

History

of the

U.S. Food and Drug Administration

Interviewee: Mark Roh

Interviewer: Suzanne W. Junod, Ph.D.

Date: September 16, 2011

Place: Silver Spring, MD

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Date: 2/7/13

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Mark Roh Interview

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Interview with Mark Roh

September 16, 2011

TAPE 1, SIDE A

SJ: We are on the White Oak campus doing an oral history interview with Mark Roh, Regional Director in the Pacific Region, and it's September 16th. You've had such a wide variety of experiences, touching on many historical aspects of the agency evolution and its work over the years.

Tell us a little about your upbringing and your education and how you came to come to FDA.

MR: All right.

Well, my first 12 years were in Montana, and I moved to the San Francisco Bay Area when I was 12 and finished grade school and high school there, and started college there and did about three years in the Bay Area in college, and then was back in Montana visiting and got an opportunity to work for the university.

SJ: The University of Montana?

MR: University of Montana in Missoula.

But I spent two years living at Flathead Lake, at the biological station, doing limnology research on the lake, which had never been done for an extended period of time, and we published a paper.

Then I went back to California and started doing some master's work, and then went to work for the Forest Service and, well, first for the Park Service in Arizona, and then back to Montana to work in the park. And it was the end of the season, so I started working for the Forest Service. And I worked for the Forest Service there and then came back to California for a series of reasons in 1976 and was working for the Public Health Service at the old Public Health Service Hospital at 15th and Lake, which is no longer there -- it closed several years ago.

SJ: How did you make that transition from biology?

MR: Biology and zoology. I had been a pre-med student in college, and so I started working for the Nursing Department at the hospital, because I wanted to get back into some sort of science in the city, but I wasn't quite sure what I wanted to do, if you want to know the truth. Here I was in my middle twenties and I was just roaming around trying to figure out what to do.

So I started working for the Nursing Department in the hospital, and I was in charge of the surgical ward. I was the surgical ward manager.

But at the Public Health Service Hospital, we serviced retired military, retired merchant seamen mostly, and they would come in primarily with cancer or some other chronic condition . . . It also had a detox ward, which was interesting. But they would

come in, and the majority of them had cancer or some sort of chronic disease, and I actually got tired of watching older men die and seeing blood on the walls from where they would vomit blood.

My office was right next to the detox room. It was interesting watching people be tied down to gurneys coming off DTs, and we used to have this one woman who came in there regularly. She would come in every couple of months. She had sickle cell anemia and she'd have to be treated, because every once in a while her sickle cells would just get out of hand. And I still remember her just moaning and crying because it was so painful when the sickled blood cells would go through her veins.

I was restless and started looking for another job. I figured I need to do something, get out of this hospital environment. And I had a friend in the personnel department, and he said, "Well, FDA is hiring." This was 1978. And I said, "Oh, really? I don't know anything about FDA." So I filled out an application, I sent it in.

About a week later I got a call from the FDA. I was at the hospital, and I got a call and they said, "Can you come in for an interview?" and I said, "Well, how about tomorrow, because I'm working today."

"What time do you get off work?"

"Well, 3:30. That's when the shift changes."

"Well, can you come in after that?"

"Well, how about if I come in tomorrow. I can be a little better dressed," because at the hospital, you know, you wear jeans and a t-shirt and you throw scrubs or something over it.

They said, "No, we need to talk to you this afternoon."

I said, "Well, okay."

So I was wearing typical hospital drag, which was tennis shoes and jeans and a t-shirt, and I had some sort of shirt or light jacket over it. So I went down to the old Federal Building at 50 United Nations Plaza in San Francisco and I got into the building, and found the office, and I went into office of the Director of Investigations office.

SJ: Who was it at that point? Do you remember?

MR: His name was John Rynd. And I was escorted into his conference room, and there was a very long table. And on one side of the table was John Rind in the middle, and to his right was a supervisor named Fred Norman, and to his left was another supervisor named Brad Landahl, and they started asking me questions: what was my education; what did I do; where did I live; why did I apply for FDA; what was my history?

And at one point they said, "Well, you know, this job requires driving. Do you have a driver's license?"

And I said, "Yeah."

They said, "Well, we need to know the number."

And I said, "Well, it's RO721965."

And one of them leaned forward and said, "You know your driver's license number?"

And I said, "Well, yeah. Doesn't everybody?" And they sort of kibitzed back and forth.

And they said, "Thank you. We'll call you."

And I said, well, that's pretty weird. And so I left, and the next day they called me and they hired me.

SJ: Attention to detail.

MR: To this day I'm convinced it was because I knew my driver's license number.

I started about a week later, and as it turns out, I was a backfill for some previous hires who didn't work out. There was about seven of us, seven or eight of us who were hired, unbeknownst to me, until we got into the training program. I showed up about a week later, well, two weeks later, I guess. I gave the hospital two weeks' notice. And we were backfills. This was in September of 1978.

SJ: Is this still Project Hire?

MR: No, no. We were backfills for a couple of people who were hired in Project Hire in 1976 that didn't work out that they had let go. I forget how many of us there were, six or seven or eight. They had six or seven or eight positions they needed to hire, so we were backfills for those Project Hire people that didn't work out.

And that's how I ended up at FDA, and that was 34 years ago. That was September of 1978, and it's been a great run.

SJ: And what did they have you doing when you first came on? Inspector?

MR: I was a Consumer Safety Officer, and we had . . . Well, for the first week or so, we were just given two enormous manuals, one the IOM, the Investigator's Operation Manual, and the other, I guess it was the ITM, the Investigator's Training Manual, and we were told to read these things and look them over, and they were giant, three-ring binders. And so we'd lug them home and we'd go through them, and I recall reading one in the laundromat one day. And every Friday we would have formal training. So during the week, in the beginning, it was pretty much reading stuff, and then we'd go out on on-the-job training. And every Friday we'd have formal training in the training room, and one of the supervisors or one of the experts would give us training in investigation technique or food manufacturing, biologic regulation, whatever happened to be the subject of the week.

And I will never forget one of my first OJT adventures to a medical device firm. And I went out with a GS-12, he was an experienced GS-12, and I was a new hire GS-7. His name was Mike Davila. The Government cars were parked in the garage of the city hall, the civic center garage in San Francisco, in the main area, underground.

SJ: What kind of cars are we talking here?

MR: We're talking funky little, I don't know, General Motors cars from 1978, whatever they were. Chevrolets and Ford Pintos.

And we get to the garage and we put our things in the trunk, and then he proceeds to crawl under the car. And I said, "Mike, what are you doing?"

And he said, "I'm checking for bombs."

And I thought to myself, "Oh, my gosh, what have I gotten myself in for here?" because there had been, a couple months prior to that, before I started employment, there had been some firebombing of government cars in the garage downstairs, because, well, obviously, it was anti-government people were firebombing government cars. So Mike was checking for any kind of bomb or any kind of incendiary device before we got in. And I thought, well, I signed up for this. Let's see how it works out.

So we toddled off to the inspection, and every time I went out with Mike Davila, he would crawl under the car and look for bombs. And I sort of got used to it after a while. I started going out with some other people, but they didn't crawl under the car and look for bombs, but Mike did, and he was taking no chances.

SJ: I'm very interested in FDA's involvement in regulating medical devices. You came right in after the passage of the '76 Medical Device Amendment.

MR: I did.

SJ: Tell me as much as you can about your experiences in that particular area.

MR: Well, that was a great time to be new because most of the other people had been involved in foods, of course, and drugs, and some minor blood banks and plasma center inspections, and nobody knew anything about medical devices. Basically, prior to 1976, medical devices had been sort of unregulated. They had been regulated as drugs, but not

really. And nobody really knew much about it, and it was early in the medical device arena for FDA to really start looking at them.

