

History
of the
U.S. Food and Drug Administration

Interviewee: Richard Baldwin

Interviewer: Ronald Ottes
Robert Tucker

Date: September 2, 2003

Place: Rockville, MD

RT: This is another in series of FDA oral history recordings. Today we are interviewing Richard Baldwin, senior science advisor to the associate commissioner for regulatory affairs. The date is September 2nd, 2003. Interviewing Mr. Baldwin are Robert Tucker and Ronald Ottes. The transcription of this interview, together with the tapes, will be placed in the National Library of Medicine and become a part of the Oral History Project.

Dick, to begin this interview, would you give a brief biographical sketch of where you were born, educated, and any relevant work experience prior to coming to FDA.

RB: Sure. I was born in Philadelphia and grew up in South Philadelphia. Was educated in the parochial school systems there and eventually graduated from St. Joseph University with a bachelor's and a master's degree in chemistry.

While I was in graduate school getting my master's degree, I started teaching at a local high school called the School of the Holy Child in Rosemont, Pennsylvania. Then also worked for a time at McCrory's in Center City [District], Philadelphia, as a short-order cook. So I learned how to multitask a long time ago. I also worked for the International Resistor Corporation, which was eventually absorbed by TRP, and they made electronic components and things like resistors, transistors, and those kinds of products.

After getting my master's degree, I started with the Food and Drug Administration in Philadelphia as a chemist. I spent about five years there, eventually specializing in

pharmaceutical analysis and the development of systems to automate analysis of products for uniformity of dosage form and related kinds of assays and analysis.

In 1975, I transferred to headquarters for the first time, into the education and training branch as their resident chemist, although I spent about 85 percent of my time developing training programs for the investigators. About two years after that reassignment, I became the director of the education and training staff and stayed there until 1982, when I transferred to Baltimore as a lab director.

RT: Dick, while you were in that training branch, you were involved in one of our big recruiting—FDA's recruiting—

RB: Project?

RT: Project Hire.

RB: Right. Right.

RT: So what part of that training program did you take part in?

RB: Well, I wouldn't want to say that I, you know, took part in all of it, but Harold Post was my supervisor at the time, and Harold actually wrote the training manual for what we called then inspectors—now we call them investigators—and he was the driving force behind a lot of what

ultimately became the basic training for investigators. My role was mainly to find the right people and schedule the training; make sure that we accomplished our objectives.

One of the things that I did was to create what we called the course advisory group, and that course advisory group was designed to bring the right people together to address whatever training needs we had and provide effective training for our field staff, whether it's investigators, scientists, compliance officers, supervisors. At that time, the role of the training branch was very global. Everything from basic training to advanced training.

Back then we had 200C credentials for folks who were doing preclinical or clinical investigations, and we had, in a sense, a hierarchy of training programs, so that in addition to just knowing how to gather evidence or how to do an analysis and do it effectively, people could progress in their career and have a better understanding of not just the basic drug program, where, you know, you might actually make some tablets or capsules, but advanced programs in parenterals and other kinds of products, antibiotics, that have their own unique issues. And making sure that the field staff—we had sufficient quantity of folks with those knowledge, skills, and abilities to do an effective job.

RT: Where did we train this mass of employees?

RB: Funny you should ask that, Ron. I bet that's a leading question, because one of the things that we did is to try to look for the most economical places to do that, and one of my projects actually took us to what used to be then the Breech Training Academy. It was a TWA facility in Kansas City.

And what we figured out, with a piece of paper, a calculator, and a pencil, was that was the cheapest place to go at that time, while we were doing nationally sponsored training. The facility itself was naturally set up for doing training to a large number of folks, and the rates that they charged us were miniscule at that time, and it was also the cheapest place to travel in the country, when you looked at airfares and things like that.

RT: How many did we train during that period, do you remember?

RB: We hired, I think, somewhere between 500 and 600 folks, when we did Project Hire, so all those folks would have gone through the basic training over the course of, say, two or three years. But what we also were doing was continuing our training of folks for, say, the advanced drug course, the parenterals course, the antibiotics course, foods courses, and things like that at our lab scientists that we were hiring. So it was really busy for a, you know, significant period of time.

RT: Okay. Sorry for the interruption.

RB: That's okay. A little nostalgia is good.

So now I'm moving to Baltimore as a lab director. I spent six years in Baltimore as the lab director. Some of the things that we did in Baltimore that I think were kind of unique was, we serviced other components of the region in, say, the pesticide program in microbiology, and that posed some kind of unique challenges, because I couldn't just run downstairs and chat with

the director of investigations in Philadelphia. I had to call her on the phone and get involved in their work planning and whatnot.

And we also had a unique capability there for in vitro diagnostics. In a sense, we were the national service center for that program, and I think those kinds of activities were precursors to later, in a different part of my career, looking at specializing our labs, consolidating lab functions, and having a larger number of folks with capabilities to be more efficient and effective.

After serving some time at Baltimore as the lab director—

RT: While you were in Baltimore, had they started any of their specialized laboratories? You were in, at that time, anyway, Region Three with—

RB: Right. With Dick Davis and Tom Hooker. Right.

