JS: So this is a bag of sea salt that we're looking at.

MW: Of sea salt. But this is what the people had used. Well, bottom line, it was sodium nitrite that they had put in this. It wasn't bioterrorism. These are the patients.

I remember that night, and they said, "Can you take it?" and I said yes. And it was me, so I called USDA, Goldman in DC, and I said, "Okay, we're going to do it. Anything you want me to do, I'll keep you informed." I even called my counterpart in Egypt because we were worried that if it was in this country, was this mislabeled, and was it sodium nitrite, and were people in Egypt who would be at risk. No, it hadn't been mislabeled but sodium nitrite put in the sea salt bag by those in the home. I was on the phone to CDC, I was on the phone to many people -- I was coordinating everything. We got the sample at four o'clock that day, and we had it nailed by midnight, as sodium nitrite. I called the attending physician in the emergency room to get the symptoms of the people, and he's the one who said, "I've treated this before. It looks like nitrite." You always talk to the attending physician if possible. And he was right, and he treated them for that and he saved them. Nobody died.

But at the time, samples were collected by guys in bunny suits from helicopters. They thought it was bioterrorism. And we didn't have any food in the lab or restaurants nearby. I remember I had only $40. We were working. I don't think it got done until 1 or 2 in the morning. So I just gave one of the chemists -- I said, "Well, here's $40. Go out and get food for all of us, as much as you can get to feed all of us in the lab." and he did, and we ate pizzas.

MW: It's the CDC's WMMR.

JS: Right, for July 26, 2002.

MW: Correct, yes. And what they say is within 48 hours of onset of illness, the FDA laboratory testing confirmed the presence of sodium nitrite. Well, we didn't get the sample till four, so it was really within eight hours that we had it. But what this did, we all worked together

with the health department, the local health department in New York, with USDA. We didn't argue and say, "No, meat's not our jurisdiction." Some of the samples collected were meat samples – we just did it. And they gave me credit here. I tried to get some of the other people in here, but I couldn't. But I don't think they give FDA enough credit for all the work we did with everyone else. But it was a true collaboration, and that was forced by 9/11. And also FBI; I was talking to FBI again. A funny thing about FBI, at that time, they didn't have very good computers, and so I was sending stuff to their AOL home accounts.

JS: Somewhat unorthodox, isn't it?

MW: Well, it was whatever we could do to get stuff to them, and they were the same way, you know, expediency, we've got to move fast. And we did; we were fast.

JS: There was no reason for OCI to get involved in this, was there?

MW: I think they were, but we didn't wait for them.

JS: Okay.

MW: I don't think they would have expected this either. But, yes, they were there too, but we were dealing directly with FBI. We didn't say, "No, we can't deal with you; we have to go through OCI." I learned all this on Excedrin.

JS: In Excedrin, but also in the aftermath of 9/11. You just learned to get things done.

MW: You did.

JS: And ask questions later.

MW: And, actually, it was great having Customs there, because quite often we had cases that overlapped. They were just wonderful people. And we also had the New York City crime lab nearby, and so I remember one time we had a sample that we thought might be

cocaine, and so we were laughing, “We’ll run up to the crime lab and ask if we can borrow a cup of cocaine for standard,” you know, just joking, just joking. So we worked together with the New York City crime lab. They did an ungodly number of samples for controlled substances. It’s kind of a sad commentary on the city that there would be a need to do that, but . . . So we all did work together. We had a very good network. If anything happened, I think we could have really handled it really well.

We did, one of our people, a wonderful fellow, he’s from Egypt, and he was really instrumental in translating, and our other Arabic-speaking people in our lab translated, too. So we sent him on inspection. We talked to Jerry Woyshner. We all suspected that some of the food warehouses in, I think along Atlantic Avenue, might be controlled by Islamic fundamentalists that were of questionable friendliness towards the United States. And so we sent the employee on inspection, and he conducted a whole inspection in Arabic. And I remember he came back and he said, “They’re here.” I said, “What? What’s here?” “The Brotherhood.” “What brotherhood?” “The same guys who killed Anwar Sadat.” Apparently this warehouse was run by some really scary, really far-out Islamic fundamentalists in New York City, a food warehouse.

JS: Okay. Is this the same Brotherhood that we heard about during the Egyptian uprising?

MW: Yes, yes. So, and they had the raisin from touching the forehead to the floor in prayer. Our employee described everything. This employee -- and this is relevant-- he’s an Egyptian Christian, he’s not a Muslim. And, of course, a lot of the Christians have left Egypt because they weren’t treated too well by the Muslims, and that’s coming out in the news.

And so we went to the FBI and to the, we had the New York Police Department terrorism squad come into our lab and we told them what we'd found. And also, we had found, we did private lab reviews, as all the labs do. If you have a private lab, mostly for firms to get off import alert, you can look at their laboratory reports and see if they meet our standards. And we had found that another questionable group was running a lab, kind of validating analysis of water supplies. I think it was the State of Connecticut, and that kind of concerned us because we thought, well, gee, we started thinking like little terrorists. They could put bot toxin in there and then certify it as being very good and kill everybody. So we reported that too.

So we all got pretty active. I mean, there were a lot of things that happened in New York. That was just one example that made the press.

JS: You worked there for three years, it looks like. Your next step in this is to headquarters. But before we do, do any other particular cases come to mind that you want to talk about while you were in New York?

MW: Well, we also had another thing happen that was right up my alley with American Puffer Fish found to contain tetrodotoxin, just like the Japanese ones. And this was, actually we learned about it through a New Jersey poison control clinician who was really sharp, who recognized the symptoms as tetrodotoxin, because people were presenting with these neurotoxic symptoms.