So there was a lot of new training, and I was very fortunate because I got to go to a lot of the new medical device training and became a medical device specialist and a biologics specialist, because I always had an interest in blood, coming from the hospital, maybe, and some of my medical training, and so I gravitated to the biologics side. I loved the plasma inspections. In fact, I'm very proud that when I used to show up at a plasma center -- I found out this years later -- the director of the plasma center would call the other plasma centers and say, "He's back," because I had a reputation for finding all kinds of little problems that could have resulted in threats to both the health of the donor and the composition of the final product, and a couple of times we pulled their license. And I was actually kind of proud of that -- not that I was pulling licenses, but I was finding problems that other people had not. Particularly when you consider plasma centers, usually it was the poor, the homeless, or, you know, basically the needy people who were selling their plasma, and they were being taken advantage of, and the plasma industry was not following the rules.

So, for medical devices, it was great because I got to go to some of the first medical device training, some of the first computer and process-control training, and it was very good. I very much enjoyed doing the medical device inspections, plus it was clean. I was not really fond of dirty food warehouse inspections. You know, the first couple years, I had been trained in food, but I didn't really gravitate toward food work. I wasn't too much into pulling pallets apart in warehouses, although I did like going up those tiny little elevators in grain mills and flour mills.

SJ: I was going to ask you if you used the giant triers.

MR: Well, we used the giant triers, but I particularly liked rice and grain mills, because the little elevators in the mills are only about a foot and a half square, and you have to stand right in the middle, and you go up and they're pulled by ropes, and you go up between the floors, and there's little holes in the floor, and that's how you get from floor to floor. I particularly enjoyed those; those were very fun.

SJ: Claustrophobic. How small were they?

MR: Oh, very, very small. You had to hold onto the rope in the middle, and you couldn't move or you couldn't be carrying anything, so we had our little notebooks and sort of hugged them to our chest. And you go up and you just sort of go up and you were coming up through the hole in the floor, and there you were on a new floor. That was kind of fun.

Anyway, back to the medical devices. The medical device industry was not quite prepared to be inspected under these new rules and regulations either, so that was very interesting learning new regulations, being in the beginning of the new regulations, and there was a cadre of new people and some people who'd been around for a while that sort of gravitated to medical device manufacturing, and I got to see all kinds of new products that I never even imagined existed.

SJ: Talk about a little of that, because we think of Minneapolis as, you know, Medtronic being one of the early ones. In California, I think of Edwards Scientific, Edwards Life Sciences.

MR: In Southern California.

I was particularly interested in all the monitoring devices. You know, you go into a hospital room and you see people all hooked up to various devices, but you never really give a thought for what these devices are doing and how complicated they are in that they're monitoring either heart rates or blood pressures or they're infusing solutions or they're draining things out. And the engineering involved in putting them together, particularly with motherboards and other computer parts, and the burn-in that has to be required -- they have to burn them in for a certain number of hours to make sure that they're actually going to be able to be turned on and left on for days at a time -- fascinating stuff.

And the way they've manufactured and the change in the manufacturing processes. Initially, when I started doing inspections, people would get buckets and buckets of small pieces of stuff -- boards, nuts and bolts, and wires, and cables, and pieces of metal, and pieces of glass, and, you name it, but they would get them in boxes, and there'd be hundreds or thousands of these things that had to be inventoried. And over the years, they got away from that and they started getting components, smaller components that had been assembled someplace else, and they would get components, and then they would just put the components together. And it changed their

recordkeeping, but it also changed how they had to do the introduction of the components into their facility, because earlier on, they would just get green motherboards or wires, and that's pretty easy to look at and say, okay, here's a motherboard, here's a wire, here's a three-inch screw, here's a bolt, here's a whatever. And they could measure that against their specifications and put them on the shelf.

But you have to imagine that they had these storage units of hundreds and hundreds of different boxes with little labels on them, oftentimes little paper labels. And then as the industry evolved over the years, instead of that, they would get in prefabricated components that had been fabricated somewhere else, and that changed the way they do the inventory, but it also changed the way they did business. It also changed the way they had to accept them as components, because now they could no longer just say, "Oh, that's a three-inch screw." They had to actually look at the component and figure out a way to test it or measure it, because that component would be a collection of other subunits that had been put together somewhere else.

SJ: And a problem could occur at any level and in any piece of the component.

MR: Yes, a problem could occur at any level, at any level.

SJ: Were these smaller companies that were building these things, or . . . I'm trying to get a sense of the kinds and the size and the scope of some of these early biomedical engineering firms and products.

MR: Well, I inspected everything from garages that were manufacturing implantable screws, surgical screws, and artificial limbs -- and I mean garages, where you would go to somebody's house and he was an engineer, and he was turning on the lathe a wooden or plastic leg or pieces of metal that would be used as part of a support joint, everything from that to larger manufacturers that were manufacturing heart monitors. So it pretty much ran the gamut, particularly in the Bay Area, because the San Francisco Bay Area and Southern California were centers for creative design of new medical device products. And I don't think it moved east or to the Midwest until the early 1980s.

In the '70s, there was a lot of medical device manufacturing going on in the Silicon Valley with the evolution of the computer industry. After 12 years I left being an investigator and became the Regional Small Business Representative, and the industry grew to such sophistication that it began to exceed my understanding of the science.

Affymetrix was a manufacturer -- and I'm not even sure I can remember the whole process -- but they were able to separate out DNA on glass plates, and they were in the race to break the human genome with a firm in Massachusetts, and although Affymetrix had started and were very sophisticated in what they were doing, the firm in Massachusetts -- and I can't recall its name -- beat Affymetrix by about six or eight months in announcing the breaking of the human genetic code. But the Affymetrix technology has been used for many other advanced biopharmaceutical type drugs -- and maybe devices, simply based on their new technology. So to watch the evolution of that industry from screws turned in garages to be implanted into people's limbs, to glass

plates that had chromosomes on them, over a period of 25 years has really been an amazing gift that I've been able to watch.

SJ: I do know that when FDA began its medical device scrutiny prior to and immediately after passage of the 1976 Device Amendments, they hired a couple of former engineers from NASA, and they were very concerned about the state of operating room equipment and things like monitors and whatever because they said they weren't engineered, that the biomedical engineering was, in their mind, fairly primitive, that these things were not, they didn't have redundancies, they didn't have backup systems, and that, more importantly than that, they weren't manufactured to work together, so that each operating room had to have its own staff of, I guess, local engineering specialists that knew how to fix things when they went wrong, knew how to cobble things together so they could work and keep the patient alive during the surgery. And they were very interested in getting standards work underway and apply it to regulating devices. Were you involved in enforcing or checking those kinds of standards and surveying?

MR: I was involved in doing inspections of the manufacturers to see if they were following their own SOPs, and their SOPs had to be compliant with the regulations. And part of that was that they had to have device master records and device history records, and the master record, of course, was how they were supposed to put the thing together; and the history record was how they did put the thing together.

But in the early days on the manufacturing floors, you would see people at individual assembly stations but oftentimes, depending on the device, there may be only

two or three people involved with putting it together, and they'd be at sort of a section of a room and maybe have a big table, something like that. They'd have pieces of paper that were the device master record that were copies of something that the engineer who designed the device would put into a big three-ring binder, and there was a master copy of it somewhere. But the photocopies of the particular pages would be given out to the manufacturing people on the floor, and they would have these pages sort of stuck up on a board in front of them, and it would be like engineering drawings, and they'd be putting this thing together, welding this wire and doing this and that.

Oftentimes you'd see little notes written on the master record, and it was prior to sticky notes, so there'd be little pieces of paper either paper clipped or taped next to the master record or taped on the back of it where they had made adjustments because they got a different size screw or this hole didn't have the right number of threads or whatever it was, so they weren't always following the instructions how the chief engineer who actually designed the unit, had written for putting it together.

And so sometimes when the device would actually get put together, if it went out to the hospital and it was being used in a clean environment like an operating room, and it didn't work, they'd have to figure out how to make it work, and the hospitals all had engineers with engineering rooms that would work on their own piece of equipment to try and jerry-rig them and get them back together or have to re-sterilize them for some reason. However, during the validation for the device, they had to document if it required sterilization for reuse because it was going to be used in an operating room; usually that validation would only go through one or two sterilizations at most. Well, if you've got a device in an operating room that's going to be used repeatedly or left on, it goes through

maybe multiple sterilizations or cleaning, and many of the devices weren't validated for the real-time use they would get in the hospital.