RT: So Philadelphia was also a laboratory there. And had Philadelphia and Baltimore started specializing in certain aspects, or did that come later?

RB: Not at that time. One of the things that I wanted to mention, and I guess I'll mention it now, since you've given me that opportunity, is, during my career, I've tried to find out what it's like to live in other people's shoes, so to speak. I've taken details and investigations and compliance in some of the centers, at headquarters and whatnot, and I guess being close to headquarters in Baltimore, I would get pulled into headquarters often for either a detail in the Division of Field Science [DFS] or to write a position paper or whatnot.

During that time, in the mid- to late eighties, the issue of specialization did come up, and in fact, I was involved with the Division of Field Science [DFS] and writing some options papers and whatnot. It's not fair to say that at that time, it actually became a reality. It didn't really become a reality until later on, when Don Heulton tried to push that, and by then, I was back in headquarters in the Division of Field Science, and we made several iterations of trying to specialize. In some instances, it went very well according to plan, and in other instances, you could hardly notice the difference.

That's one of the unique things about our organization. As you kind of pan across the country, the way the regional structure is, whether we had ten or six or five folks, even though we had national policies and whatnot, and we decided to do something, there were lots of interpretations of the scripture, in a sense. You could get ten people in a room and have twenty different understandings of what was expected, and that made life kind of interesting, whether you were in the field or whether you were in headquarters, of trying to protect the integrity of what we're trying to accomplish.

RT: When you were in Baltimore, were there any major drug firms, or is that pretty much a food firm?

RB: No, there were some major drug firms. In fact, we had a very significant action against J.D. Companos, who was a contractor and also an independent manufacturer of human and animal drugs. And eventually, he got himself into quite a pickle with the agency. He had a lot of NDAs and ANDAs suspended as a result of problems that he created for himself in his manufacturing and in his record keeping and whatnot. I was instrumental in briefing the microbiologist, Linda

English, who ultimately went into the facility and, through her inspectional work, was able to uncover the discrepancies that ultimately led to us building a strong case against him.

But we did have a significant amount of pharmaceutical work there. Naturally, a lot of food work, because we had Maryland and Virginia as part of our inventory. A lot of work with the states. I spent a significant amount of time, in a sense, on the road, visiting State of Virginia, State of Maryland officials, doing joint-work planning and projects with them. We felt that was very important back then, and folks continue to see the importance of doing that today.

RT: Was Companos antibiotics or drugs or—

RB: He was a lot of antibiotics, but also some other drugs; if I remember correctly, both animal and human. He also got himself in trouble with EPA [Environmental Protection Agency], too, so there were some joint efforts going on in scrutinizing his activities.

RO: Now, you mentioned *her* a little bit ago, in investigations. Was that Janice Oliver?

RB: Janice Oliver was the director of investigations at the time. Don Sherry was the director of compliance and Tom Hooker was the district director while I was there. I think we had a really effective team. We worked well together and pretty much stay in touch with each other.

In fact, I could add a little personal side to this. One of the things that Tom Hooker had a habit of doing is, I would hire some really good secretaries. I hired Terry Ausfresser and a woman named Penny Houle [phonetic], and every time I'd hire a secretary, Tom Hooker would wind up hiring her, and this got to be a habit.

What ultimately became ironic is, in keeping in touch with Tom through the e-mail, he sent me an e-mail one day. We were just kibitzing back and forth, and he says just casually, as Tom can do, because he's an excellent poker player and can keep a straight face, but he's doing this in the e-mail. As he's closing out the e-mail, "You'll never know how much gratitude I have toward you for what you've done."

And I was clueless, and I went to my wife, Marie, and I said, "I just got a strange e-mail from Tom, and I mean, what do you think he's talking about?" So we chatted about it, and eventually I figured out the story, and he fessed up to it. Penny, who was his secretary, moved to Florida, and when Tom retired, he moved to Florida, and eventually figured out that the two of them got married.

So I guess one of the other position description responsibilities that I had, that I didn't realize was official, was being a matchmaker for district directors. I don't know if that will stay in the transcript or not, but I thought it was kind of funny that Tom was constantly finding my secretaries to be of high quality.

RT: Well, he apparently thought you were a pretty good recruiter of talent.

RB: I guess so.

Well, after Baltimore, in 1988, I returned to headquarters as the director, Division of Field Science, and that's when a lot of things began to happen with respect to consolidating our labs, lab specialization. In the early eighties, 1981, 1982, Dick Davis led an initiative for the EDRO, executive director of regional operations—at that time, I think that might have been you, Ron—to look at our laboratories and whether or not we had the right number and mix and things

like that. And he and folks like Tom Layloff and others went around the country and basically came up with a game plan of consolidating the labs. Part of this was due to aging infrastructure, facilities, and whatnot, and the expense of running a lab.

They also recognized, I think appropriately so, that some labs, say Puerto Rico, were responsible for twenty, twenty-five, thirty, forty programs and slices of the work plan at point one FTE [full-time equivalent] and whatnot, and there's a lot of equipment and expertise to go to support that. And is that an official way of doing business?