TAPE 2, SIDE B

MW: Since my love is marine toxins, I'd already gotten a guy in the lab up to speed on being able to analyze marine toxins, Tim Hawryluk, who is just a wonderful fellow. And so we got the samples and we analyzed them. And before we analyzed them, Mike Quilliam from Canada, who is one of the ones who'd been involved in domoic acid, called me. He said,

"Marleen, you'd better sit down." I said, "I understand you got the samples." He said, "I've already analyzed them." And he said, "You're not going to believe this." And he said, "It's tetrodotoxin." So he told us he'd already found tetrodotoxin, Mike Quilliam, that was our network we had with the Canadians.

So we were going to look for PSP toxin, because that's what we thought it was, which would have the same profile. So we looked for tetrodotoxin and found it, Tim did. But this was one of the first times that this had been documented in the United States, that puffer fish from the Titusville area in Florida had tetrodotoxin. It had been mostly a sports catch, some commercial fishery of puffer fish exits for the East Coast of the U.S., but a lot of times it was just bycatch.

So, again, we made WMMR reports. The first one was April 19, 2002. And when I saw this I hit the roof, because we'd seen the rough draft of it, and our names weren't in it, and especially Tim's. I wanted Tim's name in here because he'd worked all night and weekends, and I wanted him to get the credit for it. I didn't care if my name was in there or not. Well, CFSAN, a person in CFSAN, took our names out, and I let her have it. And so the next one that got done, because she said, "Well, names are never used," and I quoted all kinds of reports that I knew of where names were included. So the second one that came out, our names did get in it. And it was really more Tim, that I wanted to make sure Tim got the credit.

JS: Also in WMMR?

MW: Yes, and this was for May 17, 2002, which I'll give to you. And so those were two things that I was pretty proud of what we did.

JS: Is there much of an industry for American puffer fish?

MW: A small one, yes, a small one. It's not large.

JS: They're associated with Japan more.

MW: Well, and fugu. And I've been to Japan many times and I've eaten fugu. It's tightly controlled. You go to the Tokyo fish market, which I've been, and only a licensed fugu cook can purchase them, and then they know how to, because most of the tetrodotoxin is in the ovaries and the liver and the other organs, and they take that out. And it is allowed in the United States, in New York, a special thing that CFSAN did with licensed fugu cooks in New York City. You've got to be real careful when you transplant cultural practices from one country to another if you don't also bring in the knowledge base.

JS: Just as an aside, it must be really good fish.

MW: Well, it's interesting. I think it's more the brush-with-death sort of experience.

JS: Well, that's what I mean. It must be really good fish or something.

MW: Yes, because I remember my friend Fumiko took me with her family to a fugu restaurant, and she took my picture. She said, "Okay, picture you before you die, ha-ha-ha," but just joking.

JS: So then, in 2003, you've been in the field for your entire FDA career.

MW: Yes.

JS: And finally you come to headquarters. What led to that?

MW: Well, I could tell you a big, long, involved story, or I could tell you the truth. Steve didn't want to live in New York City. Besides he could do his job better in Rockville. By this time -- we'd known each other on the West Coast, Steve Kendall and I, who's now my husband, and we were friends for a long time. I didn't realize he'd gotten a divorce. He knew I had. And we had known each other since '87, because the managers of the three Districts of the Pacific Region always met at least once a year on the West Coast. And so by this time we're kind of, you know, the friendship grew to more, and he really, we decided he would move from

California and we'd get married, but he didn't want to live in New York City. And that seemed a fair enough thing if I'm asking him to leave the San Francisco area for the East Coast, which is like killing a West-Coaster. And this position came open.

JS: Which position?

MW: It was a Deputy Director, again a lateral 15 to CVM [Center for Veterinary Medicine]. And I knew Norris Alderson. I'd worked with him in Seattle. In fact, he would come to our research planning meetings, because he did work on fish. And I held him in very high regard. He was head of the Office of Research at CVM, and, theoretically, I'd be working for him. But by this time he had left to go to the Commissioner's Office. But I had worked with CVM quite a bit, and I thought highly of them.

JS: So this is in the Office of Research in the Center for Veterinary Medicine?

MW: In the Center for Veterinary Medicine in Laurel, Maryland.

So I knew the people. I had in fact even applied there when I was looking for a job in 1999 as head of one of their microbiology branches there, and it was between me and another guy, and he got it. I mean, you know, that happens. And then I remember Norris told me about this, and by this time I had accepted the job in New York, and he said, "Well, could you apply as Deputy?" And I said, "Well, I would love to, but I've already accepted the job in New York and I really can't go back on my word." So I could have maybe gotten the job as Deputy at CVM instead of New York in 1999, but I couldn't go back on my word to Diane. I mean, I probably would have preferred to have been in a research environment because that's where I'd been. It was actually a good experience being in New York. I never regretted it. But I couldn't, I couldn't morally just do that, go to CVM in 2000 after I'd accepted in New York.

RT: Who was the Regional Director in New York?

MW: Right there in our office in Jamaica, Queens, Diana Kolaitis, marvelous woman. I really liked her, just a character. I liked her because she trusted us. She didn't micromanage. And she had such a sense of humor, and it was just fun to go to work. So that's kind of the history of CVM.

JS: Who was the Director at the time?

MW: The Director of the Center for Veterinary Medicine was Dr. Sundloff.

JS: Stephen?

MW: Stephen Sundloff, marvelous fellow. I do like him. And at the time, the Director of the Office of Research initially had been Norris Alderson, who I really thought so highly of him, but they had hired, since I didn't go there, they had hired someone else as Deputy, and then she became the Director. But she had come from Oxford. She was an American, never worked for the government. She was really a fish out of water, a delightful person, but she didn't, she quickly -- it was too much, I think, for her. So I worked for her. And Dr. Sundloff actually -- this is a bit awkward -- they removed her and put me in as Acting Director, and that was not through anything I did, but that there were a number of things that had happened that Dr. Sundloff felt that she was not the best person for the job. It wasn't fair to her because she really hadn't the experience to be in FDA at that high a level, to start at that high a level.

