

History
of the
U.S. Food and Drug Administration

Interviewee: Richard M. Ruby

Interviewer: John P. Swann, Ph.D.

Date: May 23, 2012

Place: Silver Spring, MD

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

National Institutes of Health
National Library of Medicine
Bethesda, Maryland 20894

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INTERVIEWER(S):

NAME: Richard Ruby

NAME: John Swann, Ph. D.

ADDRESS: Food and Drug Administration
History Office, W. O. Bldg 32, Rm 3322
10903 New Hampshire Avenue
Silver Spring, MD 20993

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INDEX

<u>Tape</u>	<u>Page</u>	<u>Subject</u>
1A	1	Education, military service, early employment at General Electric on NASA projects
	8	Arrival at FDA Los Angeles District Office, early close interactions as an analyst with inspectors
	14	R. T. French case and the shift of FDA laboratory approach from bacteria counting to pathogen identification
	16	Hancock Laboratories and contamination of porcine heart valves
1B	24	
	27	Altadena Dairy and the problem with raw milk
	36	Field laboratory practice, organization, staffing; consolidation proposal
	40	Listeria in Jalisco cheese
	45	Riker Laboratories and problems with small-volume parenterals
2A	47	Problems with Hancock Laboratories heart valves, cont.
	50	Experiences with various lab directors
	52	Pacific Region and the self-directed work teams
	55	Entry-level analyst credentials and work challenges
	57	Lab facility in Los Angeles
	60	Influential FDA personnel
	63	Shifts in FDA enforcement philosophy
	65	Close interactions as an analyst with inspectors, cont.
	67	End of interview

Interview with Richard M. Ruby

May 23, 2012

TAPE 1, SIDE A

JS: This is an interview with Richard M. Ruby by John Swann of the FDA History Office. It's taking place on May 23rd, 2012, at FDA Headquarters in Silver Spring, Maryland.

Richard, welcome. Thank you so much for traveling all the way from the Los Angeles area out here. I know you had a wonderful drive on the way out here, and it's certainly my pleasure to be able to sit down and chat a little bit about your career and your experiences, particularly in FDA.

RMR: Well, it's been my pleasure to come all this way because we love to travel, and this was really an excuse to get on the road.

JS: Terrific.

Well, let's begin. I think the best place, perhaps, to begin is where you were born, where you grew up, your early education, and what, obviously, provided the stimulus for your going into a scientific career.

RMR: Well, I was born in Detroit, Michigan, in 1935, and when I was eight years old, the family decided to move to California to get away from the cold weather. So we

moved to California, and that's where I went to school, high school. My grades weren't that great. I wanted to go to UCLA, and all of my classmates went to UCLA and I didn't have the grades for it, so I went to Los Angeles City College. It was a two-year institution. I stayed there for about three and a half years, and I really didn't know what I wanted to do.

My first -- well, I thought I wanted to be a nuclear scientist, and my first semester I got a D in chemistry, an F in German, a D in math, and it completely destroyed my vision of what I wanted to be. So I brought my grades up by taking courses like geography and English and so forth. I managed to stay in school, but I didn't have a goal.

Finally, I dropped out. I decided, well, I'll let the Army decide what to make of me. So I went in the Army and I scored high in electronics, and they sent me to electronics school in Georgia, but that school was closed, so they sent me to radio operator school. So I became a radio operator and I liked that, and I eventually ended up in Korea -- this was after the Korean War -- and I really enjoyed that occupation. But after a year or so, and then I left the military, and I was a beach bum for three or four months in California, and my money ran out, so I went to a hiring agency. And because I had had one course in microbiology back at the LACC, they placed me in an independent, private lab, and so I learned microbiology in a two-man section in that laboratory.

JS: What was the name of the operation you were working in at that time, the laboratory?

RMR: The operations -- it was an independent lab, so they did testing for industry.

One of the tests they did was to look for bacterial spores in plastic material. This was related to the aerospace industry. And my supervisor at that laboratory was a Ph.D. microbiologist, so I learned microbiology for, like, six years.

And then I answered an ad. I was looking for a job and I answered an ad. At that time I didn't really pay too much attention to prerequisites and requirements and minimal requirements and that sort of thing. But I remember the ad ran, "Microbiologist desired, M.S. preferred." I didn't have a degree. I didn't even have a B.S. "M.S. preferred, looking for spores in plastic material." So I thought, well, I've had that experience. I'll answer the ad.

Meanwhile, I was taking a summer class in English, and I'd met this gal, and she had her degree already, and she had already signed a contract to teach in Sacramento in the fall.

So, anyway, I answered the ad, and then they gave me a practical exam to identify various pieces of equipment they used in their testing, and I was very familiar with those pieces of equipment. So, I got the job.

And then they asked me, would there be any problem on relocating, because the job was in Sacramento, and that's where my girlfriend went to teach. So I said, "No, no problem at all." So destiny stepped in, and that lady is now my wife.

So, anyway, I was working for this company, General Electric, and after -- I was under contract for six months, and after the contract ran out, they wanted me back at their facility in Philadelphia to do some other aerospace-related projects, so I moved back to

the Philadelphia area and I spent about four or five years with General Electric working on NASA projects.

JS: What were some of the projects?

RMR: The projects? There was one project in which we looked at rocket exhaust, and we would inoculate rocket fuel and simulate the firing, and then we would try to collect the exhaust and assay it for our test organism. And we did this all in Aerojet General facilities where we simulated rocket firings.

At that time, there was a general program in the aerospace industry called Planetary Quarantine. Anything that was shot off into space, a rocket ship or anything, had to be sterile because they were worried about contaminating Mars and Venus with earthly bacteria. That's where microbiology came in.

JS: I mean, was there any concern about the reverse issue?

RMR: No.

JS: Not coming back.

RMR: No, not at that time. But that was one project.

Another project: There was a lot of concern about astronauts on long-term space flights. What would happen to their microflora on their bodies and inside their systems if

they were living in a sterile environment? So we simulated that with rhesus monkeys, and we had four control monkeys under regular ambient conditions, and then we put four test monkeys in bio-isolation. And every week we would take samplings from those monkeys and determine what the microflora was and see if there was any change in the microflora over time, and those animals were kept in that program for six months. And, surprisingly, there were changes. The microflora of monkeys is very similar to humans'. Initially, after four or five weeks, all the enteric organisms like *E. coli* and *Klebsiella*, they all dropped out, couldn't detect them anymore, and the predominant microflora was then anaerobes and microaerophilic microorganisms.

JS: What impact did that have on the system, on the constitution?

RMR: Well, that I don't know.

JS: But there clearly was an impact.

RMR: There were changes, yeah; there were changes.

And going back to the firing, simulated firing of the rocket fuel, we had recovery from solid fuel firings at 3,000 degrees centigrade in microseconds. We were all astonished at that.

JS: So, something survived that?

RMR: Yes. Spores survived it; heat-resistant spores survived. We're talking microseconds of firing.

JS: Right.

RMR: But it was more of an engineering problem than a microbiology problem. They had to construct this apparatus to catch, to harvest the exhaust and then cool it down simultaneously with liquid nitrogen. And then the microbiologists would then take this contraption apart and assay it.

JS: Quite a surprising result, though.

RMR: Yeah, it surprised everybody.

We looked at liquid propellants, which were initially toxic to the test organism. And, of course, the test organism was killed upon inoculation. But the solid fuels, we got recovery.

So, anyway . . .

JS: So, how long were you at NASA -- or not at NASA. You were doing work for NASA but you were at General Electric.

RMR: I was there about five years (1966-1971).

When the space program was cut, I decided to go back to school and make it official that I was a microbiologist. So I ended up at Arizona State, which gave me credit for all my underdivision courses.

JS: You had done some work at Temple. Is that correct?

RMR: Well, Temple was mostly the social sciences.

JS: Okay.

RMR: But most of the other coursework I had at Los Angeles City College was accepted by Arizona State, so I only had to spend a year before I got my bachelor's degree in microbiology.

JS: That was in 1971?

RMR: That was '71.

And then a few years later, well, I stayed on in the program. My sponsoring professor wanted me as his teaching assistant, so I said, "Well, I'll stick around as long as you pay me," and so he put me on a stipend, and that's the way I got my master's.

JS: At Arizona State?

RMR: At Arizona State.

JS: Right, right.

You must have enjoyed teaching. You must have been pretty good at it, or else you wouldn't have been invited to do that.

RMR: Well, I enjoyed the lab work. I enjoyed working in the lab and teaching other people lab skills. That part I really enjoyed.

JS: So at this point in your career, did you see yourself going in any particular direction institutionally, going into private work, going into academic work?

RMR: Well, my master's degree was in the microbiology of wastewater, so initially I thought of that area, to get into water reclamations and that sort of thing. And I had my name on the register.