So, oftentimes we would go out to hospitals because we had heard of a problem with a particular device, and you'd find that the hospital engineer had been sort of jerry-rigging it and putting it back together, doing whatever needed to be done to make the darn thing work. And sometimes what would happen would be that the manufacturers were aware of some of these problems, and they would send out letters, field corrections or field notices, to the users of the device, saying, "At some point you need to do this or that," or "If this doesn't work, here's a replacement part or screw." So, wherever these devices went, there was oftentimes somebody not only who never used the device and had to be trained to use the device, but also had to be trained to fix the device.

Later the design control regulations were published in the late '80s and early '90s and they changed the requirements for how medical devices are put together, or at least how the documentation of the medical device is put together. There were some situations that occurred in the field where devices were being used that probably should not have been used and probably, had they continued to be used in the way they were, might have -- and maybe they did -- caused unnecessary deaths and injuries simply because the devices were failing, but people who were using the devices were trying to put them back together to the best they could.

SJ: What kinds of equipment are we talking about?

MR: Oh, there's all kinds. Like you mentioned, ventilators, monitors, pumps, surgical clamps, etc.

SJ: Heart-lung?

MR: Well, any kind of monitor, heart monitors, infusion pumps. Infusion pumps have been tremendously problematic over the years, either for failure to deliver at all or for delivering at the wrong rate, and maybe because they haven't been adequately validated for continued use, or maybe because there was a manufacturing flaw during the production of those particular devices. But infusion pumps have been tremendously problematic over the years, as well as some of the transplantables. I'm sure you're familiar with the heart stent problems that have occurred, what, in the early '80s, all through the '80s, stents not working right, breaking or being too rigid.

SJ: I have a particular interest in heart valves. Were you part of the Bjork-Shiley issues or any of the tissue valves, anything with valve problems involved?

MR: I had some minimal experience with the porcine heart valves, but not a lot of experience, and I wasn't involved with the Shiley valves at all. We were certainly aware of them, and we used them in training actually. We also used leaky silicone breast implants in training.

TAPE 1, SIDE B

SJ: We're still talking about medical devices with Mark Roh.

Well, any other particular reminiscences in regulating that very field? You were at a very seminal point in the development of that industry, and we think the FDA was starting to finally make an impact in terms of enforcing standards and requiring redundancies and backup systems and compatibility, really instituting full accountability for some of these.

MR: I think probably one of biggest impacts -- well, there have probably been a couple. One was on the materials that were being used, whether or not they were biocompatible, and FDA went through a lot of effort to make sure that anything that was coming in contact with the body, whether it was a Band-aid or an implantable heart device, was made from biocompatible materials, and there were a lot of problems with biocompatibility in early days of medical devices.

But I think another real impact that FDA has made has been in the design and validation of the device over time. In those early days not a lot of people kept a lot of records, and there was a lot of, I don't know, probably frustration is a good word on the part of the manufacturers that they had to start keeping records in a certain way that they had never kept before, and they had to show us that they were manufacturing the product according to an approved design that had been not only reviewed, but somehow tested and shown that it was actually going to be a functional device. And we spent a lot of time pouring over records, and I don't believe there was one company I ever went into,

not one, that did not have recordkeeping problems, because they just weren't familiar with how to do that. And I think it probably took a good 10 years to get the industry on board with how to keep records: master records, history records, validation records, and biocompatibility documents for anything that was in contact with the body. The industry went through a lot of growing pains in the first 10 years.

And then with design control in the '90s, they went through some more growing pains because, although they were required to validate the design of the product early on, they weren't required to validate each step of the design process as they are in design controls. I think we've come a long way in, what, 30 years now since the beginning of medical device regulation.

SJ: How long were you doing this work with devices? And, what was your next career step after inspecting devices?

MR: Oh, well, I spent 12 years as a front-line investigator, specializing in medical devices and biologic products, and I really enjoyed the biologic products as well.

I spent two years in headquarters, from about 1988 to 1991, working on various details for the Center for Biologics and for ORA. And I was brought in particularly because of the HIV and AIDS problem, and FDA was not prepared to deal with it in many ways, everything from drug approval to the inspection of biologic facilities. And there was a lot of concern on the part of the field investigators about going into biologic facilities, either blood banks or plasma centers, or going into any other kind of facility

where there might be a fear that they were going to be somehow contaminated with HIV. And the agency in general was also under attack because of the drug-approval process.

So I came in. I worked on two big projects over those two years. One was the evolution of the AIDS Office that was under the Center for Biologics for the early years, and I think currently in the Office of the Commissioner. I think it evolved into the Office of AIDS and Women's Health Issues or Special Health Concerns, something like that, in the Office of the Commissioner. But in the late 1980s when Frank Young was Commissioner, in the very early times because the, I worked in CBER, in the Office of AIDS, and we were primarily charged with working with the community and community health organizations because they were clamoring to change the agency's drug approval system, there was controversy and concerns about who should donate blood and who shouldn't donate blood. And so we worked on a lot of rules and regulations around donating blood.

And I had been actively involved in politics in San Francisco for many years, and so I knew a lot of people in kind of the activist community, not the senior political realm, but sort of the popular common political realm. And I was asked to work with the Commissioner's Office and also asked to work with a couple of other people on putting together community meetings between the agencies and various community health organizations around the country, everything from what was then known as the Kaposi's Sarcoma Foundation in San Francisco to the Gay Men's Health Collective in New York, and there were a few other organizations that were sprouting up around the country like African American AIDS organizations and others.

And those were very interesting times because I recall being at my desk in San Francisco, just being a regular investigator, but I had been on detail to the Compliance Office. And I recall this was about in 1986, prior to me coming to headquarters for those extended periods of time. I got a call from the Director of Compliance asking if I would come down and see him because he had been asked to somehow supply a speaker from FDA to go to this hall on a Tuesday or a Wednesday night and speak to the local community about what FDA was doing about HIV, because by that time lots of people were dying. Hundreds, thousands of people were dying, and the FDA, the drug approval system still took about 10 years to get a drug approved. And nobody else wanted to do the presentation. The Compliance Director had been ordered by the District Director to do this or find someone to do it because FDA was getting a lot of bad press, particularly in some of the major metropolitan areas around the country: San Francisco, New York, Los Angeles.

And so I agreed to do it because I knew a lot of the people and I was interested and involved. And I recall going to this very angry meeting in the Swedish Hall on Market Street in San Francisco, where this group of activists had rented this hall for the public meeting. And I tried to defend FDA's policy on what we were doing and what we knew, and say that we were working on trying to figure out what was going on, and it was not a government plot to kill gay people. Oh, my gosh, so many people thought it was a government plot; some people still do. And because of that, I had been asked to go to many other public meetings around San Francisco and various locations and speak about FDA policy and what we were trying to do, and I started coming back and forth to the East Coast to work in the AIDS Office and later in the Office of the ACRA at the

time. Ron Chesemore, ACRA, asked me to come in and work on some information documents because, for the field staff, there were many concerns about the risk of HIV during routine inspection work.

So I worked for three months in the Division of Field Investigations under the Director, Burton Love, and we developed what was called the *ORA Guide to HIV and AIDS*, which was everything from the social impact of this disease all the way to how to ship biologic product samples across the country. And we had to investigate transportation rules and regulations for shipping and postal regulations. It was quite extensive work that we did. And I also worked with what was then called the Office of Consumer Affairs, and I cannot recall the name of the Associate or Assistant Commissioner for Consumer Affairs. It was an African American man who'd been around for many years.

SJ: Nate Geary?

MR: Nat Geary. Actually, I believe Nat Geary was in the Center for Devices, Small Business Assistance office. The Consumer Affairs Associate Commissioner was very concerned and wanted to do as much good as he could and was charged with meeting with the public, particularly AIDS organizations and community activists, and trying to explain what FDA was doing. So I worked very closely with him, and we put together many FDA and public group meetings for those two years to try to explain our position.