JS: Who hired her?

MW: Dr. Sundloff. And it was over the objections of the Office of Research, because they all said this. Although she's an eminent scientist, she doesn't quite have the background and the temperament for government, for FDA, and doesn't understand.

So it was very awkward for me because I had never intended to be the Director of the Office of Research, and I didn't hire on there as that. I was perfectly content to be a Deputy,

although it was kind of hard after being a big kahuna in New York. But I thought, well, this is going to make me look like a barracuda, and I never wanted to have that kind of -- really, that was objectionable to me. And I talked about this to Dr. Sundloff.

So I was there for the whole time that he was Director, till about 2008, and then the Commissioner asked Dr. Sundloff, Commissioner von Eschenbach, to head up CFSAN after Bob Brackett left. And it was my understanding that Dr. Sundloff was asked to do that. I'll never know what the truth is. Well, then, the Director of OARSA, which is my last job, had left, and so Dr. Sundloff had asked if I would go over there to direct OARSA as Acting Director.

JS: OARSA is . . .

MW: Office of Applied Research and Safety Assessment. And it was just next door. In fact I asked him, I teased him, I said, "Well, what's in it for me?" He says, "Well, you won't have to drive 400 yards more."

JS: But before we move on to that last position, I wanted to ask about the National Antimicrobial Resistance Monitoring System. A number of interesting research projects you were involved in related to this.

MW: CVM.

JS: Right, and particularly with the melamine crisis at the time.

MW: Oh, yes.

JS: I wonder if you could elaborate on that.

MW: Oh, that melamine, that was really something. It was like another cyanide. Yes, it was absolutely amazing, and nobody knew exactly what was causing the deaths of animals. And on one day, the New York State Laboratory announced that it was aminophylline, and it wasn't. And I knew the people because I'd worked with them, and they were wonderful people,

but they were under a budget crunch and trying to make a name. It's one of those sad things in public health that sometimes happens by well-intentioned people. But anyway, I think Procter & Gamble, UC Davis [University of California at Davis], and the University of Gulph in Ontario -- well, there were a lot of people working on this, and on our own Forensic Center under the direction of Fred Fricke in Cincinnati. And I'd known Fred because he was one of the original Research Center directors of the Elemental Analysis Research Center in Cincinnati.

JS: You both were sort of at the leading edge of the research center movement in the field.

MW: Yes, we were, and he's a marvelous fellow. In fact, when I last saw him, I told him that "of all the Research Center directors, you were the most successful. You were able to leverage yours into the Forensic Center, which is just wonderful, and I'm so happy for you." But they had found it. They had found it as melamine, and they also, I think, found cyanuric acid. And so it was like both labs, private sector and FDA, found it as melamine on the same day, so it was a good confirmation.

And then I remember we were arguing with Compliance in CVM. They said, "Well, this is a compliance issue." And we said, "No. We think there's something we can do as researchers on melamine," or even before we knew it was melamine. So we kind of bulldogged our way into it, getting on the conference calls, because we were not included.

And there is somebody who needs to be named here who's just a tremendous heroine and scientist, and that's Renate Reimschuessel -- I'll write it for you later. She was head of the, she is head of the aquaculture facility at CVM. They have a whole aquaculture laboratory. She's just absolutely incredible.

JS: What is that a part of?

MW: Part of Office of Research, CVM.

JS: Okay.

MW: And Renate is not only a veterinarian with her expertise in renal function, kidney function, which is the site of attack of melamine, but she's a pathologist. And so, boy, we got her involved right away. A wonderful woman; I just totally admire her. And there was some reluctance in having research done on this because there's always that antagonism between researchers and other parts of FDA sometimes, but we didn't let it stop us. I'd been through all this before, and I just, we just pushed on.

And Renate just did an extraordinary job. And she looked at the crystals. She was able to get a kidney from a cat that had died from a veterinarian friend in Michigan, and they had done histology on the other kidney, and so she saw the crystals. This one hadn't been preserved. I think it had just been frozen. She saw the crystals. I remember she said, "By golly, these look just like urate crystals. I remember in vet school, we had to, for gout, there are these long crystal structures." And so she said, "If they are, I'm wondering if it's melamine combining with endogenous urate or something else." Well, we later found out it was melamine combined with cyanuric acid to form a urate crystal. So she was right. She also was right in remembering that urate crystals dissolve in formaldehyde. And what do histologists do to preserve tissue for future work? They put it in formaldehyde. So a lot of the vets weren't seeing the crystals. They were just seeing blocked renal tubules, the effects of the cyanurate, but not the cyanurate itself. So Renate was one of the first people to figure it out. She got on the phone to all the veterinarians, because they were having frequent national phone calls and told them, "Don't put the kidneys in formaldehyde!"

And we were able to get, we had an Animal Care and Use Committee at the Office of Research, CVM, and we had a protocol already approved for incurring residues in animals, and so we were able to amend that protocol, because it can take months for approval. So we could feed melamine and cyanuric acid to fish and to incur residues for not only the Cincinnati lab, because now we knew that we had not only a problem that chickens had been fed, we had to find a method to detect the crystals in chickens, in fish, because these animals had been fed melamine that got into the human food chain and we didn't have methods. And so we incurred residues within the week once things started coming together in fish, and got them off to the labs developing the methods, even to USDA.

That's Renate. She was able to do that, working night and day. She then started doing some studies of feeding fish and did some beautiful, elegant studies of the effects of melamine in fish with her research group, which she's published, and we continued that. Of course, later, after it was found in baby food (formula), we had all the methods. We knew what we were doing, and I was at CFSAN then. So we had a toxicology group at CFSAN, in our research group.