Back in those days, you put your name on a register for an FDA job, and eventually your name would move up in the list, and then eventually you would start getting calls for positions, potential positions. And most of the calls I got were for positions in V.A. hospitals, which didn't appeal to me very much. And all of a sudden FDA called me. Tom Burton, who was a supervisor in Los Angeles District, he called me and we had a five-minute interview on the phone, and that was my interview, and I

was hired. And the job was located in Los Angeles, which is where I grew up in. So, again, there was a little serendipity how I ended up in Los Angeles.

JS: Did you have any familiarity with FDA at this time?

RMR: None whatsoever.

JS: What, if somebody had said to you Food and Drug Administration, what would you have thought about it then? Just a government agency, right?

RMR: I had a blank, really a blank.

I had had, through my aerospace connections, I had a possibility of a job with Sloan-Kettering in their cancer research facilities in Rye, New York, about the same time that I got the call from the FDA. And Tom Burton said that he'd get me on board right away, and although their policy was to bring everyone in at an entry level, a GS-5, but he said he could, because I was more qualified and had the experience, he said I should be a GS-11 in a couple of weeks or something. So I said, "Well, that sounds good." So, that's how I ended up in Pico Laboratory, Los Angeles District lab in Pico.

JS: So it was on Pico by that time, right?

RMR: Yes. The lab was located in Pico, which is kind of in a crime area, not a very good area.

JS: Even at that time, there were crime issues.

RMR: Yes.

Meanwhile, so after two weeks, I saw that this is what I really like to do, because I was being given all kinds of different interesting assignments because of my prior experience. They quickly ran through the training program for me. There wasn't a lot of training involved because I already knew how to be a microbiologist. So my trainer spent, I think, a week with me.

By the way, my trainer was Bob Eshelman, and at that time he was a GS-11, and in those days a GS-11 was the journey-level position for the science people in the lab. The GS-12 was a specialist position, and there were very few positions available at the GS-12 level. So Bob Eshelman, he wanted a promotion, so about, I think it was two or three months later, he got an offer to work at, I think, the Center for Drugs. So he left for his promotion.

Meanwhile, I was being given all these different, exotic assignments. People who had never seen a type of sample like that before, they gave it to me, figuring I could handle that. So, I had very little training, agency training, as such. In fact, I kind of lost out on some of the training because my supervisor said -- my supervisor wanted other people to go and train. He felt that I didn't need the training, that other people needed it more than I did. So, in some cases, I lost out on training, but that didn't bother me much.

JS: You never had a course in basic food and drug law?

RMR: I had basic food and drug law, but I never took basic microbiology. There was a course in microbiology for all agency microbiologists, and I never got to go to that course.

JS: Well, you probably could have been teaching it.

RMR: Maybe. So, that didn't bother me as long as I was getting a variety of work. That's what I really loved.

So, after two weeks of experiencing this FDA thing, thinking I would get promoted anyway to a GS-11, I got a call from Sloan-Kettering, and they wanted me to be a supervisor in their facility, supervising animals. They had a lot of animals for experimentation and so forth, and because of my background with General Electric in that area, I could just walk into a supervisor's job at Sloan-Kettering, which was at that time big bucks. But I really enjoyed the FDA lifestyle because I was my own boss, in essence, because whatever I did, it was okay with the supervisor.

And I quickly established a good rapport with the investigators. We were all located in the same building. They were on the first floor and the lab was on the second floor. And during my breaks, I would go down to the investigators' room and just mosey around and see what they were working on and then offer my assistance or help in their investigations.

JS: Was this unusual to do? Was this unusual for a bench scientist to go to the investigators and have a conversation like that?

RMR: Yes, it was.

JS: Why?

RMR: Well, normally, the investigators, if they wanted a lab person to accompany them in an inspection, they would go through their supervisor, who would then contact the laboratory supervisor, and then the supervisor would arrange for a certain individual to join the team. But I sort of bypassed that procedure, and I was always looking around to see what they were doing because that interested me, because it was a different facet of what I was doing in the lab. So I just wanted more experience.

So I quickly established a rapport with the investigators, and they knew that if I went on an inspection with them, they could use me any way they wanted to use me. I would write a report, I would tell them, "Here's my report. Use it any way you feel that it helps the investigation. You can use it verbatim or extract portions from my report. That's fine with me. I don't really care." Just, I enjoyed being on the inspection.

JS: Was your supervisor in the lab okay with this arrangement?

RMR: Well, yeah. I sort of had a carte blanche on doing anything I wanted to do because of my skills.

JS: And this, for those who aren't too familiar with the way things work in FDA, this was a little unusual, wasn't it?

RMR: This was back in 1974, '75, '76. Nowadays, I could never get away with something like that. And that's why I liked the job, because I could pick my assignments. And after a few inspections, I began to realize that I was learning when I was out there on inspections. That was the perfect proving ground, training ground for me, to see what's going on in the industry, and then I could apply that to the lab.

JS: And what you saw was shocking, wasn't it, sometimes?

RMR: Well, yeah. There were some very dramatic episodes.

JS: I guess this is one way of easing into your investigatorial experiences. But before we segue into some case studies that you encountered in the '70s, in the first decade you were in the agency, how big was the lab? How many microbiologists were working with you at FDA in Los Angeles at the time?

RMR: In Los Angeles, I think there were like eight or nine microbiologists, one supervisor, and a couple of technicians. That was a pretty solid unit.

JS: This obviously -- we won't get to it quite yet -- but this does factor into some of the issues we'll be talking about later on, how big, what's going on in the lab, how many people are there, and so on. But I just wanted to get that.

RMR: There were two specialists, GS-12's in the section, and there were a lot of GS-11's, 9's, and 7's; of course 5's too. Los Angeles District had a policy that everyone that was hired had to come in at the entry level regardless of their background or their education or their experiences, so that's why I was brought on as a GS-5. And, unfortunately, Tom Burton, my supervisor, could not get me promoted. The laboratory director said no, and that was the end of that. So after, I think, a month, all of a sudden I realized I'd be a GS-5 for a whole year before I got promoted, but it didn't bother me too much. I was still, I still had my GI Bill. I was living off that's somewhat, and my wife was starting to work, so it didn't bother me too much. And I still enjoyed the work. Even if Sloan-Kettering had called, I would have turned them down, because I realized that the FDA was my career.

JS: All the better for us that that turned out to be the case.

Now, you had quite a variety of things you were working on, in fact, early on. For example, you had experience with the R.T. French Company. And I guess unfolding

from a finding that, in going through the line, they were potato . . . What did they produce, potato products? Is that correct?

RMR: Well, the R.T. French case, I was not involved in that case directly, but I read about it, and I understood the implications of it because the FDA lost that case. And it was all based on a potato product that was being processed into a final stage, and the investigational team documented a buildup of bacteria in the process. And the level of bacteria was really high, like in the billions, but the product itself eventually went through a blanching process that reduced the viable bacteria down to practically nothing. So the finished product did not have any viable bacteria in it, but it had all these dead microbial bodies. And the agency took it to court, took the company to court, and it was all based on dead microbial bodies constituting filth in the final product, and that was proven, that was shown, documented, and so forth. But we lost that case. The defense team pointed out that, so what, so there are dead microbial bodies.

So, because of that decision, there was a big change in how field laboratories worked. A lot of their work prior to this was documenting high numbers of bacteria in products. After the court decision, it was realized that numbers alone were insufficient to take action on. Okay, you have viable bacteria, but are they good bacteria or bad bacteria? There's no way to tell. So that's when the agency started concentrating on pathogens, documenting and identifying pathogens and numbers of pathogens in a food product. So, all this preparation for determining actual numbers, total numbers of innocuous bacteria went out the window, and that was a big part of the field operation for microbiology. So all of a sudden we had to switch gears, and then we're only looking for

pathogens and not total numbers, which meant that we didn't have to have the staff to handle doing all this labor-intensive documentation of numbers. So that's how that came about.

JS: Okay. So that did have an impact on the operations of the group.

RMR: Right.

Not too long after that -- well, there was always a funding problem with the agency. This went in cycles. Sometimes there was money and sometimes there wasn't, and we fell into an area where there was little funding, and there was a freeze on hiring. So eventually our microbiology unit was reduced to, eventually, four microbiologists, one supervisor, and a couple of technicians.

JS: Right. And then the lab was put in a position to deal with someone's outside judgment that you've essentially atrophied -- not atrophied, but you've reduced our staffing levels so much. And then you argue that this is no longer a critical mass, an interesting argument which we're going to get to shortly.

But I do want to visit a couple of things that I know you were involved in during the 1970s, and one of those involved the Hancock Company and some problems they were having with porcine heart valves.

RMR: Porcine heart valves. In 1977, CDC began receiving reports from hospitals that this prosthetic device, the porcine heart valve, was contaminated with some kind of

bacteria, and there was something like 24 reports from various hospitals into CDC. CDC alerted the FDA, and the FDA initiated an inspection of Hancock Laboratories in Irvine, California, and I was on that inspectional team.