And what really happened was we tried to forge a coalition between the public and between FDA so that we could get the public to understand that this was not an FDA

plot to kill people, nor was it a government plot to infect people, but that these were the rules that FDA operated under in terms of clinical trials. But then, at the same time, this was a public health problem that was existing, and we had to put it on the table that FDA's rules and regulations were inadequate to deal with an immediate national public health crisis. In fact, government public health policies in general were inadequate to respond to a national public health problem of this nature.

SJ: You acknowledged that.

MR: Absolutely. I'm particularly proud of the fact that we reinstituted and put back on the table the, a personal importation practice, because there were several products that were being tried or were approved in foreign countries that were not approved in the United States, and through personal importation, people were allowed to get those products and actually try them. There were some flaky products then, of course. But the whole point was that people should be allowed to try products if they were going to be in a situation where they were going to get sick and die, and the United States had nothing to offer.

Simultaneously, I was very pleased and proud to be able to work on the revised drug approval system, where we went to expedited clinical trials and expedited approval. So, after two years, using either surrogate markers or actually maybe sometimes using the disease condition itself with people who wanted to volunteer, if we had enough positive data, we could approve the products with a shorter time span of two to three years, and get it actually on the market, and also expand clinical trials where we could get more

people on the clinical trials on a voluntary basis to actually use these experimental products. I'm very proud to have worked in that area.

Of course, the rebound of that over the years was now FDA gets accused of approving products too quickly, so you can't win for losing sometimes.

But there was so much going on in those days. I remember working with the Center for Devices on condom labeling, and condoms had been probably minimally used historically over the years for birth control, but they were coming into play as a form of disease protection. And condoms were, I would say, almost barbaric at that point. They were made from materials that were probably not very comfortable. They were not well labeled. They were not well packaged. And so I remember working with Tom Lowe, who was the Director of the Division of some sort of consumer division in CDRH, and we worked together. For three years, we tried to get new condom labeling approved through the Office of the Undersecretary of Health. And the new product labeling that FDA had approved included a stick drawing, and it was a stick drawing of how to use a condom. And the Undersecretary of Health, who happened to be a Mormon, refused to approve this label that had a stick drawing of a penis with a condom on it. He refused to approve that labeling, and for the three years that he was the Undersecretary, we could not get that condom labeling approved, until he left, and that was during the administration of Ronald Reagan, who, as I understand it, never used the word AIDS until the last year of his eight-year presidency, and he was president all during the first eight years of the pandemic.

I believe that one of the reasons for the anger against the government was a silly thing like that. The President never used the word AIDS. We could not get revised

condom labeling approved through the Undersecretary of Health, because he was a Mormon and would not approve what he almost considered to be a pornographic drawing of how to use a condom.

In the Center for Drugs, the Director of New Drug Approval, Ellen Cooper, was adamant that any change to FDA's clinical trial process would weaken the Agency and the drug approval process. And even though the Agency had to change to meet this new public health challenge -- and I have to sort of admire her on one hand for trying to uphold FDA standards . . .

And on the other hand, I was angry with her for not being more flexible in the face of a public health emergency. But she finally agreed, before she left the agency, to allow for expedited approval and to broaden the clinical trials and allow for more people to be involved in the clinical trials process.

SJ: I believe she was pretty much vilified, and I think the stress eventually led to her to get out. And Carl Peck, as I recall, took responsibility and said, "I did not give her the support. I left her to handle this on her own, and it's clear to me that this needed to be more than a discussion that should have been held among a much wider variety of people, including me, rather than just her division/office."

MR: And she was vilified.

But, again, I think it showed, you know, those days showed how the institution that had grown to be the FDA had, was so proud of its public health protection record and what it had evolved to, forgot to include flexibility. And I think that was a good lesson

that FDA learned, that even though we maintain our standards, we have to be able to be flexible in the face of public health emergencies, and sometimes rigidity has to give way to flexibility. And I'm very proud to have been involved in all of that, everything from condom labeling to expedited drug approvals.

SJ: When I came to the agency, one of the things that appalled me the most was when -- I was in a meeting with Ron Chesemore and the whole ORA staff at Parklawn at the weekly red-phone meeting, and the concern was that health officials were putting out the word that condoms could help protect against the spread of HIV/AIDS, but that people were using, I think, because you were talking about the problems with latex condoms, they were using sheepskin condoms, and they weren't by any means sure that these were actually protective against transmission of the virus. And FDA had to conduct an investigation to see if sheepskin provided adequate protection, but I don't remember what the outcome was. I believe they probably weren't.

MR: Well, I think the outcome was that sheepskin does not protect against the virus because of the -- I don't want to call them holes, but the distance between the cells is greater, because it is a natural fiber, and the virus could go through that space, as opposed to latex, which does not have that issue.

But there were so many side issues, like the Nonoxil-9 issue, where Nonoxil-9 had been used in vaginal foam as a birth-control measure. It was somewhat effective in killing the virus but irritated tissues, thus making them more receptive to infection.

SJ: It was part of the sponge, the contraceptive sponge.

MR: It was used in several products. But it was used as a birth-control product, and it was also determined that it could kill HIV, so people were putting it on condoms, and condoms were being distributed lubricated with Nonoxil-9 before it became approved. And then the whole personal lubricant thing came into play, things that FDA had never dealt with in the past, because now people were putting Nonoxil-9 in personal lubricants that were being used during sexual activity, and in some cases the Nonoxil-9 was causing greater irritation and allowed for greater transmission of the HIV virus due to irritated tissues. So it was a very exciting time because so much was being learned about science, and the agency was being challenged at every turn, everything from drug approvals to clinical trials to device applications. It was a very challenging time. And I think it showed the agency that it had to be more flexible when it addressed these public health issues that couldn't simply rely on historical, albeit strong, but historical procedural practices and prevention -- very fascinating time, and I'm very excited and I'm very happy to have been working in those programs during that time.

SJ: And one reason I wanted to talk with you about AIDS during this period is because a friend of mine, the former NIH historian, Victoria Harden, is writing a book on HIV/AIDS centered on the National Institutes of Health response to the crisis. She wanted to include FDA, however. In addition, at least one or two of the books that have been written about AIDS, you were actually complimented in print for your ability to

work with these groups and make that transition. You were perceived as someone who both listened and communicated effectively.

MR: Well, I tried.

You know, I remember one meeting. It was in San Francisco and it was a very large meeting. There must have been 200 people there, and I can't remember why it was even called. And I was asked to speak about something, and I just went and tried to explain how FDA was trying to do the right thing. When the meeting was over, I just started to cry because sick people had been brought to the meeting and were begging to be involved in clinical trials and had been refused drugs, and had been refused entry into clinical trials by the Agency that I worked for that I loved. And I was caught in this dichotomy: what do I do to try and help with this public health emergency of which I'm intimately involved, but at the same time maintain the sort of structure and strength of the Agency that I truly believe in? And it was very hard times for a lot of people, both inside and outside the Agency. And, you know, when we're put in that position, we do the best we can, whatever it happens to be.

SJ: And there were only 24 hours in a day.

MR: There's only 24 hours in a day. That's right.

SJ: Who were some of the people that were also instrumental in working during this period on AIDS?

My experience was that when I came back from a trip and had read Randy Shultz' book, however biased and however criticized it became, it was still an eye-opening experience, and FDA was already looking to see how they could create some awareness about AIDS. I remember that they were looking at New York, as a model program for outreach to the gay community, and I said, "But wait a minute. Why are you using New York's model?" It was San Francisco that was much more proactive in reaching out to the gay community and making aware of the stark realities of AIDS.

MR: Right.

SJ: And I think that opened her eyes as well. I mean, FDA was truly operating in the dark at that time, and Frank Young, you know, his eyes were opened, and once they were, he moved quickly, I think, to amass the resources to meet the concerns. I mean, he was managing a ship that was at least trying to turn directions.

So, were they efforts within FDA to meet public health needs and outreach?