And I just saw Bob Sprando, the Director of Toxicology. They just finished a study, because they asked the question, does it get to milk if women are fed melamine and nurse; does it get to the fetus? Does it get to? And he's done some elegant studies with rodents and melamine, together with Renate. So when I went to CFSAN, I pulled the people from the Office of Research so we could work together more, to collaborate more. So they published some elegant work, and they've got to give them the credit for it. I tried to get them the resources they needed and to argue for their even doing their research against people who felt it wasn't necessary, because in the literature, melamine was listed as nontoxic. You could feed milligram

amounts to animals and they didn't get sick. As Renate started digging, she found that that wasn't exactly the case. Some of these studies had been done by industry, and some of the adverse effects were ignored. And she knew that cyanurate was used as a pool cleaner, and there had been some studies to look at the effects of cyanurate, so there was some literature, but it wasn't correct and it was confounded. And so Renate did a lot of work on that. And that went really far with protecting public health.

JS: Where was the melamine and where was the cyanuric acid? Where were they coming from? And how widely dispersed were they?

MW: The Chinese, and that's well documented, and it was an adulterant. And this is another interesting story, that if you look at the molecule of melamine, it's a benzene ring with, it has six nitrogens per molecule. Okay. Let's back up.

The world's supply of proteins, the Chinese kind of edged out U.S. manufacturers economically because we couldn't afford to make gluten and make the things as cheaply as they could. Now we know why. You've got a higher price, the more protein in your sample, so protein content determined price that you would get on the international market. The method for determining protein was the Kjeldahl, which is the measurement of total nitrogen, and so, perfect. They'd been doing this for years and we weren't determining actual protein content but nitrogen content -- I mean, nobody knew. I think what fouled them up was the stuff they used wasn't real pure melamine and had cyanurate in it, and so that's what got the crystals.

JS: So it was an adulterated adulterant.

MW: Exactly, exactly. And as it turns out -- as Renate, who's really good at looking at the old literature and she reads a lot of languages, because it happened in Italy; animals had been poisoned by melamine in Asia before, too, not in the U.S. -- it was all melamine. Even the

private firm came to us at CVM, and they knew it was melamine in their product, but they couldn't figure out why it was killing animals because it's nontoxic if you look at the toxicological data.

So this taught me another lesson that when you're doing an analysis -- and we learned this in the heparin with chondroitin sulfate form China -- you've got to make sure you're measuring what you think you're measuring. For heparin they were measuring, I think, blood-clotting time, so they weren't measuring the adulterant in the heparin that came from China that killed several people in the United States. So I think they had been adulterating, a lot of us think they'd been adulterating, with melamine for some time. In fact, we found, at CVM, that our fish feed, because we were starting to find melamine in our controls, our own fish food had melamine in it that we didn't know about. There's still melamine in the world. It's in shrimp. You can find it at real low levels, not dangerous levels in shrimp, because a lot of the products got put into the fish meal that were fed to fish. So it's still out there. And it was pretty cheeky for them to put it in the milk. We've had a lot of philosophical conversations about this, that China is kind of like we were before the, what was it, the famous thing in '38.

RT: That's sulfanilamide.

MW: Yes, the sulfanilamide. A lot of our lessons in the U.S. in health safety were using human beings as a bioassay. And the Chinese aren't there yet, and they don't have quite the infrastructure. And I think we are putting our people at risk with globalization -- I really do firmly believe that. But they're hostile. They drove our own manufacturers of protein out of business because they couldn't compete.

JS: And have we seen an escalation of pricing for these commodities now that melamine's no longer being used as an adulterant?

MW: That I don't know. I'm not a melamine economist. And what drove us in the melamine situation was when all these animals were dying -- and we'll never know how many because there's not a CDC for animals -- but it probably was thousands.

JS: Thousands of pets?

MW: Yes, yes, and the veterinarians didn't know what it was, and they quite often treated them the way they should, by giving plenty of fluids, because they could see it was renal damage. But we were all concerned because we've all been there with all these toxins that have been found in human foods, or pathogens. Quite often the first thing that shows up is toxicity in animals, and we were all worried, before we knew it was melamine, because we wondered "are we all being fed this stuff?" We were all pretty worried. And that drove us, not only a love for animals, but . . . And then when we found it was melamine, I think, I suspect a lot of the mass-spec guys in FDA were testing their own urine, or they should have been, because we were all worried that we had all been subjected to this.

So that was, I think, again, FDA at its finest. I think people worked together really well.

JS: And so that was a large focus, a substantial focus of your activity both in the Office of Research at CVM and after you moved to CFSAN?

MW: Although CFSAN, when it was the baby food (that is, the infant formula), it was mostly the Office of Nutrition and Compliance. I mean, they were ones in the forefront. The research kind of came later. They already knew, and we had all the data, and so we didn't play a major role in milk. We played kind of a background role in trying to do more research to fill in the data gaps.

JS: When you were at CFSAN, to what extent did these really high-profile foodborne disease outbreaks, how did that affect the work of the laboratory, the spinach and so on, all these other crises?

MW: Oh, quite a bit. The spinach. Again, the research component usually comes in later, because when you have an outbreak, you've got the other components of CFSAN and ORA, you know, investigators. They're trying to get the stuff off the market, figure out what it is, and use a lab if you can, and it's later that you come in. So our group got the spinach isolate, our geneticists, and they found some interesting things about it. It was a little more lethal. It had two copies of Stx2 toxin, which is the more lethal toxin. In *E. coli 0157*, which this was, it contains Shiga-like toxin. It's very similar to the toxin found in *Shigella*. And there's two Shiga toxins, Shiga toxin 1 and Shiga toxin 2. Shiga toxin 2 is the more lethal of the toxins. And it also causes hemolytic uremic syndrome, and that's what kills the kids. Children are more susceptible. It's terrible.