Initially, I spent the first week at the firm just studying the process. I'd never heard of prosthetic devices and it was a whole new technology for me, so I had to, essentially it was a learning process for me. I would stand at the observation window and observe the workers, what they were doing, and I think it was like three or four days, that's all I did, was just study the process before I could even begin to make assessments of what was going on.

JS: But these are, we're talking about actual byproducts of an agricultural commodity.

RMR: The pig valve is very, symmetrically very similar to a heart valve, a human heart valve. So, John -- what was his name -- Hancock, I forgot his first, John Hancock, I think it was, developed this technique, this technology of excising the valve from the pig heart and then working it, and then attaching it to a stent, which is the support unit, and then sterilizing this device, and then it was ready for implantation.

Before this, he did a lot of experimentation with dogs where he developed this technique, this technology, and he was the first one to do it.

The contamination, when we heard about it, nobody knew exactly what kind of microorganisms were involved in the contamination. It was just, the hospitals were finding contamination. So, through a series of investigational techniques -- and my part

of it was looking at the laboratory, the quality-control laboratory, and seeing how they processed and how they tested the raw valves and the completed valves and so forth. And for months and months, I looked at their logbook, their testing logbook, and they had page after page of red entries, meaning a contaminated valve.

And in those days, they didn't test the valve itself. What they did, during the process they would take the valve from the pig and then start cutting away all the extraneous material from the valve until they got it into a configuration in which they could then attach a support stent to it. Well, all these extraneous trimmings were kept with the valve, and these trimmings are what was tested. The valve was never tested. The trimmings themselves were tested. And if they tested positive for something, then that valve was discarded.

JS: One wonders, though, the trimmings weren't used in the final product, right?

RMR: Well, not exactly.

JS: Okay.

RMR: The final product was a valve sewn to a stent, and attached to this valve was a serial number in a plastic strip. And along with the serial number, there were two of these trimmings attached. During patient implantation, the surgeon would remove the ID tag along with the trimmings and send the trimmings to the lab for testing. And that whole thing was sterilized together, and it was a cold sterilant that they used. It was a

glutaraldehyde, a basic glutaraldehyde solution that not only sterilized, but it immunologically fixed the tissue material so it wouldn't be rejected by the human body. It was like a tanning process using glutaraldehyde. All the radicals were knocked off the molecules or whatever. So it was essentially an inert product after it went through the glutaraldehyde process.

The problem was that all the validation work was done using a test organism that they thought was the most resistant to glutaraldehyde. And the test organism was a *Bacillus subtilis* spore. And it is, in fact, very resistant to other types of sterilization like heat sterilization and so forth. But against the glutaraldehyde, as it turns out, the spore was not affected much by the glutaraldehyde. There was something about the spore where the cold glutaraldehyde in low concentrations would not destroy the cell.

Now, the problem with the Hancock valve was that if they used too high a concentration of glutaraldehyde, it would make the product unsuitable for implantation because it's too brittle. It had to be flexible. So they had to find a happy medium between having it flexible enough as an implant, at the same time having a solution strong enough to sterilize. So all their studies, the validation studies, were based on *Bacillus subtilis* spores. As it turns out, the *Bacillus subtilis* spore was not the most resistant strain against glutaraldehyde. A Mycobacterium was much more resistant to glutaraldehyde than those spores because the mycobacteria had a capsule, a gelatin capsule around it. So it survived the sterilization process, and that was what was showing up in the valves in hospitals.

JS: The Mycobacterium.

RSR: The Mycobacterium. But at the time, nobody knew this; nobody knew what that organism was. And initially, the consultant for Hancock thought it was a Mycobacterium avium-intracellulare, which is a close cousin of tuberculosis. And because that's associated with pigs, well, how do you test for tuberculosis in FDA facilities? You just don't do that because it's a highly contagious organism. You have to have special facilities for that.

So I, along with Warren Campbell -- that was another microbiologist that worked with me -- we took some training at Los Angeles County Health Department facility that handled tuberculosis, so we spent a week at the facility learning how to handle mycobacteria.

So then we took those skills back to our laboratory. Now we could use that knowledge to test for the mycobacteria in that product.

As it turns out, it wasn't Mycobacterium avium-intracellulare; it was a very low-grade mycobacteria that was called chelonae, which is found in nature. It's like if tuberculosis was a Grade I level of virulence, the chelonae was a Grade IV. It was way down on the list, as was its pathogenicity. So then we didn't need special facilities to test for Mycobacteria chelonae.

Meanwhile, this inspection, this heart valve inspection, lasted a year because all of a sudden other companies, Shiley and American Edwards, they were also producing porcine heart valves -- not in the quantity that Hancock was producing them, but, still, they were producing them, so they were added to the inspection. So here we had three firms, and they were all located in Irvine. They knew what each other was doing.

JS: And is it fair to say this is where most of these types of valves were coming from, from these three firms?

RMR: Yes.

JS: They had most of the market?

RMR: In the world.

JS: In the world.

RMR: Yes. So they had market, well, Hancock had 90 percent of the market for that type of valve, and Shiley and American Edwards were just starting to get involved. And each used the cold sterilization process, glutaraldehyde. However, the other two firms had different concentrations they used for sterilizing, so they didn't have the problem that Hancock had. But then their valves weren't as good.

Anyway, getting back to Hancock, the agency wanted a final product collected, which was a lot of money in those days. It was like \$600 for just one valve, to purchase one valve. Of course, if you found it positive, you didn't have to pay for it. But if you just collected it randomly, who had that kind of money to collect 10 valves at \$6,000?

So what we did, we went into the firm and we looked at their processing records, and we correlated the finding of these trimmings -- they're called coupons -- the positive

ones, with the serial number of the valve itself. So, going back into Hancock's records, it took weeks of cross-referencing the records.

We finally came up with 80 possibilities, so we collected these trimmings, which are kept in reserve. And from the trimmings, you could trace where that valve was. And we collected 80 trimmings from different lot numbers, and I took them back to the lab and analyzed them, and one of the 80 turned up positive for this *Mycobacterium chelonae*.

So we looked at the records, and that valve, the accompanying valve, was sitting in a children's hospital in Boston, so we had the investigators in Boston collect that valve and ship it back to me, and then I took the valve and I cut it up three ways, and I sent a third to CDC for concurrent testing, and I tested a third of it, and I kept a third in reserve. And my findings matched CDC's findings. We both found *Mycobacterium chelonae* in that valve, in that finished valve. So, that was quite an episode.

Now, getting back to what was the source of that *Mycobacterium chelonae*, everyone thought it came from the pig. As it turns out, a year later I went back for a re-inspection of Hancock. I was walking through the laboratory and I looked into the incubator, and I saw these blood agar plates that were open. And I said to the microbiologists there, "Why are those plates open?"

And he said, "Well, that's how they monitor if they had any mites around." And then he tells me that back in the era of all those contaminated valves, they theorized that *Mycobacterium chelonae* came in through an exotic mite, a little mite, an insect, and they theorized that the mites came in with these plants that decorated the offices. And these

mites, they could crawl in and out of test tubes, stoppered test tubes, and that's how there was all this cross-contamination going on at that time.

JS: But how could they get into a sterile facility, though?

RMR: They were going into the facility. You can't stop a mite from crawling under a door.

JS: So, is that something we confirmed, that this was the source?

RMR: Well, at Hancock. To Hancock's satisfaction, that's what caused the problem. They got rid of all their exotic plants in the office.

JS: Wow.

RMR: But nobody knew this at the time, and it was quite a revelation to me.

JS: You said you recovered one valve. Who knows when that would have been implanted in someone, the one from Boston.

Overall, do you know what was the mortality or morbidity associated with this problem overall?

RMR: The mortality was not very high. There was a lot of morbidity. There were a lot

of people that had this Mycobacterium in their parts, but it wasn't affecting them dramatically. It would, if it grew on the valve enough, it would produce symptoms that a doctor then could observe, and then they could go into that patient and replace that valve. So there was no attempt to try to remove the valve unless the patient was having problems with it. It wasn't a high-grade pathogen.

JS: But I assume there were cases where some patients had to have their valves . . .

TAPE 1, SIDE B

JS: So there were some patients that had to have the valves replaced. Fortunately, it wasn't a problem that caused widespread fatalities.

RMR: Symptoms could present themselves in the patient where there was enough time to go in and replace the valve.

Prior to the porcine heart valve, this was not the case. If a mechanical valve failed, it usually failed all at once and the patient died. That's why the surgeons preferred the porcine heart valve.

Now, the other two firms, Shiley and Edwards, had their own unusual problems with organisms, with microorganism contamination. Shiley had a problem with what was called a *Vibrio extorquens*, which turned out to be a very resistant organism to glutaraldehyde, much more resistant than mycobacteria.