MR: Well, there were so many people that we worked with: Janet Aerosmith, Tom Lowe, Naomi Kulakow, Frank Young, and other people I can't even remember. Janet Woodcock was involved at that time. She was in CBER. She was working on cytokine biology research. There were just so many people involved. Ron Chesemore was very supportive of trying to figure out what was going on for the investigators and how we were going to have to deal with this from an investigative point of view, as was Burton Love.

Who was the Director of CBER at the time? He actually was very famous for having developed a vaccine.

SJ: Paul Parkman?

MR: Paul Parkman. He tried to be supportive, but he didn't know which way to go because it was so new and there were a lot of people that were confused about what to do next. And there was a lot of stigma around HIV too, because it primarily was affecting, at that time, the gay community as well as the drug-using community and Haitian immigrants.

SJ: And Haitians had been banned from donating blood.

MR: And Haitians, which are, of course, black people. And those three groups were not very high on the social ladder, and there was a lot of ignoring and trying to sweep the problem under the rug, until it really started to gravitate more into the more traditional heterosexual community and the young people. When young heterosexuals started getting becoming infected, government started paying more attention.

But in the early days it was very much of a big struggle because nobody wanted to be associated with the disease or the affected population.

I remember working in the Division of Field Investigations Office, *ORA Guide to HIV and AIDS*. And one of the women in the office, and I'm still in touch with her to this day, came to me and said, "You know, I have this friend in the Division of Field Science

across the hall, and he wants to know,” and she asked me a bunch of questions about HIV transmission, illness, drugs, and what we knew, etc., because she was being the go-between for this person, her friend in the Division of Field Science, who wanted to know but was afraid to come to me and talk to me personally because everyone knew that I was the gay person from the West Coast working on the HIV issue.

TAPE 2, SIDE A

SJ: You were talking about being the gay guy at FDA.

It seems to me like you were respected for that.

MR: No. I was feared for that. People did not want to be associated with me because FDA can be quite a conservative place. Maybe it's not as conservative as it was 30 years ago, but quite a conservative place to work. Well, any kind of scientific organization and regulatory organization tends to be fairly conservative. That's the nature of the people who gravitate to science. And so a lot of people did not want to spend a lot of time with me or be associated, particularly if they were people who wanted to climb the career ladder, because they weren't quite sure what would happen.

So I wrote a lot of information down on paper and also told intermediaries what we knew, and they either gave the paper to someone or orally told someone what was going on. And I only found out a couple years later -- actually, in one case, I found out about eight years ago who this mystery person was in DFS at the time, and I won't reveal his name just out of personal privacy. But I was quite shocked because that person had

indeed climbed the corporate ladder, as it were, but I was really amazed that that was the person, one of the people in DFS, in the Science Branch, who was asking me questions through an intermediary. And I'm sure there was a lot more of that going on in FDA that I just wasn't aware of.

SJ: And you were the only gay person working on it that you're aware of?

MR: That I knew of at the time, yeah, yeah.

SJ: None in the Centers or . . .

MR: No.

SJ: Certainly not openly gay.

MR: No, no.

I recall giving a presentation to a bunch of community people. Frank Young was in the audience. Several people from the Center for Drugs were in the audience. And the presentation was about some of the things that the community had been calling for that they wanted FDA to do, but FDA didn't want to do it because it was so different from what we traditionally did. It probably had to do with more inclusion in clinical trials.

The people in the community felt that FDA didn't understand them or didn't understand reality of the public health need, and the people in FDA felt that the

community was being much too radical and didn't understand science, and they weren't meeting, they weren't communicating very well, there was a lot of bickering, and I found myself kind of in the middle because I felt like I understood a little bit of both sides of the equation. And during the presentation, to get my point across, and this was not part of the presentation, I said, "As an HIV-positive man, I understand the need and the desire to want to do this, and I would be willing to try something untried if I knew . . ." Well, when I said that, there were these gasps in the audience that, you know, people were shocked, one, that I was gay, but, two, that I was HIV-positive.

And I will admit that I used that as a power play to get my point across to the power brokers at FDA, and I think they did listen. And I'm certainly not responsible for all the changes in FDA. But I think that opened up a lot of people's eyes to the fact that if I could understand this because either I was gay or I was HIV-positive, I certainly wasn't the only well-educated scientific person who felt this way. And maybe some of the more conservative people that were holding on to the more traditional values at FDA really had to start to look at and examine whether or not our structure was really meeting the needs of the public health of the United States citizens. And I think that was a good change. That was the start of a change in FDA for which I've witnessed lots of changes over the years, and that was a very positive change. I'm very proud of that, actually.

SJ: But now, wait a minute. Certainly you must have become infected after AZT was approved or something like that. You're still living.

MR: I'm still here. Better living through chemistry, as we used to say in college.

SJ: Because those early drugs were very difficult to take.

MR: In the early days I was very strongly in favor of HIV testing and treatment. The HIV test came out in spring of 1985, and I was a very strong advocate for people being tested, everyone being tested, simply so we could identify who was and who wasn't positive so that we could try and stop the infection rate or at least slow it down, because my desire was that people would be talking to one another before they engaged in any kind of activity, and they would take some precautions. And the majority of the communities who were at that time at risk -- of course everyone was at risk, but the prevalent communities -- were adamantly opposed to testing because it was risking their privacy, and if they had to be reported to the state health department for being HIV-positive, then they were at risk for losing health insurance or not getting jobs. I mean, who knew where this would end up? Certain politicians wanted to relocate and isolate all people who were HIV positive.

So I tested in 1985 as positive, and I'm not surprised that I was positive because I was quite sexually active in my youth. And if HIV came to the United States in the late '70s, who knew? I mean, I was not surprised. I was very disappointed and saddened, but not particularly surprised. I mean, I was living in an area where it had one of the highest infection rates in the country, in the world at that time.

SJ: But you hadn't been feeling bad.

MR: No, no, no, not at all.

SJ: You were asymptomatic.

MR: I didn't start doing medication until 1989.

SJ: Oh. That seems extraordinarily long.

MR: Yeah. Well, all my family lived well into their nineties or later. And my grandmother didn't die until six weeks before her hundredth birthday, so I have longevity in my family. And also, what we know about the virus, there's 12 or 13 known strains of the virus, and I could have a very weak strain.

SJ: And we did not know that at the time.

MR: And we did not know that at the time. We know that now. We know a lot more now about the science, about viruses, than we did then. And I could have a weak strain and also good genes, longevity, so I'm very fortunate.

SJ: Well, that's certainly operated to FDA's benefit as well.

MR: Thank you.

SJ: Do you have a copy of the *ORA's Guide to HIV and AIDS*?

MR: I do. I have, I think, one of the last remaining copies.

SJ: Well, we would love to have it for the archives.

MR: Well, it's probably buried, surprisingly, probably half of it is out of date and half of it is still right on target after 30 years.

SJ: That sounds like an extraordinary endeavor, and knowing ORA and how thorough they are, it's quite an accomplishment, actually, to be that thorough and comprehensive.

MR: Well, and there's a lot of people to compliment. Burton Love and Ron Chesemore took a very progressive and supportive attitude.

They both took risks by putting this on ORA's plate, that here's a problem, a major public health problem. We have to deal with it not only for the public, but particularly for our staff and how we protect our staff. And they put it out there, and they deserve some credit for that. Maybe other people would have done that, but those two in particular really deserve credit.

SJ: What was your reaction when AZT was approved? We've got Bob Temple's

perspective on how that came about so quickly, but what was your reaction when you heard that there was finally something besides snake oil to attack the retrovirus?

MR: Well, it was sort of joy and anger. Finally there was something available that people could take. But there was kind of anger, too, that this product had been sitting on some shelf at NIH for many, many, many years. It had been developed and tried for something else, and people sort of knew it might do something, but nobody really knew enough, so people were studying it. And then I think it was licensed to a private company, and NIH gave over the license to the private company even though it's an NIH molecule.

SJ: Burroughs-Wellcome.