But they found some genetic anomalies in the *E. coli 0157* in the spinach in 2006, and so what we do is we look at outbreak strains, tear them apart, try to figure out if there's anything unusual about it. Is this an organism, like we asked the questions, is this an organism -- and this was done before I got there. But it's typical of the questions we ask. Has it evolved to maybe find a niche in spinach that it wasn't in before? Because these things, *E. coli* especially, can exchange genetic components, whether it's antibiotic resistance or virulence, genes that encode for virulence. And so that's what we would do. We would look at, like the peanut butter strain. We had that. We did a lot of work with outbreak strains, trying to characterize them, with the idea of trying to have a method maybe to control them eventually, you know, reduce illness. But

you've got to first figure out the beast you got. Unfortunately, there are two research groups in CFSAN, and there's a bit of competition between them.

JS: What's the other?

MW: The Office of Regulatory Science. And they're right at the mother ship, at College Park, and we were off in Laurel. And so I think that's not exactly a healthy thing, that you have the two competing groups with overlapping expertise. It used to be that in Laurel, before I got there, the previous director, they were the experts in genomics, and they did the sequencing and all that. And then one of the people from the Laurel lab went over to the College Park lab and then started duplicating everything that was done in Laurel. And I really don't want to go any further into that, but that was not a particularly good thing when you had two competing research groups.

JS: Well, it seems particularly so for a Center, and certainly maybe not recently, but in the not-too-distant past, I know before FDA started getting the kind of funds that it did, I know CFSAN was very much strapped, much like ORA and some of the other components.

MW: Yes, they were.

JS: And so if you have two laboratories, that can make it seem a little worse.

MW: Yes. And there are excellent researchers in both. Like OARSA, where I was, we had the toxicologists and the animals. I had veterinary staff, so we did all the animal work. We had a virulence assessment group and we had the geneticists, and they had a long history of excellent publications in genetics. Also the virology; we did the virus work. And the other group had mostly chemists, but then they had some microbiologists, so even before I got there, there was some overlap. And I don't think any of us would have been happy with the solution, because it would have meant giving up some things, and so it was never really addressed.

CFSAN is the only group in FDA I know of that's had a psychologist on board for over 30 years, and they have a second one now. Dear sweet man.

But scientists are very competitive, I mean, they are, and you learn that in grad school. But I've always been more trying to be collaborative and to work together. It's been my history, and I enjoy that more.

JS: I think that comes through. What we've been talking about.

MW: And I'm not comfortable with the competitive mode, and I think the director of the other group, who's a good scientist, is more in the competitive mode. So that was one of the stressors.

JS: Right. Now, you mentioned, one of the last things you were involved in, you served on the Science and Technology Committee for the Commissioner. I wonder if you could say a little bit about that.

MW: Well, that's, I think that's the name of it. That's something that Jeff Ferrar heads up, and that was, I think, the whole purpose, to try to coordinate the research in CFSAN, ORA, NCTR, and I think a very good way of going about it. And I was honored to be asked to be on that, and so I gave that up when I retired. And my deputy, Marianne Solomotis, who's now Acting Director, is on it, because I argued that we still had to have representation on that.

JS: Right. Were there some issues? Can you point to some issues where there were problems in responsibilities between those three entities?

MW: I think defining roles and responsibilities has always been an issue in research, in science and FDA, between ORA and CFSAN. There are people in CFSAN -- and I don't agree with them -- who think that research should only be done here in CFSAN, in headquarters, and I don't agree with that. I think in the field and ORA laboratories, you need to have a few research

minds, because when the "Excedrin" comes up, when you have bodies associated with the consumption of food or drugs, it's a mini research project, and you need those kinds of minds in the field immediately, right there, to help solve those problems. And I think our SPRC group did get involved in a lot of those. They also had some good research minds in the Seattle regulatory lab too. You also need people who are just content analyzing samples.

I'll give you an example. When I was in New York -- and it's Tim Hawryluk who was our marine toxins guy -- we had this Project Liberty where we were analyzing samples, preparing for bioterrorism. And we got these samples and we were looking for bot toxin. We were using an ELISA, enzyme-linked amino-absorbent assay. It's an alternative to an animal assay for bot toxin . . .

TAPE 3, SIDE A

RT: You were saying, Doctor, that you got a hit.

MW: Yes. Tim Hawryluk was analyzing the samples, and he found a positive in raw milk for bot toxin F. And so, rather than scream and yell, "Oh boy, we've got bot toxin in milk," you know, a false result from the lab makes the FDA look worse, I think. And so Tim had done work in developing ELISA assays, and he knew the problems with them. So he took the raw milk, and he knew problems of cross-reactivity, and he took the raw milk and he looked up the temperature for pasteurization, and so he took some of the sample and pasteurized it, and he still got a hit. And so it wasn't heat-labile, which bot toxin might be. And he did a number of other things to pretty much definitely show that that ELISA was giving us a cross-reaction, and it

wasn't bot toxin F, because he actually got some of the . . . I mean, he did all the beautiful work to show that really fast.

And so we reported it as a cross reaction, and a couple other labs reported it as bot toxin F in raw milk. And so if he had been just a technician, just an analyst blindly running and reporting the results and not questioning, it would have made the agency look really bad. In this case people wouldn't die or anything. But it could be -- you need questioning minds in those field laboratories that can question the anomalous results, that can ask the right questions, because oftentimes, if you have an emergency, you've got to have some idea what you're looking for. Are you looking for a *Clostridium perfringens*? Are you looking for nitrite? I mean, that night in New York, we had 28, 30 samples from that house. Where do we start?

So you need those kinds of minds, and so I don't agree that research should be only here in Washington, D.C., and technician work done in the field. I just don't agree with that. It doesn't serve the agency and it doesn't serve public health.

JS: Commissioner Kennedy didn't agree with that either, with that sense, and that's why the research centers like yours were started.