In fact, as I had mentioned earlier, one of my things is to try and learn more about how other components of the organization operated. Jim Beebe, when he was the regional director up in New York, asked me to take a detail to Puerto Rico as the district director. And one of the things that I did there was a little study of the district, not just the lab, but the district in general, and made some recommendations to him about things like the lab and perhaps specializing that lab to a drug lab with some food capability. Because when you looked at the industry in Puerto Rico, that's basically what [unclear].

But anyway, back into DFS. I spent a significant amount of time when I got to DFS dealing with the recommendations from that group, Dick Davis, Tom Layloff, and whatnot, on the consolidation issue. It became very political, to the point where Congress inserted a sentence, and I think it was the 1982 appropriations, that we would not use any appropriated funds to implement that.

So our initial effort at—and I put this in quotes for the folks that are going to transcribe this—“consolidation” really didn't go where we wanted it to go. That's what led to taking a look at specialization, and that was the next round of initiative in looking at our labs and trying to figure out how to best utilize our resources there.

So we put out an initiative, and I'm pretty sure this was under Don Heulton, to specialize the labs. And the way it was done is, it was kind of delegated to the regional directors to do that. In some instances, it worked real well, because WEAC [Winchester Engineering and Analytical Center] became, in a sense, an ideal component or result of this specialization, because their prime responsibility is to support the device program in the country.

In the Pacific, it didn't work so well. Because when you looked at the three labs, when the specialization plan was actually put out, there were still three labs pretty much doing what they were doing before.

RT: Did this specialization initiative involve transfer of science personnel?

RB: What we wanted to do was to primarily start off transferring programs, and then training folks in situ to support those programs. In other words, if Philadelphia, Baltimore, and New York, when you looked at the country, had the bulk of the pharmaceutical program responsibilities, along with Puerto Rico and some West Coast, now, what we were saying is that your resources ought to be put there to support that, because—and this was an important thing that came out in the '82 study that Dick Davis did—you can send a sample anywhere in the country overnight, and that's still the reality today. So we could concentrate the expertise.

For example, in Puerto Rico, I had two microbiologists doing a bunch of work, and if one of the got sick or wanted to take leave, and I had a situation, I was out of luck. Practically right away, then, I would be thinking of sending the work to Atlanta. At that time, Puerto Rico was part of the Northeast region—Region Two, the old Region Two in New York. Technically, I'd have to ship it up to New York. And from Puerto Rico, that's a challenge.

But anyway, what we initially focused on is, let's look at the programs first. Let's look at where the industry is. Let's try and come up with some strategies to consolidate our resources to support those kinds of activities. And this actually is something that you can look at in the investigational area, too. I mean, where do you have the industry? How many investigators do you need to adequately cover the industry? And at least the training issues, at least the infrastructure issues and that sort of thing. But our initial cut was, let's look at the programs, let's figure out where we ought to put the resources.

In some regions, Region Five, which I believe was Chicago and whatnot—they used to call it the Midwest, and it doesn't exist anymore, because now it's part of the mid-Atlantic—they did concentrate, say, the microbiological program in Minneapolis and whatnot. So in some places it already happened. And in Atlanta, you really didn't have to do much consolidation, because, in a sense, you had a regional lab already in Atlanta, servicing Florida, Nashville, and the other districts in what would be Region Four then. So it was spotty, and it really wasn't satisfactory, because it didn't really get us to where we wanted to be.

RT: Were the so-called research centers established while you were in DFS, or did that come later?

RB: Research centers were established, I think, right as I was coming into DFS in—I'd actually have to go back and look at the dates. I remember Don Heaton being the driving force behind that, and I think it was '82 or '83, and it might have been as I was making the transition in there, because I remember reading a lot of the material on that. The research centers, I think, were a noble idea, but unfortunately, we never got the resources to fully implement that idea. And what

happened is, we were limping along, trying to accomplish some things with the research centers, but with inadequate staff and whatnot.

We also had an issue of integrating the activities of the resource centers with the program work of the labs, and I think there was some parochialism from time to time about what we were really trying to accomplish. Then we got into dialogues over which short-term research, which long-term research, and a whole—and that actually led me, as the division director, to implement some changes in how we managed research, and the way we moved the managed research was to actually try and get folks to produce something, whether it's an analytical method or knowledge of dietary supplements or transfer of technology using LC mass spec or whatever.

We actually created a research technology committee to oversee this and scrutinize the research proposals on a periodic basis to kind of nudge management, local management, to make sure that the person got the time to do the research and was actually developing the method, collaborating it, and delivering something that is valuable to ORA [Office of Regulatory Affairs] and the organization.

RO: How did the centers accept these research centers?

RB: They were not happy campers about it. There was, I think—years ago, the centers, particularly CFSAN, Center for Food Safety—or whatever they were called back then, Bureau of Foods; that really gets us back a few years—and the Center for Drugs felt that they had the primary responsibility for developing methods and whatnot, so there was a lot of tussling back and forth and not necessarily a lot of cooperation.