MR: And then it was put out, and of course it was very expensive, and people didn't know a lot about it, but at least we had something. And I think that was the beginning of the whole new era of treatment course for viral infections, be it HIV or anything else. So I was very delighted, although, of course, there was initially, at least, the problems with toxicity.

The dosage, the recommended dosage at the time was far too high, which caused many side effects. And it took about two years to learn, or maybe longer. But the dosages that were being prescribed at the time were so toxic that many people couldn't take it. And years later we learned that it was effective at lower dosages and didn't need to be prescribed at the higher dosages. And so I just wonder how many people either

didn't take it and got sicker or took it and got sicker just from the drug because we were giving it at such high dosages.

SJ: It was a heroic effort against a deadly, rapidly spreading disease, so I think the tendency to employ heroic medicine is probably understandable.

MR: Well, it was a shot in the dark. It was the first thing, so, hey, let's try this. And I was very pleased when something came out.

SJ: We're back after lunch talking with Mark Roh, and we're going to pick up where we left off and discuss where you went next after the AIDS epidemic stopped taking all of your time.

MR: Well, actually, it was kind of an interesting transition because I spent two years back here on details, various details, and a position came open in the Pacific Region office, which was the Small Business Representative, and it was a promotion. And I applied for it and I got selected. I got selected while I was back here, so I had to finish some work I was doing back here and then went back out west.

The Small Business Representative (SBR) position was instituted when the Medical Device Amendments came online, and it was instituted as the result of pressure from the Small Business Administration because many small medical device manufacturers were complaining that suddenly they had to adhere to all these new device regulations. They didn't know anything about it and they needed help. Under the Small

Manufacturers Assistance Act for a company with less than 500 employees, the government had to provide assistance to when new regulations became effective. And so the Center for Medical Devices was planning on putting Center employees in each Regional Office. Well, ORA objected to that and said, "Oh, no you don't. We'll take care of this. We'll take care of meeting these new small-business rules. So ORA developed the SBR position.

SJ: And why would they want to do that?

MR: What would who, ORA? Because they didn't want the Centers infiltrating the field.

And so each region had a Small Business Representative, and the position came open. It had been occupied for about eight years and then it became vacant, and so I applied for it.

It was a promotion, and I got it, and it was one of the greatest jobs I had at FDA because it was a paid consultant to the industry by FDA. So it was a free, no-hassle, no-harm visit by the Agency to the industry at their request to help them get over a problem, avoid a problem, fix a problem, whatever it might be, and so they got free agency advice with no threat of problem because the rule was we would not report anything back to the Compliance Office unless we saw something that was considered to be an immediate threat to health. And if we saw something that we thought was an immediate threat to health, we'd report it to Compliance, and then to the Center, whichever center it was, because the SBRs covered all products, not just devices, but the Centers would convene

their Health Hazard Evaluation Committee, and so it would be up to the Health Hazard Evaluation Committee to determine whether or not what was being reported to them was an immediate threat to health. And if they agreed, then there would be an inspection. So we always told the companies that how the program worked.

But never once in my eight and a half years of doing that did I see anything that I would consider to be an immediate threat to health, because if I saw something that was problematic, that was my job. I would tell them, "Hey, you need to fix this, and this is how I've seen it fixed in the past." I couldn't say, "You need to do this."

SJ: Competitors did this.

MR: Well, I couldn't say, "You need to do this," but what I could say was, "I have seen it working this way in other locations, and it works well, so you make the decision."

And that was a great job because I got to go out to all kinds of new and interesting companies and see what was going on, provide advice, and the nice thing about it was that they would invite me out and they welcomed me, rather than when I was an investigator. Nobody wants to see an investigator show up at the door. But when I was the Small Business Rep, they really welcomed me and they welcomed my advice, and I put on a lot of workshops for industry that helped the agency. When new initiatives would come down the line, we'd do a lot of workshops for that particular industry, and it was very, very good, very, very -- it was a great job.

But I would get an average of 35 to 50 phone calls a day from industry, making requests for this, that, or the other thing, and I had an elaborate filing system, and I

worked very well with most of the offices in the Centers. There was the Office of Small Manufacturers' Assistance in Devices; there was one in Foods; there was not one in Biologics; there was an Office of Communication and something in the Center for Drugs that was responsible for working with the public, and I had good relationships with all of those offices.

So, I had an elaborate filing system of current guidance documents and procedures and all kinds of great stuff that we could share with the industry. It was pre-Internet, so everything was still on paper. And I had about a 40-year history file of *The Federal Registers*, particularly for the OTC monographs and other things, because if a generic drug manufacturer or an OTC drug manufacturer wanted to see the monograph and what was in the preamble to the rule and all that stuff, I could pull that out. So I spent a lot of time talking to people on the telephone, saying, "This is what I suggest you do, and I'll send you the guidance documents," and we had a whole system for how we would pull guidance documents and send them out. It was all hard copy then. Like I said, it was before the Internet.

And then slowly, the computers came online and the Centers started putting things on the Internet, and we started trying to figure out how to guide the industry to new rules and regulations on the Internet. Not everything was there. CDRH was actually the first one to really get their Small Business Manufacturers' Assistance up to speed electronically. And that was a great job because I traveled all over the Region and gave a lot of presentations and walked through a lot of companies and suggested many changes, you know, "This is what you need to do to meet the regulations," and so on..

SJ: And you could see the result of what you were doing.

MR: Oftentimes, I could see the results. And I truly believe that all of the companies, except a few, took my advice. One particular company in Oregon was a female contraceptive sponge manufacturer, and they did not take my advice. The sponges were these natural sponges used in place of sanitary pads or tampons, and they had had multiple problems with contamination in these sponges. And I tried to get them to follow Agency guidelines, because there the Center for Drugs and the Center for Devices both had guidelines on what to do with these sponges. This company was trying to be “natural” at that time, and just wouldn’t follow the rules. They wouldn’t follow the drug and device guidelines on the manufacturing, sterilization, packaging of these sponges, and they kept getting complaints about toxic-shock syndrome.

SJ: In the wake of Rely, and the problems associated with it and toxic shock syndrome, wasn’t that a problem?

MR: I suppose they thought it was an alternative to the synthetic material that had been used in those tampons, because, as luck would have it too, that was in the mid-‘80s. I sort of became the tampon king in the Bay Area because I had been on a detail to the Public Affairs Office during toxic shock, and I had been asked to give some presentations about the FDA’s position on the sanitary napkin, tampon products, and toxic shock. And I managed to collect all the material used in the United States to make those products,

and had a big sort of display board of what all the materials looked like, and we were able to actually look at them and sort of compare them. We didn't do the analytical work; it was all done back here in the Centers.

But the bottom line was, in the synthetic materials that were causing the irritation and allowing for the infection problem, the new synthetic materials were really the problem products. And the sponge manufacturer in Oregon had a very similar problem because it was more of an irritating material than a soft, absorbent material. I mean, it was absorbent, but over time, using these sponges was more irritating than not, so many of their clients were ending up with some infections. They could have resolved it simply by changing a few of their practices, which they refused to do because they said it was too expensive. And they eventually went out of business. And that was one of my failed efforts, but you can only do what you can do.

Another disappointing one I had was, there was a small manufacturer of -- I can't even remember what the device was, but it was a very small manufacturing company run by a husband and wife in their fifties, maybe late fifties, and they had one guy, younger guy, help them, and he was in the manufacturing side, but it was more like a backroom warehouse kind of thing. And he was putting the products together. But I visited him several times and tried to get them on tap to follow the device recordkeeping rules. They had been inspected and they had already got the equivalent of a warning letter, which was a regulatory letter at the time, which was a threat to take action, and they were, like I say, a small family-owned company. And they didn't know what to do, so they called. And I visited them two or three times, and I spent many days with them going over their records, their manufacturing procedures, and laying it out for them.