MW: But they have fallen by the wayside because some people have come in that don't agree with that.

JS: That's right.

MW: And I have argued so much. I have written more documents, Walter Hill and me and the rest of our research group, on why research is important in FDA, because OMB would always come back and say, "FDA is not a research agency. This is done by NIH. What are you guys doing?" Well, there's nobody that's going to have the impetus to develop a method. That's not an end in itself for academia or for anyone else. But for us, for FDA, we have to have a

method to detect whatever it is. We have to have one that's rugged. Nobody can screw it up, so you've got to figure all the ways somebody can screw it up and engineer that out. You've got to validate it, make sure everybody gets the same answer with the same sample, and it's got to be able to stand up in court. Now, who else in the whole world is going to do that? Nobody. That's not fun. That's not really fun at all.

JS: Right.

MW: And so you need that because even though methods development can't be argued per se as research, there's an awful lot of research that goes into developing a method to get the wrinkles out of it, to make sure it's really rugged and robust, and tells you what you think it's telling you, with no false positives, which would hurt industry, and no false negatives, which would hurt people. It's not easy.

JS: It's an ongoing struggle that the agency has faced, interestingly, not just with Congress, but within the agency itself.

MW: Oh, exactly, within the agency. In my opinion, Janet Woodcock would have killed all research if she could have. She did a pretty good job in her own Center.

JS: [FDA's Center for] Biologics has had an ongoing struggle with trying to convince Congress.

MW: And they need it. I think that was the Center that the heparin fell under, Biologics, I think. And they still have a few good researchers who had asked the right questions. But you need people in all the Centers. There's some good research that they do at the Center for Devices. And when I was at CVM -- they had some of our labs -- they were doing research with pigs and stents. I think FDA does need research.

There's a lot of reasons for that. I could get really emotionally involved in this argument, but, first of all, you need those kind of brains, there are some questions that only FDA can answer, and you need people who don't have stock in regulated industry that can give you those answers. We're all vetted and can't own stocks in regulated industry. We have to report every year to [FDA's] Ethics office. If FDA is going to be accepted as a scientific agency and our scientists, we have to be able to live that double life of scientist and be viable on the outside of FDA and be respected by our fellow scientists and academia, and we do that by publishing our research, which is first-rate. FDA does some first-rate research. We should be proud of it. And it's on par with anything done in the world. But we've got to continue that. It costs money; it's expensive.

And you can't contract it out because you're not going to find anybody that doesn't have a conflict of interest. You just don't. We had enough trouble with the hearings that we had at CVM finding people to serve on those boards that didn't have conflicts of interest in academia. But I think also, if we're going to regulate some of these industries, we have to have people who understand them. We're a little behind in some of the biotech industries with our own technology. Nanotech. If we're going to regulate this stuff, how can we do it if we don't know enough about it? And you're not going to get it just by reading the literature. So you have people that are at state-of-the-art. And we were doing nanotech work in our research group at OARSA. It's really hard, interesting. And we had a confocal microscope and a scanning electron microscope and a transmission scope. We got those while I was there.

JS: Is there, well, a couple things. Just to follow up your comments about research as a recognized function of FDA: Because of this sort of sense by some in the agency, much less

those in Congress, that question the value of that recognized-function status of research, are we finding it difficult to recruit good scientists?

MW: I think, yes, I think we will. Right now scientists are having trouble all over the country finding jobs. But I think, yes, we're going to have trouble recruiting. And it's been my experience -- I noticed this when I was on the faculty of the University of Washington -- that fewer American-born are going into science. The guys that used to go into science -- Paul Krugman had said this in the *New York Times* -- were the ones that got us in trouble on Wall Street, because instead of becoming physicists, they became Wall Street bankers, and they ran rings around those guys, because the guys that flunked out of chemistry when I was a freshman went on to become bank presidents. And that was Paul Krugman who said that in the *New York Times*, that it's the people who would have gone into the sciences that got us into trouble because they were so smart and they did all these things like invest in derivatives and ran rings around other people. I don't know how . . . It really starts much beyond this conversation -- how do we get our young people to go into science? We live in a country that's got more superstition now, that's really anti-science. I mean, look at creationism. It blows my mind. I mean, there's a tremendous amount of support and data to support evolution in the fossil record. There's none for this other . . . I don't know what your proclivities are, but we have presidential candidates . .

JS: Well, certainly for some people there's a sense of reason, and for others there's a sense of, well, there's no such thing as global warming, there's no such thing as evolution, and so on. This is nothing new in the history of science.

MW: You know what? It's not subject to a vote, a global-warming vote. The Earth's not going to care.

JS: That's right. But you bring up very good points about where science is and should be, and not just science, but research.

MW: So I think FDA is really reflective of our society as a whole. I think we just don't have that appreciation for it. It's going to be our undoing, I think. We have been so much in the forefront, this country, in science, and we need to keep that. We're losing it. I had trouble finding, when I was with FDA, hiring American-born scientists. If you work for the U.S. government, you have to be a U.S. citizen. That's why so many of our scientists at CFSAN were staff fellows, because you could keep them on, foreign-born non-citizens, for seven years. Excellent scientists. I mean, we're getting the cream of the crop. We're very lucky. We're bleeding India's scientists and China's, too.

JS: Well, what about over the course of your career? What have you witnessed? What generalizations could you make about the role and the place of FDA as a place for women to practice science?

MW: I think it's been one of the better ones. I think -- and this has been said for the U.S. government as a whole -- that a lot of the better women went into the U.S. government, and as managers, because that's the only place they could go. And I really have found I have been treated well. I have run into some good-old-boys networks, and, you know, fine, let them do it. I've gotten tougher. But I think it's been fine. I try not to have a chip on my shoulder, and I've tried to mentor other young women and the men, too. I've mentored both. I don't draw distinctions. But I think it's been good to women scientists. And I think women now are a lot more aggressive in calling it where it may be, but you've got to be careful that you don't -- and this is true for racism as well -- that you don't automatically assume that some problem you run into is because you're either of a certain ethnic group or a certain gender. Maybe they just don't

like you. Maybe you tweaked them off. So you can't always look for that as the cause. But I think it's been good, I really do. I would laud the United States government for that, and for FDA, too. There may be little pockets of racism and sexism, but I think we have the tools to counter that.