Also, American Edwards had a different organism problem. Their organism problem was a *Chaetomium globosum*; it's a fungi. Anyway, this organism was quite an unusual organism. It would grow on the cellular webbing of a stent, a support stent. It would utilize the carbon of the cellular wrapping of the support stent. It would grow on that. So we had this fungi growing on a valve.

JS: The stent itself, not the organic matter, but the stent.

RMR: On the stent. And it was, again, very resistant to glutaraldehyde.

So here you had three different companies with three different microbiological problems, and I was just fortunate to have experienced all three being in that area.

JS: But in the case of Shiley and Edwards, did these problems that they experienced, did we become aware or did they themselves become aware of these after the Hancock issues had cropped up?

RMR: Yes. Separate inspections were done for each of the other companies, and they fared a lot better. They changed their process. But everyone, all three companies eventually went to a mixture of glutaraldehyde and isopropanol, which became effective against those organisms. So the problem was solved eventually.

JS: It sounds like that's something that kept the lab pretty busy during one span in the 1970s.

RMR: Well, it kept me busy; I spent a lot of time, not so much in the laboratory, but out on inspections. I was involved in all three inspections. In fact, for Hancock, there were two inspections during the year. So I think the whole year was tied up with heart valves for me.

JS: When the report was written up, did you collaborate with the investigators on this, or did you write your own report? I think you mentioned this previously.

RMR: I wrote my own report, and that was included in a separate section in the EIR. And eventually I was involved in rebuttal of Hancock's responses to our 483 closeout. For every inspection, there's a list of observations: that you meet with company officials and you read these observations off. It's called a 483.

Anyway, so, again, Hancock would then have a response to that, and I was involved in the rebuttal to the responses, and the rebuttal to the rebuttal to the responses, and so forth and so on.

And Tom Sawyer was the Compliance Officer at the time, and I helped him draft the recommendation for a restraining order. But because Hancock and these other two companies were the only companies producing that type of valve, and Hancock had 90 percent of the market, there wasn't any legal action that the agency would pursue to get those valves off the market, because without the valves, then the surgeons would have to rely on mechanical valves, which they didn't like. So it was a cost-benefit, risk-benefit issue that the agency decided, well, we've got to keep those valves out there.

JS: But what was the outcome as far as the company? Was there some punishment meted out to the company?

RMR: Not really. The company did issue a market withdrawal of some 2,400 valves for a certain period of time. They did do that. But there wasn't any prosecution, as such, of the company.

JS: But primarily because they had responsibility of supplying so large a proportion of the heart valve, this type of heart valve.

RMR: We couldn't take those valves off the market. It was just too valuable an item to the surgeons. But that was quite an episode.

JS: Yes, it was.

You encountered a number of others. Of course we only have so much time to spend here, and with all the cases you've been involved in, we could spend a lot more. But I did want to touch on some, particularly a few in the 1980s that you [unclear].

RMR: The raw milk issue was, I think, a highlight for me anyway, in my career.

JS: Right. Was that involving Altadena?

RMR: Altadena Dairy was the primary dairy in California that sold, produced and sold raw milk, raw milk products in California.

JS: Were they intrastate or interstate? In other words, did FDA have any responsibility for these products? Did they travel in interstate commerce?

RMR: Well, that's how the agency got involved, because Altadena was selling some of this raw milk in Arizona. So, until that happened, FDA did not have jurisdiction of the raw milk industry. It was the State of California that oversaw milk and milk products. But for years prior to this, I think for 20 years preceding this episode, the State of California tried to ban the sale of raw milk, because every time their health officials and various county health officials looked at raw milk from Altadena, every so often they would find it positive for *Salmonella*. And the way it happened, Altadena produced this milk from five dairy herds. Each dairy herd had approximately a thousand head of cattle. So, whenever a positive finding was found that related back to a certain herd, that herd was quarantined and it was taken offline, and it would be held in quarantine until the testing showed that there was no more mastitis in the cows and so forth. Then they were put back online. At any given time, there were at least two herds in quarantine because of *Salmonella* findings by the State of California or the L.A. County Health Department or the Orange County Health Department, or any other county health department that chose to sample the milk.

Well, when they sold the milk in Arizona, then we got a report from Arizona that there was something contaminated, so the state asked FDA to accompany their inspectors on an inspection of Altadena Dairy, so I was on an inspectional team, and my role was to look at the quality control laboratory. And so the quality control laboratory, there was just one major worker there. He had two helpers. So his background, he had a master's degree in food technology from Utah University, I think it was, and a bachelor's degree in microbiology from somewhere in India, so I thought he knew how to do microbiology.

So I'm checking all the different things in their laboratory, and I looked in the incubator and there's a lot of *Salmonella* isolation plates. So he brought them out and he showed them to me, and he showed me one that had a lot of black colonies on it. And I said, "Well, what are you going to do with the black colonies?"

He said, "Oh, they're *Klebsiella*, they're not salmonella, because I've tested them repeatedly and they always come out to be *Klebsiella* or something else; they're not *Salmonella*, so I don't even bother testing those anymore."

So I said, "Well, what do you do with the plates?"

"Well, we have a compactor."

"Well, don't you sterilize the plate, the media, first before you throw it in the compactor?"

"No, we just throw it in because it doesn't have any bad bacteria on there."

"But where does the compactor go?"

So he took me out in the yard at a dumpster, and there was a huge dumpster, and on the bottom of the dumpster there was this liquid, white liquid coming out of the bottom.

So we went back in the lab. Oh, and there's flies all over this dumpster.

So we went back to the lab, and I said, "Well, show me how you process those black colonies when you did do it."

So he took his inoculating needle and he picked one colony and put it on a TSIA, they call this a triple sugar iron agar slant, and that's a diagnostic media to show you what's going on with that bacteria. Anyway, he put that colony in the tube, and then he went back to another colony and picked a second colony with the same needle, without sterilizing in between, put it in the same tube. He went to a third colony and put it in the same tube.

And so he asked me, "What do you think of my technique?"

And I said, "Well, let me . . ." At the time, I couldn't believe what I was seeing. And I was trying to think, well, gee, I want to get those colonies. How am I going to get those legally?

So, anyway, he asked me what I thought of his technique, and I said, "Well, I'll tell you what. Let me borrow your inoculating loop and I'll show you my technique."

So I took another fresh plate with black colonies on there and I picked one colony, and I put it on one triple sugar iron agar slant. And I told the microbiologist, "Watch my technique, and I want you to do the same thing with that same colony, and I'll take my pick to my laboratory, analyze it, and you do the same with your pick from that same identical colony."

Anyway, we did this three different times, three different tubes, and so forth. So I took my three tubes to my lab and I analyzed them or had somebody analyze them, and it came up to be *Salmonella Dublin*. Now, *Salmonella Dublin* -- oh, we found this out from

the county; they did the speciation. *Salmonella Dublin* is an extremely invasive type of *Salmonella*. Most *Salmonella*, the food-poisoning variety where you get diarrhea, and three or four days later you're done with the episode. An invasive *Salmonella* will actually go from the gut into the bloodstream, like *Salmonella typhi* that gives you typhoid fever. Well, *Salmonella Dublin* is in that same class.

So, anyway, I called the microbiologist at Altadena lab. I said, "Hey, how did your cultures turn out?"

He said, "Negative."

I said, "Well, how did you determine they were negative?"

And he said, "Well, they didn't agglutinate against the antiserum they used to show that it was *Salmonella*."

So I went back to the lab and asked to see the antiserum that he used. He said, well, he used it all up in that one test.

The antisera comes in a lyophilized condition where you add three milliliters of broth to it to reconstitute it, and then, from that reconstituted material, you take just a minute amount to run your test. In fact, about 10 microliters is what you use to run the test typically, and then you mix it with a mixture from the culture itself. And if it agglutinates the bacterial culture -- you can see this visually -- then you have a positive. If it doesn't agglutinate, you have a negative. Well, what he was doing, he was using too much of the antisera and he was diluting the culture, so it never agglutinated; it would never agglutinate. So that was what he was doing. For years and years, he was testing all this milk and always finding it negative, and the county and the state and anybody else that tested the milk were finding positives.

JS: Was this the only lab that the company was using?

RMR: Yes. It's a control lab right there on the premises.

Well, anyway, to make a long story short, the State of California, not the State of California, but the Consumer Union, wanted to sue Altadena Dairy to have a warning label put on all raw milk products in California. They knew they couldn't ban the sale of raw milk because the legislature, because of a strong raw-milk lobby, would always turn it down. So, anyway, they went for a warning label. And the Consumer Union wanted my testimony, and they asked the Commissioner to allow me to testify on behalf of the Consumer Union, and the Commissioner turned them down.

JS: Who was Commissioner at the time?

RMR: I've forgotten who the Commissioner . . .