What I tried to do in that research-planning exercise was to involve the centers to get their input and actually have them review some of our research projects, and I think that created a valuable dialogue.

RO: How many research centers were established then, and how many are still in existence?

RB: If I remember correctly, the proposal was for like twelve research centers, and I think seven were actually created. I remember the Elemental Analysis Research Center, Animal Drugs, Seafood Products. I'd have to go back and get a list, but I think there were only seven that were created. And again, we didn't get the FTEs that we asked for.

The research centers that still exist that I'm aware of are the Seafood Products Research Center—

RT: That's in Seattle.

RB: That's in Seattle. A remnant of the Total Diet Research Center, still in Kansas City, which also includes a remnant of the Pesticides and Industrial Chemicals Research Center and a miniscule number of FTEs, maybe one or two. And a remnant of the Elemental Analysis Research Center, which is now, I think, part of the Forensic Chemistry Center in Cincinnati. I think that's what's left. I don't think the Sterility Research Center exists at all anymore. So, unfortunately, those programs have been subsumed into our regular research activities that the district directed and stuff that's managed from headquarters.

RO: Well, that's what—you mentioned the fact that giving the analysts time to do their research, and that was one of the concerns, I think, at the time, that if a regulatory sample came along, and it may have resulted in a seizure or a prosecution, why, forget the research and get on the regulatory sample.

RB: And that's true. That was my own experience in Philadelphia. When I was in Philadelphia, I was selected for a science advisors research associates program, and the only reason I actually got to do it is because I had been selected for the headquarters position, and they let me devote my time to do that research project toward the end of my time in Philadelphia, but because I, you know—I couldn't argue with management. They had a lot of things they wanted me to do to support public health in regulatory situations, whether it was Companos or finding products not meeting USP and things like that.

RT: You mentioned the science advisory program. How successful was that and is it still in use?

RB: The Science Advisors Program is, I think, still in use, and I think the success really needs to be gauged on a local basis. When I was in Division of Field Science, one of the things that I did was to upgrade that program in a couple of ways. We revised the position description for the science advisors, and we also got them a little bit of a pay raise. We kind of institutionalized that they would be paid at the GS-14, step 2, rather than the GS—whatever it was before then—to kind of recognize their contribution.

In a sense, I feel, from a headquarters perspective, with the use of John Specchio, I brought him in as a senior science advisor and had him in charge of a lot of activities with respect to the research planning and whatnot. To me, that is a successful use of the science advisors. I'd have to ask the local folks how they used their science advisors. I know from my own experience that, just by interactions with the science advisors when I was in DFS, they were all top-notch academicians, and that's basically where we drew our science advisors from, academia.

I know a lot of the science advisors have been with us for eons. The science advisor in Kansas was with us like thirty-two years and was a legend. And we used him in training programs and from a historical perspective of how our sciences evolved and technology has evolved. So I think the Science Advisors Program, I think, is extremely valuable for ORA. I certainly would like to see that continued and find some ways to enhance it.

Okay, so we're still in Division of Field Science. A couple of other things that I did in the Division of Field Science, and this caused some folks a little bit of angst, I felt that the journey level GS-11 for field scientists really didn't represent adequate compensation for the expectations that we had for them. Part of this was looking at, when I started in the agency, what you needed to know to do the job. Then, in 1985, or whenever, how that evolved.

And I thought you needed to know a lot more. You needed to know more about computers. You needed to know more about technology. You needed to know more about instrumentation. And I felt that that raised the bar of expectation of the knowledges, skills, and abilities that a scientist would need to bring to do a good job in one of our regulatory labs in the field.

So I worked with some folks, and what we did is we created a new position description and ultimately raised the journey level to the GS-12 for a field scientist. This caused a little consternation in the investigations arena, because they hadn't caught up with that. So we had to kind of catch them up and do it all at once. It was an interesting time to be around, to negotiate that through personnel and through management. And I think—hindsight is always good—that perhaps we should have also thought to raise the journey level for the first-line supervisors and come up with a better pay structure to—

[Begin Tape 1, Side B]

RB: I was raising the journey level for our field personnel. And then in raising it to a 12, then you have a compression, because the 12 used to be the specialist's grade. Very rarely would you have any nonsupervisory 13s out there. Now we have—you know, the 12 is the journey level. We have a lot of nonsupervisory 13s, and we have supervisors at the GS-13. I really do think the supervisory job should be compensated at a higher level because of the responsibilities, the judgments that they have to make on the quality of the work, and the things that they have to juggle. They're attempting to do that with Title 42, and hopefully that's working out for them.

Back then, we didn't have access to those kinds of personnel opportunities to do a better job of compensating the supervisors. What we should have done is explore raising them to either the 14, or come up with some supervisory pay scale that is somewhere between a 13 and a 14 and recognizes their role. That got to be a really interesting political exercise when we did that, but we pulled it off, and I think appropriately so.