And I have had to handle cases of sexual harassment for my employees, and the agency handled it beautifully. And we had this happen between a person from one lab and a person in our lab, one of my women, one of the women in our research group was harassed, and that other lab director was right on it. There was proof that it had happened. The person was reprimanded. So in cases where there has been something wrong that was done, it was handled well, promptly and well, as you're supposed to do it. But I always carefully investigated everything before I acted, because you could do more harm by a false charge, and so you've got to really be careful. But you don't want to blame the victim either; you want to help them. So I've had to, I've gotten involved in that. I even had to reprimand a woman who was making rather lewd remarks to some of the men. I did, and she stopped it. It works both ways. But it is rare. It's not something that's rampant out there that I could see, and I think, on the whole, most people at FDA are very professional and have been a joy to work with.

JS: But, speaking personally, from the time you started in the agency, you felt that opportunities . . .

MW: Have increased.

JS: Have they?

MW: Yes, because when I got my bachelor's in chemistry in 1964, I was told in a job interview that I didn't have a chance -- this man who was interviewing at the same time will get the job because I'm a woman and I'm going to get married. I was told that. And I said, "Well,

okay," and I didn't have any recourse. I found another job. But I also have found I have to say some of the men that, and women, who, I mean, none of us gets here by ourselves. There are a lot of people who helped us: my parents, my teachers, my grad school professors. And a lot of them gave me good advice; a lot of them helped me. I got my job with FDA through my major professor, Jack Matches, who put in a good word for me and told me about the job. I mean, I didn't get it by myself. And so I think there were a lot of men who played a really positive role in my life and helped me, and I thank them.

And I would hope that I didn't get anything in FDA or anytime in my life because I was a woman because people were trying to go the other way. You know, that's just ashes in the mouth. I really, truly hope everything I've gotten, I've earned just because of me, regardless of anything else. I mean, I slogged my way in grad school on research boats with men who didn't want a woman on board, probably because they couldn't piddle over the side. But I did it. I went with them and I pulled up the secchi disks and got wet and worked alongside of them, and I earned their respect. I had to do that, mostly because I didn't throw up when the seas got rough. So I started out in chemistry with very few women.

I actually started out in chemE [chemical engineering], but they weren't very good baseball players and the chemists were better. And I liked chemistry better than engineering. So I have a whole year of engineering. I did fine. So I was always one of the few women where I was, and there were things that happened that I just kept going. I didn't let it stop me. And my parents, they always said, "You can do anything in life if you work hard and have some innate ability. I mean, you're not going to be a concert pianist with those hands, but don't let gender stop you." And I heard that all my life, so that was a good thing, taught me to be independent and feisty.

JS: Well, that certainly comes in handy when you're running a lab of many different personalities and other things.

MW: Oh gosh, yes. I've had to handle some real sticky things.

JS: Comes with the territory.

MW: I think being a lab director, sometimes the hardest job are the people problems. I mean, you do sometimes get people who aren't performing, and you have to deal with that. For the most part, though, most people really -- nobody wants to start a job and become deadwood. That happens along the way. Nobody ever starts a job thinking that I'm going to become deadwood. No. So you've got to try to make sure that doesn't happen under your watch and that people do get opportunities and they don't feel stifled. So I tried to provide that kind of environment, and the freedom to maybe fail even, and to learn from that, and not to micromanage because people won't grow if you micromanage them. You will but they won't, and you'll do an awful lot of work.

Yes. It was hard to retire, really. I would have liked to have worked a couple more years. But it was hard. I feel like I was in a vehicle going 300 miles an hour and then came to a sudden stop and I hit the windshield.

RT: I understand that you're going on a foreign trip.

MW: Yes. I was feeling kind of grumpy that I was of no use anymore. I got asked to give a talk in Taiwan, so I'm real happy about that. I've made it clear I can't represent FDA. Of course, a lot of what I learned occurred when I was in FDA. You can't separate that. But whatever I say, I can't represent the agency, and what I say doesn't represent agency thinking. I have to be real careful.

JS: That's right. But you have a pretty rich experience, a rich understanding of how FDA thinks about things, and certainly that's worth something.

MW: I've had the good and the bad. I mean, I've had probably one of the worst managers -- from hell -- that one could ever have, who was vindictive, who, in my opinion, tried to destroy people and took great delight in that, and I would define almost as an evil person. And I learned what that was like firsthand, and I thought I would never, ever do that to anybody.

JS: Hopefully, experiences like that are few and far between for everyone.

MW: Yes, but the agency should have done something about this person, and I have lost some respect for the agency that they allowed that to happen

RT: Well, we appreciate very much your taking time to participate in the interview.

MW: I can send you more stuff if you want. And then I put some things together here for you. I haven't kept my CV up-to-date, and I think I gave you that e-mail. And then these are presentations from '64 to '99, and I don't have them since then, but that gives you some idea of our publications at SPRC. You can have it. I can send it to you electronically. But, yes, we also worked on parasites. I haven't talked about that, but we had a parasitologist, because that's a real problem, fishery products and parasites.

JS: Of course.

MW: Also, the United States-Japan Natural Resources Council (UJNR). I was elected Chair of the U.S. panel. I was real proud of that.

JS: When was this?

MW: This ended when I retired. I had to give that up. But I started that in about the year 2000. The first meeting was in '96. This was started by the State Department to encourage greater cooperation between the U.S. and Japanese scientists. And so we meet every other year.