JS: Perhaps Arthur Hayes? This was about 1982, '83?

RMR: No, before Hayes. No. It was 1987, I think it was, 1988.

JS: That might have been Frank Young.

RMR: It could have been Young.

JS: But wait. I have to ask one thing before you go on. How did your name come up here with respect to the Consumer Union's lawsuit against the firm?

RMR: Well, The Consumer Union through FOI read my section of the EIR and the Consumer Union wanted me to testify.

JS: Right, but . . .

RMR: In fact, they wanted to subpoena me to testify. So they wrote a letter to the Commissioner requesting my testimony. He turned them down on the basis that here was the Consumer Union suing Altadena. This was a private concern suing another private concern, so it wasn't any of FDA's business.

Well, Consumer Union then turned around and went to the State of California, and together the State of California and the Consumer Union sued Altadena. Now when the State of California requested my testimony, then the Commissioner agreed to allow me to testify, because now there was a governmental agency suing Altadena, so that's how I got to testify.

JS: So, how did that happen? Say a little bit about how that transpired.

RMR: Well, I spent about five hours on the phone with the assistant district attorney that was handling the case, and I had to educate him on microbiology line by line. He had my

EIR -- that's the Establishment Inspection Report -- and he had, I don't know, 15, 20 pages of my report. And we went through that report line by line, and I had to explain to him the significance of what I was seeing, line by line. And we spent about five hours on the phone doing that.

So anyway, so I went up to Alameda County -- that's where the trial was -- and I testified. I was on the stand for about an hour, and the Altadena attorney kept objecting because he didn't have a chance to depose me, and here I was testifying as an expert witness, a factual witness and an expert witness, because here I was saying what I observed and I was also explaining the significance of what I was seeing, so it was kind of unusual.

JS: Sounds like it.

So, what happened in the end with the lawsuit?

RMR: Altadena had to put a warning label on all relevant products.

JS: Asserting essentially that they're subject to contamination with . . .

RMR: Well, they had a warning label similar to what's put on tobacco products, you know: This product may be harmful, blah-blah-blah, you know.

JS: Do those products still carry the label?

RMR: Oh, yeah. All raw milk products in California carry that label.

Altadena, soon after that, Altadena no longer, well, went out of the business of raw milk. They still produce pasteurized milk, but they no longer produce raw milk anymore.

JS: Now, it's a big dairy.

RMR: It's a big dairy. Other dairies in California do produce raw milk and they do have that warning label on their products.

JS: Do you happen to know if other states have warnings on raw milk products as well, or California alone?

RMR: Other states? I don't know about other states.

JS: But this certainly had to be a precedent-setting case.

RMR: Yeah, right.

JS: Certainly a memorable one.

RMR: It was.

JS: This was around the early to mid-1980s. We're going to shift gears here a little bit and talk not so much about microbiology per se but about sort of, you know, where science is practiced and how it's practiced, and in FDA, coming to grips with what were some realities; funding issues that, as you said earlier, we see these cycles come and go where sometimes money becomes a real problem in the agency.

RMR: And it's continuing.

JS: It never stops. It's been the case throughout our history, I can tell you that.

But at this time, one of the ways the part of the agency that has responsibility for the field offices, now the Office of Regulatory Affairs, one of the ways they're going to deal with that was to look at laboratories, the field laboratories.

Most of the district offices had laboratories at this time, not all of them, but most of them did. Certainly Los Angeles did, as we know. And one of the things that the Headquarters was looking into -- I think prompted in part by some concerns and recommendations by the Bureau of Foods, as the Center for Food Safety and Applied Nutrition was known at the time -- was creating critical masses of scientists in laboratories and coming up with numbers; what constituted a critical mass of, say, microbiologists in labs. And this is something that you became very much involved in.

RMR: Well, at the time this happened -- I can't remember the time frame, probably early 1980s.

JS: It was early 1980s that it started, right.

RMR: There was a movement to consolidate labs, consolidate functions, whatever, and it was this matter of a critical-mass issue: What was the minimum number of workers in a union, in a unit, that constituted a viable unit that could function properly? And the number, for microbiology, the number was thought to be anywhere from six to eight to 10 or something; depends on who you talk to. At that time, our laboratory was down to four microbiologists, one supervisor, and two technicians, so we were on the edge there. We didn't know if we were going to exist, because here was this movement to eliminate microbiology from Los Angeles District.

JS: Well, they were actually talking about RIFing, reduction-in-force, for some of the agency employees at the time, were they not?

RMR: Yes, right. We heard talk about that. So I was shown all these memos from Headquarters. I think there was one from Don Heaton and his views of what was determined to be critical mass, and some other documents. And . . .

JS: And Don Heaton was the Director of EDRO (Executive Director of Regional Operations).

RMR: EDRO.

JS: Which was the Headquarter component that oversaw the field offices.

RMR: Right. So, Abe Kleks was our District Director at the time, and he asked me to write a response to this Heaton memo and explain why Los Angeles microbiology could still function even though we only had four people, four microbiologists. So I wrote kind of a rebuttal to all the items that Don Heaton mentioned in his memo, and he itemized one through, I think, 10 or 12 or whatever. So I took each item that he itemized and I put that in italics, and then I wrote a rebuttal in just regular type through his item, and I wrote a rebuttal for each of these items. And that memo, Abe Kleks used that to justify keeping microbiology in Los Angeles, and that memo went to the Regional Director, who then sent it to Headquarters. So I think I helped to . . .

JS: Well, as a matter of fact, in that proposal to consolidate the labs -- not just the microbiology function but other labs -- that proposal in the end did not fly, with the exception, I think, of the Boston District Office that might have combined functions with WEAC, the Winchester Engineering and Analytical Center. But other than that, I don't think it panned out.

RMR: Well, the problem was that nobody could come to a consensus. There was no consensus of what a critical mass for microbiology was.

JS: Yes. And, you know, I ran across a couple of documents, and one was a

communication in which Don Healton -- I can't remember if he was communicating this to all of the RFDDs (Regional Food and Drug Directors) and District Directors or not, but he was making a reference to communications he had had with the Bureau of Foods. He had asked the Bureau of Foods to explain how they came up with the idea that a critical mass of scientists, that 10 was the magic number. But they didn't really identify where this number came from.

RMR: I thought at the time that there was, you know, I was on the fence because I could see the advantage of consolidating labs, larger labs being maybe more efficient maybe, but I had to write it in terms of having a small lab being as efficient or more efficient than a large lab, so I focused on that part of it. I don't know if my input changed anything or not.

JS: But you know what I started to say, though, is that in this memo that announced the decision not to go forward with this consolidation, Healton had mentioned a number of reasons why. And I can tell you, because I saw the memo that you had prepared, and there were elements in that Healton memo announcing the decision not to go forward that invoked some of the reasons you gave. So it seems like it did have an impact on the final decisions.

RMR: I'd like to think so.

JS: But, as both of us know, in the next decade the agency really did consolidate a

number of its laboratories. And it was, interestingly, also a time when the field was trying to establish, in the 1980s, the mid-1980s or so, to establish these research centers around the field, like in Seattle, a seafood products research center, and a few others. A lot of the pushback they got was indeed from the Bureau of Foods, I think, because of the nature of what they were going to be studying.

RMR: Exactly.

JS: I think it's interesting for people to appreciate that people like yourself were involved in these kinds of investigations that you narrated, for example, with respect to Altadena, and there are these other things going on, too, in one's professional lives that have to take attention as well.

RMR: Again, going back to my reasons for liking the FDA was this variety. I really got it. Anyway, that Altadena inspection, I think 1982, I think it was, soon after that, I think in 1985 is when we had that outbreak of contaminated cheese, *Listeria* in cheese products.

JS: This was the Jalisco . . .

RMR: Jalisco.

JS: Jalisco. This was like a soft . . .

RMR: It's a soft Mexican-style cheese.

JS: And that really did have some disastrous outcomes for many consumers, didn't it?

RMR: Yeah. And, again, I was fortunate enough to be on right at the start of that episode, well, the start of the FDA's involvement.

This contamination was going on before FDA knew about it. CDC was involved, and the State of California. The Los Angeles County Health Department was heavily involved in the initial findings when they were doing their epidemiological trace-backs. And here are all these mostly Latino pregnant women that were aborting their fetuses because of this Listeriosis problem, and nobody knew where it was coming from, but the epidemiological data collected by CDC and the state and the Los Angeles County Health Department kind of pointed to Jalisco as the culprit.

So the Los Angeles County Health Department and the CDC asked the FDA to sit in on a meeting to determine whether or not to go public with this information with a press release. And I was asked to sit in on this meeting, and I think it was on a Wednesday that I was asked to sit in on a meeting, and the meeting was on a Friday, and they had . . . And they told me that there was a *Listeria* problem, possibly, causing all these aborted fetuses, and *Listeria* at that time was not a food pathogen; it was not considered a food pathogen.