Something else that I did—I did; I shouldn't quite put it that way. Something else that I kept on pushing for was to create a peer review process for our regulatory scientists in the field, so that they can get access to nonsupervisory grade levels 13, 14, and 15. And again, it took a while, but we eventually were able to implement that. We had folks like Tom Cairns get to the GS-15 level. Some of our national experts—our NMR [nuclear magnetic resonance] specialist in New York got to the 14 level.

I'm not quite sure what the situation is today, but I know that the program still exists, and I know that folks are being recognized for their technical contribution at the bench, and so in a sense, we have a parallel track there.

One of the things we were talking about earlier, and to kind of continue the theme, I was selected for the Senior Executive Service [unclear] to develop a program in the department in '92 or thereabouts, and while I was out of DFS, there was another effort to look at consolidation of our laboratories.

There was, as I understand it, a meeting out in San Francisco of senior management, and they came up with a game plan, and this ultimately led to a decision to take the nineteen labs that we had and consolidate them to five what they called megalabs and several specialty labs, like the Forensic Chemistry Center, WEAC, Philadelphia, and San Juan, as pharmaceutical only laboratories. And Ron Chesemore was the ACRA when this was initiated.

And we kind of got partway through it. Buffalo was kind of consolidated out of existence. Baltimore was consolidated out of existence, the Cincinnati regulatory lab, the Minneapolis micro and whatnot. So what we have now are thirteen labs. Interestingly, again politics played a role in having thirteen, because Detroit was scheduled to be consolidated into other laboratory facilities, but because of the interest of the politicians there, that lab still exists, as small as it is.

RO: What about Minneapolis? Minneapolis, I remember, was always very political.

RB: They were political, but whatever was going on locally wasn't enough to protect them, because they did close the FDA lab. Some of the people are co-located at a state facility there, but the lab, in essence, is gone there, Minneapolis.

One of the interesting things about the consolidation plan, that latest iteration in the nineties, was that Midwest region really had no laboratory capability. You might want to talk to some of the former FDA folks who were responsible for that, but that was kind of interesting.

Back in the Pacific, we're talking about consolidation. The plan still had Seattle, San Francisco, and Los Angeles. So again, it's a situation where, yes, we were moving toward trying to consolidate. We were going to go from nineteen down to twelve or whatever, but we still had situations where it didn't quite seem to meet the intended goal.

RT: Now, from the staff level, that no doubt created a lot of stress and anxiety with regard to the need to move or to cease operations they were engaged in.

RB: Now, as I had mentioned, I wasn't involved in that decision making, because I wasn't in DFS. I technically wasn't working in FDA; I was working in DHHS on that candidate development program. But Ron Chesemore and I had an interesting conversation when I came back, and ultimately he had me in his office, and he said, "Well, what would you have done?"

And that's not the kind of question that I really wanted to spend a lot of time answering, because I didn't want to be second-guessing something that's already a done deal. But in trying

to answer Ron's question as honestly as I could, I asked him a question back. I said, "But what did you want to accomplish?" I said, "If you focus on the facilities, and not the management of the facilities and the programs that need to be managed, you will come up with a different outcome in just focusing on the facilities."

And what a lot of folks did was just focus on the facilities, because they were aging, like Baltimore was thirty-five years old. All the Rayfield buildings were to the point of being decrepit. We wouldn't necessarily tolerate that with the industry, let alone ourselves.

I said—just to give you a clue of how Ron continued to press me—"I probably would not have recommended closing Baltimore. If you wanted to do a drug program, I would have suggested putting it in Baltimore, not in Philadelphia, for the simple reason that Baltimore had the capability to do microbiological analysis in addition to the chemical."

So in a sense, they were a full-service laboratory. Philadelphia never was. Philadelphia was in the Customs House, and they stopped doing pesticide analysis eons ago because the building was such that the solvents would boil off the [unclear] that they were using to do the pesticide analysis, and you just could not do good science, that kind of science, there.

Now, certainly they've remodeled and renovated and whatnot, but the point is that you really needed to look more globally at what it is you're trying to accomplish and make some—which are probably even harder—decisions about who's managing those resources. Are they doing a good job? Are you willing to put those resources there with those people that are doing a good job and consolidate from that vantage point? And then you will come up with a different game plan. I think you would.

I know that folks would probably find this hard to deal with, but I advocated that we really didn't need a lab in Puerto Rico; that, really, you could use Atlanta as the servicing lab.

Well, the folks in Puerto Rico didn't want to hear that. Same way the folks in Kansas didn't want to hear that their lab was going to be closed, or the folks in Dallas didn't want to hear that the lab was going to be closed.

The other decision that was made that I thought really put this in front of people and ground away at it, is we decided that we were going to do this over a course of twenty years. And what that did, I think, from the perspective of the folks who were involved, even though your lab might be closing twenty years from now, because that's when the lease on the facility was going to expire, it's always in your face. And you know, to me, that wasn't a good thing, and I would have advocated for, if you're going to make that decision, get the department to agree to do it today. Get it over with, get it done with, and move on.

Not having that support and then having a twenty-year time line, I think, got us to where we are now, and that's halfway through it.

RT: Did that result in resignations or seeking other employers?