Like last year (2010), I ran the meeting in Seattle when we met in the U.S. This next year will be in Japan. It should be right now, this week, but none of the American panel can travel because of the budget restraints, so they may have to -- Shigeki Yamamoto may have to set that up for March. And he's invited me to go to Japan for the 2011 meeting.

JS: Did the experience with the mycotoxin -- did that happen within the timeframe of this?

MW: Yes. And the outbreak from U.S. sprouts in Japan that claimed 9,000 illnesses happened when I was there, so we got those isolates from the Japanese. We've been able to work together with them quite a bit. On our panel we have mycotoxin experts from USDA, so they exchange toxin standards. We have the marine toxins experts from the U.S., and microbiologists. And in Japan, actually, they are higher ranking than we are. They're very highly ranked with their Ministry of Health in Japan. They're wonderful people, and they've become my friends. And then I worked in Bangkok for a couple months, so I've got a lot of international experience.

RT: Your trip, now, to Taiwan, was that invitation by the government?

MW: Yes, it was, and the genesis for that, one of my good friends, who used to be at the Astoria Seafood Lab in Oregon, Haijun An, and who's now a chemist with FDA in Los Angeles, was asked to give a talk, and she couldn't get the approval to go. So she and I are good friends, and she said, "Well, why don't you ask Marleen?" And so I got a call from Dr. Jen, who used to be Under Secretary of USDA, who's friends with Haijun, and also friends with some of my other friends, talked to me and asked if I would do it. And I said, "Well, I'll do it, but let me check with FDA first, because I just don't want to cause the agency any problems." And I checked and it was okay, so that's how it happened. But I wasn't the first choice – it was through an old

friend. I mean, the seafood research group is a small group, and you know everybody in the world.

Yes, that was painful leaving that, but I've had a good time, though. It's been a good run.

JS: Sounds like it, and now there's a chance to do other things.

MW: Yes. And I didn't retire out of any unhappiness with CFSAN either. I was quite happy there. I enjoyed it. I think some of the politics around food safety and the agency have gotten a little difficult, especially now that the Office of Foods has been created, and CFSAN has to go through them to the Commissioner. And sometimes it seems -- this is me talking, not CFSAN-- that the Office of Foods was duplicating what CFSAN had, and they have very good experts at CFSAN.

JS: Well, why do you suppose this office was created within the Office of the Commissioner?

MW: This was done by von Eschenbach when he asked David Atchison to come to the Office of the Commissioner. I don't know why. I would never venture a guess. And maybe in the long run it'll work out. I think maybe there was maybe a perception that CFSAN didn't act fast enough. I don't know; that's conjecture. They've now done this to all the Centers, so they're now equivalents of Office of Foods.

I'm not sure that's the best thing. We've seen that before with other Commissioners. I mean, I've been through a lot of them, and ups and downs. I don't think it is a good idea. I think it's better to have the Center Directors reporting directly to the Commissioner. It's just me talking, nothing I heard. But it's much better to have a Center Director talking – directly reporting -- to the Commissioner, and having that expertise in the Center and not having to go through anyone else. And I'm not trying to say anything bad about the Director of Office of

Foods or Jeff Ferrar or any of those people, because I think they are very well-intentioned. But it's another layer, and it's made it difficult, it has.

And when [Principal Deputy Commissioner Joshua] Sharfstein was here, it was even worse. We are very lucky he's gone, I think. That's my personal opinion. He was micromanaging much too much, and insulting us that we didn't know what we were doing.

JS: If this helps in any contextual framework, there are two categories in our own file system that are probably bigger by far than anything else in the History Office: one has to do with quackery or health fraud and the other one has to do with FDA organization and reorganization. That is an enormous, enormous collection, and it is obviously reflective of how we've tried over the years to change our structure.

MW: I've seen it. Yes, that's interesting, because I've seen it both ways, and it's my own personal view that if somebody's put in charge of something and they don't know what they're doing, they reorganize, because then you keep people running around like ants and they can't criticize you. That's my own personal view. But I've seen things come and go. I think certainly with the foodborne illnesses that have occurred, it's gotten more politicized, and that's not a good thing. I think we have people in the federal government and the Senate who argue about the role of the government, and FDA's gotten caught in that. And I truly believe that sulfanilamide and the melamine experiences certainly should show us that you need some regulation. People aren't always honest. You need to have some regulation to make sure you don't have economic fraud, that you have food as safe from pathogens as possible, and have an infrastructure to support that. And I don't agree with those philosophically that think you can just have no government. I just don't agree with that. But then, I worked for the government, so you can say, well, yeah, you're brainwashed.

JS: But you're also a consumer.

MW: I am a consumer, and I don't worry when I buy food that I'm going to be poisoned. I don't worry about it. That means we're doing our job, or FDA is doing its job. I don't think anybody really worries about it, and that ought to tell us that FDA is doing a good job. The degree of regulation, you know, we can argue about that. I think in the last administration, we saw our powers weakened, and whether all the foodborne outbreaks we've seen are a result of that, they may be. We also have such a huge industrialized food manufacturing system that everything's magnified now, where if you had the mom-and-pop farms and the small things, just a few people would get sick. Now if you have lettuce growers or spinach growers supplying the whole nation, you are going to affect more people. You're going to have all those problems that are contingent on storing that food, distributing it, whereas locally grown . . . But that's not economically the most efficient either. You know, there are some pretty big philosophical arguments that we ought to be having in this country. But we do manage to feed people pretty cheaply and pretty safely. And there will always be those that will try to rein us in, you know, paint us as the bad people. And to a certain extent, some checks and balances is probably healthy, because you wouldn't want FDA full of zealots that go out and shut down every food company either. You've got to have a middle ground.

RT: Well, thank you very much, Doctor.

END OF INTERVIEW