And I didn't hear from them for quite a while, and then one day I got a call from somebody at the company that they wanted to know what to do about something. They had a question and they were angry. And they put the wife on the phone, the wife of the owner. She was in her late fifties. She said her husband had had a heart attack and died, and it was because of pressure from the FDA trying to get them to be compliant, and she was very angry, the FDA killed her husband. And I felt really bad for a while that the gentleman had died, had had a heart attack maybe caused by stress, and I tried to make myself think that it was not FDA's fault. And eventually I came to believe that it wasn't FDA's fault. I mean, I was just out there trying to help them, and I was not gruff at all. I worked very hard trying to be nice to them and help them out. And it was unfortunate, but I did feel bad for a while that he died.

And those were the only two unfortunate things that happened during my eight and a half years as Small Business Representative. That was a great job.

SJ: So, what took you away from small business? Something had to lure you away.

MR: Something did lure me, and that was the prospect of another promotion, and that was to be the Special Assistant to the then-Regional Director, Richard Baldwin. But also I had burned out in the SBR job. Richard Baldwin came out to be the Regional Director, and after about a year of being there, he decided he needed a Special Assistant, and he had had me doing special projects anyway. So I was a GS-13 at the time, and I got selected to be his Special Assistant and was his Special Assistant for about a year before

he returned to headquarters for a different job. Apparently, his performance was not something that the ACRA at the time was happy with.

SJ: Did you have any insights into that?

MR: I do. The ironic thing is, he had two main ideas that, to this day, FDA is trying to implement. One is the Quality Management System that ORA has implemented, and all the other Centers are struggling with it. That was one of his ideas, and that was one of his programs that he was trying to implement. And the other was certification of the laboratories, and now all of ORA's laboratories are certified. So, even though his personality was a bit gruff and he was reassigned to headquarters, he had two very forward-thinking ideas that now, after 12 years later, ORA and the Agency have adopted. And so he deserves credit for that, for those two ideas, for putting them on the table and pushing them.

But after his absence, there was no new Regional Director for about a year, and my colleagues and I tried to manage the Region.

SJ: You were doing all of the work?

MR: Me and the Special Assistant for Science and the Director of State Cooperative Programs were acting as a team, trying to manage the Region, and the ACRA let us do that, and we did it pretty well before the next Regional Director came along, Brenda Holman. She came in 2001. Richard came in, I think, '98 and he left the end of 2000,

and Brenda came in 2001 and about a year later, in 2002, I became her Deputy. And I was happily being her Deputy for a couple of years, helping her run the region.

And then in 2006, Hurricane Katrina happened. Brenda was the only Admiral in ORA, Rear Admiral, but nonetheless Admiral, and she was called to Mississippi to help with the relief effort following Hurricane Katrina. And she worked directly under Admiral, I can't remember his name, who was in charge of the whole relief effort under FEMA. And she was gone for about four months, and during that period, I was Acting Regional Director. And she came back only for a few months, and then she left to go to headquarters to be the Executive Director of the TLT, which was the Transition Leadership Team in ORA, which is to revitalize ORA under Maggie Glavin, the then-ACRA. And so I continued to be Acting Regional Director for two years, and then two years ago, in October of 2009, I was appointed permanent RFDD. So I've been in this position for four years now, and I am trying to reestablish the region after the loss of probably 40 percent of its expertise through retirements and transfers. Of course, that's the problem in all of ORA.

But we have hired, I'm very happy to say that we have hired many new and talented folks.

TAPE 2, SIDE B

MR: We've hired, in the past three years, about 200 investigators, young investigators, who are knowledgeable, many straight out of college and some with a little industry experience, and they're enthusiastic. It's so wonderful to see the enthusiasm for ORA of

some young people who are just now coming in and may not know either the history or some of the frustrations that they will probably eventually feel. But they are very enthusiastic about what we do, and it's very exciting to watch them be trained and to see them gain knowledge and learn how to do things, and go out and find problems in industry and take regulatory action and be proud of what they're doing, and want to come back and do more. It's very exciting to see that.

And I'm very happy with that because that means when I leave the Agency, I can feel comfortable that at least my little corner of it is going to be able to operate well, and so I will feel comfortable taking my drugs and eating my food, and, if I have to get an implantable device, feel comfortable that maybe something that I had impact on, training some of these new people and working with the industry, was successful in providing a product that I'm comfortable using, taking, or having inside of me. So it's been a wonderful ride.

When I think of standing in the bathroom at the Public Health Hospital in 1977 and seeing blood all over the walls because some cancer patient had just vomited his guts out, and thinking I've got to get out of here; and when I think how I started, in 1978, and used to go to parties, and people would say, "Where do you work?" and I would say, "The FDA," and they would back off like I worked for the DEA or the FBI or something because nobody knew what FDA was, and you had to explain what FDA was and what FDA did. Back then you could take five people on the street and none of them would have an opinion about FDA because they didn't know what it was. When I think about what it was like then, coming to FDA, and what it's like now in the 32 years I've had, I'm very happy that I did what I did when I came to work here; because now, if you go

out onto the street and you take 10 people, you'll get at least five opinions of FDA.

There's nobody who doesn't know what FDA is all about and at least has an opinion, and it's been a wonderful ride watching and participating in that evolution.

SJ: You worked with a lot of ACRA's. Give us a little sense of sort of the strengths and weaknesses of each of them.

MR: Well, when I came in, Paul Hile was the ACRA, and I did not know him directly, so I couldn't say what his weaknesses were, but the strengths that I saw from the field were that he was very strongly decisive, almost rigid, but he had an idea what ORA should do and here were the procedures, and we followed the procedures because we had a reputation to uphold and we had things to do.

And later, when I was actually working in headquarters, I worked under John Taylor. I think his strength that I observed, in any case, was also that same ability or desire to maintain FDA's reputation and strength by following rules and regulations as a regulatory body. His weakness, I think, was maybe not being able to be flexible enough to see that changes were on the horizon and needed to happen. I don't fault him for that because he just found himself in a time when change was happening very, very fast, and maybe he wasn't prepared for it. But I think he was a very good ACRA.

The following ACRA was Ron Chesemore, who I have the utmost respect for even to this day. He was ACRA for 10 or 12 years. To his strengths, I saw him as being a very personable guy who actually cared about the average ORA employee, and what was going on with them. He knew almost everybody by name. And he really cared

about what you were doing and he was a very personable guy, and he wanted to be part of the change. He wanted to make sure that we were, that ORA was up to speed with what was going on at the time, whatever that challenge was. If I had to say a weakness of his, maybe it was the fact that he was just a little too nice. He did not like dealing with Congress, he did not like dealing with the Hill at all. He much preferred the operations and the operational folks. That's where he was comfortable. And maybe he just didn't have the patience to deal with the politics. And, again, I don't fault him for that, but I still have a great respect for him. The last time I saw him was about two years ago at a restaurant in Rockville, and he's still just as personable and friendly as I remember him.

And let me see. After he left, the ACRA was Dennis Baker, and Dennis Baker. I still work with him today. He is a colleague of mine, and one of his strengths is knowing a lot of detail about the operational people, about the operations that go on. He came from Texas, from the Texas Department of Health. He was in charge of the food and drug section there, and he understood every detail about what goes on at the operational level as well as all the state personnel. He's been very active in all the state organizations for many, many years. But definitely one of his weaknesses is the lack of patience, and he will admit that to this day, a lack of patience in dealing with the politicians. He did not know how to play the Washington political game, and he was removed after not quite three years of being ACRA. I believe he was kind of pushed out by political insiders.

He had his share of problems. He had the heart and back problems, and had at least two back surgeries while he was ACRA. You would call him up and he'd be talking on the phone, laying on the floor, because that was the only place he could be

comfortable. He's a Regional Director in the Southwest Region today. He's a great Regional Director.

Following him, when he was sort of pushed out, John Taylor, Jr. came in, and John Taylor, Jr. was ACRA for less than two years, I seem to remember. One of his strengths, I think, was that he grew up in FDA. His father had been ACRA, and he was an attorney, so he understood everything about food and drug law, very, very strong. I can't really talk to his weaknesses other than the fact that the field saw him as a bit isolated from us and we believed he did not have a really good understanding of the field operational level because he came to FDA from a law firm where he went from law school, so he was never an investigator in the field. He was always at a fairly high level in FDA. He has a great understanding of the everyday operation in the field. He got removed, I don't know why, by Commissioner Crawford at the time, who brought in one of his favorites or somebody he had known for a very long time, Maggie Glavin from USDA.