RB: Well, not really. Because one of the things that was also decided is that we would take care of the folks. There were only maybe one or two people who were separated because they wouldn't move or wouldn't take a reassignment. Now, that, too, caused a lot of problems, because you would be taking, say, the folks in Buffalo who were in the lab who were staying, and moving them into special assistant positions, compliance officer, investigations, and whatnot. You're still encumbering the FTEs. So to populate New York, who was getting the work, you didn't have the FTEs. So our capacity, even though we were consolidating to be more efficient, actually diminished, and then quality diminished, too, because people were concerned,

you know. “I’m going to have to move,” “I’m going to have to uproot my family,” “I’m going to lose my job,” and things like that, for a number of years, for a significant number of years.

The plan didn’t get the outcome that was expected. We lost productivity; we lost quality; we lost a lot of talent. Because people decided, “Well, I can retire. I can take an early retirement and I don’t want to move my family.”

One of the interesting things, if you look in ORA, lab folks tend to stay in one place for their career, except for those people who go into management or crazy people like me, who think they want to find out what it is to do an investigation or compliance or go to headquarters a couple of times.

When I came back to the Division of Field Science, a friend of mine, Marge Hoban, gave me a little plaque to put on my wall, and it said, “Experience is recognizing your mistakes when you make them again.” And that was just a humorous thing between the two of us.

But anyway, the investigations folks are more inclined to move around, but they’re not tied to [unclear], either.

RO: Actually, the career track for promotion for the investigator seems to mandate broader experience, whereas I suppose in a laboratory the experience isn’t that varied.

RB: Actually, it’s evolved, because a lot of folks now are spending their careers, the investigators, in one place. Because what they can do is, they can get a nonsupervisory GS-13 without a lot of hassle. And their next step is to get a national expert status as a 14, and they can do that from anywhere. And anywhere might be a place where you can continue to keep your

home and not have to put your family through the disruption of a move and things like that. So even for the investigators, that's evolved, too. There's a tendency to stay in one place.

RT: Dick, when you went into this SES program, when you came out of that, did you go back to [unclear]?

RB: Went back to DFS and stayed there for another couple years until I got the position in the Pacific region as the regional director there. I spent almost three years out in the Pacific region. Some of the notable things that I did out there was to implement a strategic plan to try and get folks to think differently about how they do their job.

What the culture was, when I got out there, was that previous management had moved toward these self-directed work groups and teams.

RT: To what?

RB: Self-directed work groups and teams. And what I found was that because the supervisors, the first-line supervisors and the compliance officers had been pulled out of the process, that these self-directed work groups had trouble understanding what needed to be done to meet the expectations of the organization. So when I took over, productivity and quality were not where they should be.

Also, our folks tend to look at the mission as inspections, investigations, and sample analysis. They don't necessarily look at it as educating the industry, defining our expectations with the industry, reaching out, helping the industry to do the right thing. It's more of a "gotcha"

thing, rather than, “We’re not going to tell you what to do, but we’re going to tell you where you need to be and help you get there.”

So what I did is I implemented a strategic plan, and I said the idea, when you look at it, is to protect the consumer, and if all you have in your toolbox are inspections, investigations, and sample analysis, you’ve limited yourself. What I want you to do is to think, okay, you have an industry. They’re having problems.

Suppose it’s a device industry in Los Angeles, and you know they’re having problems. You simply do not have the resources to inspect them into compliance. It’s just not going to happen. We can take every medical device investigator and concentrate them in Los—you’re still not going to be able to do it. You have to come up with other strategies. What are those other strategies?

Pick folks that just don’t seem to get it and make an example of them, in a sense. Work with them to get them to do the right thing, and if they can’t do it, then use some of the tools that we have in there, whether seizure, injunction, prosecution, or whatnot, to get them there, because that sends a message to the industry, too.

Also, if you know that the problems that you’re seeing are endemic to the industry, go out there and do some workshops and say, “Look, we realize that you’re having a difficult time with QCD,” or whatever it is. “What we want to do is, we want to communicate with you what it is we’re trying to accomplish.”

And those culture shifts, too, are challenging for our field folks. To make the shift from strictly GNP to QCD, where QCD is looking at what’s the management attitude of the organization first, and if that seems to be good, what we’ll do is we’ll go in and do some things to kind of confirm

that they're in charge, that they're doing the right thing, and we can assure ourselves that they're making good products.

Whereas with the GNP, what you're really looking for is—you're not really caring about is management doing the right thing. You're looking at their records and looking for discrepancies and whatnot. You're really not looking at the bigger picture. So we're also struggling with that. So I said, "Okay, come up with some game plans where you know you have issues, you know you have to meet the work plan, and plan."

The other thing that I noticed that was happening is, when I started in the agency, we used to do a lot of local work planning. We'd get the work planned. And I would meet with the investigations and the compliance folks, and we'd come up with a game plan to meet. So we did local work planning. For some reason, the organization tended to get away from that, and what they were doing is kind of waiting for something to come down the laundry chute to clean up, rather than to plan.