JS: Where would you find Listeriosis? What sort of commodities would you experience that?

RMR: Listeriosis is the disease or the illness associated by this organism, *Listeria monocytogenes*, and it was, prior to this episode, it was always considered a clinical significant pathogen. We found it in the hospitals. It was never associated with food. So this was the first time that, all of a sudden, the food is implicated, and we had a little problem on methodology. How do you test for this *Listeria*? If you use the procedures that hospitals and clinical labs used, they used the cold enrichment that would take weeks and weeks and this sort of thing.

Well, anyway, I, along with William Teachworth -- he was the investigator on the FDA -- we attended this meeting at the L.A. County Health Department, and the State of California Health Department was present, the CDC was present, the county epidemiologists were present. Anyway, we all sat around this table, and CDC and the county showed the data that they had collected, the epidemiological data, and they wanted concurrence from the State of California and the FDA to go public with this information.

Well, at the time, there was never any finding of *Listeria monocytogenes* in cheese. It was all epidemiological data. Yeah, they had recovered it from patients in the hospital clinical field, but never from a food product itself. So here the county and CDC wanted to go public that everything pointed to Jalisco as the culprit. The State of California kind of balked at this initially: Well, we don't have a positive sample yet.

And they asked us, Teachworth and myself, and we said, “Well, CDC’s data is pretty persuasive. Everything points to Jalisco as the only one, as the source of this contamination.

Anyway, later in the day there’s a press release, and it was made public that Jalisco was the source of this *Listeria monocytogenes*. And the very next day I was on the inspectional team out to the plant, and we had to go in the back door because television crews were at the front door. And, of course, Jalisco had already shut their operations down. They didn’t bother cleaning anything. And when I went into the firm, there were ants all over the place, ant trails going up the walls and into the vats and everything. So, anyway, I did my thing; I collected samples and took them back to the lab.

But, still, there was the problem of methodology. There wasn’t any method. And Joe Lovett in Cincinnati rushed a method to test for *Listeria*. So he faxed me a crudely written method, and that’s what we used.

JS: Now, this is not normally how we do things.

RMR: No, not normally.

JS: But we don’t often encounter situations like this, do we?

RMR: Normally you would validate a method before you used it. We didn’t have time to do that. So, anyway . . .

JS: And we found positives.

RMR: We found positives in just about everything I looked at. We were working seven days a week on this project. I think it was like two months straight without a day off, every day. And we had to request additional help. Again, we were down to like four microbiologists, so a couple of microbiologists were sent to us from San Francisco and a couple from Seattle, so that built up our staff so that we could handle that project.

JS: So, in the end, I think -- I don't have an exact number, but it's probably fair to say scores?

RMR: There were quite a few deaths.

JS: It looks like about 19 stillbirths. Is that possible?

RMR: It was something like that.

JS: And so, a large number of fatalities associated with this contamination.

RMR: So we determined, the investigators determined that or they theorized that raw milk was being used in making the cheese. And when making the cheese, you have to put milk through a pasteurizer before you put the milk into the vat to make cheese. So

the investigators determined the amount of milk coming into the plant, the amount of milk that went into the vats, and nothing correlated. There was a lot more milk that was coming in than could be accounted for by the process of putting it through the pasteurizer, so we knew that the cheese maker was turning the valves at night and using raw milk to add to their product. And the product was the Cadillac of the industry in taste. In fact, Jalisco had been written up just weeks before there in *Sunset Magazine*, and they had a center foldout of their facility and how wonderful this cheese was.

JS: I guess they didn't get any pictures of the ants, the floating ants or anything like that.

RMR: Well, the ants were incidental because they had shut the plant down without the cleaning.

JS: I think you were involved in this rather interesting experience where we were again in the 1980s. But there was a firm. We were looking for some training opportunities to instruct inspectors, investigators in small-volume parenteral production.

RMR: That was the Riker Laboratories. That's a subsidiary of 3M Corporation from Minneapolis. Anyway, Riker was located in the San Fernando Valley.

Anyway, the agency wanted to train inspectors in actual operations involving small-volume parenterals, and Riker offered their facilities in that manner, and they arranged a tour of investigators, Los Angeles District investigators, along with

representatives from Headquarters. So during this tour -- by the way, Riker said that their facility was state-of-the-art, so that's why there was so much interest in having this as a training ground. But it kind of turned out disastrously for Riker because the people from Headquarters, they started noticing some really bad practices in the firm, in their sterile-fill operations and so forth, and so they requested that we do an inspection of . . .

JS: It was a training opportunity, I guess.

RMR: So, again, I was on the inspectional team along with Charles Snell and Brian Sanford.

Anyway, so we spent a couple of weeks in the firm. Our 483 was the closeout inspection. The 483 was 47 pages long, typewritten observations. And Riker, or rather 3M, the parent corporation, flew out some of their experts from Minneapolis to attend this closeout session, and there was like 23 people, 23 company representatives in the room along with the three of us as we presented our findings. And the upshot was that the vice president of quality assurance was terminated; the facility was upgraded and it cost millions of dollars to upgrade their water distribution system. So that was an experiment that didn't work out.

JS: Do you suppose that the parent company was aware of their willingness to serve as kind of a training assistant?

RMR: They probably were. Again, they thought they had a state-of-the-art facility, but not so.

JS: Not so much.

Nineteen ninety-one is when you started your role as a supervisor, a supervisory microbiologist. But before we . . .

RMR: Reluctantly.

JS: Well, before we move into that, as far as your other work leading up to that, we talked about a number of things you were involved in, but anything else that we should discuss before moving on? Or any comments you'd like to make about the directors that you worked under at the time? Because I think one of the points you make -- you mentioned the rebuttal document to the Heaton report. I think one of the things you mentioned in that, among many other points, was that with a smaller laboratory, you don't necessarily need more microbiologists to be an efficient organization. If you're dealing with professional microbiologists and a good supervisor who knows how to make the . . .

TAPE 2, SIDE A

JS: Well, we were just about to mention an observation you made about how

important it is to have a manager or supervisor who knows what his or her staff is doing and can really make good, efficient use of them.

But before we go into that, I know you wanted to add just a little bit to the case of the Hancock Company.

RMR: Hancock, another interesting highlight of that inspection.

Hancock, in his experimentations, he had various files, and we wanted to look at everything in the inspectional phase, and he wouldn't let us look at what he called an ex-plant file. And this ex-plant file contained all the information about patients whose valves were replaced, and the valves that were contaminated that were removed from the patient were sent back to Hancock Labs for study. We wanted to see that data, and John Hancock would not let us see that file because he was concerned about patients' names being revealed.

JS: There is something that may or may not have bearing here. Was it obligatory on the part of the device manufacturer to report adverse reactions associated with their products under the law? The 1976 device law was in effect by this time.

RMR: Oh, yes. They adhered to that; they complied with that.

JS: They complied with that.

RMR: But here they were actually looking at the valve that was removed. It was sent

back to Hancock for studies. Now, that information was not revealed in that information for disclosure.

We wanted to see that file. We wanted to know what was in there, what the data was. Hancock would not let us see that file. So we got an inspectional warrant in which he had to reveal that file, and it was somewhat comical in that we requested a meeting with Mr. Hancock, and he thought it was the closeout meeting where we would list our observations or whatever, so he had called all of his managers into this conference room thinking that -- the investigator was Mike Stokke and myself -- thinking that we would then present our list of observations.

Well, Mike Stokke pulled out his badge and I pulled out my credentials and, with the inspectional warrant, we walked over to Mr. Hancock and presented him with the warrant. And he flew into a rage and he said, "No, I'm not going to give you the file." And he looked around and he saw all his managers in shock, and he said, "What are you doing in here? Get out of here!" and you never saw a room empty so fast.

Anyway, he left the room. He left us with the vice president sitting there, and he said, "I'm going to talk to my lawyer." So he left the room, and about five minutes later he came back. He was very much under control. He said, "Okay, I'm going to give you the file." But then he pointed at Mike. He said, "But if you ever let a name out, a patient's name, I'm going to get you, Mike!"

Mike is sort of a low-key person. He never gets emotional. He just took it in stride.

JS: But you got that, you got what you were looking for.

RMR: Yeah, we got what we wanted.

JS: I'm glad you shared that, too. That's a good part of the story as well.

Now, getting back to the change in your status in the lab, I only brought up that comment you made and the rebuttal to Don Heulton document in that you made a remark about how important it is for efficiency to have a supervisor who understands what is good, efficient work.

RMR: Not only the supervisor, but the personnel. The employees have to have good knowledge, skills, and abilities to be able to handle the workload such as that in a highly professional manner.

JS: Right. So, looking back, how many different laboratory directors did you work under in that period from the time you came on to the district office until the time you yourself became the supervisor?