SJ: Lester Crawford.

MR: Lester Crawford was the Commissioner, Acting Commissioner.

SJ: Brought in Maggie Glavin.

MR: He was Acting Commissioner for about two or more years. He brought in Maggie Glavin, who he had worked with at USDA, and gave her the charge to revamp

ORA. Why Dr. Crawford gave her that charge is still a mystery to me. Obviously he didn't like what ORA was doing. Of course, the funny thing is -- well, I don't know if it's funny, ironic -- Lester Crawford later got removed in a scandal, and Maggie Glavin retired later, but Maggie Glavin sort of tried to take ORA and turn it upside-down and put it on its head and make it look like USDA, which it's not, and it didn't work too well. And, unfortunately, the field, and ORA in general, hasn't quite recovered from a lot of that. There's still a lot of distrust, there's still a lot of pain and anxiety that results from some of the reorganization and some of the policy changes that Maggie made, and I don't think she did anything vindictive or purposely problematic, but she just did what she thought was right, but not having any experience with ORA and how FDA operates, her ideas at USDA didn't translate too well. And, in any case, she retired, and I don't think there was any love lost when Maggie left, which is kind of unfortunate.

But she appointed her then-Deputy to take over as Acting ACRA, Mike Chappell, who acted for two years, and he retired recently. He spent all his career at ORA in the field and had a good understanding of ORA and tried to do the right thing for ORA.

And the current ACRA, I'm still holding out hope that she will survive. She's been here a year now, and she is also an attorney, Dara Corrigan, and I do have some concerns that the ACRA's office is completely run by attorneys now who have never been in the field, never done an inspection, never collected a sample, and that gives me pause for concern. But maybe it's a little too early in the game to see if that will have an adverse effect or a positive effect. I'm praying every day that ORA will benefit from the current changes of being under or in development to reorganize and change the way we operate. Time will tell. Some things do need to be improved for sure.

SJ: What kinds of things are under consideration?

MR: Oh, there are many things. There's a very slow reorganization going on. There is talk of taking the laboratories out of the field and putting them into headquarters reporting structure, having them be under a science directorate, which, actually, I think is a good idea. There is a current discussion -- and we're working on a white paper now -- to elevate all the district labs into regional labs status and have all of the laboratories report to Regional Directors instead of, currently, some report to Regional Directors, some report to District Directors. There is consideration that it's nonequivalent across the board in terms of resource funding, operations, staffing, workload, everything, so the idea to put it into a science directorate and try to raise the level of ORA science, we've been kicking around for quite some time, and how to do that now is the process or the question. And I think we're going to start with having all of the laboratories report to regional directors for a year or two until we can develop a science directorate, and then put all the laboratories into a science directorate and have them operate as an independent organization within ORA. I fully support modernizing science in the ORA labs and hope to be part of that effort.

One of our big challenges now is our international inspection requirement, and we have this program called the Pharmaceutical Inspectorate, for which we've developed a certification program, levels one, two, and three, three being the highest, and right now we have a level-three certification program for drugs, and we're working on other certification programs for the other product areas.

But the problem we're experiencing is that every year the Centers want us to do more international inspections. CDER believes 80 percent of the pharmaceuticals are manufactured offshore. Everyone knows the volume of imported food that we buy and eat every day. Medical devices, the components, many of them are manufactured offshore, and now the finished devices are starting to be manufactured offshore, not just the components.

FDA can no longer continue to be the quality-control unit for all the manufacturers of the world, as we have been, by testing their products when they arrive in the U.S. and then releasing them. We have to figure out a different way to evaluate products with these increased levels of importation. We have to go to where the products are manufactured, and the products are manufactured in foreign countries. We have to go to the foreign countries and inspect manufacturers there, and we have to put the onus on the foreign manufacturer. It should not be up to FDA to determine these imported products meet our regulations, but rather it's up to the exporters and importers to prove to us that they have met our regulations. And we're going to them and inspect, but we want the foreign government to certify to us that they have noted that their companies meet our regulations. So, we're trying to expand that whole foreign program.

But the challenge here is that many FDA employees did not sign up to go into foreign countries to do inspections, and we're getting a lot of pushback from some of the long-term employees, some of the more experienced folks, who don't want to spend three weeks or more traveling to foreign countries to do inspections. And we're grappling now with, how do we make it attractive to them, or how do we mandate that this be part of their job, that part of the job is doing foreign inspections because we are an inspectional

and regulatory organization and we have to inspect where the products are manufactured, and that is a real challenge.

Some of the newer employees are very excited about doing foreign inspections. In fact, when we hired them, we wrote foreign inspections into their position descriptions. And during the interviews, we were very clear that some of your responsibility is going to be international inspection. Are you okay with that? And many of them are very excited about the opportunity of getting to do that.

But as this foreign inspection program grows, it's been very challenging to try and meet the gap of how many foreign inspections we have to do now with the people we have, and how many we will have to do in the future with the people we have when currently we don't have enough people willing to do foreign inspections on a routine basis. And, hopefully, the people we've hired in the past five years, in the future will be able to do the foreign inspections, because they're more willing, although eventually we're going to run into the same problem because the experienced people are going to retire and we're going to end up with a gap again, just like we historically do. So the foreign inspections are a major challenge about how we deal with our work.

SJ: You used the acronym FSMA.

MR: FSMA, the Food Safety Modernization Act. There is a requirement in FSMA that the foreign government, foreign manufacturer exporter, through their government, certify to us that they meet, that their products meet FDA requirements. We're trying to work out what that looks like with the foreign manufacturers and the foreign governments,

because some of the foreign governments may not have programs that are prepared to certify to either us or to the foreign firm that their products and process meet the United States' requirements.

But if we do not get that, we will not let the products into the country. We have the option of detaining and refusing, and we also have the option of whether or not we want to sample and whether or not we want to analyze. Undoubtedly, we will continue to sample and analyze to some degree. But we also have the option of putting them on import alert if their sample and analysis results are failures. So, we can do that now, but the import alert system could get completely out of hand because if some foreign manufacturer does not certify to us that their product meets our requirement, then we will refuse, and it hasn't been decided yet whether we will continue to routinely sample and analyze or whether we will just say no, your products are refused until you certify. And if they do certify, and periodically we sample and analyze and they don't, for some reason, meet the requirement, then we will refuse again and put them on import alert again. And so it's going to be a lot of work for us in the beginning, until we get it all worked out how it's going to play out. But it's really up to the foreign manufacturers to meet our requirements.

SJ: And, of course, there's the issue of user fees.

MR: User fees, yeah.

And I'm not qualified to talk about the user-fee aspect because I'm not up on the details of the user fees, with the exception that some of the industry likes the user fees and some don't. And some will tolerate the registration fees and some won't.

But I will say that the states, before FSMA was passed, lobbied FDA heavily by the states not to employ registration fees for the food industry, because many of the states' food programs are funded through service fees at the state level. And so now if the states have to or if the companies have to pay an FDA registration fee, then the companies feel like they're paying twice for the same registration and inspection service. And so some of the states are threatening to either lower the state registration fee and/or cut some of their food programs because they can't fund their food programs without state registration-fee money; whereas FDA has come back and said, if that happens, we will give you some sort of grant to continue funding the food program. So there are a lot of details that have to be worked out now. But I can tell you that some of the states were not very happy with the registration-fee portion of the FSMA, nor was some of the industry. Some of the bigger ones, yes; some of the smaller ones, no.

SJ: Mark, I would love to talk with you some more, and hopefully, maybe next time you come to town, we can make up any parts that we forgot. I'm worried about you getting to your plane.

MR: Thank you.

MR: Thanks, I enjoyed it, very fun.

END OF INTERVIEW