And if you don't have a plan, you're not going to accomplish the things you need to accomplish, because when you look at our business, we have statutory obligations, we have stuff that happens, and then we should be doing outreach, too. I think that's part of our mandate. So that the strategic plan was to say, okay, let's look at this more globally. Let's recognize that our business is consumer protection. We're here to facilitate getting good products into the marketplace, and, when we find those products that can cause harm, to get them out of consumer channels.

I basically challenged the folks out there to do that, and in the three years that I was out there, they were doing a really good job of moving that ship in a different direction and actually

accomplishing our public health mission, with the resources that we had, more efficiently and more effectively.

RT: What was the year that you went to the Pacific region?

RB: I went there in—let's see. 2000. No.

RO: '98 or—

RB: Yes, '98, '99, something like that. That's a good question, Bob. That should just kind of pop out.

RT: I'm just thinking in terms of the [unclear].

RB: Anyway, I came back here around 2001, so it would have been around ninety—it was March the first, I think, of '97 or '98.

RO: Now, Dick, when you were out there, there was a number of senior staff that retired that word came back that they really weren't ready to retire, but they were kind of unhappy, I guess, with your management style out there. Do you have any comment on that?

RB: Well, I think that some of the folks out there might have gotten comfortable doing their own thing. And some of the folks had some issues that OIG [Office of Inspector General] got involved in and things like that.

So I know that perhaps some of the senior management out there might have been uncomfortable to actually have somebody say, “I care about what we’re doing and I’m going to scrutinize it,” or, “I’m going to review it,” and, you know, “We have an expectation to meet with headquarters, to meet the work plan and our other obligations, and I’d like to get us there, because this region hasn’t met those expectations in the last ten years.”

So the folks that retired were eligible to retire. I know some of them had some physical issues that they were dealing with, and maybe the time was right for them to do that, but that’s the way it goes.

RO: Well, then you came back to headquarters.

RB: Came back to headquarters, and some of the things that I’ve been doing back in headquarters are as institutional official for animal care and use. The noteworthy thing there is that we’re actually getting our laboratories that are doing that work accredited. And those inspections took place a month or so ago. Hopefully, this month—unfortunately, I won’t be here to celebrate; I’ll guess I’ll celebrate from a distance—we should get our accreditation for Atlanta and Seattle to operate under the AAALAC accreditation for animal care. AAALAC, it’s triple-A, LAC. It’s American Association for Animal Laboratory Care.

Another noteworthy thing that I’ve been working on is, Bernie Schwetz, when he was both at NCTR and eventually our senior scientist and then acting commissioner, has been an

advocate for doing review of our science, peer review. I was heading up a group to peer review our ORA science-based programs. In particular, it was to look at everything from inspections and investigations and sample analysis and compliance outcomes, to figure out if we're doing the right thing in those science-based programs.

Now, when I was tasked to do this, I quickly figured, I can't get my arms around—I can't come up with a strategy to get my arms around all the stuff that we do, because when you think about it, we're supporting all five program centers and day-to-day contacts with the industry and consumers and whatnot, and how do you peer review that broad a science base?

We eventually narrowed it down to look at the contaminants in the pesticide program area, and I came up with a concept that I call fitness reviews. It's not doing a quality control or a quality assurance audit or quality management system audit. It's assessing the work product to make a decision that, when it was all said and done, could the person who needed to use it, the customer or the stake holder, use it to accomplish what needs to be accomplished.

In other words, if you're going out and you're doing an inspection, was it done well enough that we could make the conclusion that, yes, the place is in compliance? No problem. We're assured of that. The snapshot that we took supports that. If it's not in compliance, can the compliance officer take it to the next step, whatever that is? If a sample was collected, was it collected in a manner that the lab folks could do their thing, and that they did a good job in analyzing the sample to support what's intended as the outcome?

So ultimately, when the inspectional or investigational and the lab stuff gets to the compliance officer, they can take an appropriate action, whether it's, okay, there's no problem with this company, or there's a serious problem here. We have a health hazard issue. Let's try and jawbone them into recall or seizure or whatever.

So it's a judgment on the work that really looks at it, not from the standpoint of the person doing the work or the people involved in doing the work, but from the customer or the stakeholder cannot use this work product. So we call it fitness reviews.

We've already gotten work products consolidated around the country. The panel is ready to go out and start looking at the work products. We're also going to do some on-sites. We're looking more at management practices. We're also looking at imports, the entry review process. We'll also be looking at our research and our check sample programs to see if they're really getting us where we need to be in the context of these fitness reviews.

RO: Have you been involved in the new lab operation out—

RB: Arkansas? Yes, I was asked to go out and help Meredith Grahn, who was the lab director at the time, come up with a strategic plan to—

RT: Mary?

RB: Meredith Grahn. G-R-A-H-N. Meredith was the lab director at the time, and she was the one who was kind of tasked with getting that lab up and running. I got involved with it from the standpoint of developing a strategic plan to help her move toward being the full-capability lab that they were designed to be. Arkansas has the dioxin program, pesticides, micro capability, and other program capabilities.