RMR: When I came on board, it was Tom Burton. He retired. And then Susan Setterberg was our supervisor, microbiology supervisor. She came down from San Francisco. She was a chemist. And she took over as supervisor for the micro group.

JS: She also supervised our office at one point in her career.

RMR: And, again, I had a very good rapport with Susan. She thought very highly of my skills. Again, I had almost a blank check to do whatever I wanted to with Susan.

And then Susan left, went to Baltimore.

So then our supervisor was Smith, Marilyn Smith, and she was from New York; she was a microbiologist from New York. And she came in, and she was there for about three years, and then she got promoted back to New York as a Branch Director.

And then there was a void for a little while. We didn't have a supervisor. Nobody wanted the job. It was advertised, and I didn't want the job. And, at the time, John Stamp was our Lab Director, and he sort of twisted my arm to apply for it, and I told John, "Well, I'll take it. I'll take the job only on the condition that you'll allow me time to stay at the bench to keep my skills up."

Well, George Gerstenberg was the District Director at the time. He turned me down. I was the only applicant. He turned me down. He didn't want me as a supervisor. He said I was too valuable at the bench.

So, again, it was just acting supervisors, but it was re-advertised, and John made me apply for it again. And this time George accepted me as a supervisor.

Again, I had that agreement with John Stamp that I would have time to keep my skills up, my analytical skills up, but it never happened because there was just too much paperwork and administrative work for a supervisor to be able to do both functions. So I sort of missed that, being at the bench, but there were other benefits, other compensations, for me anyway, because I was always on the hiring team. I was always interviewing for new applicants and so forth, and just recruiting, and that part I liked.

And I hired a lot of people. I was instrumental in hiring a lot of people, investigators as well as lab people.

In fact, at my retirement last year, my supervisor, Donna Williams-Hill, who's a Branch Director, she was master of ceremonies, and the first thing she said to this full room of people, "Okay, I want everyone to stand up that was hired by Richard Ruby," and just about everyone, including Donna, stood up. That was quite a tribute.

JS: Those are memories you want to keep.

Now, there were some things that were probably less than memorable, one of them being the birth of the self-directed-teams experiment in the Pacific Region. That actually started not too long after, we were talking about early 1990s or mid-1990s maybe, right?

RMR: Yeah, mid-1990s.

JS: Tell us a little bit about how that came about and what the outcome was, and what the self-directed team was all about.

RMR: Well, the Regional Director, Ron Johnson, had this idea that if there were self-directed teams, these teams would be more efficient and could handle more work if you designed it along product lines. For instance, there was a medical device team made up of investigators, lab people. Medical devices, the only lab work for medical devices, other than the heart valves many years before, was condoms and gloves, and they tested

them for holes, leaks, or whatever. That was the only medical devices that the lab handled.

But here, there was a team formed, a medical device team, in which you had to have a lab person and an investigator and a compliance officer all working together to handle this line of product, so to speak. So I was selected to be the lab representative on this line of business, medical device team, even though there was hardly any involvement from the lab on devices. And the same with foods, the same with biologics, the same with the other line of products.

JS: This approach, not that too many other institutions have the kind of responsibilities that FDA does, but do you have any idea where the Regional Director came up with this idea?

RMR: I don't remember the man's name. There was an author of this self-directed-team progress or episode, and it was applied to industry. And industry did use this to some extent, but in industry, what they did, they would just fire everybody and then rehire those that would be suitable for the self-direction scope of this new concept. At FDA, you couldn't do that. You couldn't fire en masse and then rehire. So, in essence, we had to deal with the self-direction with people that were not self-directed. In the hiring, especially in the lab -- not so much in investigations; in the investigations, you liked to hire somebody that's self-directed because he goes off into a firm by himself. He has to be self-directed, more or less. But in the laboratory, that's not the case. In the laboratory, you hire people that follow orders, even though I was a maverick at that. But, even so . . .

JS: You were exceptional, though. But we're talking about people that are more independent-minded. Is that fair to say?

RMR: More what?

JS: More independent-minded.

RMR: Independent-minded, yeah, that could be self-directed, that would take the initiative to get something done. You didn't have that in the laboratory. So, right away, I could see a problem developing in the lab.

JS: But is this something that the Headquarters signed off on?

RMR: They didn't even know about it.

JS: They didn't know about it.

RMR: They didn't know about it.

JS: How could they not know about it? That's remarkable.

RMR: They started getting rumors about this and that and the work products or

whatever. Our Lab Director, John Stamp, had a detail back to Headquarters, and he worked in the ACRA department. And the ACRAS asked John, "Hey, what's going on out there in the Pacific Region?" and John told them about the self-direction. And soon after that, Ron Johnson was moved out of that position and we went back to the old way of doing things. I don't know what happened. I'm down in the trenches. I don't know what's going on up above in the higher echelons. Well, it wasn't working. That was it. And I guess there were a lot of complaints about it.

JS: So the Associate Commissioner for Regulatory Affairs, Ron Chesemore, authorized that this was just going to end.

RMR: It was just localized for the Pacific Region: Seattle, San Francisco, and Los Angeles. But it was . . . So, anyway, it was an experiment that didn't work, but I'm glad they tried it. At least we could see where the flaws were. It's something that could be thought of in the future.

But one thing has to be done before they do anything like that. They have to, I think, increase the standards of hiring, upgrade the hiring practices. OPM has their minimum standards for entry-level professionals. I'd always thought that they were too lenient.

JS: So you'd require more education, more training?

RMR: More education, more background for entry-level for the agency. I've always felt

that . . . Well, my vision of a field laboratory is somewhat different than reality. My vision is that the people working in the field laboratory should be, should have the KSAs to be able to handle situations and not use those KSAs for surveys and routine testing. I'd like to see Ph.D.'s and people with M.S.'s in the field laboratories mostly. If you've got a B.S., then you're suitable for technician work, because the reality is that these Ph.D.'s and the M.S.'s in the field are doing technician work, and it's a waste of talent.

JS: Well, consequently, are we able to hold on to them?

RMR: I mean, that's another problem. They get bored and they want to move on to something more challenging. The way the system is, it doesn't happen in the field labs.

JS: We've been talking about, for the last hour to two hours, the wide range of fascinating work that you can engage in in the laboratory.

RMR: Yes, oh yeah.

JS: So, why might the staff, these qualified staff, not be given those opportunities, I wonder?

RMR: Well, the way it's structured, it's all a chain-of-command. You have to get authorization to do this, that, and the other thing, and it's not like in the old days when I could pick and choose. That doesn't happen anymore. Yeah, we have some talented

people in the field laboratories, but I think they're underutilized, that's all. I would like to see the field labs as a put-out-the-fire type of unit ready to go out there and really solve a problem that industry has or whatever.

JS: Well, we're certainly faced with so many problems microbiologically and otherwise. We've seen sorts of foodborne pathogenic outbreaks that are going on, and other things. There's no lack of variety.

RMR: The science of microbiology has changed dramatically over the decades.

JS: How has that affected the FDA labs, what you just said?

RMR: Well, there are still a lot of people -- I include myself as a classical microbiologist in the classical ways of isolation and identification. But in the current technology, it's all molecular biology. Now we're looking at the gene and identifying the gene that does this or that. In the old classical systems, you look at the outcome of what a bacteria does, it changes this media to that media or whatever. It's a whole different science. And so you need people that are trained in molecular biology to implement the new techniques and to understand them. The problem with old-timers is they don't have that background. It's not something you can go for two weeks in an FDA training course and pick up. You have to go back to school and learn that science.

JS: You can't leave without talking a little bit more about facilities. Those in Los

Angeles in particular were, I mean, you've touched on this, that the lab where you started was -- the scientists working there faced very difficult circumstances, not only the equipment you were working with, but the vicinity was a tough one. You were the supervisor; you were a supervisory microbiologist at the time that the facility moved to Irvine. Is that right?

RMR: Yes.

JS: I wonder if you wouldn't mind just saying a little bit about what it was like working in the old facility and what it took to finally get to a truly state-of-the-art facility that we have down there.

RMR: I think when we started the interview, I mentioned that Pico lab, where Los Angeles District was located, was located in a crime area, so we had drive-by shootings. When we left the building, we had to look, left and right and make sure the coast was clear. In fact, I personally had my car stolen from the back street. It wasn't in the lot. It was right on the street next to the lot, and it was stolen and recovered three weeks later without the radio. Anyway, we had this environment.

And then in 1992, we had the race riots, with the Rodney King beating and all that, and we had to close up our lab and get out of there. We couldn't work because we were in that crime area.

So then there was a strong emphasis to look for a new lab, so we formed various teams to visit various sites, potential sites to look at. And I went to a site in Glendale, as

it turned out. It was a clinical lab that was moving to another facility. Anyway, they had a clinical lab, so it was somewhat suitable for us. It wasn't all that big, but it was suitable for our operations. So I wrote my report and the other teams wrote their report, and all these reports went to Headquarters. We were trying to figure out a site to go to.

And my report -- this was one of my low points in my career -- I wrote up my report, and I let spellcheck correct all my spelling errors. And many weeks later, I got this call from Headquarters. Somebody in Headquarters wanted to know more about the warehouse next to the chemistry section. And the way I'd written the report, I said that the chemistry section was adjacent to the warehouse, which could be used as a storage facility, and I misspelled warehouse "wherehouse," and I let spellcheck check it, and nobody caught that error until someone back there in Headquarters wanted to know more about the wherehouse.

Anyway, nothing happened. A decision was not made to go to another facility or another already built facility, and it was decided back in Headquarters they'd build a new facility for us, and that's how the Southwest Regional Lab or the Irvine lab came about. And then we moved there in 2003.

JS: Well, there's a vast difference between that and what you were in before.

RMR: Oh, yeah.

JS: I used to see pictures floating around ORA when people were lobbying to try and get better space for the laboratory there, and they referenced shots of the various

conditions, with the mold and ceilings, ceilings falling down, just water damage, and . . . That's just inside.

RMR: We had to close off the mass-spec area because there was a leak in the roof.

JS: Tough conditions. It points out one of the reasons why it might be hard to recruit the sort of people that we'd like, like you were talking about before -- not that that's representative of the laboratories. It was egregious, unfortunately. But it's things like that that maybe make it a little difficult to recruit the sort of people that you were talking about. But a facility like what you have now, I'm sure that makes it a little bit easier to make an attractive work environment, not to mention the work itself.

Looking back on the very long career you had, even before FDA, but certainly focusing on the FDA part, what sort of people kind of stand out as having a major impact on your life in the agency?

RMR: Well, there were my supervisors. Susan Setterberg was very supportive. In fact, at that time, I put in for a midlevel career training nomination, and she wrote a very nice letter of recommendation for me for that.

And Carl Bruch was, who was the Director of Microbiology in the CDRH at the time of the Hancock heart-valve episode, I got to know him quite well, and he had an impact on me too.

Who else? Abe Kleks was the District Director at the time I joined the agency, and he was very supportive of me, especially during the Jalisco episode. I spent more time in his office explaining microbiology to him.

People that I worked with were all good workers. Warren Campbell. He later left, worked at NCTR. There was Bob McDonald. He was a whiz at canned foods, can-seam teardowns. He taught me a lot on can-seam teardowns.

JS: You mentioned the case of working closely with the Center for Devices during the heart-valve case. Did you have a chance to work with scientists or others in Headquarters very often?

RMR: Not very often, no. The Hancock was an exception, as well as the Jalisco. I got to work with Joe Lovett and some of his crew. We worked together pretty good -- well, from a distance.

JS: But he was in Cincinnati?

RMR: Yeah, he was in Cincinnati.

JS: Not in the district office.

RMR: No. There was a research center in Cincinnati.

JS: The forensics lab?

RMR: Well, not part of the forensics, but maybe it was a district, but they had, they developed methods. In fact, Lovett had developed a method for *Listeria* in milk a couple of years before, but not food. So he took that milk method and modified it for cheese.

I should also mention other key personnel who had a major impact on my FDA career.

Reggie Bennett, CFSAN Scientist, who taught me everything there is to know about Staphylococcal Enterotoxins.

Steve Kendall, Los-Do Investigator, who introduced me to the salient points of an inspection.

Tom Hammock, CFSAN Salmonella expert, with whom I had had many stimulating discussions on Method Validations.

Rick Lit, currently VP of Regulatory Affairs for Amgen, who pioneered PCR methods at Los-Do during the early 1990s.

And a whole cluster of investigators who, each in his/her own way, contributed to my understanding and development in the inspectional field:

Mike Stokke and Jim Kozick (Medical Devices)

Ron Kohler (Medical Devices, Biologics)

Bill Teachworth (Foods)

Bill Chaffee (Foods, in-vitro diagnostics)

Marv Appleton (Dairy industry)

Sharon Aristoff (Heparin inspections)

Mary Woleske and John Duke (Drugs)

Andy Bonanno (Breaded Shrimp in Nogales)

David Barr (early morning food plant inspections)

Pam Schweikert (Cheese inspections)

Tina Santillanes (Cheese recalls)

Then I had some details. I did a detail in CDRH, in the Compliance section, a manufacturing section that was kind of interesting. I had to review injunction recommendations from the field, and that was kind of enlightening because the Center had their own list of categories and requirements to process a recommendation. And I quickly learned how to reject a recommendation on, you know, the stuff that they were putting in the recommendation, either frivolous or not relevant enough. So, that was interesting. And that, at that time they were trying to establish the *in vitro* diagnostic regulations, so I had to review comments from industry on those regulations. So that was kind of interesting.

JS: Well, since you mentioned that, it reminds me to ask, in the years you've been in the agency, what kind of changes did you notice from your viewpoint, from your standpoint, on enforcement philosophy? That's changed a little bit over the years, hasn't it?

RMR: Well, yes, it has changed. Although I'm not an investigator, I was acquainted with that.

JS: But you were in on plenty of investigations.

RMR: Yes. And in the old days, they went for all kinds of actions based on very minimal evidence and minimal observations and so forth, and a lot of that was eventually remedied with turboEIR and new things where you had a source to go to to see how to reverse or how to explain a violation. But from my recollection, the actions were less at the time. I can't give you any specifics.

JS: That's okay. I was just curious if you had any kind of a feeling or a sense of changes in philosophy.

RMR: There was a period where all of a sudden, instead of the good guys and bad guys, we were trying to help the industry. There was that philosophy that we're there to help, not just to punish and to find fault, which is good, and I think there should be a joint cooperative effort with industry, because industry has the state-of-the-art. They have the up-to-date technologies that we learn from them, and it's good partnering with them.

JS: Do you think that ever presents a problem for the agency?

RMR: It all depends on who's the investigator.

JS: I mean, one might wonder if being a little bit behind technologically ever puts the agency at a disadvantage when it comes to, say, microbiology.

RMR: When I first went into the agency, I was doing or helping with the investigations. Investigators were really not too well trained in the technology of the industry. In fact, there was a drug firm, I think it was, where the QA manager got me aside from the investigator and says, "I'm really glad you're here because you understand what the technology is and the investigator doesn't." I don't know if he was just buttering me up, but it made me feel good.

JS: You bring up a good point. People who will be looking at this aren't necessarily familiar with the way the agency does its business. But a lot of the cases you've narrated here are those in which someone in the laboratory has gone into plants with investigators to do some pretty major investigations, and I think it might help readers appreciate this if you could share if this was unusual or exceptional, the sort of things that you talked about.

RMR: Well, in my case, I think I developed a fast rapport with the investigators because of my background in the aerospace field, and they knew that I worked in a clean room, I had worked in a clean room, and I had to gown up in a bunny suit and all that, and I went through an air shower and I had that experience. And when it came time to do a drug inspection, they wanted somebody that knew how to gown up if we went to a facility.

JS: But I wonder if in bringing a scientist, a professional microbiologist along on an inspection, you know, one might think, well, maybe this person might see something going on there in a plant that maybe an investigator, an inspector, might not have the same appreciation for. Do you think that's possibly the case too?

RMR: Well, yes. Well, with lab people, there's a misconception, I think, out there about a microbiologist having certain skills, and a microbiologist, a laboratory microbiologist, should know how to do a sterility test, but he doesn't necessarily have to know sterilization parameters. Sterilization is a science all by itself. It's more of an engineering science than it is a microbiology science, and there's . . . In fact, the agency has a course for sterilization specifically geared for investigators. It would be nice to get microbiologists in that course, too, because they need it too, but a microbiologist's training in school and background and everything is not sterilization, it's sterility testing, so there is that misconception for a lot of people.

JS: Right. And I'm kind of reminded of what you were saying about the experience watching a QA person inoculate, and this is the sort of thing that, let's face it, a scientist is going to see.

RMR: Well, yeah. A lab person would have; an investigator might not have understood the implications. That's why you need the lab person.

JS: You know, many people have said many things about the self-directed teams, but on one hand, getting scientists and investigators together, maybe that wasn't the right way to do it, but maybe if there were a way to do that in a different way, it could be useful.

RMR: The theory is very good, but every member of that self-directed team has to have those skills. If you only have one or two and the others are followers, it won't work.

JS: Well, this has been a wonderful conversation, and I think it's going to be of great use to people interested in the development of science in the agency. I think the case studies you narrated, even by themselves, are fascinating and instructive. So, again, I appreciate your willingness to sit down and talk about some of this, especially after driving 3,000+ miles.

RMR: I look at it as a further highlight of my FDA experiences.

JS: Well, thank you; thank you so much.

END OF INTERVIEW