So I went out there quite a few times, and we worked up a strategic plan and turned that over to management. The strategic plan talked about getting the expertise and the equipment and

things to do the different program areas, sequencing it, putting in an infrastructure in the sense of first-line supervisors, branch directors, etc., to actually get them on-line. And I think they've been playing that plan out.

RT: Have they had any problem staffing that place?

RB: Actually, no. There's an interesting phenomenon there. There are folks that like to live in that kind of environment, which I will call "ultra rural," and who like to hunt and fish and be in a place like that.

There's also something that's very attractive there. Your government salary goes a long way in that kind of place, so you could pretty much get your mansion on a government salary there and do very well. And if you think about it, you're really not that far away from major metropolitan areas in Texas and elsewhere, if that kind of stuff turns you on. You want to go for a weekend in Texas, to Dallas to see the symphony, you can do it.

That's not to say that Little Rock's a bad place to be, because I spent a lot of time in Little Rock and found plenty of things to do there, plenty of great places to eat and visit, and there's a lot of history there, too. So it's pretty much what turns you on, but there were a lot of people that were willing to move there, a lot of new people, new to FDA. It was easy to attract new folks there. It was a little more difficult to have people who have already been in the agency move there.

RO: Did they interest any state people from Arkansas to come into the lab or—

RB: Not that I'm aware of, no. They've also now done some exchanges, in a sense, from NCTR [National Center for Toxicological Research] personnel coming into ARL, and ARL personnel going into NCTR. And particularly Cathy Melman, I know, was a supervisor in the micro section. She's now working in NCTR, and I think some NCTR folks have moved into the regulatory lab there, too. I know they're sharing space, too.

RT: Anything else, Dick, you want to mention here?

RB: Well, I think—

RT: You worked under a number of different commissioners and a number of different ACRA.

RB: Oh, gee, I—well, the ACRA that I remember that I started under was actually the EDRO. I think that guy's name was Paul Hile, and he's still with us. Some of the folks that I started my career with, I have a certain nostalgia for, because—particularly Paul and Ron, Ron Chesemore and John Taylor. When I think back, of ideals for public service, I really feel touched that I had the opportunity to work with them, to have them as mentors and leaders. I think they really had their hearts in the right place for what we're trying to do as a consumer protection organization. It's also a regulatory agency. And really have enjoyed thirty-three years of kind of bouncing around from thing to thing and actually accomplishing some things.

One of the things that I think I got from folks like Paul and Ron and Ron and John, is tenacity. That they were willing, even when I came up with some kind of way-out ideas like [imitates], "Raise the journey level? Do this peer review stuff?" I could make my case, and they

would support me, and we would get where we needed to be. They might challenge me and whatnot, but ultimately I think they made me a stronger manager and leader, and I think they recognized the importance of having to put a package together that sells.

So they were helping me with my marketing techniques. I didn't quite perceive it that way at the time, but it seemed to work out that way. And it's been a fun career, and I'm going to look back on it with a lot of pride and a lot of great friendships.

RT: Do you recall any of the commissioners that had a more than usual interest in the scientific aspects of the agency?

RB: Commissioner Kennedy seemed to really hone in on that. And Jane Henney seemed to really hone in on that. Different commissioners come in with different perspectives. Right now we have an economist/M.D., and he certainly has his perspective.

In the past we've had attorney/M.D.'s, and we had a lot of scrutiny on tobacco issues and whatnot. Not really a scientific thing, but certainly understandable from the perspective of a pediatrician who is concerned about that issue. Certainly how they manage their agenda had some impact on what happened with the agency, because there were certainly some folks outside the agency in the tobacco arena that weren't happy with the scrutiny that was placed on that.

So yes, the commissioners did have, I think, global impact on where we were going and the resources that we got and what—

[Begin Tape 2, Side A]

RB: For me, probably the most significant thing to say about the people I interacted with is that they're dedicated, and that I've enjoyed working with the management and appreciated, as I've kind of grown up in the organization, some of the issues that they faced.

In fact, I called Gene Stanley after I'd gotten into headquarters and had to deal with some of the issues that you deal with as a supervisor and a manager. Gene was the lab director in Philadelphia for a while. And I said to him, "You know, I had no idea what you faced as a branch director, and I just wanted to tell you that I appreciate you put up with some of my stuff, and that I don't think folks really do appreciate what gets done in spite of some of the obstacles that are placed in front of us, whether it's staffing or resources or facilities or whatnot."

RO: What prompted you to decide to retire now?

RB: To be honest with you, I don't think there was much room left for me to move up in the organization, and certainly salary-wise, there's no place to go. Not that that's my only motivation. I wouldn't have stuck around if it was, for thirty-three years, but I enjoy a challenge, and I enjoy being in management and in an executive leadership position.

I'll get that opportunity in the private sector shortly, so part of it was for my own personal well-being, to move on to something that gives me some of those challenges that, being in a senior staff position, I don't normally have. So that was a lot of it. And thirty-three years. It's time.

RT: Anything else?

RO: I guess not. We appreciate very much your granting us this interview, and we wish you success in your post-FDA activities.

RB: Thank you.

RT: Thank you.

[End of interview]